A review of strategies to promote patient involvement, a study to explore patient’s views and attitudes and a pilot study to evaluate the acceptability of selected patient involvement strategies.

Patient Safety Research Programme PS/034

P.I. Professor Ian Watt

On behalf of the Patient Involvement in Patient Safety Research Group

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University of York

May 2009
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EXECUTIVE SUMMARY

Background
It is estimated that between 300,000 and 1,400,000 adverse events occur in the NHS each year. Strategies to reduce adverse events have mainly focused on systems of care and professional behaviour, but there is a growing interest in involving patients in safety initiatives.

The overall aim of this project was to investigate how patients (and their family members and other representatives) might appropriately be involved in their health care to effectively promote their own safety, and to explore how this may vary by context, place, or demography.

Methods
The objectives were achieved in three main phases, each of which built on previous work. The first phase comprised a focused set of literature reviews, summarising current knowledge on patient roles, interventions and the potential for patients to contribute to reporting systems. The second phase involved primary research (individual interviews and focus groups) to generate new knowledge about patients’ views on their experiences of and contributions to safety in healthcare settings. The third phase involved the development and piloting of a potential patient involvement strategy.

Results
Phase 1
From the literature we identified three broad routes by which patients’ actions might contribute to their safety. Patients might help to make sure that:

- their treatment is appropriate for them (informing the management plan)
- treatment is given as planned and according to appropriate protocols (monitoring and ensuring safe delivery of treatment)
- problems and risks within healthcare systems are identified and reduced (informing systems and improvements)
A large volume of literature was identified which described a broad range of interventions. However, relatively few interventions to promote patient involvement had been tested and many of those that had had not been rigorously evaluated. The only currently available high quality evidence of improved safety outcomes through patient involvement was with respect to self management of anticoagulation therapy. We used insights from the broader review to develop an approach for appraising interventions intended to promote patient involvement in patient safety.

**Phase 2**

We found that in broad terms involvement in attempts to enhance safety was acceptable to patients and may have benefits. However most people were reluctant to think that their involvement should translated into a formal role and be relied on as a strategy for ensuring or enhancing their safety: there was a clear sense that the main responsibility for safety should lie with health care professionals and systems. Whilst people could identify with a number of roles through which they might enhance safety, there was little consistency amongst study participants on which roles they felt were appropriate for themselves or other patients, and the circumstances in which they thought they could be undertaken. Participants identified a range of factors which could influence whether patient roles in safety enhancement were adopted, including individual patient, health professional, and system characteristics. The importance of health professional behaviour and communication in facilitating patient involvement was particularly stressed.

**Phase 3**

We piloted an approach to enhancing safety which involved individual patients feeding back their particular experiences while using NHS services to relevant clinical governance groups. We aimed to use the patient stories about safety issues to facilitate interaction between patients and healthcare professionals to challenge professional norms about patient experience and involvement, and promote professional learning. This small scale pilot involved 5 patients. It suggested that the intervention is feasible, acceptable and worthy of further study to investigate its effectiveness. However we note that considerable effort was needed to support patients and staff during the planning and organisation of the meetings.
Implications

Practice
A central message from all three phases of the study is the importance of the health care professional and broader health care system in supporting patients to be involved in enhancing safety. Health care professionals need to be receptive and open to patient concerns and questions, and to facilitate patients’ attempts to be involved in their care. Brusque, dismissive or disinterested attitudes in the professional can inhibit patients from carrying out many of the roles that have been proposed as means by which they might enhance their safety. A positive patient-professional relationship seems to be crucial in enabling patients to contribute to improvements in health care safety. This makes a number of requirements of health care professionals, including appropriate attitudes and communication skills. It also places requirements on health care systems to make it easier for professionals to enable patient involvement in safety, for example by ensuring that workload demands are reasonable. Given this, we recommend that patient involvement in health care safety is better facilitated not by an emphasis on patient roles but by amending health care systems and supporting health care professionals to develop better relationships with patients. We cannot “legislate” patient involvement in health care safety, but if patients feel more comfortable in their dealings with professionals then it is more likely that patient roles in enhancing safety will occur as a matter of course, rather than as a response to an externally generated expectation.

Future research
Recommendations identified through this study include:

- an investigation of the desirability and feasibility of changing from recommendations that patients adopt particular roles or behaviours to promote their own safety towards efforts to facilitate more supportive professional behaviours and attitudes, and more supportive clinical environments (e.g. research with health professionals to improve our understanding of their experiences of patients’ attempts to be involved in enhancing safety; ethnographic studies of patient–professional interactions).
• the development and evaluation of strategies to involve patients in the reporting of error and patient safety incidents.

• a full scale evaluation of the use of patient narratives about their safety experiences to professional groups to promote greater awareness of safety issues.

Finally whilst this study has collected data to identify points of contrast and commonalities across a diverse range of settings and conditions, there is a relative lack of data from primary care and future research could usefully investigate aspects of patient involvement in safety enhancement in this setting.
# Glossary of Abbreviation of Terms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>ADR</td>
<td>adverse drug reaction</td>
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<tr>
<td>ACSQH</td>
<td>Australian Commission for Safety and Quality in Healthcare</td>
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<tr>
<td>A&amp;E</td>
<td>accident and emergency (department)</td>
</tr>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
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<tr>
<td>AME</td>
<td>adverse medical event</td>
</tr>
<tr>
<td>AORN</td>
<td>Association of Perioperative Registered Nurses (US)</td>
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<tr>
<td>CGG</td>
<td>Clinical Governance Group</td>
</tr>
<tr>
<td>DGV</td>
<td>Dutch Institute for Rational Use of Medicine</td>
</tr>
<tr>
<td>DoH</td>
<td>Department of Health (UK)</td>
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<tr>
<td>EMEA</td>
<td>European Medicines Evaluation Agency</td>
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<tr>
<td>FDA</td>
<td>Federal Drugs Agency</td>
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<tr>
<td>GP</td>
<td>General Practitioner (UK)</td>
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<tr>
<td>HCP</td>
<td>healthcare professional</td>
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<tr>
<td>ID</td>
<td>identification</td>
</tr>
<tr>
<td>INR</td>
<td>International Normalised Ratio (blood test of blood coagulation)</td>
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<tr>
<td>ISMP</td>
<td>Institute for Safe Medication Practices</td>
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<tr>
<td>IV</td>
<td>intravenous</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organisations (US)</td>
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<tr>
<td>LVHNN</td>
<td>Lehigh Valley Hospital and Health Network (US)</td>
</tr>
<tr>
<td>MEB</td>
<td>Dutch Medicines Evaluation Board</td>
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<tr>
<td>MHRA</td>
<td>Medicines and Healthcare Products Regulatory Authority (UK)</td>
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<tr>
<td>MRI</td>
<td>magnetic resonance imaging</td>
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<tr>
<td>NHS</td>
<td>National Health Service (UK)</td>
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<tr>
<td>NRLS</td>
<td>National Reporting and Learning System (UK)</td>
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<tr>
<td>NPO</td>
<td>Nil per os – (nothing by mouth)</td>
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<tr>
<td>NPSA</td>
<td>National Patient Safety Agency (UK)</td>
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<tr>
<td>NPSF</td>
<td>National Patient Safety Foundation (US)</td>
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<tr>
<td>NSAIDS</td>
<td>non-steroidal anti-inflammatory drugs</td>
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<tr>
<td>OTC</td>
<td>over the counter</td>
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<tr>
<td>PCA</td>
<td>patient controlled analgesia</td>
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<tr>
<td>RCT</td>
<td>randomised controlled trial</td>
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<tr>
<td>TB</td>
<td>tuberculosis</td>
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<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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BACKGROUND

Estimates suggest that between 300,000 and 1,400,000 adverse events occur each year in the NHS, and, for example, that about half of the adverse events that occur in the context of inpatient admissions are preventable (Department of Health, 2000). Strategies to reduce adverse events have so far mainly focused on the change of systems of care and professional behaviour. However, more recently there has been a growing interest in involving patients in safety initiatives. This increasing interest stresses the development and use of interventions to promote and support patients’ (and their representatives’) roles in securing their own safety in health care contexts.

There are a number of roles that patients (and their family members, friends, and other ‘representatives’) could potentially play to contribute to their safety as they use health services. A range of behaviours on the part of patients (and/or their representatives) might, via a variety of mechanisms, reduce their likelihood of suffering harm in the course of their care. For example, patients who know what interventions (tests, treatments, monitoring etc.) are planned for them can, at least in some contexts, check that they receive those interventions as planned, and that they do not receive any interventions that are unplanned. In this sense, informed patients can potentially serve as ‘failsafe checks’ on the delivery of their care (Institute of Medicine, 2000), and act to help intercept and avert any negative consequences of errors. Vincent and Coulter (2002) suggested that patients could also help promote their own safety by being involved in: helping to reach an accurate diagnosis; deciding on an appropriate treatment or management strategy; choosing a suitably experienced and safe provider; ensuring that treatment is appropriately administered, monitored and adhered to; and identifying side effects or adverse events quickly and taking appropriate action.

The provision of safety-related advice is the most common method currently used by health care providers to promote patients’ contributions to their own safety. There has been a proliferation, particularly in the USA, of materials advising people what they could and should do to avert errors and harms as they use health services. In addition to the books that tell people “How to get out of hospital alive” (Van Kanegan
and Boyette, 2003) and “How to survive your doctor’s care” (Gallin, 2003), there are numerous brochures, posters, videos and other materials offering tips to patients about the kinds of action they should take to ‘help to prevent errors’ and ‘get safer health care’ (e.g. AHRQ, 2009; Joint Commission, 2009; NPSF, 2007). However there have been no rigorous assessments of the effects of disseminating the advice in practice (Entwistle et al, 2005). Another way patients may contribute to improved safety is through participation in reporting systems. Some question how much potential there is for health services to learn by developing safety-reporting systems that are open to input from patients. In part, this reflects uncertainty about what kinds of safety issues patients and their representatives can recognise in the course of their care, and how these relate to the types of safety issues that health services learn about via reports from health care professionals or other sources.

Against this background, there is a need for research to inform attempts to involve patients (and their representatives) in healthcare safety initiatives. In order to help correct this situation, we were commissioned by the Department of Health Patient Safety Research Programme to undertake research to investigate how patients (and their family members and other representatives) might appropriately be involved in their health care to effectively promote their own safety. Prior to this, there had been few studies which had systematically explored or reviewed the evidence to support patient involvement in safety initiatives. In addition, the views of members of the public had been largely overlooked despite the fact that the success of such interventions depends on both their willingness and ability to engage in potentially safety enhancing tasks and processes.

PROJECT AIM AND OVERVIEW

Aims
The overall aim of this project was to investigate how patients (and their family members and other representatives) might appropriately be involved in their health care to effectively promote their own safety, and to explore how this may vary by context, place, or demography.
Objectives

1. To develop a conceptual framework relating to patient involvement in patient safety, including a typology of mechanisms by which patients might contribute to their own safety.
2. To identify the strategies which have been considered or used to encourage patients to get involved in their care with a view to enhancing their safety, and to assess the effectiveness of these.
3. To investigate how the various types of reporting systems that have been developed to improve patient safety have solicited, received and used reports from patients and their representatives.
4. To determine patients’ awareness of and concerns about health care safety.
5. To identify situations and ways in which patients or their representatives have acted to help secure their own safety.
6. To elicit patients’ views about the various roles they might play to ensure their own safety, about interventions to encourage or support them in playing those roles, and about their potential contribution to safety reporting systems.
7. To develop and carry out an initial developmental assessment of an intervention to promote patient involvement in patient safety.

The objectives were achieved in three main phases, each of which built on the previous work. The first phase (addressing objectives 1-3) comprised a focused set of literature reviews, summarising current knowledge on patient roles, interventions and the potential for patients to contribute to reporting systems. The second phase (addressing objectives 4-6) involved primary research (individual interviews and focus groups) to generate new knowledge about patients’ views on their role in and experiences of safety in healthcare settings. The third phase (addressing objective 7) involved the development and piloting of a potential patient involvement strategy. This report details the methods and results of each of these phases and discusses the findings. Each phase is presented in turn in the following sections before a final discussion of the project’s findings overall.
REFERENCES


WORK PHASE ONE

CHAPTER ONE: Scoping review of interventions intended to involve patients in patient safety.

CHAPTER TWO: Effectiveness of interventions designed to promote patient involvement to enhance safety: a systematic review.

CHAPTER THREE: The patient contribution to event reporting systems
ABSTRACT

Work Phase One

A focused set of literature reviews summarising current knowledge on patient roles, interventions and the potential for patients to contribute to reporting systems.

Aims
The reviews set out to achieve the following aims

- To how patients and their family members and other representatives might appropriately be involved in their healthcare to effectively promote their own safety, and to explore how this might vary by context, place or demography.
- To develop categorisations of safety interventions which involve patients according to how they are intended to improve safety in healthcare.
- To assess the impact of strategies or interventions designed to promote patients’, and/or their family members’ involvement in their care with a view to enhancing their own, or others’ safety in a healthcare context.
- To investigate how the various types of reporting systems that have been developed to improve patient safety have solicited, received and used reports from patients and their representatives.

Methods
Extensive systematic searches for any citations reporting (1) comment, opinion or research about the ways in which patients’ actions might (intentionally or inadvertently) enhance their own or others’ safety; (2) descriptions or evaluations of interventions to encourage or enable patients to adopt actions that might enhance their own or others’ safety; and/or (3) issues relating to patient’s willingness to adopt actions that might enhance their own or others’ safety. For review two we included only systematic reviews, experimental and quasi-experimental studies. Reporting systems were identified from previous overviews and reports, individual papers and an internet search.
Search strategy

Main results
In review one 1933 reports were identified as potentially relevant and of the 745 of these that were included in the review, 437 were descriptions of interventions, 299 comments or opinion pieces and 42 explored or described patients’ willingness and ability to adopt safety promoting behaviours.

Three broad routes by which patients’ actions might contribute to their safety were identified. Interventions were categorised according to how they were intended to improve safety. Patients might help to make sure that:

- their treatment is appropriate for them (informing the management plan)
- treatment is given as planned and according to appropriate protocols (monitoring and ensuring safe delivery of treatment)
- problems and risks within healthcare systems are identified and reduced (informing systems improvements)

The limited amount of literature which has explored patients’ willingness and ability to adopt safety behaviours indicated that these may be influenced by a number of factors.

Review two identified 14 individual experimental and quasi-experimental studies plus 1 systematic review. The majority of studies fell into the monitoring and ensuring safe delivery of treatment by self category and were all related to enhancing
medication safety. It was not possible to draw any clear conclusions as to the effectiveness of the interventions (with the exception of one specific aspect of self-medication i.e. self-management of anticoagulation) due to concerns about the methodological quality of the studies.

Eleven reporting systems in a variety of countries were identified. The majority of reporting systems (with the exception of KILEN, Meldpunt Medicijnen and MedWatch) demonstrated little evidence of real engagement with and/or uptake by patients and the reasons for this may be complex and varied.

Conclusions
There appeared to be potential for patients to use their ‘expert’ knowledge of themselves to ensure that health professionals have appropriate information to make treatment decisions. Monitoring and delivering their own care safely also seems to be within the capabilities of most patients. Some patients seem able to draw on their experience to contribute to making healthcare systems safer, however, a key feature of all these broad routes is facilitation of patient action by health professionals or the healthcare system. This ranged from provision of tools to manage anticoagulation treatment to asking a patient about his/her current medication. If patients are discouraged from adopting safety promoting behaviours because they are concerned about a negative response from a health professional then they could, presumably, be encouraged to act if assured of a positive response. Patients who are capable of safely delivering and monitoring their own treatment are, potentially, capable of monitoring the treatment given to them by others, given the appropriate information, tools and environment.

An approach for appraising interventions intended to promote patient involvement in patient safety is outlined here. This involves identification of the routes by which interventions assume patients actions might contribute to their safety, identification of the conditions that would need to be met for patients to behave and contribute as the interventions (implicitly) assume, examination of the extent to which the intervention supports fulfilment of those conditions and consideration of the potential negative effects of the intervention.
There is limited evidence for the effectiveness of interventions designed to promote patient involvement in patient safety and in general, is of poor quality. Existing evidence is confined to medication safety, in particular the self-management of oral anticoagulants. There is no evidence about the acceptability or unintended consequences of these interventions.

The majority of reporting systems demonstrated little evidence of real engagement with and/or uptake by patients and the reasons for this may be complex and varied. However, in the exceptional systems where patient reports have been successfully captured and used in reporting and learning there seem to be concerted attempts to publicize the system to make it highly visible to patients and clear information about how the information will be used.
CHAPTER ONE

Scoping review of interventions intended to involve patients in patient safety

BACKGROUND

Estimates from data collected in several countries suggest that around 1 in 10 patients admitted to a hospital will experience some sort of unintended harm. Not all of these harms will be serious and about half of them are thought to be preventable (Baker et al., 2004; Brennan et al., 1991; Davis et al., 2002; Vincent et al., 2001; Wilson et al., 1995). Strategies to reduce adverse events have, so far, mainly focused on changing systems of care and professional behaviour. However, more recently there has been a growing interest, both in the UK and other countries, in involving patients in safety initiatives. Several interventions have been introduced to promote the roles of patients and their representatives (this may include family, friends and advocates) in securing their own safety in health care.

If health service organisations are going to invest in promoting patient involvement in improving the safety of healthcare and if patients are to be encouraged to participate in such schemes there is a need to clarify potential actions that patients or their family members may adopt and their mechanisms of effect. Patients’ views about the appropriateness and likely effectiveness of these actions and, also, of any interventions intended to promote them require attention as do their practical implications in different contexts. At present, the evidence has been relatively unexplored and insufficiently critiqued. This report details the first attempt to thoroughly scope interventions which are intended to involve patients and/or their representatives in promoting their own safety while using healthcare services.

Aims and objectives of scoping review

To identify and critique the various roles and mechanisms by which patients and their representatives might act to enhance their own, or others safety as they use health services. In addition we will examine the circumstances and extent to which
patients and their representatives are able and willing to adopt these roles and the circumstances in which they have adopted them in practice.

To achieve this we have:

1. identified and explored the strategies and or interventions that have been considered or used with the intention of encouraging patients, and/or their family, to become involved in their care with a view to enhancing their own or others’ safety
2. examined the extent to which patients and their family members are able and willing to adopt safety promoting behaviours and the circumstances in which they are reported to have adopted them in practice.
3. identified broad routes by which patients’ actions might contribute to their safety to help clarify and facilitate a more precise and critical discussion about the various forms of patient involvement that might promote patient safety and their appropriateness and feasibility in different situations.

METHODS

Search strategy
The sources listed below were searched for publications relating to patient involvement in patient safety. The literature searches were designed to retrieve any study design and no language restrictions were applied to any of the searches. Databases were searched from the date of inception to November 2006 unless otherwise indicated.

The search strategies were broad in nature in order to capture relevant records for a series of linked literature reviews. A range of free text terms and subject headings were used as appropriate for both patient involvement and patient safety. Details of all the search strategies are contained in Appendix 1.1.

Sources included:
- Databases of systematic reviews
- Databases of controlled trials
• Health related databases
• Social care databases
• Economic evaluation databases
• Databases of reports, conference proceedings, grey literature
• Databases of ongoing research
• Patient safety organisations

Selection criteria
Any publications reporting either:
• roles or mechanisms by which patients and their family members may act intentionally or unintentionally to enhance their own or others’ safety
• reports of the willingness of patients and their family members to adopt these roles or the ways these roles have been adopted in practice

Selection Methods
Initial screening of bibliographic records
Two researchers screened identified titles and abstracts of records. Potentially relevant copies of the publications were retrieved in full.

Assessment of full text publications
Decisions about the inclusion or exclusion of publications from the review were made by assessing the full text. Agreement between reviewers was checked through joint assessment of a selection of publications. Any disparities or uncertainties about inclusion were discussed with a third researcher involved in the project. Publications were also classified according to whether they contained:

• descriptions of interventions intended to promote patients’ or family members’ contributions to patient safety (with or without evaluation of effectiveness);
• comment or opinion about patient involvement in patient safety;
• information relating to patients’ willingness and ability to adopt safety-orientated behaviours.

Evaluations of interventions are considered separately in Chapter Two.
Data extraction
The data from the included publications were extracted into three tables. Data extracted included author/s, country of origin, year of publication, title, summary, and, for interventions, a description of the intervention. A list of abbreviations used in the tables is available in appendix 1.2. One table contained descriptions and evaluations of interventions (Appendix 1.3); one comments and opinions about patient involvement in patient safety (Appendix 1.4) and one data relating to patients’ willingness and ability to adopt safety roles (Appendix 1.5). Figure 1.1 provides a diagrammatic illustration of the screening, assessment and data extraction process.
Figure 1.1: Diagram to illustrate screening, assessment and data extraction for scoping review

initial screening – 2 researchers, any potentially relevant literature ordered

assessment of full text – research reports included or excluded and classified as

description of interventions intended to promote patients’ or family members’ contributions to patient safety (with or without evaluation of effectiveness)

comment or opinion about patient involvement in patient safety

information relating to patients’ willingness and ability to adopt safety-orientated behaviours

Table A (appendix 1.3)

Table B (appendix 1.4)

Table C (appendix 1.5)

QUORUM statement flow diagram (1999)
RESULTS

The search strategy produced over 13,700 bibliographic records. The initial screening of these identified 1,933 publications as potentially relevant and full copies of these were ordered, of these 745 were in the review.

Included publications were extracted into the tables but some, because they were descriptions of the same intervention, were combined as one entry in the table. For example, four publications described the Patient Fact Sheet: ‘Twenty Tips to Help Prevent Medical Errors’ from the Agency for Health Research and Quality (AHRQ, 2000). These were grouped as one entry in the tables that focused on interventions but were been counted separately in the descriptions and diagrams relating to publication data which follow. A full list of abbreviations used in the tables appears in Appendix 1.2.

Interventions
This table has 437 entries and is presented in full in Appendix 1.3. Examples of some of these interventions have been used to illustrate the three broad types of route by which patients’ actions might contribute to their safety.

Comments and opinion pieces
This table has 299 entries. Examples from these comments and opinion pieces have been used to construct a patient safety timeline. A full table appears in Appendix 1.4.

Patients’ willingness and ability to adopt safety-orientated behaviours
This table has 42 entries. The data extracted were used to illustrate issues relating to patients’ willingness and ability to follow the three broad types of route by which their actions might contribute to their safety. A full table is in Appendix 1.5.

Overall description of literature included in the review

Country of origin
As expected, a large proportion of the review literature came from the United States (US) (512 out of 745 included publications). Figure 1.2 displays the distribution of publications by country of origin. Countries which contributed less than four
publications were classed as ‘others’. There were several publications that were written by collaborators in more than one country. These were classified as multinational. Thirty two publications in a language other than English were screened. Twenty eight of these were included and data extracted.

**Figure 1.2: Distribution of publications by country of origin n = 745**

![Distribution of publications by country of origin](image)

**Chronology**

The search included literature is from 1979 – 2006. Mapping of the distribution over time (figure 2.3) reveals a steady 1-5 publications a year between 1979 and the late 1990s with an initially gradual then sharp increase between 1995 (11 publications) and 2001 (47 publications). This appears to reflect the recognised patient safety watershed – the publication of ‘To Err is Human’ (Kohn et al.) in 1999 which drew attention to the consequences and cost of medical error in the US health system and other health systems worldwide. The chronology of non-US publications shows a similar pattern. If UK publications alone are examined there is an increase in numbers of publications after the formation of the National Patient Safety Agency in 2001 which was prompted by the publication of ‘An Organisation with a Memory’ (Dept of Health, (DOH) 2000) and ‘Building a Safer NHS for Patients’ (DOH, 2001).
Overview of interventions

Of the many publications examined, very few provided an explicit rationale for the described interventions or outlined the theoretical underpinnings of their approaches. Few interventions had been evaluated, the few that had been are described in detail in Chapter Two. Some interventions appeared to be ‘common sense’ responses to a particular safety incident. For example, a register was established for patients who had experienced difficult intubation to alert staff to possible difficulties in the future (Cherian et al. 1994). While organisations need to be seen to be responding to patient safety events there is no indication that this approach has been evaluated or draws on any current theories. Those interventions that do refer to theoretical approaches tend to draw on the extensive literature about patient involvement in decision-making and the positive effect this has on patient outcomes (Charles et al. 1997, 1998, 1999; Elwyn et al., 1999, Stewart et al., 1995; Stewart, 1995; Coulter, 1997) and assume that this might also be the case for patient involvement in safety promotion. In addition there has been little patient involvement in the development and evaluation of safety interventions that aim to involve patients (Entwistle et al., 2005). This appears to have led to a mismatch between the recommended
behaviours and what patients are comfortable with, and capable of, doing.

**Overview of commentary literature**

The publications classified as commentaries and opinion pieces provide useful insight into the development of interventions. Some of the publications are concerned with notable patient safety events. 1996 was the year of the first National Patient Safety Foundation conference at Annenberg, the influence of which was charted by Loeb in 1999. 1996 was also the year of the Patient Safety Act (USA) which defined a minimum required nurse patient ratio and skill mix and required providers to publish details of these (Helminger, 1996). There are comments from notable figures in the patient safety movement such as Leape, who wrote in 1998 about the work of the National Patient Safety Foundation and Hatlie (1999), who, the following year with Wagner described a programme to create a safe health culture from the viewpoint of providers, health professionals, patients, researchers and policymakers. Figure 1.4 provides an impression of the ‘first’ occurrence of topics relating to patient involvement in patient safety (these are first citings within the literature included within this review but not necessarily the first mentions within all published literature). These are presented on a time line from 1979, charted alongside notable patient safety events. This time-line appears to reflect the move from simplistic responses to patient involvement in safety promotion to increasing recognition of its complexity. For example, the first few publications are concerned with medication error and increasing patients’ knowledge of their medication in an effort to reduce this. Recognition of the link between low health literacy and poor patient outcomes (including via patients’ safety-related behaviours) would come 20 years later.

**Overview of literature relating to patients’ willingness and ability to adopt safety orientated behaviours**

The few studies exploring the willingness and ability of patients to act to keep themselves safe while using health services can be classified into four broad groups:

a) personal experience of, and reflection on, adopting safety behaviours;

b) expert commentary on the barriers and facilitators to, and concerns about, patient involvement in promoting their own safety;
c) qualitative exploration of the experience of adopting safety behaviours for patients and their representatives;
d) surveys of patients which explore the willingness of patients to adopt safety behaviours.
**Figure 1.4 Patient involvement in patient safety timeline**

<table>
<thead>
<tr>
<th>Year</th>
<th>Major Patient Safety Developments</th>
<th>Publications Raising Issues Relating to Patient Involvement in Patient Safety</th>
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<tbody>
<tr>
<td>1979-90</td>
<td>Medication error - need for increased patient knowledge through education (Christenson, 1979, Denmark; Brostad Martin, 1981, Canada; Brushwood, 1996, USA; Bakin, 1998, USA, Blaska, 1999, USA)</td>
<td>Meaningful representation of service users at board level in healthcare institutions (Hallfield &amp; Smith, 1988, USA)</td>
</tr>
<tr>
<td>1991-95</td>
<td>Importance of information sharing among healthcare professionals and between health care professionals and patients (Quemeau et al., France, 1992)</td>
<td>Call for patients to speak up if something doesn’t seem quite right and not be overawed by the ‘white coat’ (Irlander, USA, 1993)</td>
</tr>
<tr>
<td>1996</td>
<td>Patient Safety Act introduced minimum nurse patient ratios and skill mix (Heiminger, USA)</td>
<td>Patient access to medical records to check accuracy (Kirkby, UK, 1991)</td>
</tr>
<tr>
<td>1997</td>
<td>Patient perceptions of bedside handover (Cahill, UK)</td>
<td>Patient involvement in drug surveillance (van Grading and de Gier, Holland, 1992)</td>
</tr>
<tr>
<td>1998</td>
<td>Adoption of brown bag approach to medication reconciliation. Patients asked to bring all meds to each consultation (Brown, USA)</td>
<td>Importance of tailoring information to individual need (Wallenius, Finland, 1995)</td>
</tr>
<tr>
<td>1999</td>
<td>Patient perceptions of zero-risk healthcare (Quemeau and Grandfiset, France)</td>
<td>Safety issues of transitions in care (Lin, USA)</td>
</tr>
<tr>
<td>2000</td>
<td>Kaiser Permanente Institute for Health Policy roundtable discussion, patient safety reporting systems, Claremont University (Kaiser Permanente, USA)</td>
<td>Safe use of medical devices at home (Rozovsky, USA)</td>
</tr>
</tbody>
</table>

- Importance of and between health care sharing among professionals (Quemeau et al., France, 1992)
- Call for patients to speak up if something doesn’t seem quite right and not be overawed by the ‘white coat’ (Irlander, USA, 1993)
- Patient access to medical records to check accuracy (Kirkby, UK, 1991)
- Patient involvement in drug surveillance (van Grading and de Gier, Holland, 1992)
- Importance of tailoring information to individual need (Wallenius, Finland, 1995)
- Patient perceptions of zero-risk healthcare (Quemeau and Grandfiset, France)
- Safety issues of transitions in care (Lin, USA)
- Safe use of medical devices at home (Rozovsky, USA)
Figure 1.4 (cont.) Patient involvement in patient safety timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>Major Patient Safety Developments</th>
<th>Publications Raising Issues Relating to Patient Involvement in Patient Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>National Patient Safety Agency set up in UK (DH, UK)</td>
<td>Importance of patient feedback after restraint episodes for future management and safety (Petti, USA)</td>
</tr>
<tr>
<td>2002</td>
<td>Extension of yellow card adverse drug event reporting system to patients (Chesnara, UK)</td>
<td>Dangers of designing interventions without patient perspective (Ballinger &amp; Payne, UK)</td>
</tr>
<tr>
<td>2003</td>
<td></td>
<td>Including patients in developing clinical pathway tools (Koushi, Japan)</td>
</tr>
<tr>
<td>2004</td>
<td>Development and launch of National Reporting and Learning System (Woodward, UK)</td>
<td>Concerns about shifts in responsibility, lack of patient involvement in development of interventions and willingness/ability of patients to undertake these roles (Entrwistle, USA/UK)</td>
</tr>
<tr>
<td>2005</td>
<td></td>
<td>Link between health literacy and poor patient outcomes (Peota, USA)</td>
</tr>
<tr>
<td>2006</td>
<td>WHO Patients for Patient Safety Initiative (WHOS)</td>
<td>Importance of both patient and staff engagement in initiatives such as 'clean your hands' campaign (Teague, UK)</td>
</tr>
</tbody>
</table>
Organising framework

A framework for organising the literature was developed. This is based on three broad routes (each with several sub-routes or pathways) by which patients’ actions might contribute to their safety. These are presented in fig 1.5 with illustrative examples from the literature:

**Figure 1.5: organising framework for ‘interventions’ literature**

<table>
<thead>
<tr>
<th>Informing the management plan:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- helping to ensure the appropriate treatment plans are formulated by:</td>
</tr>
<tr>
<td>- sharing relevant information with the health professionals involved in formulating plans</td>
</tr>
<tr>
<td>- e.g. by making sure that health care professionals know about any allergies or adverse reactions to medication (Johnson et al., 2001).</td>
</tr>
<tr>
<td>- making sure that a proposed plan is appropriate</td>
</tr>
<tr>
<td>- e.g. by asking if there are any alternatives to the treatment recommended (AHRQ, 2005).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitoring and ensuring safe delivery of treatment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- helping to ensure that patient treatment is given as planned, and correctly by:</td>
</tr>
<tr>
<td>- helping to ensure safe delivery of planned treatment by health professionals</td>
</tr>
<tr>
<td>- e.g. by checking on a chemotherapy calendar that the correct dose of medication is given at the right time (Hutcherson and Gammon, 2007).</td>
</tr>
<tr>
<td>- helping to ensure safe delivery of treatment by self</td>
</tr>
<tr>
<td>- e.g. by monitoring blood INR levels and modifying self-administered anticoagulant medication dose in response to this (Henneghan et al., 2006)</td>
</tr>
<tr>
<td>- acting to minimise any potential problems of treatment and responding appropriately if they occur</td>
</tr>
<tr>
<td>- e.g. by following instructions for self-care after surgery and contacting the surgical team if any notifiable symptoms occur (Arias, 2003).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Informing systems improvements:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- helping to ensure that problems and risks within healthcare systems are identified and reduced by:</td>
</tr>
<tr>
<td>- providing feedback about experiences of health quality and safety</td>
</tr>
<tr>
<td>- e.g. by completing a post-discharge survey (Agoritsas, 2005).</td>
</tr>
<tr>
<td>- acting as a patient representative</td>
</tr>
<tr>
<td>- e.g. by serving on a patient and family advisory council to identify and appraise possible safety improvements (Connor, 2002).</td>
</tr>
</tbody>
</table>
Some of the interventions identified in the review may relate to more than one of the above routes and sub-routes because they aim to enable patients to contribute to their safety in more than one way. For example, patient use of a treatment diary could be categorised as **informing the management plan** if the intention was that patients complete and update the diary with information relating to their medical history, concurrent conditions, allergies and responses (including adverse reactions) to medication and then share this diarised information with the health professionals with whom they consult. Additionally, the use of the diary could be categorised as supporting **monitoring and ensuring safe delivery of treatment** if the diary (a) enabled patients to check care was being delivered as planned because it contained general information about warning signs and symptoms to look out for, or about the kinds of tests that were recommended or (b) encouraged patient record-keeping that facilitated professional or personal monitoring of care delivery and responses.

Behaviours and interventions are dynamic and interactive so although **informing the (original) management plan** ‘comes before’ helping to **monitor and ensure safe delivery of treatment**, new information will keep re-informing a plan which might need to be re-formulated in the light of new information. In categorising behaviours and interventions it is important to consider the means by which interventions were intended to enable patients to contribute to their safety as this was not always made clear in descriptions of interventions.

Figure 1.6 illustrates broadly how the interventions identified in the review are distributed within the framework. Numbers refer to the number of interventions, not number of publications. Commentary and opinion pieces have not been categorised in this way. More than half of the interventions promote patient contribution to safety via more than one broad route. The figure shows that the bulk of the interventions identified in the review are categorised as promoting both informing the plan and delivery and monitoring of treatment. These interventions are mostly the tip sheets and advice leaflets issued to or available to patients which suggest behaviours that they might adopt to enhance their safety while using health services.
This type of intervention is examined in more detail after exploring the range of interventions proposed that aim to promote safety through each of the three broad routes already described.

**Informing the management plan (1)**

*by sharing all relevant information with health professionals involved in formulating plans*

This includes information about past adverse events, allergies, reactions to medication as well general medical and drug history. To do this, patients need to know what information might be relevant and what they need to share with health professionals. Patients need to be aware that information does not always move freely between health teams so when they are being treated by multiple health professionals they need to share relevant information with all of them. Patients might be encouraged to do this by being reminded, through tip sheets or verbal reminders but also through the use of tools such as personal medication lists, health portfolios or wallet cards detailing their particular past adverse reaction or problems with procedures.
Most of the interventions in this category tended to be aimed at groups of patients that had particular characteristics which, if not recognised, could threaten their safety while they are interacting with health services. For example Johnson et al., (2001) described a programme to enable patients who had experienced an adverse reaction to a drug to share this information with health professionals. Patients were given written and verbal information by a pharmacist and supplied with a medic-alert bracelet. Interventions for other high risk groups such as those who are immuno-compromised (O'Keefe, Shaindlin and Egan, 1997); pregnant women at high risk of birth complications (Foust, 1996); those at risk of falling (Gillespie et al., 2003); the very old (Curry et al., 2005) and the very young (Cohen, 2002) were also described.

There may be situations where a patient’s ability to recall and give health professionals relevant information may be compromised. Patients with chronic mental health problems who may experience periodic psychiatric crises as part of their condition are likely, along with their family to have identified triggers for these crises and effective management strategies. Formulation of a management plan for crises that may occur involves patients and their representatives sharing this information. Langan (2004) described how the plans aimed to reduce the risk of harm to the patient, staff, other service users and the public when a psychiatric crisis occurs.

**Informing the management plan (2)**

*by making sure that a proposed plan is appropriate*

This might involve patients seeking a second opinion, an option not open to all, but standard practice on some US insurance plans prior to non-emergency surgical procedures (Finkel et al., 1982; AHRQ, 2005) They might also ask if recommended tests are necessary, if there are any alternative treatments to that proposed or raise concerns about their ability to cope with the demands of a particular treatment regime (AHRQ, 2005).

**Monitoring and ensuring safe delivery of treatment (1)**

*by helping to ensure safe delivery of planned treatment by health professionals*

This might involve patients in making sure that the treatment that has been planned for them is administered and monitored as planned, for example making sure that
the right operation is carried out at the right site. Or they might check that scheduled
tests and investigations are carried out as planned. To do this they need to know
what the plan is and ways they might do this included asking questions or being
given written information about the plan. For example Hutcherson and Gammon
(1997) described how patients about to start a course of chemotherapy were given a
‘calendar’, a written schedule of treatment which aimed to enable them to check that
the treatment given was the right dose planned for that patient given at the right time.
A treatment diary, such as described for those being treated with methotrexate
(NPSA, 2004), can work in a similar way, with scheduled tests being marked so
patients can help to make sure they are carried out. If the treatment is not being
given as planned patients are expected to ‘speak up’ or ‘ask’. For some of the
interventions, such as pre-operative checking, patients will be given this opportunity
by staff and asked to state their name, the operation and operation site or side, thus
checking with staff. For some, such as patients being encouraged to ‘check your
chart’ patients were expected to check–up on staff behaviour, and in speaking up,
challenge health professionals while drawing attention to a possible deviation from
the management plan.

Patients might also help ensure safe delivery of treatment by checking that health
care professionals are practising safely. For example, they might consult quality and
safety information, which is increasingly available, to check data such as infection
rates at hospitals and check the expertise or reputation of a particular practitioner
(AHRQ, 2005). In addition patients are increasingly being encouraged to help reduce
the incidence of hospital acquired infection by asking health professionals if they
have washed their hands prior to touching them (NPSA, 2004).

**Monitoring and ensuring safe delivery of treatment (2)**

*by helping to ensure safe delivery of the management plan by self*

Self-monitoring by patients could involve them making sure they take medication as
instructed by the prescriber, store it according to manufacturers’ guidelines and
dispose of any unwanted medication according to local guidelines. This might be
facilitated through the provision of information, verbally and possibly written by the
prescriber, written information on the medication pack and on the drug information
insert. In addition there may be local guidelines for the disposal of unwanted
medication. Patient self-management of anticoagulation involves patients following a treatment protocol and modifying medication dose according to blood test results (Heneghan, 2006). Patients might also self-administer medication while an inpatient (Pereles, 1996). Preparation for this was through instruction on practical procedures, information giving and checking of understanding.

Patients can also help to ensure their own safe treatment delivery by adopting health and safety policies and procedures at home. Increasingly treatments such as enteral feeding and renal dialysis are carried out in the home. Patients can be involved in planning and modification to a home to improve safety as well as adopting safety protocols and procedures. Some of these might involve them being given information, for others they may require more focused education techniques as well as access to expert help.

Approximately half of the interventions identified aimed to encourage or facilitate safe self medication by patients. This was by far the largest single pathway/subcategory.

**Monitoring and ensuring safe delivery of treatment (3)**

*by acting to minimise potential problems of treatment and responding appropriately if they occur*

Again this requires patients to have access to information about what could happen, how to reduce the likelihood of it happening and how to respond if it does happen. This usually meant patients being given information about what to expect in terms of their condition and progress, for example, on discharge from hospital and involved patients contacting health professionals if they experience a described set of side effects or symptoms, for example, surgical patients calling a dedicated surgical team after discharge if they experienced signs of post operative infection (Arias et al. 2003). There may be some cases where patients have not been given set criteria or guidelines about the appropriate signs or symptoms which should prompt consultation with a health professional but they have concerns. Various interventions have been designed to facilitate expression of these concerns. These included, giving patients permission, either verbally or in writing to ‘speak up if …’ (JACHO 2002) or the initiation of formal procedures such as ‘condition H’ which involves a
patient or his/her family summoning an emergency team because a they have concerns about their condition and the treating team have not responded in a way that addressed those concerns (Fabregas, 2006).

**Informing systems improvements (1)**

*by feeding back individual experience of health quality and safety*

Patients might feed back their experience in a number of ways including surveys but also by reporting safety events. In the literature reviewed, the main emphasis was on reporting the adverse effects of medication (van Grootheest, K. and de Jong-van den Berg L., 2004) but patient reporting of other safety events was also described (NPSA, 2005; Weingart, 2005). This might be initiated by others, for example a questionnaire sent to patients after a hospital stay. It may be a response to an invitation to report adverse medication effects either online, by phone or by post. In most cases information gained from these reports is used for wider learning about the side effects of medication but some systems facilitated individual feedback and possible treatment modification to a patient reporting system (Campbell and Howie, 1998). A review of current systems which do accept reports from patients and the public forms a separate part of this report (Chapter Three).

**Informing systems improvements (2)**

*by acting as a patient representative*

Individual patients may act as representatives, providing insights from their own and/or other patients’ experiences and views with respect to safety concerns and proposed safety improvements. This might be as part of a project to redesign a patient area in a hospital or equipment (Reiling, 2005; Sipilainen, 2005). Patients may be part of a panel developing patient information sheets for pharmaceutical products (Coulter, 2006; Anselmi, 2005). In some health institutions representatives from patient panels were invited to join management committees (Connor, 2002) or project teams that were working on design or safety/quality improvement issues. There are some consumer organisations, formed by patients and their representatives affected by patient safety events which were set up to provide support for those in similar circumstances and to campaign for safety improvements. These groups such as Patients for Patient Safety (P4ps) in the US and Sufferers of
Iatrogenic Neglect (SIN) in the UK are consulted for their viewpoint by health organisations and government.

**Patient safety advisories**

A large proportion of the interventions intended to promote patient involvement in patient safety are the tip and advice sheets issued by various bodies including patient safety organisations (AHRQ, NPSF, NPSA, JACHO, 2000-2006); consumer groups (Four Leaf Enterprises and P4ps, 2005; ASHRM Foundation, 2005) and health institutions. This section summarises the nature of the tips and recommendations. The tone, for the majority of the lists, appears to attempt to engender a sense of duty ‘make sure’; ‘play it safe’; and a sense of responsibility pointing out that as health care professionals and health institutions play their role in safety promotion, patients should too. Introductions sometimes give some indication of the scale of medical error then indicate that ‘patients can help too’. For a more detailed discussion of this see Entwistle et al., (2005)

For ease of management, some of the individual tips from the tip sheets have been grouped according to the patient safety promoting behaviours already discussed and presented below Fig 1.7). Most of the tip sheets comprise a number of tips which collectively would fall into two or three categories.
Fig 1.7 Examples of tips from a number of lists

**Helping to ensure safe delivery of treatment by self**
Find out about/become an expert on your condition; access online drug formularies; be knowledgeable about medication and how to take them; read drug package inserts; know the colour and shape of pills; keep a copy of your records; read the information provided about over the counter medication; know how to use medication administration devices; store medication safely and appropriately; keep medication in the original container; safely dispose of old and expired medication; make sure you know the generic name of your medication; follow the treatment plan; take medications exactly as prescribed; use home medical equipment and supplies only as instructed.

**Sharing all relevant information with the health professionals involved in formulating plans**
Share information about over the counter, herbal and dietary supplements; inform health professionals how you (or your child) take medication; share information about illegal drug use; share information about other treatments you are receiving; take medication to consultations; be an active member of the health team; keep an up to date list of all your medication.

**Making sure that a proposed plan is appropriate**
get a second opinion; ask if test/treatment is necessary; ask if there are alternative treatments available.

**Helping to ensure safe delivery of planned treatment by health professionals**
if you are having an intravenous infusion ask how long it should take to run out; pursue test results; check your chart; make sure scheduled tests are done; make sure you have discharge instructions before you leave hospital; make sure that staff check your identity before giving you any medication or take you for any investigations; state your name before taking any medication; make sure you know what the plan is.
Use the same pharmacy for all prescriptions; find a good doctor; use a surgeon who is skilled at the operation you need; find a hospital where the procedure is carried out a lot; make sure you can read prescriptions; avoid hospitals at night times, weekends and holiday time if possible; check that your surgical team use the universal protocol to minimise the risk of wrong site/patient/side surgery; make sure online pharmacies are legitimate; know the team who are providing your care, ask for their credentials; ask staff if they have washed their hands before they touch you.

**Acting to minimise potential problems of treatment and responding appropriately if they occur**
be knowledgeable about potential problems with your medication; find out what kinds of errors can occur; ask how new medication will affect other meds; ask if concerned; question anything that seems odd; speak up if you think you have been mistaken for someone else; get the surgeon to sign your operation site.

Several tip sheets recommend that patients have someone to act as their advocate when they are unable to adopt safety promoting behaviours so that person would be available to take on those behaviours listed on behalf of the patient.
Most of the lists of tips and recommendations reviewed (90%) are aimed at US health-users. Figure 1.8 is an example of one such recommendation. Examination of these advisories and the safety promoting behaviours they aim to encourage reveals the cultural and attitudinal differences to healthcare in the United States compared to, for example, the UK. The introductions to the US lists, suggest that patients have a key role to play in making their own healthcare safer ‘This fact sheet tells you what you can do to get safer health’ (AHRQ, 2003). They inform patients what they need to do in order to stay safe within the US healthcare system.

Figure 1.8 AHRQ’s Five Tips to Safer Healthcare (2003)
http://www.ahrq.gov/consumer/5steps.htm

| 1. Ask questions if you have doubts or concerns. Ask questions and make sure you understand the answers. Choose a doctor you feel comfortable talking to. Take a relative or friend with you to help you ask questions and understand the answers. |
| 2. Keep and bring a list of ALL the medicines you take. Give your doctor and pharmacist a list of all the medicines that you take, including non-prescription medicines. Tell them about any drug allergies you have. Ask about side effects and what to avoid while taking the medicine. Read the label when you get your medicine, including all warnings. Make sure your medicine is what the doctor ordered and know how to use it. Ask the pharmacist about your medicine if it looks different than you expected. |
| 3. Get the results of any test or procedure. Ask when and how you will get the results of tests or procedures. Don’t assume the results are fine if you do not get them when expected, be it in person, by phone, or by mail. Call your doctor and ask for your results. Ask what the results mean for your care. |
| 4. Talk to your doctor about which hospital is best for your health needs. Ask your doctor about which hospital has the best care and results for your condition if you have more than one hospital to choose from. Be sure you understand the instructions you get about follow-up care when you leave the hospital. |
| 5. Make sure you understand what will happen if you need surgery. Make sure you, your doctor, and your surgeon all agree on exactly what will be done during the operation. Ask your doctor, “Who will manage my care when I am in the hospital?” Ask your surgeon: |
| - Exactly what will you be doing? |
| - About how long will it take? |
| - What will happen after the surgery? |
| - How can I expect to feel during recovery? |

http://www.ahrq.gov/consumer/5steps.htm

The US health writer Barbara Loecher in ‘Get out of the hospital alive’ lists ways in
which patients can protect themselves from ‘mistakes made in the name of medical treatment’ (2001). The tone suggests that patients have little choice – if they want safe treatment they must take action to protect themselves. This includes checking the suitability of a health institution, its staffing levels and staff competence (Figure 1.9).

**Fig 1.9: List of questions to ask (Loecher, 2001)**

<table>
<thead>
<tr>
<th><strong>How to interview a hospital</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ask:</strong></td>
</tr>
<tr>
<td>Do you keep concentrated Potassium Chloride on the wards?</td>
</tr>
<tr>
<td>Does a pharmacist participate in daily rounds?</td>
</tr>
<tr>
<td>Do you have a computerized physician order entry system?</td>
</tr>
<tr>
<td>What is the ratio of patients to registered nurses?</td>
</tr>
<tr>
<td>Do you have house staff?</td>
</tr>
<tr>
<td>Does an intensivist oversee the intensive care unit?</td>
</tr>
</tbody>
</table>

In contrast, the UK’s National Patient Safety Agency’s online ‘Top 10 tips for safer patients’ (Figure 1.10) states its aim as helping ‘you become a more informed patient and one who worries less’. It goes on to say ‘there are times when things can go wrong no matter how dedicated and professional the staff. And that’s why the NPSA is working with the NHS to make it safer for you’. The tone is different and seems to suggest a request or desire for patients to be involved to help the healthcare system make sure that their care is safe.

Other publications in this category described tips to reduce the risk of error for high risk patient groups such as children (Starr, 2001), older people (De Villermay, 2002), those with poor health literacy (Woods, 2003), and those taking methotrexate (NPSA, 2004); high risk points on the patient journey (such as transitions between care services) (HCPro, 2006; David, 2002; NPSF, 2003, 2003); for medication generally (Cohen, 2003, Sandroff, 2004); and for surgery (JACHO, 2002, AHRQ, 2005).
Most of these patient advisories are in paper form but there are alternative media including DVDs and videos (Four Leaf Enterprises and P4ps, 2005; NPSF, 2002; McCollum, 1978) which were available for patients to view either at home or sometimes as an inpatient on admission or prior to admission to hospital (Anthony et al., 2003).

**Willingness and ability of patients to adopt safety-orientated behaviours**
A small proportion of the literature explored the willingness and ability of patients to adopt recommended safety promoting behaviours. Data were extracted from a variety of commentaries, stories of personal experiences, qualitative studies and surveys. They provided some insight into what the facilitators and barriers to patient involvement in safety promotion might be. They largely reflected concerns that, although patients may appear to be ideally placed to act to keep themselves safe there are a number of factors which can make this problematic. These were:

1. the varied characteristics of individual patients including knowledge and health status which can affect their ability to act in particular health contexts;
2. patient experience of and beliefs relating to medical error;
3. patient preference for collaborative rather than confrontational behaviours;
4. the anticipated and actual response of health professionals to patient’s efforts to contribute to their care and safety.

Using the categorisations already identified and some examples from the literature the report will discuss the limited information identified in relation to patient attitudes to recommended safety behaviours and the factors that might impact on their ability to engage with them.

**Informing the management plan (1)**

*by sharing relevant information with the health professionals involved in formulating plans*

This seems to be a behaviour which patients recognised as part of their role. US consumers surveyed about health quality and safety by AHRQ and Kaiser Family Foundation in 2004 and again in 2006 indicated in the latter survey that they were increasingly volunteering information about allergies and adverse reactions even when not asked by health professionals (AHRQ, 2004, 2006). Patients were likely to be relatively comfortable with these information sharing behaviours because they were perceived as collaborative and not confrontational (Swift, 2001; Hibbard et al., 2005). Collaborative behaviours for patients are those where they are working alongside health professionals to improve safety, for example, sharing information about their current medication. Confrontational behaviour might be asking a doctor to rewrite a prescription because the patient cannot read it (Florida Health Coalition, 2003).

For patients to share relevant information with health professionals they need to know what constitutes relevant information. People who participated in the above AHRQ and Kaiser Family Foundation Survey appeared to understand that it was important for them to pass on to health professionals information about them, their medical history and any adverse reactions in the past (AHRQ, 2004, 2006). Patients also need to know when it is appropriate to pass on this relevant information. They may think that once information is recorded in their medical notes that they do not
need to then pass on this information to other healthcare professionals. Figures from
the National Reporting and Learning System (NRLS) in the UK show that the
majority of adverse events concerning discharge reported to the system in 2007
were due to lack of or inadequate communication between healthcare providers or
professionals (NPSA, 2007). Patients may assume, sometimes wrongly, that
information about them is being passed between healthcare professionals and
providers although parents of children with cancer were aware of the need to make
sure new staff knew details of their child’s condition such as food allergies and their
treatment history (Losowski et al., 1993)

However, there may be reasons why patients do not share what they know to be
relevant information with health professionals. These reasons might range from
difficulty or discomfort with communication to reluctance for details such as illegal
drug use or problems with alcohol to be ‘on record’ with consequent implications for
employment. Patients also cited embarrassment, time constraints, anxiety about
consequences, concerns about visits to their house and potential interference in their
lives of health and social services as reasons for not sharing relevant information
with their community physician (Brown et al., 2006; Goeltz, 2003).

**Informing the management plan (2)**

*by making sure that a proposed plan is appropriate*

Importantly, for patients to help to make sure that the treatment plan is correctly
implemented, they need to agree that the plan is right for them. A study of the
construction and management of risk for patients and staff in a day hospital revealed
that some patients did not adhere to the fall prevention programme designed for
them because they were more concerned about the risk to their personal and social
identities of being classed as ‘fallers’ than of the physical risk of falling (Ballinger and
Payne, 2002).

Rosanne Goeltz describes in some detail her experiences ‘partnering’ with health
professionals and her questions to them to make sure that the treatment planned
was right for her. Some of the health professionals she worked with were happy to
answer her questions and work with her to come up with a plan with which they were
both comfortable, some were not. She continued to work with the former and
stopped consulting with the latter (Goeltz and Hatlie, 2002). This is not, however, an option for all patients.

**Monitoring and ensuring safe delivery of treatment (1)**

*by helping to ensure safe delivery of planned treatment by health professionals*

This is dependent on patients having access to appropriate information about the treatment they should expect in a form that they can understand. Bedside handover by nurses at the end of one shift and beginning of another aims to involve patients in treatment monitoring and Cahill’s study of patient perceptions of this process revealed that while patients were happy to contribute and correct information when it was about them personally they were less likely to take part when discussions were about which treatment options should be considered, possibly because they felt less well informed (Cahill, 1998). Patients seem to feel they are expert about themselves and their response to the plan but had less to contribute about the plan and treatment generally. Monitoring the treatment plan might also be problematic without knowledge of the health system. Goodman (2004) writes about the importance of this for patients and their representatives’ involvement and of ‘taken for granted’ information which is often not passed on by staff, such as times of consultant rounds. Medicare beneficiaries felt they were limited in this role by their ability to evaluate medical information and some were reluctant to seek out information because that might increase anxiety (Swift, 2001).

Patients also appear to have a clear notion of the boundaries of their role and, for example, perceived their role in medication checking as limited to reading the drug information insert and checking that the medication label was right (Nau and Erikson, 2005). Medicare beneficiaries reviewing patient safety tips viewed messages that called on patients to intervene at any other stage in the medication ‘process’ (for example, checking that what was dispensed was what was prescribed) as unnecessary because they thought there were already systems in place to do this e.g., pharmacists ringing the surgery to verify scripts (Swift et al., 2001).

These essentially ‘checking’ safety promoting behaviours are likely to be more problematic for patients because they may involve challenging health professionals’ practice and may imply a lack of trust that patients do not wish to convey. Asking
practitioners if they have washed their hands is a role which has been identified for patients but when asked many patients said they would not do it (Swift., 2001) and those who said they would do it found it difficult in practice (Waterman et al., 2004). Patients may be concerned about the ramifications of their actions for their own treatment, or in the case of parents or carers for their child or relative (Hurst, 2001; Lozowski, 1993; Goeltz, 2003). Entwistle et al., (2005) highlight the problems this acting out of ‘role’ might bring, particularly when patient advisories are promoting the notion of a ‘good’ patient who speaks up and adopts behaviour which may be perceived as challenging or confrontational by both patients and healthcare professionals, in conflict with the widely held perception of a ‘good’ patient as one who is passive and follows instructions (Jadad et al., 2003).

Several commentators express doubts about patients’ ability to act as consumers of healthcare due to their lack of specialist knowledge of health conditions and the health system (Goodman, 2004; Robinson and Nash, 2000). The list of questions that patients are encouraged to ask when interviewing a hospital (fig 1.9), for example, could prove extremely difficult for patients who lacked this knowledge. Even if they could find an individual within the hospital who had the answers to all these questions, if they were to go on and use the answers to these questions to promote their own safety, they would still need to know, for example, the ‘ideal’ ratio of patients to registered nurses for the speciality where they are to have treatment; to be in possession of information about how wards are staffed and staff hierarchies as well as being able to judge if a ‘maybe’ or ‘sometimes’ answer to some of these questions would be good enough.

The literature exploring patients’ willingness and ability to adopt safety-related behaviours suggests that patients have tended to adopt more low key approaches to checking the practice of their health team. Those about to undergo brain surgery revealed that they were reassured by positive reports of their surgeon’s performance by their friends and colleagues and by their own interaction with him (Bernstein et al., 2004).

**Monitoring and ensuring safe delivery of treatment (2)**

*by helping to ensure safe delivery of the management plan by self*
The safety promoting actions or behaviours recommended in previous sections require a good deal of knowledge seeking and becoming well-informed ‘become an expert on your condition; know your medicines and how to take them’. Some people may not have the ability to do this either because they lack the capability or because they do not have physical access to the facilities. One Medicare beneficiary in the study by Swift et al (2001) commented ‘If you go to a medical book, how are you going to understand [the information]’ (p82,). Patients in this study, who reviewed safety statements from patient safety advisories, also indicated that they preferred clear instructions for safety-related behaviours, for example ‘Make sure that all of your doctors know about everything that you are taking’ to vague guidance such as ‘know that more is not always better’ (Swift et al., 2001.p.80)

**Monitoring and ensuring safe delivery of treatment (3)**
*by acting to minimise potential problems of treatment and responding appropriately when they occur*

Again this relies on patients having access to and understanding information about the potential adverse effects of medication and treatment, what to seek advice about and, (if this is necessary) how to get access to this advice. Even if this process is unproblematic – the patient understands the advice, recognises the symptoms, rings for advice and receives it – there may be other reasons why a patient may choose not to, for example, report expected side effects of a medication. The individual may not have complied with instructions such as not drinking alcohol as advised while taking a new medication (Brown et al., 2006).

**Informing systems improvements (1)**
*by feeding back individual experience of health quality and safety*

Many patients appear to be happy to be involved in trying to make systems safer by feeding back their experiences. A study in Australia found that patients preferred survey-level involvement but were reluctant to be involved in more time consuming ways. Those most likely to volunteer for involvement which required more commitment such as patient panels were people who were already members of consumer groups or patients who regularly attended hospital for treatment. Patients also needed to believe it was worthwhile to take part in such initiatives (Johnson and Barment, 2002).
Informing systems improvements (2)

by acting as a patient representative

As detailed in Johnson and Bament’s study (2002), there was some evidence that particular types of patients tend to volunteer to be patient representatives. In addition Lozowski (1993) found that being a member of a user group increased the likelihood that parents of children with cancer would speak up if they thought their child’s care was not as it should be.

For both survey and more direct involvement methods of contributing to systems, patients may be constrained by the way the intervention is formulated. Often a survey will be designed by health professionals or employees of healthcare institutions and may focus on questions that providers rather than patients feel are important and patient panels are usually convened and facilitated by others (Draper and Hill, 1995).

Other factors which influence willingness and ability to adopt safety behaviours

All of the above behaviours to a greater or lesser degree require patients and their representatives to be well-informed, about their own health circumstances and about standard protocols and procedures which may govern or impact on their treatment. The capacity to do this varies between individuals and is affected, not surprisingly, by educational level, achieved income and cognitive skills. These are all recognised as factors associated with differing degrees of health literacy, which is the ability to process and utilise health information effectively. Recent evidence suggests that those with low health literacy are more likely to be affected by adverse clinical outcomes (AHRQ, 2004, 2008a; JACHO, 2007). Losowski’s study of parents of children with cancer found that parental intervention to keep their child safe could be understood mainly in terms of the characteristics of parents, including annual income and education rather than other factors such as the child’s condition (Losowski et al., 1993).

Knowledge about medical errors and how and why they occur may also influence the safety promoting behaviour of patients. Knowledge that participants gleaned from a
study which explored patients’ views about their role in preventing medical error made them more likely to believe that the adoption of safety behaviours would be effective (Hibbard et al., 2005). Several US surveys have revealed that a large proportion of those asked believed that error by individual healthcare staff was the most likely cause of medical mistakes and prevention strategies should be based around removing ‘bad’ health workers (Robinson and Nash, 2000). This was echoed in the AHRQ, Kaiser Family Patient Safety and Quality Surveys of 2004 and 2006. However, this is in direct conflict with the main thrust of patient safety interventions which are focused on improving safety systems rather than targeting individual practitioners.

Experience of medical error has been proposed as a potential stimulus for vigilant behaviour (Davis et al., 2007) but patient experience of ‘preventable problems’ in primary care, after the initial feelings of anger, mistrust and resignation, produced a continuum of responses from patients ranging from complete refusal to engage with the health system again to extreme vigilance with several stages such as acquiring knowledge and seeking a second opinion in between (Elder et al., 2005).

Other factors which were associated with patients’ willingness and ability to adopt safety behaviours included age, which was found to be a factor in some studies. Johnson and Bament, (2002) found that older people were less likely to adopt safety promoting behaviours, but other studies did not support this (Waterman et al. 2004); personality traits, with patients assessed as having an ‘extrovert’ personality more likely to say they would ask health care professionals if they had washed their hands (Duncanson and Pearson, 2005). Anxiety about medical error was suggested as a better predictor of adoption of safety promoting behaviours than perception of risk of medical error (Peters et al., 2006).

A proportion of this literature, exploring patients’ willingness and ability to be involved in promoting their own and others safety relies on patients speculating about the potential for them to adopt safety related behaviours in certain situations (Hibbard, 2005; Swift 2001, Stoor and Hookway, 2005). For example, patients might be asked if they would be happy to ask if a health professional had washed their hands before touching them. Waterman et al (2006) found that this was not necessarily a reliable
way of predicting whether or not patients would adopt such behaviours with much larger proportions of patients saying they would than actually acting. This was especially the case for safety promoting behaviours which required patients to act in ways that might be perceived as confrontational by patients and health professionals. Although patients appeared to be willing to adopt safety-related behaviours this did not always translate into action.

**Using the framework to appraise interventions**

In order to demonstrate how the categories developed might be used to help examine strategies intended to involve patients in promoting safety two interventions are now ‘unpicked’. To do this we have combined the description of the intervention with information from the review about patients’ willingness and ability to adopt patient safety promoting behaviours. Mindful of the comments which have been made about the largely atheoretical approach to this area we draw on Greenhalgh et al’s (2005) theory-driven examination of the use of patient reported outcome measures to change the behaviour of health professionals. This paper identified the intended outcome and mechanism of interventions using the ‘theory of change’ approach based on the work of Connell and Kubisch (1995) and Pawson (2002). The authors then went on to identify ‘implicit assumptions’ that must be fulfilled if the intended outcomes are to be achieved. We apply this same theoretical approach to safety interventions which aim to involve patients. To appraise an intervention we suggest the following approach:

- identification of the ‘route(s)’ by which the intervention assumes patient behaviours might enhance patient safety
- identification of conditions that would need to be met for the patient to adopt the behaviours and make an effective contribution (this includes conditions relating to the patient and their family, the health professionals involved in their care, and the healthcare organisation/systems within which care occurs).
- examination of the support offered by the intervention and consideration of whether and to what extent it would ensure that the necessary conditions could be fulfilled (This is a context dependent examination)
- consideration of the potential negative effects of the intervention
Figures 1.11 and 1.12 illustrate examples of how this approach could be used to demonstrate the application of the framework.

**Example:** Patients beginning a course of chemotherapy are given a calendar to track their treatment and check that the right medication and total dose are given (Hutcherson and Gamon, 1997)

**Intended to prompt patients to** help to ensure the safe delivery of treatment by health professionals

**Conditions to be met for patient contributions to be effective include:**
- that the patient is capable of knowing and is well informed about what the plan is (medication and dosing schedule) and how it should be implemented (dose delivery plan)
- that the patient can detect deviations from the plan
- that the patient will speak up if there is any deviation from the plan
- that health professionals will respond appropriately if the patient speaks up

**Questioning the support provided by the intervention:**
- Is the information about the plan delivered in a form the patient can understand? Patients’ capacity to take on information varies between individuals and at different times on the patient journey. Interventions which include information giving are rarely tailored to individual patient needs and there is little indication in the literature reviewed of awareness of the need to check understanding. Patients may just not understand the information they are given and may not feel well informed enough to take any safety action. However, this intervention does involve face to face education by a pharmacist which has the potential to be individualised and reinforced if necessary.

- Can patients access and understand the information needed to monitor treatment delivery? Checking the dose and type of chemotherapy administered should involve checking of the label on the medication, whether intravenous or oral, and the medication chart. These items are professional tools and patients may feel they need permission from health professionals before doing this.

- Do staff provide opportunities for the patient to voice concerns? Speaking up could be perceived by patients as challenging the professionalism of staff so this is likely to be problematic for patients. The giving of a chemotherapy calendar may be perceived as permission to act by both patients and staff.

**Potential negative effects**
- If patients do not feel capable of performing this role either because they lack the ability or confidence to do it or they are not well today and they do not have access to an advocate this may cause unnecessary anxiety
Example: ‘share relevant information about yourself with prescribers’ (from tip sheet for patients and carers issued by The Institute for Family Centered Care, 1999).

**Intended to prompt patients** to help ensure the appropriate plans are formulated by sharing relevant information with the health professionals formulating plans

**Conditions to be met for patient contribution to be effective:**
- the patient is capable of deciding what is relevant information
- that the patient will share this information with all prescribers
- that health professionals will encourage (or not discourage patients from volunteering information)
- the health professionals will respond appropriately if the patient volunteers information

**Questioning the support provided by the intervention:**
- Is information about the relevance of information provided? *Patient and professional understanding about what is relevant information may differ. Patients may not consider that taking of herbal medication or dietary supplements is relevant to a prescriber or that it could be classified as ‘medication’. They may believe that a past adverse reaction to a medication was caused by them not following instructions properly or that health professionals will disapprove of them taking ‘alternative’ treatments (Brown et al., 2006; Barnes et al., 1998)*

- Will the health professional facilitate patient involvement by encouraging or not discouraging their contribution and responding appropriately if the patient volunteers information? *Tip sheets, unless they are part of an organisational strategy to stimulate patient involvement which includes encouraging health professionals to act as facilitators, do not provide support for this aspect of the intervention. Patients do not know how health professionals will respond to their input. We know that patients will share information if prompted by are also easily discouraged by perceived or actual health professional response*

**Potential negative effects**
- Patients may worry about what is relevant information especially if they are not given the opportunity to share what they feel is relevant with health professionals.
- If patients do not feel willing able or well enough to perform this role today this may cause unnecessary anxiety
DISCUSSION

Where this review fits
This review represents the first attempt to scope and describe the large amount of literature concerning patient involvement in patient safety. Most related reviews have critiqued patient safety literature more widely although many have a chapter or section about patient involvement (Pizzi et al., 2001; Coulter and Ellis, 2006). Overall conclusions appear to be largely similar to this review – evidence for effectiveness of recommended safety related behaviours is lacking, patients have, largely, not been involved in the development of interventions and we know very little about patients’ willingness and ability to adopt recommended patient safety promoting behaviours (Entwistle et al., 2005; Pizzi et al., 2001; Maillard et al., 2005). However, this review, as well as describing the literature, systematically reviewing studies of effectiveness (Chapter Three) and reporting these findings has attempted to categorise interventions by how they are intended to improve safety, while at the same time exploring the factors which affect patients’ willingness and ability to adopt the recommended behaviours. This builds on the work of Vincent and Coulter (2002) and Koutanji et al., (2005) who identified roles for patients in promoting safety and Davis et al., (2007, 2008) who have explored and categorised the factors which influence patient participation in patient safety and the willingness of patients to question staff on quality and safety issues. This review extends this body of work in terms of unpacking the mechanisms by which patient involvement might enhance patient safety and identifying the broader conditions that may be necessary to ensure these can be effective. In this way we may be able to begin to see which kinds of interventions might be relatively unproblematic for patients.

Strengths and limitations
This is an extensive review. All identified potential sources were searched with no date or language restrictions. This, inevitably, produced a large volume of literature but, should ensure that most relevant literature has been appraised and included. Publications have not been excluded on grounds of quality and peer reviewed publications sit alongside self help guides to ‘survive your hospital stay’ (Kanegan and Boyette, 2003). This was necessary to gain a wider sense of the movement to
involve patients in patient safety, much of which has involved disparate, common sense responses adopted by individual organisations or in particular areas.

A large part of this literature originates in the US and refers to their health systems and for this reason applicability in other courtiers may be limited. However, the range of interventions described from different countries with different health care systems illustrate that similar approaches are being adopted within many systems. The practitioner/patient relationship which is at the heart of all health organisations and systems appears to have key similarities worldwide, that is a knowledge and status imbalance which means that the ability of a patient to adopt safety-related behaviours is profoundly affected by their own capacity to access and use knowledge and health professionals’ response to their taking on this role. The framework and analytical approach developed here should facilitate the consideration of these issues in relation to particular contexts and so be helpful to those considering transfer of patient involvement strategies to different settings.

There may be studies which have not been captured by the searches where patients have been involved and safety will be improved but safety improvement was not the primary, or even stated, aim of the intervention. This might especially be the case with older publications at a time when the term ‘patient safety’ was less frequently used.

The searches were conducted at the end of 2006. Although we have not systematically searched all reports published since this date we have, through monitoring relevant publications, attending conferences and maintaining contact with experts in the field through the project steering group, closely observed the field for any new themes or ideas. We are not aware of any literature which would change our overall conclusions.

**What this review adds to current knowledge**

We have identified three broad means by which patients can contribute to their own safety by identifying the purported mechanism of effect. This categorisation has provided a framework to identify what kinds of things need to happen to for patients to be involved and to contribute effectively to their safety.
For example:
There is some indication that patients being involved in making sure that they deliver and monitor their own treatment safely has been evaluated as a potentially effective means of improving their own safety albeit one for which patients have varying needs for support. Another pathway on the delivery and monitoring route involves patients monitoring the delivery of treatment to them by others. One key difference between these two ways of contributing to safety is the way that, for the former, patients are involved in the health system as a matter of course. Patients, who have been prescribed anticoagulants and selected to self manage their treatment, for example, are provided with appropriate equipment and shown how to use it; have access to health professional advice if they have problems. In contrast the patient who is just generally encouraged to ‘check your chart’ has no guarantee of a recognised space to voice concerns and the system may or may not provide them with the information they need to make sense of the chart so they can fulfil the role of vigilant observer.

This identification of broad routes and examination of the intended mechanism of effect allows us to think about what patients may be willing and able to do and look critically at the design of patient involvement interventions. This should bring more conceptual clarity and facilitate more careful consideration of these interventions.

**The negative effects of patient involvement**
The literature reviewed reveals little exploration of the potential negative effects of patient involvement in promotion of their own or other’s safety. In the few papers which do, there are suggestions that strategies to involve patients may: impact negatively on relationships between health professionals and patients; halt or limit other safety strategies; increase anxiety for patients and unfairly transfer responsibility for safety onto patients (Cahill, 1998; Entwistle et al., 2004, 2005; Swift, 2001). Such strategies may also disproportionately burden already disadvantaged patients. Calls for patients to take on some of the responsibility for their safety while using healthcare services does not appear to take into account the variability in the condition of the patient throughout a treatment journey; the capacity of patients and their carers to adopt safety promoting behaviours and the potential for no or negative responses from health professionals if patients or their
representatives do express concerns (Entwistle, 2004). Use of the framework and analytical approach developed should facilitate identification and consideration of these potential negative effects and ways they might be avoided.

Further research
There are good reasons for the lack of evidence for the effectiveness of patient involvement in patient safety. The complex nature of healthcare makes separating safety from other outcomes problematic. However, rigorous evaluations of interventions are needed. There are a range of study designs to choose from both experimental and non-experimental. Several commentators have engaged with this topic, suggesting possible avenues of investigation. (Brown et al., 2008; Brown and Lilford, 2009; Vincent et al., 2008). This area is further complicated because many patient involvement safety strategies are already being implemented, often in a piecemeal fashion with different interventions being implemented simultaneously. Robinson and Nash (2000) argue that concentration on a few patient safety interventions, such as medication review; checks prior to surgery and chasing lab results would be within the capability of most patients and would help to move the focus from the commonly held notion of individual blame for patient safety events to systems of care. Our framework should help to identify promising approaches before large scale investigations are carried out.

CONCLUSION

There has been a large volume of literature generated by the huge interest in the potential for involving patients in promoting their own and others’ safety. This involvement has widely been seen as desirable and potentially beneficial based on experience of patient involvement in decisions about their care and chronic disease management. Few of the interventions have been evaluated for effectiveness or acceptability, many appear to be ‘knee jerk’ reactions to adverse events and their theoretical basis has not been established. There appears to have been little consideration of the mechanism of effect and of what conditions and circumstances are required for patients to adopt safety roles. In addition there has been little exploration of the potential negative effects of patients’ involvement in promoting their own safety.
Identification of expected outcomes of interventions and their purported mechanism of effect has revealed that some ways that patients might be involved are both effective and within the capabilities of most patients. These are interventions which call on patients to ensure that they themselves monitor and deliver care safely and are characterised by facilitation by health professionals and supportive tools as a matter of course. Exploration of other ways of being involved using the little we know about patients’ willingness and ability to be involved reveal potential in those interventions which involve patients in informing the management plan as these largely involve safety promoting behaviours which are comfortable for patients and draw on their ‘expert’ knowledge of themselves. Some patients are happy to become involved in helping to make healthcare systems safer by drawing on their experience as a patient. However, a large proportion of the recommended safety behaviours are potentially problematic for many patients. Patients’ and their carers’ willingness and ability to be involved vary hugely, among individual patients and along individual patient journeys. It would be useful then, to not only explore which safety-related behaviours that patients are willing and able to adopt might be effective, but also which patients might be able to act to promote their own safety and where on their treatment journey they might do this most effectively.

There are some ways that patients might effectively be involved in keeping themselves safe while using health services and patient involvement in their wider care seems desirable. The approach we have developed on the basis of this scoping review encourages attention to the mechanisms by which patients might contribute to their safety, the conditions under which their contributions are likely to be successful and the extent to which these interventions are likely to ensure those conditions are filled in particular contexts. This approach should facilitate consideration of how and how well existing and future interventions might support patients’ contributions to patient safety in different contexts.
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CHAPTER TWO

Effectiveness of interventions designed to promote patient involvement to enhance safety: a systematic review

INTRODUCTION

This chapter reports the first systematic review of the research evidence on the effectiveness of interventions designed to promote patient involvement in patient safety, in a healthcare context. It has been conducted in conjunction with a broad-ranging review of strategies to promote patient involvement in patient safety (Chapter One).

Objectives
To identify, appraise and summarise evaluations of strategies or interventions which have been used with the intention of promoting patients’, and/or their family members’ involvement in their care with a view to enhancing their own, or others’ safety in a healthcare context.

METHODS

Criteria for considering studies for this review
Types of studies
The following study types were included:
1. Systematic reviews
   We did not wish to duplicate systematic reviews that had previously been undertaken. Therefore, if an existing systematic review of a relevant intervention(s) was located, the findings of that review were reported (rather than the individual studies themselves), provided the review was a high quality systematic review and recently published.
2. Experimental studies
   Participants are allocated to intervention or control groups by means of randomisation.
3. Quasi-experimental studies
Allocation to intervention/control groups is under the control of the investigator but falls short of genuine randomisation.

Types of participants
The review included any health service users or potential health service users in any health care context.

Types of interventions
We included any intervention which promoted or supported patients, (and/or their family/representatives), in activities relating to their healthcare with the explicit intention of enhancing patient safety. Studies that promoted or supported patients in activities relating to their healthcare, but did not aim to enhance safety were excluded. For example, in-patient self-medication which aimed to improve pain control or, coaching and question prompts which aimed to improve clinical decision-making.

Types of outcome measures
All reported outcome data were extracted. Outcomes of interest were

1. patient safety incidents.
   Including measures such as:
   a. Adverse incidents
   b. Adverse events
   c. Near misses.
   d. Other patient outcomes e.g. medication error rates, infection rates.

2. implementation aspects
   Including measures such as:
   a. Rates and patterns of uptake of the intervention (among patients and/or health professionals) and of any behaviours/practices it was designed to promote.
   b. Patients’ and/or health professionals’ attitudes relating to the intervention.
   c. Patients’ health status and sense of wellbeing.
   d. Other behaviours relating to health service delivery or use.
e. Patients' assessments or evaluations of health care quality, including their perceptions of involvement, of the quality of their interactions with health care professionals, and of their safety.

3. Intermediate outcomes.
Changes to structure or processes which may be expected to affect patient safety outcomes.

Search strategy for identification of studies
This review was conducted in conjunction with a broad-ranging review of strategies to promote patient involvement. Therefore, the search strategies were broad in nature in order to capture relevant records for each of the literature reviews. Search terms for ‘evaluations’ were not included as this would have risked missing potentially relevant records for the broad-ranging review. A range of free text terms and subject headings were used as appropriate for both the patient involvement concept of the question and the patient safety element.

The sources listed below were searched for papers relating to patient involvement in patient safety. The literature searches were designed to retrieve any study design and no language restrictions were applied to any of the searches. Databases were searched from the date of inception to the most recent date available, unless otherwise indicated. Two journals (Health Expectations and Quality and Safety in Healthcare) were hand searched for relevant publications. Full details of the sources searched, plus all the search strategies are the same as in Chapter One and can be found in Appendix 1.1.

Sources

Databases of Systematic Reviews
- Cochrane Database of Systematic Reviews (CDSR) (Issue 3, 2008)
- Database of Abstracts of Reviews of Effects (DARE) (July 2008)

Databases of Controlled Trials
- CENTRAL (Issue 3, 2008)
Health Related Databases
- CINAHL (1982 to July 2008)
- EMBASE (1980 to Week 29 2008)
- HMIC Health Management Information Consortium (July 2008)
- MEDLINE (1966 to July 2008)
- MEDLINE In-process & other non-indexed citations (July 2008)
- PsycINFO (1967 to July 2008)

Social Care Databases

Economic Evaluation Databases
- NHS Economic Evaluations Database (NHS EED) (July 2008)

Databases of Reports, Conference Proceedings, Grey Literature
- Agency for Healthcare Research and Quality (July 2008)
- Dissertation Abstracts (July 2008)
- Health Services/Technology Assessment Text (HSTAT) (July 2008)
- Health Technology Assessment Database (HTA) (July 2008)
- Index to Theses (July 2008)
- Inside Conferences (1993 to July 2008)
- ISI Science & Technology Proceedings (1990 to July 2008)
- ISI Social Science & Humanities Proceedings (1990 to July 2008)
- National Technical Information Service (NTIS) (1964 to July 2008)
- Zetoc Conferences (1993 to July 2008)

Databases of Ongoing Research
- Current Controlled Trials (August 2006)
- Health Services Research Projects in Progress (HSRPROJ) (July 2008)
- National Research Register (NRR) (Issue 3, August 2006)
- The Research Findings Electronic Register (ReFeR) (August 2006)
Patient Safety Organisations

- Australian Patient Safety Foundation (August 2008)
- Consumers Advancing Patient Safety (CAPS) (August 2008)
- The Health Foundation (August 2008)
- Institute for Healthcare Improvement (IHI) (August 2008)
- Institute of Medicine of the National Academies (IOM) (August 2008)
- Joint Commission on Accreditation of Healthcare Organisations/ International Centre for Patient Safety (August 2008)
- National Patient Safety Agency (NPSA) (August 2008)
- National Patient Safety Foundation (NPSF) (August 2008)
- Partnership for Patient Safety (p4ps) (August 2008)
- Picker Institute (August 2008)

Selection of studies

One author screened citations of the title and abstract (if available) for ordering. On receipt of the full paper, two researchers independently applied the inclusion criteria for all potentially relevant papers. If disagreements occurred, a third researcher was consulted.

Data extraction and management

Two researchers independently extracted data from the included papers into an ‘excel’ spreadsheet. Disagreements were resolved by consulting a third researcher. Extracted data included the following:

- Country
- Study design
- Patient group(s) and clinical setting in which the intervention was evaluated.
- Inclusion and exclusion criteria
- Characteristics of the participants
- Number of participants allocated to intervention and control
- Description of the intervention and control conditions
- Length of time to follow-up and losses to follow-up
- Outcomes (all reported outcome data were extracted)
Assessment of methodological quality of included studies

Quality assessment of the included studies was carried out independently by two researchers. Disagreements were resolved by consulting a third researcher. Systematic reviews were assessed according to the Quality of Reporting of Meta-analyses (QUOROM) statement (Moher 1999). Experimental and quasi-experimental studies were assessed according to criteria recommended by the Centre for Reviews and Dissemination (CRD), (CRD 2001). Full details of the assessment criteria are available in Appendix 2.1.

Data synthesis

After looking at the included studies in terms of participants, interventions and outcomes, it was not considered appropriate to undertake any meta-analyses. Therefore, to gain a better understanding of the interventions included in this review, three broad routes by which patients’ actions might contribute to safety were identified. The categorisations were:

- **Informing the management plan** – helping to ensure the appropriate treatment plan is formulated (e.g. patients make sure that health professionals have information about any of their allergies or adverse reactions to medication).
- **Monitoring and ensuring safe delivery of treatment** – helping to ensure the management plan is correctly implemented by:
  a. helping to ensure safe delivery of planned treatment by health professionals (e.g. checking that the correct dose of chemotherapy medication is administered at the right time).
  b. helping to ensure safe delivery of treatment by self (e.g. patient self-management of anticoagulation treatment).
- **Making systems safer** – helping ensure that current and future healthcare systems are safe (e.g. patients acting as patient representatives on a hospital safety committee).

Some of the interventions may be included in more than one category. For example, patient use of a treatment diary could be categorised as informing the management plan if the intention was that patients complete and update the diary with information about themselves. In addition the diary could also be categorised as supporting
monitoring and ensuring safe delivery of treatment if it contained general information for warning signs and symptoms to look out for and list routine tests that should be carried out.

Indirectly, all interventions could contribute to making systems safer but for the purpose of this review only those which explicitly set out to involve patients in ways that would have impacts on patient safety beyond the scope of their own care have been categorised as such.

**Description of Studies**

**Results of the search**

Over 22,000 references were retrieved by the searches (Figure 2.1). Sixty eight references were identified as potentially relevant and the full papers were ordered. On reading the full papers, 15 studies met the eligibility criteria. Four additional papers were identified as co-publications that reported aspects of the same study. To date, one paper has not been received and awaits classification. The search did not identify any on-going studies that fulfilled the inclusion criteria.
Included studies
There were 14 individual studies with 8460 participants (although there were 17,270 participants prior to post-randomisation exclusions) and 1 systematic review (included 16 RCTs). The systematic review also included a review of non-randomised controlled studies and is not reported here because a number of the study designs did not fit the inclusion criteria for this review.

Design
One included study was a systematic review and meta-analysis (Connock 2007). Amongst the 14 individual studies included in the present review 11 were an experimental design and the remainder were quasi-experimental (Atkin 1998, Fisher 1987, Varkey 2007).

Of the total 15 studies, 13 were journal publications and two were doctoral dissertations (Kennedy 1990, Punekar 2003). The dates that the papers were either
published or completed ranged from 1976 (Ley 1976) to 2007 (Connock 2007, Varkey 2007). The majority of the individual studies were conducted in the USA (n=9), plus 1 in Canada (Pereles 1996), 1 in Australia (Atkin 1998), 1 in Nepal (McKellar 2005), 1 in Belgium (Van haecht 1991) and 1 in the UK (Ley 1976).

The length of follow-up in these 14 individual trials ranged from immediately following the intervention (McKellar 2005, McMahon 1997) up to 12 months (Atkin 1998). In the systematic review, the duration of the included studies varied from 2 months to 24 months (Connock 2007).

Sample sizes
About 17,270 people were recruited to the 14 individual studies in the present review. 8810 were excluded for a number of reasons following randomisation (Fisher 1987, Punekar 2003). Of the remaining 8460 participants, 950 were lost to follow-up (11%). Sixteen randomized controlled trials (RCT) with 4283 participants were included in the systematic review and meta-analysis (Connock 2007).

Setting
Amongst the individual studies included in the present review eight took place in a hospital setting (five ward based and three in out-patients), three in general practice clinics (Atkin 1998, Van Haecht 1991, Varkey 2007), one in a health centre (McMahon 1997), one in a ‘senior’ centre (Neafsey 2002) and one in a community setting (Punekar 2003).

Participants
In five of the individual studies the participants were elderly patients, three as in-patients (Kennedy 1990, Kim 1981, Pereles 1996) and two as out-patients (Atkin 1998, Neafsey 2002). One study recruited parents of paediatric patients (McMahon 1997). The other eight studies included adult participants who were either in-patients (Schnipper 2006, Weingart 2004), primary care patients (Varkey 2007), collecting a prescription for oral antibiotics/tricyclic antidepressants (Fisher 1987), prescribed NSAIDs (Van Haecht 1991), prescribed a medication and illiterate (McKellar 2005), psychiatric out-patients (Ley 1976) or members of a drug benefit scheme (Punekar 2003). The mean age of the participants varied from
approximately 38 years to 80 years and the proportion of male participants in the studies ranged from 12% to 55%.

Interventions
The interventions employed in the 14 studies and the systematic review were all related to the use of medications and were classified as follows:

- In two studies the interventions er classified as informing the management plan (Atkin 1998, Varkey 2007).
- Eight individual studies and the systematic review reported on interventions that addressed monitoring and ensuring safe delivery of treatment (Connock 2007, Kim 1981, Ley 1976, McKellar 2005, McMahon 1997, Pereles 1996, Punekar 2003, Van Haecht 1991, Weingart 2004). In one study the intervention was concerned with helping to ensure safe delivery of planned treatment by health professionals (Weingart 2004). The remainder were helping to ensure safe delivery of treatment by self.
- In three studies the interventions were classified as informing the management plan combined with monitoring and ensuring safe delivery of treatment by self (Kennedy 1990, Neafsey 2002, Schnipper 2006).
- In one study, the intervention was classified as informing the management plan combined with making systems safer (Fisher 1987).

Informing the management plan
Two studies were classified as informing the management plan (Atkin 1998, Varkey 2007). Varkey et al evaluated a multifaceted intervention in primary care aimed at both patients and staff. There were two patient-level interventions; mailed letters before appointments to remind patients to bring all medication or an updated medication list to their clinic visit combined with verification and correction of the medication list in the electronic medical record by the patient. Atkin evaluated the effect of asking patients to bring all their currently used medications to each consultation with their GP (Atkin 1998). All patients were also given a ‘medication record card’ (completed by their GP) to bring to each appointment, which listed the patient’s current medication according to GP records and were visited by a pharmacist after each visit to their GP.
Monitoring and ensuring safe delivery of treatment

Eight individual studies and the systematic review were classified as monitoring and ensuring safe delivery of treatment. Eight were ensuring safe treatment by self and one was concerned with ensuring safe treatment by health professional (Weingart 2004). In three of the individual studies included in the present review the intervention comprised written information regarding the patients’ medication (Ley 1976, Van Haecht 1991, Weingart 2004). Three used some form of verbal instruction (Kim 1981, McKellar 2005, Pereles 1996), one study combined verbal instruction with a safety promoting ‘tool’ (McMahon 1997) and one combined written information with a safety promoting ‘tool’ (Punekar 2003). The systematic review by Connock assessed the effects of patient self-monitoring or self-management (self-testing and self-dosage) of anticoagulation (Connock 2007).

Ley evaluated the use of leaflets at three different reading levels (easy, moderate and hard) that informed depressed people about their medication. In the study by Weingart, hospital in-patients were given written drug safety information and a list of their current medication to prevent medical error. Van Haecht studied a patient package insert that was written in lay terminology and used simple syntax to educate patients receiving a prescription for NSAIDs.

In the three studies using verbal instruction, Pereles employed a nurse intervention to promote self-administration of medications by patients in hospital and in the study by Kim, the lead author/nurse studied the effect of varying the pace of medication instruction for elderly in-patients. Thirdly, in a rural Nepalese out-patients department medical auxiliary trainees (who were lay volunteers) were trained by McKellar to educate illiterate patients to improve dose understanding. Finally, verbal instructions plus the issue of a safety promoting ‘tool’ were used in the study by McMahon; parents’ of children receiving liquid medication were supplied with a syringe (or a syringe with the correct dose marked on it) to assist them in the correct dosing of their child’s medication. Parents in all groups (including the control) were also given verbal dosage instructions.

In the study by Punekar a ‘Medication Risk Reduction Behaviour Intervention’ was evaluated, which comprised a brochure containing a list of medication tips focusing
on patients’ understanding and sharing of medication related information with health care professionals. A second component of the intervention in the Punekar study was a ‘wallet card’, which included a list of questions for patients’ to ask their health care professional plus a blank space for them to record personal medical data.

**Informing the management plan combined with monitoring and ensuring safe delivery of treatment (by self)**

Three studies were classified to this category (Kennedy 1990, Neafsey 2002, Schnipper 2006). In two studies, health care professionals delivered the intervention; Schnipper employed pharmacist counselling to identify drug related problems. Kennedy examined a ‘Home Medication Behaviour Program’ which was an individualised teaching plan based on the patient’s medication and assessment data. This was implemented by a nurse and also included written information about their discharge instructions. The third study used an intuitive, interactive computer program to teach older adults about drug interactions (Neafsey 2002).

**Informing the management plan combined with making systems safer**

One study was classified to this combination of categories (Fisher 1987). Fisher examined a patient initiated reporting system for adverse clinical events. Patients were receiving a prescription for either oral antibiotics or tricyclic antidepressants.

**Outcomes**

A variety of outcomes were reported in the included studies. Six individual studies, plus the systematic review reported at least one patient safety incident outcome such as adverse drug events and reactions (Fisher 1987, Schnipper 2006, Van Haecht 1991, Weingart 2004), close call drug errors (Weingart 2004), medication errors (Ley 1976, Kennedy 1990) and adverse clinical events (Fisher 1987, Connock 2007). Nine studies reported a wide variety of ‘intermediate’ outcomes which may be expected to effect safety outcomes. For example, outcomes associated with patient knowledge of medication (Kim 1981, Neafsey 2002, Pereles 1996), accuracy and understanding of medication and/or dose (Atkin 1998, McKellar 2005, McMahon 1997), medication discrepancies in patient records (Varkey 2007), risk perception (Van Haecht 1991) and health care utilization (Schnipper 2006). Patient outcomes
such as morale (Pereles 1996), satisfaction (Neafsey 2002, Schnipper 2006, Van Haecht 1991) and self-efficacy (Neafsey 2002) were also reported.

Further details of the included studies are available in Table 2.1.
### Table 2.1 Characteristics of included studies

Mean age: years (standard deviation).

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Methods</th>
<th>Participants</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atkin 1998</td>
<td>Quasi-experimental (4 GPs: 2 recruited participants to either intervention or control). Follow-up 12 months.</td>
<td>Australia. Elderly patients attending GP clinic, taking at least 3 medications. Median age, (range): 75 (60-94). Gender, % male: 33%.</td>
<td>Intervention (n=104) MRC-plus MRC (Medication Record Card) - listed patient's current medications. MRC was given to the patient. After recruitment visited at home by a pharmacist. Patients were asked by their doctor to bring their MRC to all subsequent medical consultations and to produce it for updating at every consultation. Pharmacist visited each patient immediately after each GP consultation to physically inspect their medications. Additionally asked to bring their currently used medications to each consultation for the doctor to inspect. Request was made by the doctor at the time of recruitment as well as by mailed reminder or telephone call by practice receptionist, timed to reach the patient a day or so before a scheduled consultation. Control (n=102): MRC-only (as described above)</td>
<td>Accuracy of the MRC, presentation of MRCs and medications; frequency of consultation.</td>
<td>Patients in MRC-plus group made significantly more frequent visits to their doctor. However, authors state that for all patients the number of consultations was not a predictor of MRC accuracy; for all patients there was no significant difference in median frequency of consultations between those with accurate MRCs at 12 months and those with inaccurate MRCs.</td>
</tr>
<tr>
<td>Connock 2007</td>
<td>Systematic review and meta-analysis.</td>
<td>Adults on anticoagulant therapy irrespective of the indication for treatment.</td>
<td>Intervention: Self-testing (n=5) Self-management (n=9) Both (n=1) Control: Primary care/family doctor management (n=6) Specialised clinic (n=7)</td>
<td>Anticoagulation control, adverse events including bleeding events and thromboembolism, patient satisfaction and QoL</td>
<td>This is a report for the Health Technology Assessment NHS R&amp;D HTA Programme.</td>
</tr>
<tr>
<td>Study</td>
<td>Design/Methodology</td>
<td>Intervention (n=5371): patient-generated reports via telephone of ‘adverse clinical events’. On collection of prescription a removable sticker gives a toll-free telephone number along with more details about how to report any new or unusual symptoms during the next two weeks. Toll-free telephone was available from 9am to 8pm Monday to Friday. At other times, answering matching available. Control (n=4732): staff-generated reports. Interviewed by telephone approx 2 weeks later.</td>
<td>Symptom information reported by the groups</td>
<td>Baseline demographics not presented for all participants (only available for those that reported an ADE – significant differences between intervention and control on number of Hispanics and those taking concomitant medication. Of those randomised many were later excluded/invalid for a number of reasons.</td>
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<tr>
<td>Fisher 1987</td>
<td>Quasi-experimental (monthly alternation between two pharmacies). Follow-up 14 days</td>
<td>USA Out patients receiving a new prescription for either oral antibiotics or tricyclic antidepressants.</td>
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<td></td>
<td>No blinding.</td>
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<tr>
<td>Kennedy 1990</td>
<td>RCT (computer-generated list). Envelopes. Follow-up 30 days. Patient and outcome</td>
<td>USA Medical-surgical in-patients, English-speaking, aged 70 years and over.</td>
<td>Knowledge of medication; medication administration skills; medication error rates.</td>
<td>Violation of randomisation: to avoid having two patients in same hospital room assigned to different groups the second subject received the same group assignment as first person in the room.</td>
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<tr>
<td></td>
<td>assessor blind to allocation.</td>
<td>Intervention (n=32): Home Medication Behaviour Program. Based on assessment data an individualised teaching plan for each patient was devised using the Home Medication Behaviour Program. Patient receives written copy of the discharge orders/instructions. Nurse discussed the following areas with the patient as necessary: any previous difficulties with following prior medication regimens; ways to overcome potential barriers to compliance; individual counselling and standardised written materials on all prescribed medications; reinforcement of hospital discharge instructions sheet info regarding medication administration and additional information as necessary; assisted patient to establish and maintain accurate record of medication regimen; opportunity to select additional reminder aid e.g. home care pill box container. Summary of assessment and plan of care kept in patient’s chart. Family members, nursing staff and discharge planner all informed of the plans. Following</td>
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<td>Control (n=28): Staff-generated reports. Interviewed by telephone approx 2 weeks later.</td>
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</table>
discharge, patient contacted by phone within one week to determine if any problems taking medication, emphasise importance of taking meds as directed and to answer questions.

Control (n=33): patients informed that in approx 30 days a nurse would contact them to schedule home visit to review medications. Nurse investigator informed participants nurse that the patient had been evaluated for knowledge and skills for self-medication. Marked deficits in patient's knowledge or skills were reported to assigned staff nurse. No further intervention took place, traditionally the assessment of the educational needs of patients and families is responsibility of the staff nurse. In preparation for discharge the staff nurse is to clarify instructions regarding prescribed medications. Patient receives written copy of the discharge orders/instructions.

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Country</th>
<th>Description</th>
<th>Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kim 1981</td>
<td>RCT (block randomisation)</td>
<td>USA</td>
<td>Elderly inpatients with a chronic disease requiring a prescription for a diuretic, antihypertensive or digitalis drug. Mean age: 77 Gender, % male: 38</td>
<td>Knowledge of medication; response errors; self-paced response time.</td>
</tr>
<tr>
<td></td>
<td>Follow-up 1 day.</td>
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<td>Intervention 1 (n=15): Medication instruction at normal pace. Instruction included five areas: name of the drug, purpose, frequency, dosage and time of drug administration. Instruction was presented to the patients using audiotape and written learning material. Audiotape was used to control the presentation of learning material at a pace of 159 words per minute. Each patient received instruction for one prescribed medication and took approx 5 to 10 minutes. Intervention 2 (n=15): Medication instruction at slow pace. Audiotape was used to control the presentation of learning material at a</td>
<td>Knowledge of medication; response errors; self-paced response time.</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Setting</td>
<td>Intervention</td>
<td>Control</td>
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<tr>
<td>Ley 1976</td>
<td>RCT (random blocks within strata)</td>
<td>UK Psychiatric out-patients requiring tranquillizers or anti-depressant.</td>
<td>Intervention (n=40 in each group): one of three information leaflets which differed in reading level. All contained info on name of drug, what to do if tablet was forgotten and an explanation that the medication would take some time to have its full effects. Readability differed as measured by Flesch Formula. Control (n=40): normal procedure.</td>
<td>Medication errors.</td>
</tr>
<tr>
<td>McKellar 2005</td>
<td>RCT (alternation)</td>
<td>Rural Nepal Hospital outpatient department. Illiterate patients prescribed at least one medication.</td>
<td>Intervention (n=50): Community Medical Auxiliary On the Job Trainees (OJT) were trained to deliver dose counselling to illiterate patients, to check understanding and to repeat counselling until patients understood. Control (n=50): No intervention. Once outcome data collected control group were given the medicine counselling.</td>
<td>Correct understanding of medication dose regimen.</td>
</tr>
<tr>
<td>McMahon 1997</td>
<td>RCT (method unclear)</td>
<td>USA Parents attending health centre with children &lt;4 years of age diagnosed with otitis media and placed on an antibiotic suspension.</td>
<td>Intervention 1 (n=30): Received verbal instructions and a syringe. Researcher demonstrated the dose. Parents gave verbal confirmation that they understood the dosage to be given. Parents then went to pick up prescription and returned to clinic to give a dose of medication using syringe. Intervention 2 (n=30): Received verbal instructions and a syringe with correct dose permanently marked on it. Parents then went to pick up prescription and returned to clinic to give a dose of medication using syringe.</td>
<td>Accuracy of dose.</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Follow-up</td>
<td>Setting</td>
<td>Participants</td>
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<tr>
<td>Neafsey 2002</td>
<td>RCT</td>
<td>28 days</td>
<td>USA</td>
<td>Elderly people attending senior centres. Mean age: 73.8 (6.5) Gender, % male: 27%</td>
</tr>
<tr>
<td>Pereles 1996</td>
<td>RCT</td>
<td>40 days</td>
<td>Canada</td>
<td>Elderly hospital in-patients. Mean age 80 (7). Gender % male: Intervention 27 Control 14</td>
</tr>
<tr>
<td>Punekar 2003</td>
<td>RCT</td>
<td>42 days</td>
<td>USA</td>
<td>Member of drug benefit plan with at least one prescription filled in the three months. Gender, % male: Intervention 32.4 Control 31.6</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Setting</td>
<td>Intervention</td>
<td>Control</td>
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<tr>
<td>Schnipper 2006</td>
<td>RCT (computer generated algorithm).</td>
<td>USA</td>
<td>In-patients on general medicine wards. Mean age 58. Gender, % male: 34.</td>
<td>Usual care</td>
</tr>
<tr>
<td></td>
<td>Sealed opaque envelopes by those recruiting. Blinded assessment of outcome.</td>
<td>Follow-up 30 days.</td>
<td>Intervention (n=92): Pharmacist counselling at discharge with follow-up telephone call 3 to 5 days later. Counselling included medication reconciliation and discussion of current medications such as indications and directions for use and potential adverse effects. Follow-up call to compare patient self-reported medication with discharge list, plus also asked about possible adverse effects and adherence. Control (n=84): Usual care</td>
<td>Control (n=84): Received routine review of medication orders by a ward-based pharmacist and medication counselling by a nurse at time of discharge. Nurse counselling typically focused on medication directions and may have included a discussion of indications or potential side effects, especially for new medications. These sessions sometimes included informal medication reconciliation, such as comparing discharge medications with those currently prescribed in hospital.</td>
</tr>
<tr>
<td>Van haecht 1991</td>
<td>RCT (Restricted randomization in permuted blocks using a table of random sampling numbers). Numbered packages. Care provider (also the outcome assessor) and patient were blind to</td>
<td>Belgium. Patients attending GP with acute locomotor injury requiring NSAIDs. Mean age 38 (15). Gender % male: 55%.</td>
<td>Intervention (n=161): Patient Package Insert (PPI). Uses explicit headings, lay terminology and simple syntax. Layout and overall look identical to traditional insert including small character size.</td>
<td>Traditional insert.</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Setting</td>
<td>Intervention Details</td>
<td>Control Details</td>
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<tr>
<td>Weingart 2004</td>
<td>RCT (random numbers).</td>
<td>USA</td>
<td>Adult medical in-patients. Mean age: Intervention 57.9 (18.8) Control 61.8 (20.1) Gender, % male: Intervention 42.1 Control 31.4</td>
<td>Blinded outcome assessment. Follow-up 1053 patient-days at risk.</td>
</tr>
<tr>
<td>Varkey 2007</td>
<td>Quasi-experimental (allocation based on date of consultation)</td>
<td>USA</td>
<td>Adults visiting primary care clinic Mean age: Intervention 49.94 (12.86) Control 53.56 (13.36) Gender, % male: Intervention 4 (8) Control 9 (16.7)</td>
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</tbody>
</table>
Control (n=57)
Medication history obtained from the patient by the provider and documented as usual in the medication history section of the EMR.
Excluded studies
Forty eight potentially relevant studies were excluded from the review. The main reason for exclusion (29 papers) was that the study design was not a systematic review, experimental or quasi-experimental design. For example, other study designs employed included individual case studies, surveys, uncontrolled designs and retrospective control studies. Five papers (four individual studies and two systematic reviews) that examined the self-management of anticoagulation were excluded because a high quality, recently published systematic review was located in which they were included. A further three reviews were considered and excluded because they were either not systematic (Coulter 2006, Pizzi 2001), or were out-of-date (Ioannidis 2001). The remaining 10 studies were excluded because they did not consider patient involvement (5) or were not concerned with patient safety (5). Full details of the characteristics of excluded studies can be found in Appendix 2.2. References for excluded studies can be found in Appendix 2.3.

Methodological quality of included studies
Overall, the methodological quality of the majority of the included studies was poor. Of the 11 RCTs, in only 6 studies was it possible to determine that the assignment to groups was really random and none of the included studies provided details regarding concealment of the allocation. Nearly all the studies specified eligibility criteria and it was also possible to determine baseline similarity in the majority. In most cases, the care provider and patient were not blinded to the treatment allocation (or it was not possible to tell from the report). Only four studies provided details of blinded outcome assessment, the remainder did not undertake blinded assessment or it was not possible to ascertain from the report. Five studies presented the point estimate and measure of variability for the primary outcome measure; the remainder provided either partial data (the most common omission being no SD) or none at all. Only two studies included all participants in the analyses, nine did not and in two reports it was not possible to determine the numbers used in the analyses.
The quality of the systematic review and meta-analysis of self-management of anticoagulation was good, addressing all the items on the QUOROM checklist. Further detail of the methodological quality is available in Appendix 2.4.

RESULTS

The results have been organised according to the categories defined in Chapter One for organising the interventions employed in the studies: informing the management plan, monitoring and ensuring safe delivery of treatment (by health professional or by self), making systems safer, or a combination of the above. A brief overview of the findings for each classification is presented. This is followed by a more detailed breakdown of the outcomes of interest to this review. The outcome categories of patient safety incidents, implementation outcomes and intermediate outcomes are also detailed in subsequent tables. (Tables 2.2, 2.3 and 2.4 respectively).

Informing the management plan

The interventions that encouraged the patient in informing the management plan reported a beneficial impact on intermediate outcomes (Atkin 1998, Varkey 2007). There were no patient safety incidents or implementation outcomes reported.

1. Impact on patient safety incident outcomes
   None reported.

2. Implementation outcomes
   None reported.

3. Intermediate outcomes
   In the study by Atkin, significantly more of the patients who were requested to bring their currently used medications to each doctor appointment had an accurate medication record card compared to the control group (Atkin 1998).
Varkey et al reported that patients who were reminded to bring their medication to appointments and corrected their medication list in their electronic medical record had significantly fewer discrepancies on their medication lists, compared to usual care (Varkey 2007).

**Monitoring and ensuring safe delivery of treatment by self**

Interventions that encouraged the patient in monitoring and ensuring safe delivery of treatment by self reported beneficial impacts on some intermediate and patient safety incident outcomes, but no effect on implementation outcomes.

1. Impact on patient safety incident outcomes

An evaluation of information leaflets which differed in reading level reported that those receiving the ‘easy’ leaflet had significantly lower medication error scores than those receiving ‘moderately difficult’ leaflets, who in turn obtained significantly lower medication error scores than those receiving ‘difficult’ leaflets (Ley 1976). There was no difference in medication error scores between those who received the difficult leaflet and a control group who received no leaflet at all. Pereles reported that at 40 days follow-up, the ‘Self Medication Programme’ intervention group made significantly fewer medication errors compared to the control group who received ‘standard care’ by ward nurses (Pereles 1996). Van Haecht reported a significant increase in spontaneous reporting of adverse drug reactions by participants in the intervention group (‘patient package insert’ with NSAID prescription) compared to the control group (traditional insert) (Van Haecht 1991). The systematic review of patient self-management of anticoagulation versus usual care reports that pooled estimates showed significant reductions in thromboembolic events and death, but not major haemorrhage (Connock 2007). However, Connock et al highlight a number of caveats to take into account. Firstly, the differences in complications and deaths were not consistently associated with differences in anticoagulant control; therefore the observed reduction in complications and deaths may be attributable to other explanations, including other components of the interventions (e.g. patient education or training) and systematic or chance errors. Secondly, there is a
lack of evidence about whether patient education or training alone is sufficient to reduce the risk of complications and death. Finally, the reductions in complications and deaths by patient self-management were mainly observed in trials conducted outside the UK, although this was derived from a post-hoc sub-group analyses and ‘should be interpreted with great caution’.

2. Implementation outcomes
In the study by Pereles (self-medication programme) there were no differences between groups in the number of patients self-medicating on discharge and patient morale (Pereles 1996). In the Van Haecht study there were no differences in overall patient satisfaction between those that received the ‘patient package insert’ or the ‘traditional insert’ or in the percentage of each group who read them (Van Haecht 1991). The review of self-management of anticoagulation reported improved outcomes of self-efficacy, treatment satisfaction and perception of daily hassles for the intervention group. There were no differences between groups in Quality of Life. The review authors also report data on issues related to patient acceptability of self-management, for example lack of confidence and difficulties using the equipment were cited by participants as reasons for either refusal to participate or withdrawal from a study. A narrative review of available cost-effectiveness data was also undertaken (five studies favoured self-management, in two superiority was not clear) and concluded that based on a UK study self-management does not appear to be cost-effective for the NHS compared to usual care (Connock 2007).

3. Intermediate outcomes
In a study comparing normal and slow paced medication instruction (with a no instruction control group) Kim reported that the slow paced group significantly outperformed the normal paced and control group on gain score and that the slow group made significantly less response errors than the normal paced group (Kim 1981). No differences were found between groups on self-paced response time. McKellar reports a significant improvement in correct understanding of medication dosage for illiterate patients who received dose counselling compared to a control group that did not receive counselling
McMahon reported that parents receiving a syringe, or syringe with correct dose marked on it, were significantly better at accurately dosing their child’s liquid medication compared to a control group who received verbal instructions only (McMahon 1997). There were no differences between the two intervention groups. The medication brochure/wallet card intervention by Punekar reported no differences between groups for ‘medication risk reduction behaviours’ (Punekar 2003). Self-management of anticoagulation was associated with improvements in the time in therapeutic range compared to usual care by family doctor and was also as effective as specialised anticoagulation clinics (Connock 2007).

Monitoring and ensuring safe delivery of treatment by health professional
One study reported no differences between groups for patient safety incidents and implementation outcomes. No intermediate outcomes were reported.

1. Impact on patient safety incident outcomes
In a study of hospital in-patients in which the intervention group were given a list of their current medication plus a one page medication safety consumer guide no differences were observed in adverse drug event rate or close-call drug errors compared to a control group who received the one page guide only (Weingart 2004).

2. Implementation outcomes
Weingart reported no differences between groups in the patients’ ‘experience’ (Weingart 2004).

3. Intermediate outcomes
None reported
Informing the management plan combined with monitoring and ensuring safe delivery of treatment

Interventions that encouraged the patient in informing the management plan plus monitoring and ensuring safe delivery of treatment reported a beneficial impact on some outcomes in all three categories.

1. Impact on patient safety incident outcomes
Patients receiving a ‘Home Medication Behaviour Program’ made significantly fewer medication errors compared to a ‘usual care’ control group (Kennedy 1990). Schnipper found that in participants who received pharmacist counselling significantly fewer ‘preventable’ adverse drug events were detected at follow-up, compared to ‘usual care’ by ward-based pharmacist and nursing staff. However, there was no difference between the groups for total adverse drug events (Schnipper 2006).

2. Implementation outcomes
Neafsey reported that patients participating in an interactive computer program about potential drug interactions had significantly greater self-efficacy compared to conventional care and control groups but did not find any differences between groups in patient satisfaction (Neafsey 2002). Schnipper (pharmacist counselling intervention) found no differences between groups in health care utilization (Schnipper 2006).

3. Intermediate outcomes
Intervention group participants in the Kennedy study performed significantly better on outcomes of knowledge of medication and medication administration skills (Kennedy 1990). Intervention group participants in the Neafsey study also had significantly greater knowledge and decrease in adverse self-medication behaviours compared to the conventional and control groups (Neafsey 2002).

Informing the management plan combined with making systems safer
The intervention that encouraged the patient in informing the management plan combined with making systems safer reported a beneficial impact on
patient safety incident outcomes. There were no intermediate or implementation outcomes reported.

1. Impact on patient safety incident outcomes
In the study by Fisher, the authors reported that a patient-initiated system yielded information comparable to staff-initiated controls (Fisher 1987).

2. Implementation outcomes
None reported.

3. Intermediate outcomes
None reported.
Table 2.2 Summary of effect on patient safety incident outcomes

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Patient Safety Incident Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Favour prevention</td>
<td>No difference</td>
</tr>
<tr>
<td>Informing the management plan</td>
<td></td>
</tr>
<tr>
<td>Medication Record Card/ bring all meds/ visit by pharmacist, Atkin 1998</td>
<td>NR</td>
</tr>
<tr>
<td>Reminder to bring meds/ verification of med list, Varkey 2007</td>
<td>NR</td>
</tr>
<tr>
<td>Monitoring and ensuring safe delivery of treatment by self</td>
<td>Reduction in death; reduction in thromboembolic events</td>
</tr>
<tr>
<td>Self-management of anticoagulation, Connock 2007</td>
<td></td>
</tr>
<tr>
<td>Medication instruction at normal or slow place, Kim 1981</td>
<td>NR</td>
</tr>
<tr>
<td>‘Easy’ read information leaflet, Ley 1976</td>
<td>Decrease in medication errors</td>
</tr>
<tr>
<td>Medication dose counselling, McKellar 2005</td>
<td>NR</td>
</tr>
<tr>
<td>Dosing instruction/ syringe with dose marked, McMahon 1997</td>
<td>NR</td>
</tr>
<tr>
<td>Nurse intervention to promote self-administration of medication in hospital, Pereles 1996</td>
<td>Decrease in medication errors</td>
</tr>
<tr>
<td>Medication tips brochure/ wallet card, Punekar 2003</td>
<td>NR</td>
</tr>
<tr>
<td>Patient package insert, Van Haecht 1991</td>
<td>Increase in patient reporting of adverse drug reactions</td>
</tr>
<tr>
<td>Monitoring and ensuring safe delivery of treatment by health professional</td>
<td>NR</td>
</tr>
<tr>
<td>List of current medication/ one page medication consumer guide, Weingart 2004</td>
<td></td>
</tr>
<tr>
<td>Informing the management plan/ monitoring and ensuring safe delivery of treatment</td>
<td>Reduction in medication errors</td>
</tr>
<tr>
<td>Individualised teaching plan by nurse, Kennedy 1990</td>
<td></td>
</tr>
<tr>
<td>Personal education plan via interactive computer, Neafsey 2002</td>
<td>NR</td>
</tr>
<tr>
<td>Pharmacist counselling, Schnipper 2006</td>
<td>Reduction in preventable adverse drug events; reduction in total adverse drug events</td>
</tr>
<tr>
<td>Informing the management plan/ making systems safer</td>
<td>NR</td>
</tr>
<tr>
<td>Patient-initiated reporting system, Fisher 1987</td>
<td></td>
</tr>
</tbody>
</table>
Footnotes
NR: None Reported

Patient Safety Outcomes: e.g. adverse incidents, adverse events, near misses, medication error rates, infections rates.
Informing the management plan: helping to ensure that appropriate treatment plan is formulated.
Monitoring and ensuring safe delivery of treatment: helping to ensure the management plan is correctly implemented.
Making systems safer: helping ensure that current and future healthcare systems are safe.
<table>
<thead>
<tr>
<th>Intervention</th>
<th>Favour intervention</th>
<th>Implementation Outcomes</th>
<th>Favour control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informing the management plan</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Medication Record Card/ bring all meds/ visit by pharmacist. Atkin 1998</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reminder to bring meds/ verification of med list. Varkey 2007</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Monitoring and ensuring safe delivery of treatment by self</td>
<td></td>
<td>Self-efficacy; treatment satisfaction; perception of daily hassles</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>Self-management of anticoagulation. Connock 2007</td>
<td></td>
<td></td>
<td>Cost-effectiveness (based on 1 UK study)</td>
</tr>
<tr>
<td>Medication instruction at normal or slow place. Kim 1981</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>‘Easy’ read information leaflet. Ley 1976</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Medication dose counselling. McKellar 2005</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Dosing instruction/ syringe with dose marked. McMahon 1997</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Nurse intervention to promote self-administration of medication in hospital. Pereles 1996</td>
<td>NR</td>
<td>Able to self-medicate; patient morale</td>
<td>NR</td>
</tr>
<tr>
<td>Medication tips brochure/ wallet card. Punekar 2003</td>
<td>NR</td>
<td>Patient satisfaction; benefit/risk perception of medication; read insert</td>
<td>NR</td>
</tr>
<tr>
<td>Monitoring and ensuring safe delivery of treatment by health professional</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>List of current medication/ one page medication consumer guide. Weingart 2004</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Informing the management plan/ monitoring and ensuring safe delivery of treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individualised teaching plan by nurse. Kennedy 1990</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Personal education plan via interactive computer. Neafsey 2002</td>
<td></td>
<td>Self-efficacy</td>
<td>Intent to make behaviour change</td>
</tr>
<tr>
<td>Pharmacist counselling. Schnipper 2006</td>
<td>NR</td>
<td>Patient satisfaction</td>
<td>NR</td>
</tr>
<tr>
<td>Informing the management plan/ making systems safer</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Patient-initiated reporting system. Fisher 1987</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Footnotes

NR: None Reported.

Implementation Outcomes: e.g. rates of uptake of the intervention, patient/healthcare professional attitudes relating to intervention, patient health status, sense of wellbeing.

Informing the management plan: helping to ensure that appropriate treatment plan is formulated.

Monitoring and ensuring safe delivery of treatment: helping to ensure the management plan is correctly implemented.

Making systems safer: helping ensure that current and future healthcare systems are safe.
Table 2.4 Summary of effect on intermediate outcomes

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Favours intervention</th>
<th>Intermediate Outcomes</th>
<th>Favours control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informing the management plan</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication Record Card/ bring all meds/ visit by pharmacist. Afkin 1998</td>
<td>Accuracy of medication record card</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Reminder to bring meds/ verification of med list. Varkey 2007</td>
<td>Accuracy/completeness of med list; accuracy/completeness of prescription only meds; severity of error ratings</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Monitoring and ensuring safe delivery of treatment by self</td>
<td>Time in therapeutic range (where control is usual care by family doctor)</td>
<td>Time in therapeutic range (where control is specialist anticoag clinic)</td>
<td>NR</td>
</tr>
<tr>
<td>Self-management of anticoagulation. Connock 2007</td>
<td>Knowledge of medication; response errors</td>
<td>Self-paced response time</td>
<td>NR</td>
</tr>
<tr>
<td>Monitoring and ensuring safe delivery of treatment by health professional</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>List of current medication/ one page medication consumer guide. Weingart 2004</td>
<td>NR</td>
<td>Knowledge of medication</td>
<td>NR</td>
</tr>
<tr>
<td>Monitoring and ensuring safe delivery of treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individualised teaching plan by nurse. Kennedy 1990</td>
<td>Knowledge of old medication; knowledge of new medication; medication administration skills</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Personal education plan via interactive computer. Neafsey 2002</td>
<td>Knowledge; adverse self-medication behaviours</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Pharmacist counselling. Schnipper 2006</td>
<td>NR</td>
<td>Medication discrepancies; healthcare utilization</td>
<td>NR</td>
</tr>
<tr>
<td>Informing the management plan/ making systems safer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient-initiated reporting system. Fisher 1987</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>
Footnotes

NR: None Reported

Intermediate Outcomes: changes to structure or processes which may be expected to affect patient safety outcomes.
Informing the management plan: helping to ensure that appropriate treatment plan is formulated.
Monitoring and ensuring safe delivery of treatment: helping to ensure the management plan is correctly implemented.
Making systems safer: helping ensure that current and future healthcare systems are safe.
<table>
<thead>
<tr>
<th>Study ID</th>
<th>Type of Intervention</th>
<th>Impact on Patient Safety Incident Outcomes</th>
<th>Implementation Outcomes</th>
<th>Intermediate Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atkin 1998</td>
<td>Informing the management plan</td>
<td>Presentation of MRCs and medications: 161 patients who remained in the study for 12 months had a combined total of 1648 consultations over that period, of which 1280 (77.7%) involved the use of an MRC. No significant difference between the two groups in terms of frequency of MRC use at consultations. Of those completing the study, 96.3% of MRC-plus patients showed their medications to their doctor at least once in 12 months, compared with 5% of MRC-only patients who did this spontaneously (&lt;0.0001). The MRC-plus group doctors physically inspected their patients' medications a median of twice per patient (range 0-19) with only two patients never having their medications inspected. Frequency of consultation over 12 months: intervention median 10, control median 7, p 0.0001 For all patients over 12 months: accurate MRC median 8.5, inaccurate MRC median 8, p=0.19</td>
<td>Accuracy of medication record card at 12 months: intervention 34/81, control 8/80, p &lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Monitoring and ensuring safe delivery of treatment by self</td>
<td>Thromboembolic events, n trials (n participants), risk difference (95% CI): 15 trials (4091) Risk difference -0.0224 (-0.0334 to -0.0115) Deaths, n trials (n participants), risk difference (95% CI): 15 trials (4091) Risk difference -0.0170 (-0.0287 to -0.0053) Major bleeding, n trials (n participants), risk difference (95% CI): 15 trials (4091) Risk difference -0.0039 (-0.0154 to 0.0077)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time in therapeutic range/INR tests in therapeutic range, n trials, % in range: 15 trials Intervention 71.8% Control 61.8% Time in therapeutic range, n trials, % in range: 12 trials Intervention 67.4% Control 63.4%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Six trials reported Quality of Life data using a number of different measures. In three using same questionnaire found increased distress about treatment in patients given education but no control over monitoring/dosing, increased self-efficacy in patients who self-monitored and increased treatment satisfaction, self-efficacy and reduced perception of daily hassles for those who self-managed. No significant differences in measured Quality of Life between groups using other measures.

Patient acceptability: in 15 trials 33% eligible patients agreed to participate, 80% randomised to intervention group were successfully trained and/or able to conduct self-management. 87% of those who started self-management completed the allocated intervention. Reasons for refusing trial entry were fear of blood sampling, satisfaction with current service provision, lack of confidence and a preference not to contemplate illness. Reasons for withdrawal during studies included difficulties with blood sampling or operation of the coagulometer, lack of confidence in ability to self-monitor or self-manage or a preference to return to physician management.

Economic evaluation: 7 trials, 5 favoured self-management but superiority not clear in 2. In UK study, self-management does not appear cost-effective £417 vs £122 per patient-year.
<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Adverse clinical event reporting:</th>
<th>Knowledge of old medication, mean (sd): intervention 4.01 (5.30), control 10.08 (9.16), p &lt; .030</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fisher 1987</td>
<td>Informing the management plan and making systems safer</td>
<td>Of 69 symptoms in each drug class (oral antibiotics and tricyclic antidepressants) only two showed significant differences in reporting between the two groups.</td>
<td>Knowledge of old medication, mean (sd): intervention -7.41 (5.33), control 0.40 (5.0), p &lt; .0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medication errors, mean (sd): intervention 4.01 (5.30), control 10.08 (9.16), p &lt; .030</td>
<td>Knowledge of new medication, mean (sd): intervention -9.88 (7.06), control -4.56 (5.49), p &lt; .005</td>
</tr>
<tr>
<td>Kennedy 1990</td>
<td>Informing the management plan and monitoring and ensuring safe delivery of treatment</td>
<td>Knowledge of old medication, mean (sd): intervention -7.41 (5.33), control 0.40 (5.0), p &lt; .0000</td>
<td>Knowledge of new medication, mean (sd): intervention -9.88 (7.06), control -4.56 (5.49), p &lt; .005</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Knowledge of new medication, mean (sd): intervention -9.88 (7.06), control -4.56 (5.49), p &lt; .005</td>
<td>Medication administration skills, mean (sd): intervention -5.93 (6.13), control 4.62 (6.69), p &lt; .0000</td>
</tr>
<tr>
<td>Kim 1981</td>
<td>Monitoring and ensuring safe delivery of treatment by self</td>
<td>Knowledge of medication, mean gain score (sd): Intervention 1, 2.8 (2.81), Intervention 2, 7.40 (4.17), Control 1.27 (2.74), p &lt; .01</td>
<td>Knowledge of medication, mean gain score (sd): Intervention 1, 2.8 (2.81), Intervention 2, 7.40 (4.17), Control 1.27 (2.74), p &lt; .01</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Response errors, mean (sd): Intervention 1, 3.267 (1.751), Intervention 2, 2.200 (1.373), p &lt; .05</td>
<td>Response errors, mean (sd): Intervention 1, 3.267 (1.751), Intervention 2, 2.200 (1.373), p &lt; .05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Self-paced response time, shorter or longer than common median value: Intervention 1, 10 shorter 5 longer. Intervention 2, 4 shorter 11 longer. Control, 8 shorter 7 longer. P &gt; .05</td>
<td>Self-paced response time, shorter or longer than common median value: Intervention 1, 10 shorter 5 longer. Intervention 2, 4 shorter 11 longer. Control, 8 shorter 7 longer. P &gt; .05</td>
</tr>
<tr>
<td>Author</td>
<td>Year</td>
<td>Description</td>
<td>Results</td>
</tr>
<tr>
<td>-------------</td>
<td>----------</td>
<td>-------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>McKellar 2005</td>
<td></td>
<td>Monitoring and ensuring safe delivery of treatment by self</td>
<td>Understanding of medication dosage, % correctly repeating advice given: Intervention 88 Control 70. p=0.03</td>
</tr>
<tr>
<td>McMahon 1997</td>
<td></td>
<td>Monitoring and ensuring safe delivery of treatment by self</td>
<td>Accuracy of dosing liquid medication, % accurate: Intervention 1: 83 (p=.005) Intervention 2: 100 (p=.005) Control: 37</td>
</tr>
<tr>
<td>Nealsy 2002</td>
<td></td>
<td>Informing the management plan and monitoring and ensuring safe delivery of treatment</td>
<td>Self-efficacy: both PEP (Personal Education Program) and conventional groups had significant higher self-efficacy than controls at all time points (p&lt;0.05). Also, PEP group had higher self-efficacy scores than conventional group at all three time points (p&lt;0.05). Patient satisfaction with PEP, mean (sd) overall score: 4.52 (.60) Knowledge: both PEP and conventional groups had significant higher knowledge scores than controls at all time points (p&lt;0.05). Also, PEP group had higher knowledge scores than conventional group at all three time points (p&lt;0.05). Adverse self-medication behaviours: Significant decrease in adverse behaviour in PEP group &lt;0.05</td>
</tr>
<tr>
<td>Pereles 1996</td>
<td></td>
<td>Monitoring and ensuring safe delivery of treatment by self</td>
<td>Medication errors, as % of total doses since discharge: Intervention 14 Control 25, p&lt;.001 Self-medicating at 1 month (n): Intervention 35, Control 35 Patient morale, mean (sd): Intervention pre 15 (5), post 16 (4). Control pre 15 (5), post 16 (4). p=.164 Patient knowledge about medication, % of correct responses in each knowledge category: No significant differences between groups (no overall score presented).</td>
</tr>
<tr>
<td>Authors</td>
<td>Title</td>
<td>Interventions</td>
<td>Control</td>
</tr>
<tr>
<td>----------------------</td>
<td>----------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Punekar 2003</td>
<td>Monitoring and ensuring safe delivery of treatment by self</td>
<td>Medication risk reduction behaviours, mean:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention pre 3.59, post 3.71</td>
<td>Control pre 3.60, post 3.71</td>
</tr>
<tr>
<td>Schnipper 2006</td>
<td>Informing the management plan and monitoring and ensuring safe delivery of treatment</td>
<td>Presence of preventable adverse drug events at 30 days post discharge, n/N:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention 1/79, Control 8/73, p=0.01</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Presence of total adverse drug events, n/N:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention 14/79, Control 12/73, p=0.99</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patient satisfaction (scores of 4 and greater on 5 point scale), n/N:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention 60/71, Control 57/65, p=0.63</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Health care utilization (emergency dept visit or readmission), n/N:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention 28/82, Control 25/84, p&gt;.99</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medication discrepancies, n/N:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention 44/72, Control 43/66, p=.72</td>
<td></td>
</tr>
<tr>
<td>Van haecht 1991</td>
<td>Monitoring and ensuring safe delivery of treatment by self</td>
<td>Patient satisfaction with insert, scale 1 to 7, (mean):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention 6, Control 6, p= 0.9952</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefit/risk perception of medication, scale 1 to 7, (mean):</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Intervention 2, Control 3, p=0.0163</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Proportion who did not read the intervention, n/N, (%):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention 44/161 (27.3), Control 48/156 (30.8)</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Objective</td>
<td>Medication Lists with Discrepancies</td>
<td>Discrepancy Severity</td>
</tr>
<tr>
<td>--------------</td>
<td>---------------------------------------------------------------------------</td>
<td>-------------------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Varkey 2007</td>
<td>Informing the Management Plan</td>
<td>All medication lists</td>
<td>A.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control 3/102 (2.9)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>B. 0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C. 21 (17%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>D. 102 (82.9%)</td>
</tr>
<tr>
<td>Weingart 2004</td>
<td>Monitoring and ensuring safe delivery of treatment by health professional</td>
<td>Adverse Drug Event Rate, n/N (%)</td>
<td>A.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control 3/102 (2.9)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>B. 0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C. 21 (17%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>D. 102 (82.9%)</td>
</tr>
</tbody>
</table>
DISCUSSION

This review identified evidence of safety benefit for patient involvement in one specific aspect of self-medication, but little evidence of effectiveness in other aspects of health care.

The majority of studies fell into the monitoring and ensuring safe delivery of treatment by self category and the interventions were all related to enhancing medication safety. Only half of the included studies evaluated at least one outcome related to patient safety incidents. Of those that did evaluate patient safety incidents authors’ reported improved outcomes for the intervention groups compared to controls where the interventions aimed to encourage patient involvement in:

- Informing the management plan/ monitoring and ensuring safe delivery of treatment (individualised teaching plan by nurse, pharmacist counselling).

We also examined implementation and intermediate outcomes from the included studies. Authors’ reported improved implementation outcomes for the intervention groups compared to controls where the interventions aimed to encourage patient involvement in:

- Monitoring and ensuring safe delivery of treatment by self (self-management of anticoagulation).
- Informing the management plan/ monitoring and ensuring safe delivery of treatment (personal education plan via interactive computer program).

Authors’ reported improved intermediate outcomes for the intervention groups compared to controls where the interventions aimed to encourage patient involvement in:
• Informing the management plan (medication record card/med reminder/pharmacist visit, med reminder/verification of med list).

• Monitoring and ensuring safe delivery of treatment by self (self-management of anticoagulation, medication instruction at normal or slow pace, dose counselling, dosing instruction/syringe with dose marked).

• Informing the management plan/monitoring and ensuring safe delivery of treatment (individualised teaching plan by nurse, personal education plan via interactive computer).

However, it was not possible to draw any clear conclusions as to the effectiveness of the interventions (with the exception of one specific aspect of self-medication i.e. self-management of anticoagulation) due to concerns about the methodological quality of the studies.

As stated above, a major caveat regarding the findings of the individual studies (experimental and quasi-experimental) was their methodological quality and hence, their internal validity. We assessed the studies in a number of areas including; method of randomisation, allocation concealment, use of blinding, outcome data and analysis. In general, most were methodologically poor, with a few notable exceptions that were rated more favourably (Kennedy 1990, Schnipper 2006, Van Haecht 1991, Weingart 2004). Studies with inadequate methodological approaches are associated with bias and have been shown to yield larger estimates of treatment effect (Schulz 1995). Whilst most of the criteria against which the included studies were assessed are entirely relevant and achievable, it should be noted that the blinding (masking) of patients to group allocation may not be simple, or indeed may be impossible, due to the nature of the interventions. Despite this difficulty, the conclusion of poor methodological quality overall is unaffected since many important aspects of internal validity that are feasible to achieve were not undertaken or were poorly reported.
In addition to concerns regarding internal validity, the evidence does not sufficiently address all areas of patient involvement in patient safety that are relevant to this review. For instance, the included studies and interventions were all pertaining to patient involvement to ensure medication safety. Whilst medication safety is an important area of investigation for patient safety, the review did not find evidence for initiatives that aim to promote patient involvement to enhance safety in other areas of healthcare. In particular, there are no evaluations of the many ‘advisories’ offering ‘hints and tips’ to patients about how to ensure they stay safe when using healthcare services, nor the high profile initiatives such as the patient empowerment element of the ‘Clean your hands’ campaign (although ongoing work by the NPSA aims to provide ‘evidence of robust evaluation’ in the future, http://www.npsa.nhs.uk/cleanyourhands/in-hospitals/pep/). Furthermore, the interventions employed by the studies in this review tend to be ‘passive’ in nature, requiring patients to simply read or listen to information and instructions. The advisories offering hints and tips tend to require more active and challenging behaviour from patients (if they adopt their advice), some of which may be problematic for patients. Therefore, it is of particular importance that these kinds of intervention are evaluated and include data on potential, unwanted harms e.g. impact on perception of safety, patient-practitioner relationship, shifts in responsibility (Entwistle 2005).

The development processes of the interventions in the review are also of concern. None of the studies reported any patient involvement or consultation in the development of the interventions prior to evaluation. Since the success of these interventions depends entirely on their uptake by patients their views and preferences should be taken into account prior to implementation and evaluation. In addition, it is not clear from the reports what the intended mechanisms of the interventions are (how they will work) or where they will impact on the ‘causal chain’ (where they will work). At present studies appear to identify a problem and then evaluate an intuitive, common sense initiative, rather than closely considering the ‘how’ and ‘where’.
In addition to limitations concerning interventions in this review evidence was also limited in the type of participants and reported outcomes. Participants were primarily adults and elderly patients. Targeting elderly patients to improve medication safety would seem to be a reasonable strategy since they are a group where co-morbidity and poly-pharmacy are more common. However, it is important that patients’ ability to be involved in ensuring their own safety is evaluated in other particularly vulnerable groups such as those with communication difficulties and those with low health literacy or understanding.

The included studies reported a number of outcomes, including those having a direct impact on patient safety and those ‘likely’ to have an impact (intermediate or surrogate outcomes). However, some that claim to be measuring safety outcomes are arguably not doing so. For example, medication error rates were calculated by comparing pill counts of what should have been taken and what was actually taken. Patients may choose not to take prescribed medication for a number of reasons (e.g. side effects, inconvenience) but these should not be described as ‘errors’, rather they are issues of compliance. Whilst this method of measuring medication error rates may capture some errors it is impossible to disentangle these from issues of non-compliance. Few studies reported on the uptake of the interventions by patients or considered measuring their effect on the level of patient involvement (i.e. whether it increased the level of involvement or not). A major omission in the outcomes relevant to this review is the lack of consideration of potential, unwanted effects that may result from uptake of the interventions, for example their impact on patient perceptions of safety and patient-professional interactions.

Taking into consideration the limitations of the evidence (in particular, that evaluations of patient involvement in enhancing safety are limited to medication safety only) the findings of this review and the effectiveness of the interventions cannot be generalised to other areas of healthcare in which patient involvement is used to promote or enhance safety. Current interest in both the UK and other countries to involve patients in safety initiatives is not
informed by, or based on robust evidence of effectiveness (with the notable exception of patient self-management of anti-coagulation).

The findings from this review are similar to those of previous reviews. A general survey of patient participation in safety in 2001 noted little evidence for the effectiveness of such interventions (Pizzi 2001) and a more recent non-systematic review in 2006 also reported that ‘few patient-focused initiatives have yet been developed and even fewer subjected to a formal evaluation’ (Coulter 2006). Furthermore, in a study of US based ‘advisories’ offering safety ‘hints and tips’ to patients the authors reported that none had been formally evaluated before widespread implementation (Entwistle 2005).

Limitations of the Review
It is acknowledged that this review has a number of potential limitations. Firstly, whilst the search for this review was comprehensive, never the less, there is the possibility that studies (both published and unpublished) have been missed. Secondly, citations of titles and abstracts were not screened by two authors independently (although they were validated by a random sample check). Thirdly, to be included in this review, studies had to explicitly state that their aim was to improve safety; many other interventions that involve patients may, indirectly, also impact on safety but were excluded from this review. Thirdly, to be included in this review, studies had to be couched in a ‘patient safety frame’, explicitly stating that their aim was to improve safety. Many similar interventions that involve patients may, indirectly, also impact on safety but were excluded from this review because they were not presented as evaluations of safety-promoting activities and may also not have been identified by our search strategy. For instance, we are aware of a body of literature pertaining to interventions that involve patients with the aim of enhancing medication adherence. A recent Cochrane review of this literature selected RCTs that reported an intervention to improve medication adherence and treatment outcome (Haynes 2008). The review included 93 interventions of which many were very similar to those identified in our review. For example, more instruction or counselling for patients, involving patients in self-monitoring of blood pressure, dose-dispensing units and mailed
communications to patients. The findings from the Cochrane review suggest that ‘the literature concerning interventions to improve adherence with medications remains surprisingly weak’ with little evidence that medication adherence can be improved consistently and lead to improvements in treatment outcomes.

CONCLUSIONS

Implications for practice
There is a major international movement to increase patient involvement with a view to enhancing patient safety. However, there is scarce evidence of benefit. This review identified evidence of safety benefit for patient involvement in one specific aspect of self-medication, but little evidence of effectiveness in other aspects of health care.

Implications for research
Future research should focus on areas other than medication safety. In particular, interventions in most urgent need of evaluation are those that are currently widely used but unevaluated, for example ‘20 tips to help prevent medical errors’ and ‘Please Ask – Be Informed’ (AHRQ, NPSA). Evaluations should include the assessment of outcomes related to patient safety incidents should also consider unintended consequences and the effectiveness of these interventions on the level of patient involvement. In evaluations using the RCT, then robust, well documented methods should be employed. The use of bespoke outcome measures should be avoided and researchers should ensure that outcome measures such as medication error rates are measures of safety and not compliance.
REFERENCES

Included studies


Punekar YS (2003). Development and validation of a patient medication risk reduction behavior scale and application in a managed care population, Purdue University: 190.


Other references


Patient Safety Research Programme. 


CHAPTER THREE

The patient contribution to adverse event reporting systems

BACKGROUND

The previous chapters have provided an overview of the literature on patient involvement in patient safety and of the effectiveness of interventions to promote their participation in keeping themselves and others safe. This chapter concentrates on a specific area of patient involvement in patient safety, safety incident reporting systems. This review of reporting systems addressed objective three of the planned project.

- To investigate how the various types of reporting systems that have been developed to improve patient safety have solicited, received and used reports from patients and their representatives.

One of the ways in which patients may be able to contribute to ensuring their own and others safety is through participation in safety-orientated reporting systems. There is a recognition that patients and their representatives could, potentially, be in a unique position to contribute to collective learning about delivery of safe healthcare and improvements to the safety of health systems by providing information about safety issues that they have identified or experienced. A number of countries now have reporting systems either for medical error/harm or for adverse drug events or both, some of which accept reports from patients.

The development and implementation of systems for the reporting of patient safety incidents has been designated a major national priority in the UK (DoH 2000) and elsewhere (Kohn, 2000). Existing reporting systems operate within a variety of models and fulfil a variety of roles. Some, such as NRLS (UK) among others, were developed by government agencies to provide
information to improve patient safety. Others such as the systems in Australia and the JCAHO in the USA are the initiatives of private or non-government bodies and a small number have been set up by patient organisations, (eg, KILEN in Sweden). Some systems accept reports of any patient safety incident and some only concentrate on monitoring medication safety. Each system differs but Emslie (2005) suggests 6 categories which describe the objectives of incident reporting systems overall.

- Identifying and reporting safety incidents
- Data analysis
- Root cause analyses
- Prioritising, implementing and evaluating actions
- Demonstrating and sustaining safety improvements
- Dissemination of learning

It is suggested that patient reporting can provide new information about safety incidents (BEUC, 2008, Agoritsas et al 2004); there is some evidence that information provided by patients is useable and of comparable quality to that provided by health professionals. Much of the empirical literature concentrates on the area of ADRs and there is evidence that patients are able to discriminate between ADRs and other symptoms (van Grootheest et al., 2003). Patients may also report ADRs more quickly than health professionals (van Grootheest et al., 2005; Egberts et al., 1996). Patients have been, and still are encouraged to report ADRs through a health professional but the latter do not pass on all suspected ADRs reported to them by patients (Hughes, 2002; Jarernsiripornkul et al., 2002) especially those related to medication used to treat psychiatric disorders (van Grootheest et al. 2004) . Half of all patients who reported to Lareb, the Dutch reporting system, in the first six months of its operation, said they were motivated to report because they had not been listened to or were not convinced that their report would be passed on (van Grootheest and Jong-van de Berg, 2004).
Several authors suggest that patients are in a unique position to observe and comment on their care in a broader context (Vincent and Coulter, 2002; Forster et al 2003). A patient may experience an injury that does not manifest until after discharge from a hospital and therefore is not otherwise captured. Patients may be better positioned than their care providers to identify failures in hand-overs and gaps between providers across the continuum of care. Patients often report a desire to ensure action taken to prevent future harm to others. Reporting can initiate that process. Patients may report otherwise unidentified issues that help health-care organizations understand where the holes in their safety nets are, identify root causes, and mitigate harm.

Possible concerns about negative effects of direct patient reporting such as usability of patient reports (due to poor quality or extraneous ‘noise’) and systems being overwhelmed by the volume of reports have been examined by several authors and such concerns may be unfounded (van Grootheest and Jong-van de Berg, 2004). The concerns about patient reports are further complicated by the lack of data which explores how the uptake of reporting systems by patients could be best captured and appraised. For instance, it is unclear what volume of reports would indicate that a reporting system has successfully engaged.

This part of the patient involvement in patient safety project concerned itself with investigating how the various types of safety incident reporting systems have been developed and how they have solicited, received and used reports from patients and their representatives. It also aimed to ascertain the extent to which patients have been involved in the system’s development and evaluation.

METHODS

A list of reporting systems which accept reports from patients and the public was developed from a variety of sources. This included examination of several overviews and reports of reporting systems (Emslie, 2005; Blenkinsopp,
2006: WHO, 2005), as well as individual papers which describe or evaluate reporting systems; internet searches for reporting systems (to look for systems not recorded in the published overviews and reports, to ascertain whether systems that had previously been described were still functioning; and to search for further information about particular reporting systems on websites of patient safety organisations such as the Agency for Healthcare Research and Quality (AHRQ). Once identified each system was assessed using a form constructed to elicit details such as country of origin, what formats reports take, what happens to completed reports (see Appendix 3.1). Efforts were then made to establish a contact at the organisation behind the reporting system. This contact was sent a copy of a short questionnaire (Appendix 3.2) which requested details of how or if patient involvement influenced the design and, where appropriate, evaluation of the system as well as information about the number and proportion of patients reports received. The initial searching was carried out in 2006 and updated in January 2009 for this report. Organisations were sent one reminder by e-mail two weeks later if they had not responded.

FINDINGS
Eleven systems in a variety of countries were identified. Their key features are summarised in table format to facilitate comparisons (Table 3.1). This is followed by more detailed description of the systems and the level of patient involvement in their development and evaluation if this information could be obtained.
Table 3.1 Summary table of reporting systems which accept reports from patients

<table>
<thead>
<tr>
<th>Organisation name</th>
<th>Country</th>
<th>Funding</th>
<th>Who reports</th>
<th>How</th>
<th>What is done with reports?</th>
<th>What is reported</th>
<th>Anonymity</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Adverse Medicines Event Line</td>
<td>Australia</td>
<td>national government</td>
<td>patients/public</td>
<td>on-line form or phone</td>
<td>information fed back to relevant authorities and 'accurate advice and information given to consumer' but format of this not clear</td>
<td>reports about drug reactions or adverse events relating to medication</td>
<td>optional</td>
</tr>
<tr>
<td>Canada Vigilance Programme</td>
<td>Canada</td>
<td>national government</td>
<td>public</td>
<td>online, fax, mail, phone</td>
<td>reports checked, assessed for seriousness and used to check for new safety concerns about a product</td>
<td>reports about the quality and safety of healthcare products</td>
<td>no</td>
</tr>
<tr>
<td>Danish Medicines Agency</td>
<td>Denmark</td>
<td>national government</td>
<td>patients/public and healthcare professionals</td>
<td>on-line form (different for patients &amp; HCP)</td>
<td>serious side effects forwarded to WHO and European Medicines Agency</td>
<td>reports about adverse reactions to medication</td>
<td>no</td>
</tr>
<tr>
<td>DGV</td>
<td>Netherlands</td>
<td>consumer organisations</td>
<td>patients/public and HCPs</td>
<td>downloadable form</td>
<td>reports forwarded to LAREB</td>
<td>reports of experiences of medication</td>
<td>no</td>
</tr>
<tr>
<td>Organisation name</td>
<td>Country</td>
<td>Funding</td>
<td>Who reports</td>
<td>How</td>
<td>What is done with reports?</td>
<td>What is reported</td>
<td>Anonymity</td>
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<tr>
<td>Lareb</td>
<td>Netherlands</td>
<td>independent national gov subsidy</td>
<td>patients/public, HCPs and market authorisation holders</td>
<td>on-line form</td>
<td>customised feedback given to reporter after assessment by pharmacist or physician</td>
<td>reports of suspected adverse drug reactions</td>
<td>no</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>reports discussed weekly, quarterly report produced for medicines evaluation board</td>
<td></td>
<td></td>
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<tr>
<td>KILEN</td>
<td>Sweden</td>
<td>consumer organisation</td>
<td>patients/public</td>
<td>on-line form, e-mail, phone</td>
<td>used to develop reports disseminated to gov agencies and other relevant parties</td>
<td>adverse events associated with medicines</td>
<td>optional</td>
</tr>
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<td></td>
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<tr>
<td>MHRA</td>
<td>UK</td>
<td>national government</td>
<td>patients/public &amp; healthcare staff</td>
<td>yellow card available at GP surgeries, can report online and by phone</td>
<td>assessed by team of medicine safety experts and used to inform medicines safety profiles</td>
<td>details of side effects from medicines</td>
<td>no</td>
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<tr>
<td>NPSA</td>
<td>UK</td>
<td>national government</td>
<td>patients &amp; healthcare staff</td>
<td>online form (different for patients and health professionals) telephone</td>
<td>information collated from reports reviewed by board and review group and used to produce recommendations for NHS Trusts</td>
<td>Any health care safety incident or issue (details of patient, condition, incident, location, results)</td>
<td>yes</td>
</tr>
<tr>
<td>Organisation name</td>
<td>Country</td>
<td>Funding</td>
<td>Who reports</td>
<td>How</td>
<td>What is done with reports?</td>
<td>What is reported</td>
<td>Anonymity</td>
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</tr>
<tr>
<td>ISMP Consumer med safety</td>
<td>USA</td>
<td>charity and educational grants</td>
<td>patients</td>
<td>online form</td>
<td>information forwarded to FDA and used to identify and address drug related problems</td>
<td>Medication errors (details of patient, condition, incident, location, results, what might have prevented it happening)</td>
<td>optional</td>
</tr>
<tr>
<td>JCAHO</td>
<td>USA</td>
<td>independent not for profit</td>
<td>patient/public</td>
<td>online form, by e-mail, by letter</td>
<td>may prompt JCAHO visit/request for a written response. May be incorporated into quality monitoring database</td>
<td>narrative account of concern or complaint naming health care organisation</td>
<td>no</td>
</tr>
<tr>
<td>Medwatch</td>
<td>USA</td>
<td>national government funded</td>
<td>patients/public and healthcare staff</td>
<td>on-line form, can also be downloaded, completed and posted</td>
<td>reports entered into database analysed, trends identified, info used to produce safety reports and alerts</td>
<td>reports about serious adverse events involving drugs and medical devices</td>
<td>yes</td>
</tr>
</tbody>
</table>
Characteristics of the Reporting Systems

AUSTRALIA. The Adverse Medicine Events Line.

http://www.mater.org.au/ame/ The Australian Commission for Safety and Quality in Healthcare (ACSQH) identified reduction in patient harm due to medication use as a priority area for national action. Building on a successful project being conducted in Queensland, the Adverse Medicine Events Line was established in October 2003 and funded by the National Prescribing Service. The AME Line was ‘established to provide an avenue for the community to report their suspected AME’s possible errors or “near misses” with their medicines.

Reporting how, what and whom? Reports can be made regarding drug reactions or adverse events related to medicines by patients or the public using an on-line form or by telephone. Personal information is optional but is requested in case further details of the case are needed. Patients who report by phone consult a pharmacist who will give advice about medication safety. Patients can also report using a blue card either by post or online.

What happens to reports? The report is then forwarded to the Adverse Drug Reaction Advisory Committee (ADRAC) which comprises independent medical experts who decide on an appropriate response to reports.

Were patients involved? We have not received any information about patient involvement in the development or evaluation of this system although we understand that an evaluation took place after an 18 month trial which comprised a questionnaire to consumers (Blenkinsopp, 2006).

Do patients report? The system received 1909 calls in its first year of operation. A fifth of these resulted in the submission of an ADRAC report. Twenty percent of the adverse effects reported were not listed as such in product information at the time (Blenkinsopp et al., 2006)

How is the system publicised? Reports are invited from the website.
CANADA: Canada Vigilance.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/reporting-declaration-eng.php#a1

Health Canada have a section on their website which directs consumers to the Canada Vigilance Programme which has been accepting reports about adverse drug reactions from health professionals and consumers since 1975.

**Reporting how, what and whom?** Reports can be submitted online, by fax, mail and phone. Patients are encouraged to submit a report with their health professional but reports are accepted directly from patients. Guidance is available about how to complete a report. Personal details are requested and the reporters are thanked for their contribution and given a reference number so they can report further effects, if any. They may also be contacted for more information.

**What happens to reports?** Reports are checked, assessed for seriousness and then 'used to check for new safety concerns about a product'.

**Were patients involved?** Canada Vigilance did not provide a response to our questionnaire about patient involvement.

**Do patients report?** We did not find any published data on numbers of patient reports.

**How is the system publicised?** Reports are invited from the website.
DENMARK: The Danish Medicines Agency

The Danish Medicines Agency is part of the Ministry for Health and was set up in 2003, in part, as a response from the Danish Consumers Council. It collects and handles reports of adverse drug reactions in order to inform both pharmaceutical companies and the authorities of Denmark and other countries of possible adverse reactions of medicinal products.

**Reporting how, what and whom?** The agency has two on-line forms, one for patients and one for healthcare professionals. Patient forms collect general information about the medicine, including dose and side effect as well as other medications. It also collects information about the patient and the reporter (if different). Reports can only be made on-line although the information sheet about the system has an enquiry phone number to ring.

**What happens to reports?** The data from patients is treated in the same way as that of health professional reports and is forwarded to the World Health Organisation (WHO) and the European Medicines Agency (EMEA) when the side effects are classified as serious. It is the responsibility of the Danish Medicines Agency to make sure that the pharmaceutical industry acts on the adverse drug reactions reported.

**Were patients involved?** The Danish Medicines Agency did not provide a response to our questionnaire about patient involvement.

**Do patients report?** Results presented at the Health Action International Seminar on patient reporting of adverse events cited a figure of 149 reports from patients which amounts to 7% of all the reports submitted in 2003-4. One third of these events were not described on the relevant Summary of Product Characteristics (HAI, 2005).

**How is the system publicised?** Reports are invited from the site. There is a downloadable information sheet on the site but no information about whether or how widely hard copies of this are distributed.
NETHERLANDS: Meldpunt Medicijnen (DGV)
http://www.meldpuntmedicijnen.nl/

Meldpunt Medicijnen is an internet-based medicine reporting system launched on 11 May 2004. It was initiated by DGV, The Dutch Institute for the Proper Use of Medicine, a not for profit organisation which advises on and implements evidence based interventions for the safe and effective use of medicines; the Science Shop for Medicines and patient and consumer organisations.

**Reporting – how, what and whom?** Individuals are able to report their experiences with medicines anonymously by completing an online report form. Users of the medicine themselves as well as their relatives, acquaintances or (professional) carers, can report an experience. The report form contains items which request information on age, gender, type of medicine used, nature of the experience, a description of the experience and the relevance of the experience. Individuals filling in the report have to indicate whether the experience is related to either effectiveness, a side effect, a practical issue (e.g. difficulties with swallowing tablets) or a reimbursement issue. More than one experience related to the same drug can be submitted.

**What happens to reports?** Reports are forwarded to the official government pharmacovigilance system LAREB, and the results from both systems are widely circulated to government, pharmaceutical companies, academics and health professionals.

**Were patients involved?** The system and online questionnaire were developed in conjunction with patient organisations and patients are still represented on the advisory board of Meldpunt Medicijnen. The system is continuously evaluated by the advisory board. Small practical changes have been made as a result of on-going evaluation.

**Do patients report?** The system received almost 2,000 reports from patients in the first 12 months of the scheme. Almost half the reports detailed
medication side effects and a third of these were not mentioned in patient information leaflets for the drug concerned (Blenkinsopp, 2006).

**How is it publicised?** The organisation is publicised in the publications of patient organisations, clinicians and pharmacists and sometimes via press releases.
The Netherlands Pharmacovigilance Centre has accepted reports from patients since 2003. Lareb was founded in 1991 and is an independent foundation, supported by Government funding. The Lareb board consists of representatives from the major medical and pharmaceutical professional organizations as well as representatives from patient organisations. Lareb tries to increase health professionals’ involvement in pharmacovigilance, so they will be motivated to report adverse drug reactions in daily practice.

Reporting, how, what and whom? Reporting is by online form only and reports are accepted from health care professionals, patients and market authorisation holders.

What happens to reports? After a report is received, it is assessed by a pharmacist or physician. Customized feedback will be sent to the person submitting the report. The anonymised reports are filed in their adverse drug reaction database. All reports are discussed on a weekly basis. Lareb informs the Dutch Medicines Evaluation Board (MEB) of their work in a quarterly-report. The Medicines Evaluation Board has online access to the anonymous data. Anonymised copies of all new reports are forwarded to the European Medicines Evaluation Agency (EMEA) and the World Health Organisation (WHO) global database that is managed by the Uppsala Monitoring Centre in Sweden.

Were patients involved? Lareb did not provide a response to our questionnaire about patient involvement.

Do patients report? Most patient reports are received via DGV (see previous reporting system) but in the two years after beginning to accept direct patient reports Lareb received 450 from patients (out of 6300 overall) and this is gradually increasing.

How is it publicised? Reports are invited from the site.

The Consumer Institute for Medicines and Health runs a public voluntary reporting system and had been receiving reports from patients since 1978. Funding for the scheme has now been withdrawn but it is currently operating on a voluntary basis. There are some reports of official hostility to the scheme (HAI, 2005).

**Reporting, how, what and whom?** KILEN receives reports of any adverse event associated with medicines from both the public and health professionals via e mail, an on-line form and by telephone. Reporters can provide personal details or withhold them as preferred.

**What happens to reports?** Reports developed by KILEN are disseminated to government agencies and other relevant parties. Important results are also disseminated via the KILEN webpage. If reporters provide contact details they will receive feedback about their report.

**Were patients involved?** KILEN have discussed the form they use with consumers and changed wording according to feedback from this consultation process.

**Do patients report?** Patients do report although promotion of the system is limited due to a lack of resources. Between 1984 and 1988 KILEN received 420 patient reports about the sedative Lorazepam in comparison to health professional reports which numbered 18 over twice the time period.

**How is it publicised?** The site is promoted through brochures, posters, press and radio advertisements

The MHRA is the government agency which is responsible for ensuring that medicines and medical devices are effective and safe. Set up in 2003 to bring together the functions of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA), they encourage the public and healthcare professionals as well as industry to report any problems with a medicine or medical device, so that they can investigate and take any necessary action.

**Reporting, how, what and whom?** Reports are made via the ‘Yellow Card’ system, so named because people who report are required to fill out a distinctive yellow card to report side effects from medicines. Reporters are encouraged to register with the site so information gathered is not generally anonymous. The ‘Yellow Card’ is also available online and by phone.

**What happens to reports?** Information gathered from Yellow Card reports made by patients and health professionals is continually assessed at the MHRA by a team of medicine safety experts made up of doctors, pharmacists and scientists who study the benefits and risks of medicines. If a new side effect is identified, information is carefully considered in the context of the overall side effect profile for the medicine, and how the side effect profile compares with other medicines used to treat the same condition.

**Were patients involved?** An evaluation of the Yellow card system, funded by the UK Department of Health is currently in progress and will report on patient involvement.

**Do patients report?** A pilot study in 2003 produced 40 reports from patients in one year (HAI, 2005). However, the scheme was extended nationally and is currently being evaluated with report due imminently.

**How is it publicised?** Some patient groups direct members to the site but the system is not widely promoted.
UK: The National Reporting and Learning System (NRLS)
http://www.npsa.nhs.uk/nrls/reporting/

The NRLS is co-ordinated by the National Patient Safety Agency, a public agency formed in 2001 and directly funded by national government which leads and contributes to promoting safer healthcare. The system was rolled out across the NHS during 2004. It is an on-line reporting system through which both patients and NHS staff can report any patient safety incident.

**Reporting – how, what and whom?** Reports can be made by healthcare staff or patients via online form or by phone. The forms for patients and professionals are different. A report of any ‘safety incident’ can be made, although no guidance is given about how this might be defined, and all reports are anonymous. The form gathers general information about the characteristics of the patient, their condition, the incident (including which of the previous characteristics the incident was related to), where and when the incident occurred on the patient journey through healthcare, the location and the results of the incident.

**What happens to reports?** The NPSA review groups and board have access to the information collated from reports. The information is used to develop recommendations from national trends in reports. However there is no statutory obligation for NHS Trusts to implement these recommendations.

**Were patients involved?** The National Patient Safety Agency did consult patients and the public when they constructed the reporting system. Patients and patient organisations were involved in considering patient reporting and associated issues. The NPSA had a project oversight group which included lay representatives and was involved in testing and piloting the form. Further public review six months later concluded that because the reports were anonymous with no direct feedback to the person reporting the incident that patients believed the reports to have limited value.
Do patients report? Only 96 reports from patients were received by the system between January and August 2006 compared to a total of 788,188 incidents reported up to the end June 2006 as reported on the NRLS website. Healthcare worker reports to the site are increasing but there has not been a corresponding rise in patient reports. This part of the system is currently under review. Our subsequent work (reported in Chapter Four) demonstrated that the majority of patients we interviewed were not aware of the system or of the National Patient Safety Agency.

How is the system publicised? When the system was launched over 300,000 leaflets were distributed to over 8000 GP surgeries. Reports are invited from the website.
USA: The Institute of Safe Medical Practice

The Institute of Safe Medical Practice is a non-profit making organisation which aims to educate the healthcare community and consumers about safe medication practices. The ISMP was established in January 1994 as a non-profit agency that works closely with practitioners, regulatory agencies, healthcare institutions, professional organisations and the pharmaceutical industry to provide education about ADRs. This organisation operates the Medication Errors Reporting Program (http://www.consumermedsafety.org/) which is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention to appropriate agencies.

Reporting, how, what and whom? Patients can report via a dedicated website (consumermedsafety.org). Reports are structured in a free text box by a series of questions which gather general information about the medication and dosage involved, the outcome, the place of delivery and how the error was identified. Patients are also asked for recommendations to prevent further error. Anonymity is optional but if patients opt to provide contact details they could be contacted by the reviewing nurse or pharmacist for any necessary follow-up information.

What happens to reports? Reports are reviewed by a nurse or pharmacists’ analyst within 24-48 hours of being submitted. They are then forwarded to the Food and Drug Administration, manufacturers and others to inform them about pharmaceutical labelling, packaging, and nomenclature issues that may contribute to errors through their design. Case studies are published by ISMP which aim to alert healthcare professionals and others about recommendations to prevent errors.

Were patients involved? ISMP did not provide a response to our questionnaire about patient involvement.
Do patients report? We did not find any published data on numbers of patient reports

How is it publicised? Reports are invited from the website
USA: The Joint Commission on Accreditation of Healthcare Organisations. [http://www.jointcommission.org/GeneralPublic/Complaint/](http://www.jointcommission.org/GeneralPublic/Complaint/)

The Joint Commission claims to be the predominant standards-setting and accrediting body in health care in the USA and has been in existence since 1910 but known by its current title since the 1950’s. It evaluates and accredits more than 15,000 health care organizations and programs in the United States. An independent, not-for-profit organization, The Joint Commission is governed by a 29-member Board of Commissioners that includes physicians, administrators, nurses, employers, a labour representative, health plan leaders, quality experts, ethicists, a consumer advocate and educators. It has a primary interface with government agencies and with Congress with the aim of improving the quality of health care and working with Congress on legislation involving the quality and safety of health care.

**Reporting, how, what and whom?** Patients or members of the public can report to the Joint Commission using an online form, via email or in writing. The report can be anonymous or with personal details as the reporter prefers. The relevant institution needs to be named. The report is a less structured format than many forms perhaps reflecting the focus of the organisation on quality as well as safety. The reporter is asked to provide a narrative account of the incident.

**What happens to reports?** Where serious concerns have been raised about patient safety or standards compliance, the Joint Commission will conduct an unannounced, on-site evaluation of the organization. In other cases they may ask the health care organization to provide a written response to the report. They may incorporate the report in the quality monitoring database that is used to continuously track the performance of health care organizations over time or review the complaint at the time of the health care organization’s next scheduled accreditation survey if it is scheduled in the near future.

**Were patients involved?** JACHO did not provide a response to our questionnaire about patient involvement.

**Do patients report?** We did not discover any published data on numbers of patient reports.
How is it publicised? Reports are invited from the website.
USA: MedWatch [http://www.fda.gov/medwatch/how.htm](http://www.fda.gov/medwatch/how.htm)

Medwatch is the US Government Food and Drug Administration safety information and adverse event reporting programme. The FDA is a longstanding institution in the USA but has an established reporting culture of ADRs since the 1980’s.

**Reporting, how, what and whom?** Patients and health professionals can report on drugs and medical devices using an on-line form. There is also a downloadable form which can be completed by hand and returned via freepost. Reports are anonymous.

**What happens to reports?** Reports are entered into a database, evaluated and the database is examined for similar reports, trends are identified and appropriate action is taken, for example: information is used to produce safety alerts and modifications to drug safety information.

**Were patients involved?** When the system was launched in 1993 there was no consumer involvement. There has been no systematic evaluation but changes to the system and documentation have been made as a result of consumer feedback.

**Do patients report?** Thirty per cent of the 108,000 reports received by Medwatch between July and September 2008 were from consumers (FDA, 2009).

**How is it publicised?** Pharmacies are required to list the Medwatch number on the medication vial, label or other information materials. The number is also publicised through television advertisements, on the website and other literature.
DISCUSSION

**Patient reporting – what works and what doesn’t.**
This review of current reporting systems along with previously published reviews, descriptions and commentaries has allowed us to explore patient use of these reporting systems. It has also enabled us to begin to identify the characteristics of systems which seem to work more or less successfully for patient reporting.

**Consumer focused**
It appears that those systems which have attempted to give patients access to existing systems designed for health professional input are less likely to attract patient reports than those which have been developed with consumers in mind. The former tend to have terminology which may be unfamiliar to patients. A comparison in the UK of patient and physician reports about reactions to the antidepressant group of drugs known as SSRIs found that patient data, not subjected to the restrictions of a minimum dataset was much richer and provided information that the data from professionals could not (Medawar et al., 2002). Narrative reporting does introduce problems concerning usability of data but appears to have the potential to bring new understandings of adverse reactions to medication (Blenkinsopp et al 2006).

**The perceived value of personal feedback?**
Some commentators and patient groups have argued that patients are more likely to report to systems if they receive personal feedback, however, for two of the systems which receive a high number of reports from patients, DGV in the Netherlands and the USA’s Medwatch, reports are made anonymously, precluding individual feedback. KILen, however, does provide feedback for patients if they leave contact details. It may be that what is more important to patients is evidence that their reporting is treated as worthwhile and will make a difference.
**Publicity**

One of the findings from the primary research conducted as part of this project was that patients in the UK are largely unaware of the reporting systems open to them (See chapter 4). Promotion of these systems in the UK appeared to be restricted to information on the website and in surgeries of general practitioners. We found that patients did not generally know about the organisations behind the websites, so would be unlikely to access them.

In contrast DGV is publicised through the patient organisations who were involved in setting it up as well as via the media, similarly KILEN uses the media to promote their reporting system. The Medwatch number is placed on all medicines dispensed by pharmacists either on the label or information sheet issued with the medication.

There is a suggestion that one of the reasons for not enthusiastically publicising reporting systems may be concerns that the system will be overwhelmed by patient reports (Blenkinsopp et al., 2006). Several reports and reviews have suggested that this is unlikely to happen (RCGP, 2006; van Grootheest 2005). Not all patients report, and those who do tend not to report all the ADRs they experience (Jarernsiripornkul et al., 2002) – this might be because they are prepared to tolerate some adverse effects as a ‘trade-off’ for the benefits of the drug (Blenkinsopp et al., 2006).

**Organising body**

Our findings in relation to whether the organising body was seen as associated to the state or a consumer body were equivocal. KILEN and DGV are both consumer organisations, which are likely to be perceived as being at arms length from government. DGV was set up because the ‘official’ Dutch reporting system, shared with health professionals was not perceived as consumer friendly. KILEN, in its consensus document, advocates an independent organising body with access to experts in pharmacovigilance and consumer affairs. However, a third of the 40,000 reports received by Medwatch in the USA in 2008 were from consumers. This system is run by the FDA, a government organisation, and consumers and health professionals
report on the same form. The question of whether the state or voluntary sector runs the reporting systems may be less important for issues of uptake than the questions of whether the systems are well publicised and perceived as likely to make a difference.

**Ease of Access and use**

Although access to the internet is increasing there are still a significant percentage of patients who do not have access to it. Older people, a group likely to be at high risk of adverse effects of medication, taking multiple medications to treat multiple conditions are also most likely to lack IT skills (Alemagno et al., 2004). Other groups who are less likely to have access to the internet include those who are culturally disadvantaged and those with low health literacy, precisely those who are also more likely to suffer adverse effects from medication (AHRQ, 2007; ONS, 2008). Some reporting systems do accept reports by phone or by post but publicity is often via the website and forms for posting are ‘downloadable’ from there.

**Limitations of the Review.**

As well as reviewing currently available reporting systems which accept reports from patients and updating previous research, this report begins to identify some potential barriers and facilitators to patients using safety reporting systems which aim to encourage their input. However, the national contexts in which these systems operate vary and successful characteristics of a reporting system in one country will not necessarily transfer to another which makes comparisons difficult. What may be of immediate and realistic concern is the apparent lack of patient uptake in many of the systems which aim to solicit reports of adverse events or drug reactions from patients.

We have only been able to review those systems which can be accessed by English language speakers. There may be other systems outside this group although they are not detailed in other recent reviews (Blenkinsopp, 2006; HAI, 2005). In addition the current interest in patient safety and in involving patients means that systems are changing constantly and we may have been unable to capture some of the more recent or planned reporting systems.
Of the 11 reporting systems identified in this review we received questionnaires back from 3 organisations (NPSA, DGV and Medwatch) and had direct discussions with 2 (NPSA and KILEN). Any additional information presented here was available on the websites of the reporting systems identified.

Future developments
We are aware that there are several recent developments in the area of patient reporting systems. Significant funding has been allocated for a project to design a consumer reporting system for patient safety events by AHRA in the USA. This has been awarded to RTI International (a research institute in the areas of health and pharmaceuticals) in collaboration with Consumers Advancing Patient Safety. A recent report by BEUC the European Consumers Organisation has made a response to the EC public consultation on Pharmacovigilence. In the UK the reporting system run by the NPSA is currently under review due to low numbers of patient reports and the MHRA yellow card system is the subject of a formal evaluation which is shortly due to report.

There is little indication of evaluation of reporting systems and the ways in which this might be achieved. Few, if any, reporting systems describe the entire process of development, implementation and evaluation generally or in relation to use by the public (Armitage and Chapman, 2006). There seems to be little agreement about what data are valuable for to reporting systems. For example quantitative and qualitative data have advantages and disadvantages in terms of the information they are able to provide. There is no indication as to how many reports are needed to provide meaningful data which might lead to appropriate change. This is an area which requires more consideration if reporting systems are to be evaluated and statements about their ability to address their aims can be substantiated.
CONCLUSION
Several sources have established that patient reporting of adverse drug effects can complement that of health professionals as well as increase the rates of reporting. Two of the reporting systems described have indicated that around a third of adverse effects reported by patients were new, that is not mentioned in information sheets for the medications concerned (Blenkinsopp, 2006). There is also evidence that patients are also able to identify and report other adverse events in healthcare but there is still relatively little experience of this. This review of current systems points to several ways in which systems can be made accessible to patients in order to complement health professional reports.

Systems into which patients are invited to report should be designed in consultation with patients. The opportunity to submit free text descriptions can contribute new knowledge although this needs to be balanced with the ‘usability’ of data. Use of standard terminology such as that developed by WHO will facilitate international comparisons and allow information to be collated at European and International level. This applies to both patient and professional reports. Data at this level would facilitate identification of less common adverse effects.

Many systems need to be better publicised. The approach adopted by Medwatch in the USA where pharmacists are obliged to include the Medwatch contact details on the packaging of any medication they dispense seems to engage patients and resulting reporting rates are high. The use of the media also appears to be a successful strategy for alerting patients to the presence of a system into which they can report. While the use of computers is increasing and, for many people, commonplace, over-reliance of systems on access to the internet may limit reports from some groups of patients. Patients should be provided with alternatives to online reporting to increase access to reporting systems.

A system which provides anonymity for patients does not necessarily provide the feeling of security from reprisal which system providers possibly
envisaged. What seems to be more important is that both patients (and professionals) feel that the evidence of safety events they provide is used appropriately for learning. If the way in which the reporting system treats patient reports is clear and patients perceive their reports as useful and treated seriously they may be more likely to be motivated to provide reports. The motivation may stem from the belief that feedback means that the report has actually been seen by an expert or a belief that the organisation responsible for the system has the regulatory power to influence change and improve safety.

The majority of reporting systems investigated in this review (with the exception of KILEN, Meldpunt Medicijnen and MedWatch) demonstrate little evidence of real engagement with and/or uptake by patients and the reasons for this may be complex and varied. However, in the exceptional systems where patient reports have been successfully captured and used in reporting and learning there seem to be concerted attempts to publicize the system to make it highly visible to patients and clear information about how the information will be used. It would seem the system may not need to be seen as independent of the State (with a latent assumption of impartiality) but does need to be seen as using the information to inform reporting and learning.
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WORK PHASE TWO

CHAPTER FOUR: PRIMARY RESEARCH TO INVESTIGATE PATIENTS’ VIEWS
ABSTRACT

Work Phase Two
Primary Research to Investigate Patients’ Views

Aims and objectives

- To determine patients’ awareness of and concerns about health care safety
- To identify situations and ways in which patients or their representatives have acted (or considered acting) to help secure their own safety
- To elicit patients’ views about the various roles they might play to ensure their own safety, about interventions to encourage or support them in playing those roles, and about their potential contribution to safety reporting systems

Methods

Qualitative research methods (in-depth individual interviews and focus groups) were used to describe, explore and explain patients’ (and their representatives’) views and experiences of safety in relation to using health care services.

In-depth interviews proved a highly effective way of exploring people’s experiences, beliefs and meanings, from the perspective of the respondent, and provided a ‘rich’ data set, grounded in the experiences of the interviewees themselves.

Focus groups were conducted after the in-depth interviews in order to stimulate general discussion about patients’ roles in ensuring the safety of health care. Group discussion was supported through a ‘roles exercise’, and vignettes describing health care situations in which patient safety might be
compromised. Vignettes were developed from incidents described in individual interviews and relevant patient safety literature.

**Populations studied**
Study participants (patients and their associated family members or representatives where appropriate) were strategically selected from six different groups in order to explore the views of patients with diverse clinical, demographic and social characteristics, and to consider different patient safety issues in a variety of health care contexts. The study sample included: patients with diabetes; women who had undergone treatment for breast cancer; parents of children hospitalised with asthma; people scheduled for joint replacement surgery; people who had raised a (safety related) issue with the Patient Advice and Liaison Service (PALS); and people with severe and enduring mental health problems.

Within each clinical group, we included males and females across a range of ages and ethnic backgrounds. For some clinical groups, we deliberately sought to include people with particular demographic or social characteristics of likely interest (for example, among adults with Type II diabetes we sought to interview people aged over 65, because there is evidence that older people are generally more reluctant to participate in decision making about their health care).

In addition, a second group of participants were recruited from national and local ‘consumer’ or patient support groups, as it was anticipated that they might share collective views or experiences which might not be accessed via the accounts of individuals.

**Data analysis**
Individual interviews and focus group discussions were audio-taped and fully transcribed. Transcripts were analysed using the ‘Framework’ approach as it is especially well suited to applied qualitative research where the objectives of the investigation are typically set a priori. Moreover, ‘Framework’ provided a
visible method which could be operated by the individuals working collaboratively in the research team.

Rigour in data analysis was promoted through multiple data analysis; assessment of inter-rater reliability of coding; constant comparison of data within and across the data set; use of analytic ‘memos’; attention to ‘negative’ cases; and the use of reflexivity in data collection and analysis.

**Main results**

Findings from the study revealed that patients were willing to engage with the topic of patient involvement in patient safety and that they had a broad understanding of the issues involved.

Overall, study participants were largely unaware of national reporting systems, and they had limited knowledge of local systems. Features of reporting systems cited by participants as conducive to reporting included: high visibility; easy accessibility; incorporation of feedback mechanisms; optional anonymity; and freedom from repercussions, for both staff and patients.

Study participants expressed a desire to be involved in promoting and enhancing their own safety, but differed widely in their views about which patient safety roles they considered appropriate for themselves or others to adopt, and the circumstances in which patients should act to promote their own safety.

People indicated that their willingness and ability to adopt patient safety roles would be affected by a range of factors which related to themselves as individuals (including how ill or well they were feeling, and their emotional state); the nature of their relationship with HCPs; the gravity of the situation in which they found themselves; and features of the wider health care system.
Study participants emphasised the importance of health care professionals’ attitudes and behaviour in facilitating their involvement in safety roles. An enabling or facilitative environment was perceived as one in which staff:

- ‘invited’ patients to ask questions about their diagnosis, condition, investigations and treatment; took time to respond appropriately; were prepared to provide information that was relevant to the individual patient at that particular time point.
- gave patients ‘permission’ to raise concerns, and refrained from reacting in a dismissive, defensive or hostile manner; indicated to patients that their concerns would be listened to, acknowledged, and, if necessary, acted upon; ensured that patients did not suffer any form of recriminations because they brought their concerns to the attention of staff.
- responded to patients in a consistently positive manner. Patients who met with a favourable response the first time they ‘spoke up’ suggested they were more likely to do so on future occasions.

Consequently, patients’ (and their representatives’) perceptions about the nature of their relationship with health care professionals appeared to be crucial in their decision making about whether, how and to what extent, they might become involved in promoting their own safety.

**Conclusions**

It would appear that recommendations for consistent or blanket adoption of patient safety roles may not be appropriate, and that patients can not, and should not be expected to, routinely adopt safety roles as means of acting as a safety check in their own care. While it seems that patients should not be relied upon as a check, many would be willing and naturally inclined to play a role in their own safety if the context and the nature of the relationship with health care providers were appropriate.
The study findings appear to suggest that patient involvement in patient safety could be enhanced by a shift away from the current emphasis on the prescription of specific patient safety roles, towards a focus on the provision by health care professionals of a broadly supportive environment in which patients (and their representatives) are routinely given information and encouraged to be actively involved in their own safety and to raise concerns, if and when they feel able, without fear of recriminations. In order to be able to offer patients the time and attention that might facilitate their involvement in patient safety activities, health care professionals need to be supported within the wider clinical environment.
CHAPTER FOUR

Primary research to investigate patients’ views

INTRODUCTION

There is growing international interest in how patients (and their family members) might help ensure their safety as they use health services (Vincent & Coulter 2002; Lyons 2007; Weingart et al 2005; Sang 2004; Koutantji 2005). It has been suggested that patients and their associated family members or representatives are uniquely positioned to monitor and improve patient safety in health care settings, as they are often ‘expert’ in their knowledge of their own condition and treatment, and are well placed to observe care processes (van Kanegan & Boyette 2003; Entwistle 2004). Although many organisations offer advice to encourage patients to adopt safety promoting behaviours (Weingart et al 2009), such as checking medications to avoid drug errors, little is known about patients’ views of their potential contributions, or the acceptability of such interventions from the patients’ perspective (Entwistle 2007; Davis et al 2007).

This phase of the study aimed to investigate patients’ (and their representatives’) awareness and concerns about health care safety; to explore patients’ (and their representatives’) views of the various roles they might play to promote their safety when using health care services, and their perceptions of factors which may facilitate or impede adoption of safety related behaviours; and to identify situations in which patients acted (or wanted to act) to help ensure their safety.
Theoretical underpinning

Role theory

Role theory concerns how individuals behave, how they feel they ought to behave and how they believe other people should respond to their actions (Biddle 1979). It is therefore well suited to serve as a theoretical underpinning for this study which focuses on patients’ (and their representatives') perceptions of the various roles they might play in ensuring their own safety, and the potential barriers and facilitators to their involvement.

Role expectations and role behaviour: A ‘role’ is a pattern of behaviour typical of person who occupies a particular social position, such as the ‘role’ of the patient or health care worker. Attached to every role is a set of standards and norms of conduct that the role occupant (and others) expect from the holders of the role. Social norms are behavioural expectations common to all group members against which the appropriateness of individual feelings and conduct may be assessed. A role expectation differs from a social norm in that whereas the latter applies to everyone in the group, a role expectation is specific to the individual.

In this study, we were interested in exploring patients’ perceptions of role boundaries and responsibilities vis a vis health care professionals with regard to keeping patients safe during health care delivery. Individual perceptions of ‘correct’ role behaviour are likely to vary with personal characteristics and contextual circumstances, and we wished to uncover when these variations might occur, and the meanings and explanations participants attached to them.

Actual behaviour in a role may or may not conform to expectations, either those of the person occupying the role, or those around them. We therefore asked patients (and their representatives) how they thought they might behave with regard to adopting particular safety roles (role expectations), how they thought others might act (social norms), and we also asked them to
describe specific instances when they did adopt (or considered adopting) a particular patient safety role (role behaviour, or enactment).

Role theory offered a useful framework for in-depth consideration of various aspects of patients’ perceptions and behaviour relating to the adoption of safety roles in a health care environment where they are interacting with health care professionals.

**Role incompatibility:** a common cause of role incompatibility is the difference between how the individual perceives his or her role and how other people expect the occupant of the role to behave. For example, a health care professional may expect a patient to carry out instructions without questioning them.

**Role ambiguity:** role ambiguity arises when roles are not adequately defined; the more explicit and specific the expectations attached to a role the easier it is for the person to conform to role requirements, since the individual then knows precisely how he or she should act; role ambiguity can result in stress, insecurity and loss of self-confidence. Role ambiguity may be present when parents and health care professionals share the care of a sick child and responsibilities are ill-defined.

**Role conflict:** this occurs when a person does not behave in accordance with expectations attached to a role because to do so would place too great a strain on the person. For example, a patient may wish to ‘speak up’ to challenge the decision or action of a health care professional but does not do so for fear of arousing confrontation or suffering reprisals.

**METHODS**

Qualitative research methods (in-depth individual interviews and focus groups) were used to describe, explore and explain patients’ (and their representatives’) views and experiences of safety in relation to using health care services. The rationale for selecting a qualitative approach was threefold. Firstly, little research has been conducted in this area to date;
qualitative methods are ideally suited to reveal the range of particular patient views or practices and key issues that might be missed through the use of more structured data collection instruments. Secondly, in-depth interviews are a highly effective way of exploring people’s experiences, beliefs and meanings, from the perspective of the respondent, in order to provide a ‘rich’ data set which is grounded in the experiences of the interviewees themselves. Thirdly, one of the strengths of qualitative research is its emphasis on the processual and dynamic nature of social life (Bryman 1998); in other words, it can identify the complex ways in which particular beliefs or experiences are likely to influence behaviour.

Phase Two of the study was designed to explore how patients’ desire to be involved in their care might vary according to health care setting and in relation to patient demographics, and we employed sampling strategies and data collection techniques that allowed for an inductive, hypothesis generating approach to interpretation of the data.

**Populations studied**

In order to explore the views of patients with diverse clinical, demographic and social characteristics, and to consider different patient safety issues in a variety of health care contexts, study participants (patients and their associated family members or representatives where appropriate) were strategically selected from six different groups: patients with diabetes; women who had undergone treatment for breast cancer; parents of children hospitalised with asthma; people scheduled for joint replacement surgery; people who had raised a (safety related) issue with the Patient Advice and Liaison Service (PALS); and people with severe and enduring mental health problems.

The majority of patients included in the study were recruited in primary or secondary care, from hospital clinics and GP lists, located within two geographical areas with contrasting characteristics. The first of these is a large metropolitan district, with areas of suburban affluence and inner city
deprivation, serving a population which includes a high density of people of South Asian origin – from India, Pakistan and Bangladesh. It has one large acute trust, and three primary care trusts. The second study site spreads across a wide rural area, includes a number of small market and two larger urban towns, with a mainly white British population, and is served by a large primary care trust and several acute hospital trusts.

Participants from the first three groups were individuals who had considerable experience of accessing health care in a variety of settings, often with clear guidelines for the progression of their care or treatment. The group of surgical patients were able to provide insight into expectations and actual experiences of safety and error at two key points in time, namely, prior to, and after, hospitalisation for surgical treatment. The final group of patients, those with severe and enduring mental health problems, augmented the study by providing their perceptions of errors and adverse consequences of medical, psychological and social interventions in mental health, including organisational interventions designed to co-ordinate care.

In addition, a second group of participants were recruited from national and local ‘consumer’ or patient support groups, as it was anticipated that they might share collective views or experiences which might not be accessed via the accounts of individuals.

In all cases, patients were offered the option of bringing an advocate or other person of their choice along to their interview; where advocates or other companions contributed views about the patient’s experiences of safety, these were, with permission, treated as data. Advocates and carers were also invited for interview.

**Ethical approval**

Ethical approval for this phase of the project was obtained from an appropriate NHS Research Ethics Committee. Research Governance approval was obtained from the relevant NHS Trusts. In the case of any subsequent
proposed changes to the study protocol (eg changes in the recruitment pathways after consultation with clinical collaborators) approval from Research Ethics Committee was also obtained. (Copies of the relevant letters of approval are appended in the final pages of the appendices section of this report)

**Recruitment and consent**

Recruitment procedures were tailored somewhat differently according to the different circumstances of the six groups, and varied slightly for interviews and focus groups, but in all cases, participants were contacted in the first instance by an appropriate representative of the organisation via which they were identified (for example, their GP, hospital consultant or consumer group director). They were sent information about the study and asked to return a short slip, or contact the research team by email or telephone, if more convenient, if they were willing to discuss participating in the study.

A member of the research team then contacted respondents to explain the nature and purpose of the study, stress that participation was voluntary, confirm arrangements for safeguarding participants’ anonymity, emphasise that the research would not directly help them seek a remedy or redress for any problems they may have experienced in their care, and give them plenty of opportunity to ask any questions they might have about the study. Where people expressed willingness to participate, the researcher made arrangements to hold an individual interview at a time and place convenient for the respondent (usually in their own home, or a private office or a local health care facility), or advised of likely dates and venues and checked availability for focus group discussions.

Prior to the commencement of interviews and focus groups, the researcher reminded participants of the purpose of the research, and ‘ground rules’ (see Appendices 4.1 and 4.2) to assure confidentiality and anonymity; the researchers asked respondents if they had any further questions, checked that they were still happy to take part, reminded them that they could stop the
interview or withdraw from the study at any time, and asked them to sign two copies of the consent form if they were happy to proceed (one copy given to the participant to keep). The costs of participants travel to interviews or focus groups discussions were reimbursed.

Participants were offered the opportunity to hear and discuss a presentation of the research findings before publication (at an event held at Bradford Royal Infirmary, 23rd March, 2009 (see Appendix 4.3 for the programme) and to be sent a copy of any publications arising from the study.

Key characteristics of the six groups, the partners who assisted with recruitment, and key features of sampling within the groups are summarised in Table 1 below.
<table>
<thead>
<tr>
<th>Group</th>
<th>Salient characteristics</th>
<th>Recruitment</th>
<th>Sampling notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults with type II diabetes</td>
<td>People with a chronic condition, probably knowledgeable about their condition, closely involved in self-management. People at risk of co-morbidity and hazards of polypharmacy. Management mainly in primary care. Guidelines specify numerous things that ‘should’ happen in care.</td>
<td>General practice in North of England PCT offering specialist diabetes care; general practice in York (urban) ‘Diabetes UK’ /local patient support group</td>
<td>Deliberately sought to include people over 65</td>
</tr>
<tr>
<td>Adults who have been treated for breast cancer</td>
<td>Women with experience of a life-threatening condition. Patients likely to have had several ‘major’ treatments, including chemotherapy, radiotherapy, surgery. Management crosses primary and secondary care. Guidelines specify what ‘should’ happen in certain situations.</td>
<td>Breast clinic, Trust in the North of England Breast cancer care local patient support group</td>
<td>Women recruited at least two weeks after their primary treatment.</td>
</tr>
<tr>
<td>Parents of children who have been hospitalised with asthma</td>
<td>Self-management supported by parents and school teachers. Parent-child relationship important factor in health care encounters. Hospitalisation may be a sign that the asthma is not well managed at home or in primary care.</td>
<td>Hospital lists; Trust in the North of England; assistance from specialist asthma nurse ‘Asthma UK’ consumer organisation</td>
<td>Sought to interview parents after child’s discharge from hospital.</td>
</tr>
<tr>
<td>People scheduled for joint replacement surgery</td>
<td>People likely to have had long term pain and functional problems, and encounters with primary and secondary care People facing surgery and at risk in hospital of wound infection, pressure sores, falls.</td>
<td>Hospital schedules: Trust in the North of England Total Hip replacement User Group (THUGS) patient support group</td>
<td>People recruited pre-admission. Interviewed twice: pre-admission and post-discharge (to allow exploration of changes in perceptions of safety, and their roles in securing it, with experience of hospitalisation)</td>
</tr>
<tr>
<td>People who have raised a (safety related) issue with PALS or made a complaint about their health care</td>
<td>Variety of possible clinical conditions and aspects of health care. People have experienced care that they perceive as sub-standard, and acted to report it.</td>
<td>PALS and risk managers, primary and secondary care, Two Trusts in the North of England ‘Sufferers of iatrogenic Neglect’ (SIN) support group</td>
<td>Recruitment in consultation with Trust risk managers.</td>
</tr>
<tr>
<td>People with severe and enduring mental health problems</td>
<td>Disenfranchised and disempowered population of patients. More experience of advocacy. People whose illness may at times affect their capacity to recognise safety problems. Treatment of severe and enduring mental illness is highly contested.</td>
<td>Care Programme Managers and senior clinicians in community care settings in North Yorkshire Stakeholder/ advocacy group: ‘Together, working for well-being.’</td>
<td>Interviewed patients, advocates and carers who are involved in both the innovative and more traditional models of care delivery.</td>
</tr>
</tbody>
</table>
Details of study sample

We recruited approximately ten people within each of the six groups for in-depth interviews via appropriate health care providers; patients undergoing joint surgery were interviewed twice, before and after their operation (N=71). We also recruited up to ten people from each clinical group for focus group discussions; for each clinical group, one focus group comprised people who participated in individual interviews (supplemented where necessary by people recruited via the same means as for the individual interviews), and the other focus group comprised up to 10 people recruited via national consumer organisations (N=12 focus groups, 68 participants).

Within each clinical group, we aimed to include males and females across a range of ages and ethnic backgrounds. For some clinical groups, we deliberately sought to include people with particular demographic or social characteristics of likely interest (for example, among adults with Type II diabetes we sought to interview people aged over 65, because there is evidence that older people are generally more reluctant to participate in decision making about their health care). (While we had hoped to include some patients with diabetes living in residential care, our recruitment strategy did not enable us to access individuals from this target population).

In summary, 71 in-depth interviews were carried out, with patients and their representatives and/or carers. In total, twelve focus group discussions (6 ‘patient’ and 6 ‘consumer’) were held with 68 participants.

Details of the study participants can be found in Appendices 4.4 and 4.5

Data collection

The aim of the interviews and focus groups was to explore patients’ general awareness and understanding of safety issues; their personal experiences and perceptions of safety in the context of their own health care; their views of different types of roles that patients and their representatives might play to
promote and enhance their safety in health care context; and their thoughts about contributing to national and local reporting system. While they shared similar aims, the emphasis in the interviews and focus groups was different.

1. In-depth interviews

In the individual interviews (conducted prior to the focus groups) the emphasis was on eliciting detailed accounts of patient’s own experiences of health care, their perceptions of safety during specific health care episodes, their awareness of any errors or threats to their safety in the course of their care, and examples of situations in which they had acted or considered acting to help ensure their safety. A topic guide (see Appendix 4.6) covering these investigative areas was developed and piloted, and subsequently refined before interviews commenced with the target patient population. After the first few interviews, some minor alterations were made to the wording of one question, to make it more easily comprehensible. Towards the end of interviewing, a new question was introduced, pertinent to Phase 3 of the study, to elicit views about patients reporting back their concerns about safety to clinical governance groups.

The ‘core’ topic guide was modified slightly to make it more appropriate for use with parents of children (see Appendix 4.7). In the case of patients undergoing joint surgery who were interviewed twice (before and after surgery) their views were initially sought using the ‘core’ topic guide in the first instance, and then they were re-interviewed, after hospitalisation for surgery, using a topic guide specifically adapted as a ‘follow up’ to the first interview (see Appendix 4.8).

A number of interviews were conducted with study participants who did not have English as their first language; in two cases, a member of the respondent’s family (who also acted as their carer) participated in the interview process, and assisted with translation.
2. Focus groups

Focus groups were conducted after the in-depth interviews, and here the emphasis was more on general discussion about patients' roles in ensuring the safety of health care. During the focus groups, discussion was stimulated and supported through the use of a ‘roles exercise’ and the use of vignettes describing health care situations in which patient safety might be compromised, both developed from the individual interview data and relevant literature. The vignettes used in the focus groups were primarily based on ‘exemplars’ of incidents with implications for patient safety that were drawn from individual interviews, and developed into ‘stories’, according to well established methods (Hughes and Huby 2004). We hoped that the vignettes would appear interesting, realistic and relevant to focus group participants. Each vignette was constructed to incorporate a set of ‘open’ questions to be used as the basis for the exploration of participants’ views and to draw out descriptions of their own experiences of situations where they had believed their own (or another’s) safety was potentially (or actually) threatened (see Appendix 4.9).

Focus groups were homogenous by patient group (as outlined in Table 1). Within the six strategically chosen ‘clinical’ groups, two focus groups took place, one with patients recruited directly from health care settings and the other with participants from consumer groups.

Although English was not the first language for some focus group participants, all had sufficient command of the language to understand and participate in the group discussion.

Focus groups were all conducted with at least two members of the research team present, one taking the role of lead facilitator (or moderator) and one acting as a co-facilitator. Guidance for the conduct of the focus groups was developed and adhered to, along with a set of ‘ground rules’ covering issues of confidentiality and anonymity for participants (see Appendices 4.1 and 4.2).
Individual interviews and focus group discussions were audio-taped and fully transcribed. Transcripts were analysed using the ‘Framework’ approach advocated by Ritchie and Lewis (2003). This approach was selected for several reasons. Firstly, it is especially well suited to applied qualitative research, in which the objectives of the investigation are typically set a priori, and shaped by the information requirements of the funding body, rather than wholly emerging from a reflexive research process. Secondly, Framework Analysis provides a visible method which can scrutinised, carried out, and discussed and operated by individuals in a team. Lastly, the approach lends itself to reconsidering and reworking ideas because the analysis follows a well-defined procedure, which can be documented and accessed by several members of a research team. Although the Framework analytic process is systematic and disciplined, it constitutes more than a mechanistic approach to analysis as it relies on the creative and conceptual abilities of the analyst(s) to determine meaning, salience and connections.

‘Framework’ comprises the following steps, which were adhered to during the analytic process.

- familiarisation with the data, sometimes referred to as ‘immersion’
- thematic analysis was carried out in order to develop a coding scheme
- data were systematically coded
- charting of data was carried out, using an ‘Excel’ spreadsheet. Charts contained summaries of data (supported by references to data-points in the original transcripts) so the research team were able to build a matrix to see across cases and the range of data under themes
- mapping and interpretation of the data in order to explore relationships between the codes
Data sampling

Sampling decisions always fluctuate between the aims of covering as wide a field as possible and of doing analyses which are as deep as possible (Flick 2006). A strategic decision was made to aim for depth in analysing the qualitative interview data, as we sought to present findings which were ‘rich’ in relevant information. Thirty five interview transcripts were therefore purposively selected for in-depth analysis, to represent diversity in the total data set of 71 interviews. The interviews were selected strategically from the complete data set using maximum variation sampling (Kuper et al 2008); that is to say, they included ‘typical’ cases (reflecting the views of the majority of respondents); ‘deviant’ cases (extreme cases of the phenomena under investigation); and ‘critical’ cases (those that appeared to be especially information rich and thus particularly illuminating). These 35 interviews related to 30 participants (5 participants from each of the six patient groups; patients undergoing joint surgery were interviewed twice), and included interviews with males and females, of different ages, ethnicity, and social background, who had with wide-ranging views and experiences of patient safety issues (see Appendix 4.4 for participants details). The twelve transcripts of the focus group discussions (6 patient; 6 consumer) were all included in the analysis reported here.

Rigour and transparency in the analytic process

Analytic rigour and accurate interpretation of data were promoted and enhanced in a number of ways.

1. Analysis of focus group data

There is controversy about whether the individual or the group is the unit of analysis in focus group interviews; we adopted the approach advocated by Kidd & Parshall (2000) that neither one was the unit of analysis, whereas either or both could be a focus of analysis. A major aim of the analysis of the focus group data was to identify areas of agreement and controversy to better understand how perspectives concerning patient safety arise and are modified
within the group. Whilst it is can be relatively straightforward to identify areas of disagreement, it can be difficult for the analyst to evaluate whether apparent agreement is the result of coercion or self-censoring of members with alternative viewpoints. Stevens (1996) has suggested a list of 12 questions (Table 4.2) that can be used to help the analyst to understand the collectivity of the group discussion and how interactions build one upon the other, and these were used to guide analysis of the focus group data.

Table 4.2 Stevens’ list of 12 questions used to ‘interrogate’ the focus group data

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>How closely did the group adhere to the issues presented for discussion? Why, how and when were related issues brought up?</td>
</tr>
<tr>
<td>Which statements seemed to evoke conflict?</td>
</tr>
<tr>
<td>What were the contradictions in the discussion?</td>
</tr>
<tr>
<td>What common experiences were expressed?</td>
</tr>
<tr>
<td>Were alliances formed among group members?</td>
</tr>
<tr>
<td>Was a particular member silent, or viewpoint unheard?</td>
</tr>
<tr>
<td>Was a particular view dominant?</td>
</tr>
<tr>
<td>How did the group resolve disagreements?</td>
</tr>
<tr>
<td>What topics produced consensus?</td>
</tr>
<tr>
<td>Whose interests were being represented in the group?</td>
</tr>
<tr>
<td>How were emotions handled?</td>
</tr>
</tbody>
</table>

2. **Multiple data analysis:** at significant points during the process of data analysis, the researchers most closely involved in data collection and the early stages of analysis (JH, MP, DMcc) met with members of the wider research team with extensive qualitative (VE, BW) and clinical (IW, JW) experience, to discuss emerging codes and categories, the interpretation of key texts, and potential new lines of enquiry, thereby drawing on the combined insights of those ‘handling’ the data closely and members of the team with a wider perspective of methodological and patient safety issues. One such meeting took place in order develop the thematic framework used in coding the interview data (see Appendix 4.10), with a further meeting held prior to analysis of the focus group data.
3. **Inter-rater reliability of coding:** towards the end of the analysis of the qualitative data, a member of the wider research team (VE) examined ten transcripts which had been coded by the members of the team most closely involved in data collection and analysis (JH, MP, DMcC), as an independent check on the assignment of codes to data.

4. **Comparison of data within and across cases in the data set** was facilitated by the use of the analytic matrix which forms the basis of the ‘Framework’ approach. Comparing data within cases allowed for the exploration of contextual meaning, while comparing cases across the data set facilitated the search for regularities (key themes) and exceptions (negative cases).

5. **Use of memos:** the careful use of memos (by the prime analyst) during initial stages of analysis provided a visible ‘audit trail’ as the analysis moved from ‘raw’ data, through interpretation, to the production of findings.

6. **Attention to ‘negative’ cases:** analysis included a search across the dataset for ‘negative’ cases (evidence that contradicts, or appears to contradict, the explanations being developed) and alternative ways of explaining the data were considered. Systematic searching for negative cases or ‘outliers’ can help illuminate the connections that link the other cases together.

7. **Reflexivity:** reflexivity relates to sensitivity to the ways in which the researcher and the research process may shape the data collected, including the role of prior assumptions and experience.

   (i) Prior assumptions and experience
   Within the context of the current study, the members of the research team involved in face to face contact with study participants needed to consider the ways in which their interactions with participants might be influenced by their own professional background, experiences and prior assumptions (two of the team (MP) and (DMcC) are registered nurses; JH is also a qualified health
An important question we needed to address in drawing conclusions from the data concerned whether knowing about our professional background could have impacted on patients' willingness to talk openly about any negative encounters with health care professionals, or how this knowledge might have shaped what they said.

(ii) Awareness of social setting and the social ‘distance’ between the researcher and the researched

The majority of patient interviews were conducted in patients' homes, as this was usually more convenient for them. Although we were invited in as researchers, we were also mindful that we were guests in people's homes; respondents were therefore given the lead in 'setting the pace' of the interview and choosing who should be involved (themselves alone, or to include a carer or other representative). By deliberately adopting a 'back seat' approach in setting the scene for the interview to take place, the researchers hoped that participants would feel they were exercising a measure of control over the interview process.

Patients invited into the study were informed that they may, if they wished, be accompanied by a family member or advocate during their interview, in recognition of the fact that individuals are often interdependent, rather than independent, and embedded within a complex web of social relations. In many instances, the patient's spouse was present in the family home during the interview and they frequently contributed to what was being said, usually in a secondary role, supplementing, elucidating or, sometimes, challenging the accuracy of what was being said by the prime informant. In effect, their remarks often served to stimulate a process of reflexivity within the main respondent as the interview was in progress. Where permission was given, these additional observations were analysed alongside those from the patient participant. These 'joint' interviews yielded 'rich' data; the family member had usually been present during the patient's encounters with health care services and often held a slightly different view of what had occurred, so data capture was frequently augmented and enhanced.
(iii) Fair dealing
Dingwall (1992) has suggested that one way of reducing bias in qualitative research is to ensure that the research design explicitly incorporates a wide range of different perspectives so that the viewpoint of one group is never presented as if represents the sole truth about any situation, an analytic technique he has referred to as ‘fair dealing’.

Our study was designed to elicit contributions from people whose voices are often not heard and whose views are frequently overlooked (patients with severe and enduring mental health problems, and people from minority ethnic groups whose English language skills were limited or non-existent). During the analytic process however, the views of these participants were not ‘privileged’ over those of others; that is to say, data analysis included a process of constant comparison between accounts from these participants and others, to uncover similarities and differences, which were subsequently highlighted (for example, patients with mental health problems, more so than other participants, identified other patients as a threat to personal safety when they were in hospital).

A main goal of data analysis was the identification of common themes that emerged from comparison across cases (individual interviews). However, equal importance was attached to focusing on the minutiae of individuals’ accounts relating to specific incidents concerning patient safety; in the analysis, we sought to identify the views and experiences of individuals, as well as the majority, particularly where these diverged.

(iv) Awareness of wider social and political context
As a research team, we discussed the fact that focus group participants recruited from national and local ‘consumer’ groups might show a strong commitment to a particular personal or political agenda, or wish to raise particular issues during group discussions which may relate only tangentially, or not at all, to the main purpose of the discussion. We discussed how we might handle this situation if it arose; we decided how we would brief participants prior to the start of the group discussion, emphasising that the
purpose of the group coming together was to focus on the research questions; we talked about how to facilitate proactively during group discussions, so that everyone who wished to, would have the opportunity to contribute to the discussion, not only the more dominant individuals; and we explained to participants that there would be an opportunity for individual members to meet and discuss their personal concerns informally after the group discussion had closed. For the most part, this strategy appeared to be successful in keeping participants engaged in the research process.

(v) The role of the research team as collaborators in knowledge production

Collaborative research is highly valued for its ability to bring together multiple researchers with distinctive and specialist perspectives to tackle large or complex research problems, though frequently the ‘putting together’ of multiple perspectives in the construction of knowledge is not described (Mauthner & Doucet 2008).

Within the Patient Involvement in Patient Safety (PIPS) research team, there was a strong commitment from the outset to work collaboratively in the collection, analysis, interpretation and reporting of the qualitative data, though individual involvement with the various stages of the research process necessarily varied. The three team members most closely involved in fieldwork (MP, JH, DMcC) met frequently (at least once per week) to discuss the progress of fieldwork and reflect on data collection; meetings intensified during the early stages of analysis, when themes and codes were beginning to be identified. At this crucial stage, input was sought from other members of the research team with extensive experience of qualitative research and a broad knowledge of patient safety research (VE, BW) to assist with ‘firming up’ the coding framework. An all-day meeting was convened in a location away from the interruptions of the office environment, which served as a kind of ‘interpretative retreat’. Throughout the day, we focussed intensely on a sample of transcripts, representative of the total dataset (which had been sent to VE and BW in advance), in order to draw up the coding framework that would serve to underpin the analysis (and interpretation) of the all the interview data. This endeavour resulted in an analytic strategy that was
informed by insights from team members with a broad understanding of the research field and methodological issues, and those with field-based contextual and experiential understanding. (The process was repeated prior to analysis of focus group data, and included input from the study Principal Investigator, IW).

(v) Potential for psychological harm
Members of the research team involved in fieldwork (JH, MP, DMcC) were acutely sensitive to the possibility that focussing on the research topic could potentially provoke anxiety in patients concerning their safety; at the end of each interview, researchers took time to reassure patients that for most people, most of the time, health care delivery is safe.

FINDINGS FROM INDIVIDUAL INTERVIEWS

1. AWARENESS, UNDERSTANDING AND EXPERIENCE OF HEALTH CARE SAFETY ISSUES

Section 1 is concerned with patients’ general awareness and understanding of health care safety issues and reports on the following topics:

1.1 Participants understanding of the terms ‘medical error’ and patient safety
1.2 Sources of information about things that can go wrong in health care
1.3 Participants’ views about the frequency and severity of safety issues and how these are distributed within health care services
1.4 Anticipated levels of risk when using health care services
1.5 Perceived reasons for failures in safety
1.6 Anticipated response from health care professionals (HCPs) in the event of patient safety failure
1.1 What do the terms ‘medical error’ and ‘patient safety’ mean to study participants?

The term ‘patient safety’ appeared largely unfamiliar to the majority of study participants and respondents did not readily engage with the notion of patient safety as an abstract concept. For example, two study participants (102) and (106) linked notions of patient safety with road safety, while one patient (407), when asked directly about any concerns that she might have about patient safety, referred to the anxiety that patients might experience in connection with the safe keeping of valuables while in hospital. Only two participants (508 and 607), both trained health care professionals, revealed some understanding of the term ‘patient safety’ as it is commonly used in the literature.

In general, patients interpreted the term ‘patient safety’ in a broader manner than is usually found in the literature; for example, one respondent (508) raised concerns about the fact that female patients had to use the showers on a ward for male patients, which, in her mind, was potentially linked to a threat to her personal safety.

Patients with severe and enduring mental health problems referred to the possibility of the occurrence of harm to themselves or others as a result of their own actions or those of other patients, as well as harm arising from the decisions and actions of health care workers. They also indicated that when they were acutely ill, they would give no consideration to their own safety when using health services.

In order to elicit views about patient safety, study participants were asked to describe any general concerns that they might have about using healthcare services, and to talk about the kinds of things that might go wrong. In response, participants provided ‘rich’ descriptions of a broad range of specific incidents or events incorporating potential threats to, or actual breaches of, safety (either their own or family members’) and they described situations where they believed they had suffered physical or psychological harm.
(described in detail in section 2.3). They also described perceived shortcomings in the quality of the care they had received from health care providers, across a range of settings.

Study participants used terms such as ‘mistakes’, ‘genuine mistakes’ and ‘human error’ when referring to incidents or events which might be broadly classified as ‘medical error’ in the literature.

The terms ‘neglect’ and ‘negligence’ were distinguished by a number of respondents; ‘neglect’ was used to refer to harms attributed to lack of due care and attention (usually on the part of nurses), while use of the ‘negligence’ was associated with doctors, and implied a notion of grave or deliberate harm.

1.2 What they have learned from the media, family/ friends or colleagues about things that can go wrong in health care?

The predominant concern reported by those interviewed in the study was the possibility of contracting a hospital acquired infection (HAI) during a stay in hospital, linked to a widespread perception that standards of cleanliness in hospitals have been in decline in recent years.

Patients who were about to have or, who had recently undergone, surgical procedures appeared most anxious about the possibility of contracting Methicillin-resistant Staphylococcus aureus (MRSA); for some, the prospect was enough to deter them from going into hospital, or to consider paying for private treatment. In addition to information that they received about HAIs from health care professionals, these patients cited friends, relatives and the media, both newspaper reports and television programmes, as further sources of information about MRSA that provoked anxiety.

Patient (401), about to undergo an operation for joint surgery, described how his fear of contracting MRSA was fuelled by what he had read in a newspaper, and by his inability to obtain information through ‘official’ channels.
‘well the media is so full of it…I’d be surprised if there was anybody in the country that didn’t know about MRSA. Of course, it registers far more with somebody who is going into hospital…you see in the paper deaths caused by it, frightens you to death…I made a point of asking [during a pre-operative appointment] was there any particular area of surgery in which MRSA is more prevalent…and whether there were any recent figures what percentage of patients in [name of hospital] were getting MRSA, and she [the nurse] couldn’t answer any questions.’ (401)

In contrast, several study participants, including one of those having joint surgery, said that they would be wary about what they read or heard about MRSA in the media, or about what they heard from others, preferring to rely on their own experiences to inform their opinions.

‘I mean these things always get high profile, don’t they, probably unnecessarily, but at least you need to be aware of it, don’t you? I’m aware of it, but it doesn’t frighten me, let’s put it that way’ (406)

‘I feel it is the care that you have, you know, what your experience is through it, so I don’t often listen to other things’ (303)

Only two (102; 104) of the thirty study participants included in this analysis stated that they had not heard of MRSA from any source; these were both elderly patients with diabetes, from minority ethnic groups; patient (104) did not speak English.

Respondents appeared to gain a great deal of their information about what could go wrong in health care in general from the media, and frequently referred to reports in local and national newspapers, magazines, and television programmes, including news reports, ‘undercover’ investigative documentaries and hospital-based ‘soap’ series. Just under half of those interviewed recalled examples of severe medical errors that they knew about from the media, including reports of wrong operations being performed; a
range of drug errors; an incident in maternity care leading to a baby being deprived of oxygen at birth; a missed diagnosis (broken ankle) of a child in Accident and Emergency; an incident where a child had been taken from a paediatric ward without the parents’ consent; and the death of a young girl after being given an overdose of radiation during treatment for a brain tumour.

Two interviewees (408) and (309), mentioned watching ‘undercover’ investigative television programmes that focused on general issues relating to quality of care, one focussing on a maternity unit, and one on an elderly care ward.

‘it was one of these so called spies going in and finding out what was happening on the wards and…they went on an old people’s ward and some of them looked very unhappy…and they were just completely neglected. They weren’t being looked after, they weren’t being helped to the loo or given bedpans, they just laid there, they weren’t even being given their drinks’ (408)

A local ‘scare story’ seemed to exert a powerful influence over four patients’ perceptions of safety regarding a specific aspect of health care. These interviewees recounted hearing about, or reading in the local press, the story of a woman who was prescribed penicillin, despite an established allergy, and who subsequently, it was reported, was comatose for a long period of time before her death. One of the participants, herself an NHS employee, mentioned the story, but within a wider context, suggesting that the media could benefit from ‘hyping’ these kinds of stories.

‘I mean there’s always cases in the paper, aren’t there, and there are always people seem to be making a lot of capital out of them as if this is more typical, and I don’t think it is, I think there are obviously places where things have gone wrong and maybe people have had the wrong treatment…but there are thousands of people having all kinds of treatment and they go in and they come out and they’re fine.’ (202)
The experiences of friends, and, particularly, family members appeared to be an important source of information for most people about the kinds of things that can go wrong during the delivery of health care, raising concerns not just about the particular circumstances of the individual involved, but also at a broader level.

‘I mean my father had got Alzheimer’s and I’m off to see him because he is not very well, he’s in a nursing home now and he’s 87, and it’s very sad with what is happening to older people in certain nursing homes where their safety is jeopardised because of the drugs that they’re on and the way that, sadly the way that some of them are mistreated, which is terrible.’ (609)

Four interviewees suggested they would disregard criticism or reports of mistakes from other people, preferring to rely on their own experiences as a basis for formulating their views concerning safety of health care.

‘I mean you do hear about mistakes happening when you speak to people. You hear about mistakes a lot, but as I say, I can only speak from experience’ (509)

1.3 Views about the frequency and severity of safety issues and how these are distributed within healthcare services

(what are they? how often they occur? where they occur? which are most severe?)

Overall, the majority of patients believed that ‘mistakes’ in health care were a common occurrence; that health care professionals could take (or omit to take) precautions to avert errors; that the most serious errors were associated with surgery, including the risk of contracting MRSA; and that hospitals were less safe than other health care service delivery environments, partly due to the nature of the treatments and procedures carried out in hospitals, but also because of their size and organisational complexity.
Most respondents felt that mistakes are inevitable in health care delivery, and they suggested two main reasons for the common occurrence of errors; firstly, that any form of treatment is inherently risky; and secondly, that health care professionals are as susceptible to making mistakes as any other group of workers. Four of the 30 study participants (106, 109, 401 and 509) disagreed with the latter view, stating that certain types of mistakes should not be made by health care professionals.

‘everybody makes mistakes, but when it comes to making mistakes in tablets, injections or diagnosis, there shouldn’t be mistakes – not in hospitals. These doctors have years of training, these nurses have years of training.’ (106)

There were opposing views as to whether errors in health care are becoming more or less frequent.

‘before they didn’t make many mistakes, but now it’s becoming more common’ (104)

‘now I think they’re getting really good, so maybe years ago I would have put it at probably 20 in a hundred but now I don’t think so. Now I think they are pretty good so maybe 10…’ (203)

Personal experiences of healthcare were not necessarily indicative of perceptions of the likelihood of error at some future point. Some of those whose personal experiences to date were predominantly positive nevertheless expressed concern that in future their care could be compromised in some way, while others, who had had negative experiences, viewed these as atypical.

‘…although my experiences have been very good I am concerned about which is the side of health service that I haven’t seen and could I be a victim of some of those other experiences that you know, cause people to criticise the health service…’ (203)
1.3 (i) Patients’ perceptions regarding severity of safety issues

Patients’ perceptions of the severity of safety issues appeared to be mainly understood in terms of the amount or degree of harm suffered by patients, and encompassed notions of psychological as well as physical harm.

Analysis of the 30 interview transcripts revealed that just under half of respondents thought that the most serious threats to patient safety were likely to occur in a hospital setting; and that they were related to having surgery; and that one of the greatest threats to safety was the likelihood of acquiring an infection, specifically MRSA.

Errors or breaches in safety resulting in death or permanent injury were considered the most severe type of error by three respondents (203, 303, 402).

Breaches in safety frequently identified by patients as severe relating to surgery included wrong site operations, or a swab or instrument not retrieved before completion of an operation.

Other errors classed as serious (primarily drug errors) were ones that could occur in any health care setting.

Missed diagnosis, misdiagnosis and delay in diagnosis were identified as serious errors that would primarily occur in general practice.

Three of the five patients with mental health problems identified their own actions, or those of co-patients, as potentially posing a severe threat to their safety.
1.4 Anticipated levels of risk when using health care services

During interview, respondents were asked to state how many people out of a hundred would be likely to experience an error in their care when using health care services. Most people found this a difficult question to answer, either because they said they had never seen any relevant statistics, or simply because they had never given the matter any thought.

A minority of respondents attempted to differentiate between different types, or severity of error, in relation to frequency of occurrence; of the four who did, three were themselves qualified health care professionals (603; 607; 508); (507) had worked as a teacher in the past. Participants (507) and (508) suggested that people’s perceptions of frequency of errors could be affected by media ‘hype’.

‘I mean if you listen to the media it could be 90% of people and obviously it can vary from bed sores to blood infections, anyway in between. I don’t know…5%’ (507)

‘things like wrong operations…because they are so rare they make the news and then everybody thinks they are very, very common.’ (508)

Most people were prepared to make a ‘guesstimate’ of the percentage of people using health services who might suffer an error, and the figures quoted ranged from 1% - 50% (see Appendix 4.11 Participants’ Estimates of Probability of Error, Perceptions of Serious Errors and Attribution of Error). There did not appear to be any association between suggested percentages and the clinical specialties from which participants had been recruited. Two patients (609 and 304) quoted a high percentage figure of 50%. (609) referred to ‘horrendous stories’ he had heard from aunts who were nurses with experience of working in operating theatres, while (304) cited ‘negligence’ on the part of nurses as the main contributory factor, an issue she focussed on in her interview where she described her experiences of a series of specific incidents that had occurred when her child had been in hospital.
Study participants thought that patients were more likely to encounter threats to their safety and/or errors in their care in hospital than in any other health service location, due to (1) the nature of the procedures and treatments carried out in hospitals; (2) perceived risks associated with surgery, particularly the risk of contracting a HAI; (3) a perception that the potential for error is greater in large organisations where inter-departmental communication can be problematic; (4) a shared perception amongst patients with severe and enduring mental health problems that the poor facilities in many psychiatric hospitals pose a threat to safety.

General practice was considered by a majority of respondents to be a relatively safe environment in which to receive health care; only a small number of participants, those who had experience of a missed, delayed or misdiagnosis affecting themselves or members of their family adversely, suggested otherwise. Computerisation of records found in general practice was cited by one respondent (603) as a means whereby patient safety was enhanced.

Of the five patients with diabetes who were regular users of a particular general practice which acted as a referral centre for the provision of advanced and specialist diabetes services, none were concerned about the possibility of errors in their care.

‘I could not recollect a particular thing which I can see or I can describe that was a problem as far as safety goes’ (102)

Accident and Emergency services were generally considered safe; only one participant, (102), expressed concern about this service, relating to waiting times to be seen by a health care professional.

With regard to provision of maternity care, lack of basic cleanliness in local maternity hospitals was highlighted as a threat to patient safety by four female
respondents (the only ones who referred to this issue) who said that they or their friends would choose one hospital rather than another, according to standards of hygiene.

1.5 Perceived reasons for failures in safety
(whether they are attributed to individuals, systems, policies or chance)

Patients identified a range of factors that they believed contributed to failures in safety, described in more detail below.

- Poor communication, within organisations, between healthcare professionals, between healthcare professionals and patients;
- Fallibility on the part of individual staff (mainly, but not always, perceived as linked to shortcomings in systems);
- Lack of patient involvement;
- Policies (inadequate, inappropriate, not implemented);
- Inadequate staffing levels (by far the largest category of attribution);
- Other ‘systems’ failures

1.5 (i) Poor communication

Breakdowns in communication between different sectors of the health care system, within and between various departments of one or more organisations, and across teams of health care professionals were identified by patients as a frequent occurrence which posed a potential threat to safety and undermined patients’ confidence.

‘Having confidence that yes, there’s your file, there’s your notes but sometimes people just didn’t have those, they hadn’t spoken to one another, they didn’t have the information and I think the onus can be put on you as a patient, they rely on asking you...but you haven’t got the full picture...it’s the size of the organisation, how they manage the paperwork, getting your stuff up to date and making sure it’s there for your next appointment, you know,
liaising between departments and communication can really make all the difference’ (205)

Poor communication between health care staff and patients was identified as taking several forms: difficulties with language, when English was not the first language of the patient or the health care professional; doctors using medical terminology or jargon not understood by patients (although younger doctors were generally considered to have been better trained to communicate with patients); doctors and nurses making assumptions about how much patients understand; staff not taking time to check patients’ understanding of information of instructions; health care professionals not taking time to listen to patients or discuss their concerns, particularly if they were elderly, deaf, had learning disabilities, or were unable to process information readily due to their illness, or because they had received some bad news.

‘sometimes there are foreign doctors, their English can be a bit difficult to understand…it’s not just understanding the medical aspect of it, it’s actually understanding what they are saying, so if the patient is a bit deaf, or if you are very sick, then it might just be a bit too much…if you’re frightened or if you’ve had bad news…if you are given a diagnosis of cancer…’ (607)

A number of patients, particularly, though not exclusively, those who had experienced in-patient treatment in psychiatric hospitals, also identified the attitude of health care professionals towards patients as a barrier to communication with could have implications for safety.

‘they really just seemed to have an attitude of ‘we really couldn’t care…if you would ask them for something, they would almost ignore you…they wouldn’t sort anything out for you, they made you feel so unimportant and as if you were an absolute pain…’ (605)
1.5 (ii) Fallibility on the part of staff: human error

There was widespread recognition amongst patients that health care staff were prone to ‘human error’.

‘we are all human beings and can go up and down’ (102)
‘people are human, nurses are human, we all make mistakes’ (402)
‘nobody is perfect’ (603)
‘they’re human beings aren’t they, doctors and nurses, they can do stuff wrong if they’ve had a bad day, just like anybody else’ (203)

However, three respondents (106; 109; 509) thought that health care professionals’ training should ensure that they do not make mistakes.

‘everybody makes mistakes, I don’t care who they are, but when it comes to hospitals and doctors, you know, there shouldn’t be mistakes.’ (106)

In most cases, study participants made reference to ‘human error’ in connection with hospital care and treatment. Patient (605) was one of the few who attributed breaches in safety to errors on the part of individual general practitioners, drawing on her own family’s experiences of missed and misdiagnoses, delayed diagnoses, and delay in referral to psychiatric specialist services.

1.5 (iii) Lack of patient (or family member/representative) involvement

Just under over a quarter (8) of the 30 study participants suggested that patients’ non-involvement in their own care, or non-compliance with instructions from HCPs, could contribute to failures in safety.

‘Doctors and nurses can only do so much. I do feel that …if you don’t tell them that you’re feeling a certain symptom or that you’re worried about something and then it does turn out to be something else that you never told them, then you’ve got nobody but yourself to blame’ (208)
Elderly people were thought to be less likely to speak up for themselves to avert potential errors in their care; participant (509) expressed a view shared by many respondents, that older patients needed someone with them during hospital admissions to speak up on their behalf.

‘pensioners or people not watching what is happening and things, allowing things to go on for too long before they said something’ (402)

‘I feel dreadful for those who haven’t got somebody looking out for them and there are many elderly people in hospital who don’t have anyone watching out for them, you know’ (509)

Two participants (106, a patient with diabetes, and 303 the mother of a child with asthma), held the view that failures in safety could result from patients not following health care professionals’ instructions, for example, not taking their medications as instructed.

1.5 (iv) Policies

Hospital policies viewed as impinging on patient safety related primarily to measures to stop the spread of infection; the cleaning of wards (there was a widespread perception that standards of cleanliness had declined when contracts were handed over to private firms); and whether or not policies for hand-washing and isolation of infected patients were being implemented correctly on hospital wards. Several respondents expressed concern about the lack of policies to prevent nurses wearing uniforms when travelling to and from work, regarded as a potential source of infection.

Other hospital policies viewed as potentially having a negative impact on safety were hospital admission procedures and the way in which patients were allocated to wards within hospitals, as well as discharge policies.
Respondents highlighted concerns about possible safety issues that might arise from patients being admitted to wards that were not optimally suited to the deliver the type of care they needed (specialist units were regarded as providing better levels of care and treatment than general wards) and they expressed concerns about patients being moved from one ward to another within a single episode of care in hospital.

Patients with mental health problems described facilities in many psychiatric hospitals as completely inadequate, and suggested that policies for accommodating patients were often ‘overridden’; patients who were acutely ill, and potentially aggressive, were said to be frequently accommodated alongside those who were less ill.

Respondents also expressed concerns about hospital discharge policies; they suggested that patients were discharged from hospital too quickly, due to pressure on beds, with implications for treatment outcomes; additionally, hastily arranged discharges were said to result in information not being transferred to family members in a timely fashion, and a lack of continuity of care from community services, both of which could have serious consequences for patients’ safety.

There was a high level of awareness amongst participants of the existence of policies concerning the checking procedures routinely carried out by HCPs undertaking certain clinical tasks and surgical procedures, and patients suggested that deviations from these procedures could potentially lead to error. For example, patient (202) quoted from an article that she had read in a magazine about the identification of surgical sites by marking.

‘I was reading about saying about policies vary about whether the right body part is identified before surgery, you know the right breast is marked…whatever it was they were saying that some hospitals don’t even mark up in any way, but it does sound like a potential for being misinterpreted.’ (202)
Two further issues were raised by two separate respondents in relation to policies and patient safety. Participant (508) cited the lack of hospital policies to ensure ‘protected time’ during meal times in hospital as a reason for patients’ nutritional needs not being adequately met; while participant (208) believed that the formulation of criteria of national policy for the classification and referral of patients with suspected breast cancer led to a delay in her receiving treatment.

1.5 (v) Inadequate staffing levels

In the main, study participants seemed to view human error as the consequence of health care professionals working within systems which were likely to lead to failures in safety; in other words, they tended to suggest ‘mitigating circumstances’ to explain why health care professionals made mistakes.

The systems failure identified by most patients as the most likely to impact on their safety in hospital related to issues of workload and staffing levels. Staff shortages were described as ‘unsafe’ (605); hospital wards as ‘horribly busy’ (508); staff as ‘overstretched’ (106), and prone to making errors: ‘hurry makes mistakes’ (603). Patients who had had experience of in-patient hospital wards described their reluctance to disturb staff or divert them from the task in hand, as they could see them working under intense pressure.

Staff shortages led some patients to fear for their physical safety; other patients described suffering unnecessary post-operative pain, or physical or social neglect; three respondents reported that routine checking procedures in the administration of medicines were omitted due to a lack of qualified staff.
Further staff-related issues perceived as potentially impacting on safety included: patients being cared for by inexperienced or untrained staff and lack of supervision of these staff (respondents cited examples of inexperienced junior doctors who were reluctant to seek advice from more senior staff, and health care assistants carrying out tasks for which they did not seem to be adequately trained); doctors’ working hours thought to be too long; nurses spending too much time on paperwork and not enough time with patients (for example, not attending to patients’ needs for hydration and nutrition, assisting them to walk to the toilet or bathroom, talking to them about their concerns).

The lack of a recognisable ‘matron’ figure was perceived as a systems failure by a majority of those interviewed. It was suggested that the role of a matron

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Patient 401 was interviewed after a knee operation; his wife described how he suffered preventable pain during his stay in hospital, which she attributed to staff shortages.

Patient 401: ‘I think there were about 3 staff on for the whole ward…

Patient 401’s wife: ‘…there were 3 staff and 24 patients and half of them had had an operation…they’re very good and they do what they can but they are very short staffed. They’re dreadfully short staffed. I mean at one point you were without morphine for how many hours, was it without your morphine drip being fixed on the second day, purely because nobody could come’ (401)

Participant 508 was a qualified nurse who made a complaint about an ‘unpleasant’ stay on a busy medical admissions ward, with few staff, when she and other patients were subjected to verbal abuse from another patient.

‘It is a very busy ward that has patients coming all the time…there was certainly some aggressive drug or alcohol fuelled situations…we did worry a little bit about safety…the guy who had come in with the fight and walked in to our bay and [threatened to assault the patients] and I’m sat there thinking, okay, how do I handle safety on this ward…the lady nearest the door was terrified…that night we didn’t get much sleep…’ (508)

Participant 205 felt forgotten and neglected in a busy cancer unit while waiting to be seen by a consultant to talk about her diagnosis

‘I was left there another hour and a half because somebody hadn’t crossed my name off. I should have been more or less on time, it’s literally human error…and they just hadn’t crossed my name off and I literally sat there, you know, quite an important appointment to me…’ (205)
would encompass liaising with patients and discussing their concerns, checking that staff were performing their duties correctly and ensuring that hospital wards were cleaned thoroughly.

The main reason suggested by respondents for staff shortages was lack of funding, but issues associated with management, at the ward or at a higher level within the organisation, were also highlighted.

‘I mean it was only on the telly yesterday about these hospitals being in debt. There’s 80,000 doctors – no, it wasn’t it was saying pen pushers or whatever you call them being dismissed…I don’t think the money goes where it should do. I think there are too many chiefs and not enough Indians really. I think nurses should get a proper salary, there should be more patient care and not so much form filling’ (106)

‘the night staff seemed to be very few and far between. I think there were two trained staff and I health care assistant and obviously the doctor who was floating around at times and they did seem to be extremely busy and I can imagine faults would occur…I suppose it is hard for people to determine staffing levels to know what’s right…’ (202)

1.5 (vi) Perceptions concerning other ‘systems’ failures

A minority of patients revealed a broader understanding of the causes of systems failures. Patient (208) suggested that major errors could be precipitated by an apparently trivial occurrence, while respondent (508), a qualified nurse who had attended risk assessment lectures as part of her professional development training, referred to the ‘Swiss cheese’ model (Reason 1997) of failed safety defences. Participant (509) described content from a television programme that he had watched about systems level measures that could be taken to prevent mistakes occurring in the administration of epidural injections.
'it can be something very trivial for example, a lost piece of paper or change of staff – a hundred and one things that can go wrong’ (208)

‘…the holey cheese…it’s usually a chain of events and it’s usually more than one person involved or somebody has made a mistake which is then exacerbated by the time person B gets to it…” (508)

‘they’ve got a different kind of a cap and a different fixture so that you can’t join another one and also they should be colour coded as well I think’ (509)

1.5 (vii) The role of chance

Three of the patients (401; 402; 406) interviewed prior to undergoing joint surgery, and a small number of other patients, implied that luck or fate could be influential in whether or not anything was likely to go wrong during a stay in hospital.

Patients referred to being ‘in the lap of the gods’ when going into hospital (406) or said that they were ‘hoping for the best’ (209).

Participant (402) believed the chances of experiencing an error were probably low, due to the many safety checks that were routinely carried out, and he said that he would therefore consider himself unlucky if something untoward happened.

‘I think you’re unlucky if something goes wrong, something that is vital goes wrong. I think people make mistakes all the time but I think they do take an awful lot of care especially in hospital to make sure that your wristband matches with whatever they’ve got on their sheet…I’ve never been in a hospital where they haven’t asked me what my name is and my date of birth and checked my wristband before they’ve given me anything. (402)

Patient (203) expressed her anxiety about her hospital admission being scheduled for Friday 13th, a date traditionally associated with bad luck.
1.6 Anticipated response from HCPs in the event of patient safety failure

The majority of participants believed that in the event of patient safety failure, healthcare professionals would respond by attempting to cover up the error or mistake, dependent on how serious the error was, and how the patient reacted. It was suggested that the more serious the error, and the more ‘fuss’ the patient made, the more difficult it would be to ‘push it under the carpet’ (406). These respondents’ comments revealed that they perceived that healthcare professionals worked in an environment where blame was likely to be attached to individuals, with concomitant consequences which could range from the relatively minor, to ones which could affect the healthcare professionals’ livelihood.

‘I think they might try and push it under the carpet but I think if something went seriously wrong then it would be investigated properly and I think a lot would depend on how much fuss the patient would make about the error that had been made’ (406)

‘they would feel really guilty and they might get a rollicking’ (209)

‘I would imagine they would be mortified. I mean it’s their reputation that’s on the line…and it doesn’t look good for them…I mean somebody could be struck off for it if they made a serious error, so that’s their life at risk’ (308)

One participant (609) expressed views that were more extreme than any others’ concerning how certain individuals try to hide clinical error. In his opinion, based on conversations with nurses and information from the media, surgeons who are not professionally ‘up to the mark’ hide their mistakes by exercising power over the clinical teams working with them, so that they are too frightened to act as whistle-blowers.

‘surgeons that are not up to it and killing patients and hiding the fact that they’ve bungled the operation and the team that work with those surgeons still
would not whistle blow because within the system is this – the surgeon in charge of that team has absolute say...they know that if they do, the hospital is going to get sued and they are told in no uncertain terms, obviously you don’t dare tell.’ (609)

Contrasting with the views described above, six participants (including all but one of the healthcare professionals included in the study sample of participants) believed that staff would or should react to a mistake by being ‘open’, that is, by admitting to the patient that an error had occurred and discussing with them how the situation would be remedied. The health care professional participants were also more likely than other respondents to reveal an awareness of systems that may be in place to support individuals when mistakes occur.

‘going on some of the things that I know I’ve dealt with over the years, trying to be open about it, trying to cover up is a bad idea. Be open about it and be open about the possible implications of whatever has gone wrong.’ (508, qualified nurse)

‘I mean healthcare professionals certainly doctors with their medical defence unions they’re told, you know, you should apologise and be open…depending on what the mistake is, you might want to take legal advice first, but that’s often what patients want, an apology’ (607, qualified doctor)

Amongst the healthcare professionals included in the sample, only participant (603), who worked in a care home for elderly people, implied that if a nurse made a mistake, they might try to shift the blame from themselves to a deficiency in the wider environment in which they worked.

‘they will try to save themselves from the situation...people will find some or other means of escaping, they will try to find out some means of escaping...suppose in my care home I’m working, if the other unit staff they didn’t come and they didn’t call the agency and they didn’t overcome the
shortage, if I’m working and if 2 things are happening at the same time, I can simply tell them…I will try to find out the means of escape myself…’ (603)

Two of the participants (303 and 309) who reported that they expected staff to behave in an open manner if an error occurred, were parents of children with asthma who indicated that they shared close bonds with the staff looking after their children on a regular basis.

‘I think with us having such a relationship, you know, that closeness and trust …if you’ve got that relationship with the nurse or the doctor I think they can be open enough to explain it to you, why it happened and what went wrong’ (303)

However, a third participant (302) also the mother of an asthmatic child, whose experiences of nursing staff on different wards were more varied, held an opposing view of how staff might behave.

‘I think they panic and they start getting worried and they’ll be questioning themselves…probably one of the nurses wouldn’t even say nowt…because they might get into trouble themselves’ (302)

Participant (208) drew a distinction between the way that errors might be handled by the frontline clinicians and those employed in an organisation to deal formally with complaints. In her view, clinical staff would strive to make amends, while management would be more likely to dismiss the patient’s concerns.

‘nurses do everything in their power, and doctors do everything in their power to make it right…I think it depends on the staff and level of dedication. But I think on the whole, they do try and sort it out and what people above them try and do if it goes to paperwork way…is sweep it under the carpet, make excuses whatever. I don’t think you get that from face-to-face contact with doctors and nurses, I think it’s much harder to do something like that face-to-face than it is over a telephone or letter.’ (208)
Based on prior experiences, two respondents anticipated negative responses from nurses at a personal level if they reported an error to a member of staff; (401) thought staff would be ‘patronising’, while (509) reported that he was might be ignored or even insulted.

**Section 1 Summary Points**

- The majority of study participants were unfamiliar with the term ‘patient safety’. In general, they appeared to interpret the term in a broader sense than is usually found in the literature. They incorporated notions of psychological as well as physical harm.

- The possibility of contracting a hospital acquired infection was a predominant concern for many of the study participants.

- Patients with severe and enduring mental health problems viewed other patients as a potential threat to their safety.

- Just under half of those interviewed recalled examples of severe medical errors that they knew about from the media.

- Overall, the majority of patients believed that ‘mistakes’ were a common occurrence in health care because health care treatments are inherently risky, and health care professionals are susceptible to error.

- Patients’ estimates of probability of them experiencing an error in their care ranged widely, from 1%-50%, though the majority suggested around 10%, the percentage figure most commonly cited in the literature.

- Inadequate staffing levels were identified as the main reason for failures of safety in care in hospitals, and poor communication at various levels was highlighted as an important source of error.
• The majority believed that health care professionals would attempt to cover up an error or mistake, dependent on how serious the error was, and how the patient reacted.
2. SPECIFIC PERSONAL EXPERIENCES OF ERRORS, HARMS AND THREATS TO SAFETY

Section 2 of the report presents information from participants concerning their personal experiences of mistakes, harms that might have been preventable, and things that did or could have gone wrong during health care delivery; their views about why these ‘undesirable events’ occurred; and they types of actions they considered taking, or took, to try to avoid errors or avert harm.

This section comprises the following subsections:

2.1 Specific examples of mistakes, harms that might have been preventable, and things that did or could have gone wrong
2.2 Nature of undesirable events described by participants and views about their causes
2.3 Situations in which patients acted or wanted to act for themselves (or others) with a view to avoiding errors, averting possible harms, or ensuring problems were promptly dealt with, and to identify the types of actions they took or considered taking

2.1 Specific examples of mistakes, harms that might have been preventable, and things that did or could have gone wrong

During interview, study participants were asked to give examples of any mistakes that had occurred during the delivery of their health care; to describe any harms they had (or might have) suffered; to talk about any situations they had experienced or witnessed where things did go wrong (or could have gone wrong). These data were coded under the umbrella term ‘undesirable events’.

Across the data set of 35 interviews, a total of 128 undesirable events, or ‘chains of events’, were identified by respondents. The majority, 91, (71%), were said to have occurred during in-patient hospital stays; 18 (14%) were reported as happening in primary care (general practice, community...
pharmacy and community nursing services); 10 (8%) in Out Patient Departments; 5 (4%) at the interface between different healthcare service sectors; and 4 (3%) involved the ambulance service and the Accident and Emergency department.

The number of undesirable events reported by participants varied across the clinical groups from which participants were recruited, ranging from 13 (across the 5 patients with diabetes) to 32 (across the five participants who had raised a safety issue with PALS or made a complaint about their care) (see Appendix 4.12: Number of undesirable events identified by respondents from each clinical group and the location where they occurred).

The number of undesirable events identified by individual study participants ranged from none (participant 209) to 12 (participant 401, interviewed just after an operation for joint surgery) (see Appendix 4.13: Specific numbers of undesirable events recounted by individuals from each clinical group).

It must be emphasised that the events reported by patients reflect their perceptions about errors or shortfalls in their care and (as denominator data was lacking) that the reported information cannot be used to make valid judgements about rates of error, nor can it be used comparatively to draw inferences across patient groups or health care settings.

2.2 Nature of undesirable events described by participants and views about their causes

The 128 undesirable events and situations described by participants in their interviews have been broadly categorised (below) according to the focus of their concerns, which include consideration of psychological as well as physical harms that can result from encounters with health care professionals.

Under each category heading are specific examples of incidents or situations perceived by respondents as potentially impacting on patient safety (italic print) which have been derived from the interview transcripts of individual
participants. It should be emphasised that these categories were developed as a means of sifting the incidences mentioned in patients’ interviews and sorting them into distinctive groupings. These descriptive categories are grounded in the context of the data captured during the study, and do not represent a broader attempt to classify errors or adverse events.

- Medications (errors in prescribing, dispensing, administration; lack of information about side effects)

  over-prescribing of methotrexate (106); wrong dose of heparin injections supplied by pharmacy (203); child given double dose of medication as one given by nurse not recorded (303); patient not informed of side effects of Indomethacin (406); nurse was going to give injection to wrong patient (401); drug given in correct dose but by wrong route (512); routine checking procedures for administration of medicines not carried out (605)

- Misdiagnoses, missed diagnoses, and delays in referrals to other services

  patient fainted and told due to ‘change of life’; later test revealed high blood pressure and metabolic imbalances (309); elderly father had X-ray after fall, but fractured femur missed (511); son’s diagnosis of depression missed by GP (605); delay in patient’s referral to psychiatric services (607)

- Cleanliness on hospital wards, and the risk of contracting a hospital acquired infection (HAI)

  patient with compromised immune system would not go into hospital for fear of getting MRSA (106); nurse did not wash hands prior to treating child (303); bathroom/toilet areas on ward not clean (408); patient said he had refused admission to hospital for treatment when he had an open wound (401); ward area not cleaned thoroughly (508)
- Neglect by hospital nursing staff of patients’ physical and emotional needs

  patient’s emotional needs not addressed during treatment with chemotherapy (205); baby left crying all night, not attended to by staff (304); post-operative pain not monitored or controlled (401); development of pressure ulcers (401); husband taken to toilet and ‘forgotten’, resulting in fall (408); patients’ nutritional and hydration needs not met (507); lack of monitoring of infusion containing antibiotics (509); nurses unwilling to spend time engaging patients in talk and activities (602)

- Poor communication (between health care professionals, across teams working within or across particular health care settings; between healthcare professionals and patients)

  conflicting information received from different doctors (202); arrangements for community nurses to give follow up treatment not set in place prior to discharge from hospital (408); daughter not told about elderly mother’s discharge from hospital, or informed about her medications; GP also unaware (507); healthcare staff did not take time to communicate with elderly with problems with impaired hearing or poor eyesight (507); patient told to ‘go away’ when she tried to talk to staff (605)

- Clinical and checking procedures apparently incorrectly executed

  theatre staff did not follow protocol for documentation (208); investigative test carried out on child resulted in severe dehydration (304); health care assistant did not carry out blood pressure readings correctly (508); nurse did not appear to know correct procedure for flushing surgical drain (509)
• Inadequate facilities

female patients had to use showers in male ward (508); physical environment unsuitable for accommodation of patients who are a risk to their own personal safety (602); acutely ill patients share accommodation with less severely ill in psychiatric in-patient wards (603)

• Threats to safety from the actions of other patients (reported mainly, but not only, by patients with severe and enduring mental health problems)

patient felt alone and vulnerable in X-ray department late at night (509); threats to personal safety of patients on a medical admissions ward from drunk and aggressive patient (508); fellow patient set fire to carpet in bedroom (603); psychiatric in-patient witnessed aggression and violence towards staff from fellow patients (605)

• Administrative and systems factors

patient’s blood sample ‘lost’; X-rays ‘lost’; medications ‘lost’ (401); mistaken identity (401); waiting times in Accident and Emergency: respondent (102) (a teacher) accompanied an ill child to A&E and waited 3 hours to be seen; pressure on hospital beds: (104) told no bed available for daughter with baby that had died ‘in utero’; (509) thought wife discharged too soon after major surgery because of need for beds.
2.3 Situations in which patients acted or wanted to act for themselves and other patients with a view to avoiding errors, averting possible harms, or ensuring apparent problems were promptly dealt with, and to identify the types of actions they took or considered taking

Analysis of the interview data uncovered a range of situations in which patients acted, or considered acting in particular sets of circumstances to protect their own or another’s safety. Detailed analysis of the specific situations described by individual participants revealed that decisions to act or not to act, and the type of action contemplated or taken, appeared to be associated with a number of factors, relating to:

- respondents as individuals (socio-demographic and biographical details, personal characteristics, point on the illness trajectory, feelings of physical or emotional vulnerability, whether alone or accompanied, whether acting for self or on behalf of someone else)

- the nature of the situation in which they found themselves, perceived immediacy and gravity of threat to safety, perceived ‘busyness’ of the health care environment, the extent to which they were sure of grounds for action, fear of repercussions)

- the anticipated or actual response from health care professionals (prior experiences, perception of nature of relationship with HCPs, the perceived level of ‘challenge’ associated with the proposed action)

A complex interplay between these factors seemed to be influential in respondents’ decision making about whether or not to take action.

In order to provide a detailed picture of the types of situations where respondents acted, or considered acting, relevant data from interview transcripts have been gathered together (below) under broad category headings, with specific examples of situations provided in the form of
summaries, or synopses, incorporating verbatim quotations. In most instances, a synopsis is preceded or followed by a brief commentary (by the researcher) to draw attention to salient issues. Where participants suggested how a situation might have been prevented, or its consequences ameliorated, these details have been included in the text box in bold type.

2.3 (i) Situations and type of action taken

Situation (A): patient perceives themselves (or another) to be in immediate danger of a serious error or harm

Study participants who perceived that they (or another) might imminently suffer a serious harm or error in their care alerted healthcare professionals to their concerns by ‘speaking up’. ‘Speaking up’ on behalf of a family member (child, elderly parent or spouse) was more commonly reported than speaking up on behalf of oneself, or a fellow patient, and respondents appeared more ready to challenge or confront healthcare professionals in a direct manner when they were acting to protect another. In some situations, the initial act of ‘speaking up’ by the patient (or their representative) was sufficient to prevent an error, avert harm or result in a problem being resolved. Where respondents felt that the response from the HCP(s) had been unsatisfactory, the initial act of ‘speaking up’ was often followed by a more confrontational interchange between patient and HCP, or a verbal or written complaint (see Synopsis 2 (below) for example, and ‘Model of ‘cascade’ of events’ on page 39).

Synopsis 1 summarises participant (401)’s ‘speaking up’ in a situation of mistaken identity in hospital, which he believed could have resulted in serious harm for himself. His words highlight the fact that patients whose mental or physical capacities are impaired due to illness may be unable to ‘speak up’ for themselves.
Respondent (401) was a white British male in his seventies, with a background in sales and a long history of using hospital services since he was a child. He believed he was someone who could always speak up and look after himself. Recently in hospital for a successful operation on his hip, he commented that he was well looked after by medical staff, but was less pleased about ‘a few mundane things that weren’t satisfactory’; his dressing had not been changed prior to discharge and his blood sample, X-rays, and drugs had been ‘lost’, which he put down to the general busyness of the ward and the pressure of workload. While recovering from his operation on the ward, he found a nurse coming towards him with an injection of insulin, which was meant for another patient. (401) spoke up to prevent the error, commenting that fortunately he was in a fit state to be able to do so.

‘at one point somebody came to give me an insulin injection, which was a complete mistaken identity and had I been feeble or semi-conscious I don’t know what would have happened. So I was compos mentis to say, ‘On your bike, you’re not going to give me an insulin injection.’ I don’t know whether it was a doctor or a nurse… and he said, ‘Oh, I’ve come to give you an insulin injection’ and I said ‘no, I don’t think you have’ and so he just went and a nurse later on apologised and said, she’d got mixed up and there was another [name] in one of the other wards. So something like that could have been serious I suppose.’ (401)

Situation (B): patient believes delay in treatment is contributing to a deterioration in their (or another’s) condition

Facing a delay in their own or a family member’s treatment frequently led to participants ‘speaking up’, often in an increasingly confrontational manner if the delay continued and they believed their own or their family member’s condition was deteriorating.

In synopsis 2, participant (512) described how she spoke up forcefully on behalf of the baby in her care as she watched him deteriorating while waiting for an investigation to be carried out.
Participant (512) was a foster carer who took a very ill baby to hospital. After a long delay waiting to be seen by the doctor, (512) was told that the child would need an ultrasound examination to be carried out urgently, and that the he should not be fed until it was carried out. The ultrasound was delayed until the following day, and the child had become dehydrated. As (512) became increasingly worried about the child, her anger flared and she became more outspoken in her dealings with staff; the situation was exacerbated when she found out from another doctor that she had been misinformed, and that the baby could have been fed after all. At this point (512) initiated the transfer of the baby to a specialist unit, and she followed up on the incident with a written complaint.

‘at 2.30pm I thought, ‘well, I’ve just about had enough of this’ and I took [name] in his pushchair up to the nurses’ station and I stood with my arms folded until somebody said to me, ‘are you alright?’…and I said, ‘well, actually, no, I’m not,’ only I didn’t say it as politely as that, I was quite hard…I said [name] hasn’t been fed now for going on 6 hours. I was promised an urgent ultrasound last night and then this morning we haven’t had it, and she said, ‘Oh, didn’t I tell you to feed him at 11 o’clock?’ So I said, ‘no you didn’t tell me to feed him at all…’ ‘Oh’, she went, ‘apologies for that’ and flounced off. Then they started phoning the ultrasound department. By this time I was livid…’

(512) believed the situation could have been prevented if an ultrasound examination could have been carried out immediately and if there had been better communication between staff; the consequences could have been ameliorated if the child had been transferred more quickly to the specialist unit.

In synopsis 3, respondent (104), an Asian Pakistani by birth, overcame her inability to speak English by finding a nurse who could translate for her so that she could speak up on behalf of her daughter who, she believed, required immediate admission to hospital.
Participant (104) recounted (via a translator) how she decided to accompany her daughter to hospital to insist that she was admitted after her child had died ‘in utero’. Her perception was that staff at the hospital were not paying sufficient attention to her daughter, even though she could speak English, that they weren’t listening to her concerns and that therefore her treatment was being delayed. Respondent (104) decided to ‘speak up’ on her account, although she believed that patients should be able to rely on health care professionals, and should not have to ‘speak up’.

‘they weren’t really paying much attention to her and then 8 days passed and the baby is dead inside her and her daughter was going back and they weren’t doing anything and she said, ‘I went with my daughter and I said to the nurses, if anything happens to my daughter, then I will hold you responsible’…because the child was dead inside her for 8 days before they removed it…she [participant 104] was a bit of a midwife in Pakistan and she was just saying that she was just angry, the fact she knew what her daughter was going to go through, and she had to say it…she was quite firm…the excuse they gave to her daughter was there were no beds in the hospital, and she says, when I put my foot down they created a space and they accepted her…she was just saying she [the nurse] was quite harsh was the nurse and she said, that if anything happens to my daughter I will put a case against you and that’s when they admitted her in’ (104)

(104) attributed her daughter’s situation to staff not listening to her when she attended the hospital by herself; the situation could have been avoided if her daughter had received proper attention in the first instance.

In Synopsis 4, participant (607) faced a delay in receiving treatment which she perceived as a threat to her safety; however she reported that she was unable to act in any way to improve her circumstances because the delay seemed to be inherent in the way the system of referral to mental health services operated in primary care. Diagnosed as having bipolar disorder some time after the incident that she described, (607) said that she had subsequently taken actions to avoid a similar situation arising in the future, having drawn up a crisis resolution plan, obtained appropriate medication and the contact details of the mental health telephone helpline. With increased knowledge and experience of her disease, she said she would now by-pass primary care and go directly to accident and emergency if she thought she was becoming acutely ill.
Participant (607) described a situation where she had ‘gone full blown manic’ and had gone to the GP hoping for treatment, but the GP referred her to the psychiatric senior house officer at a hospital about half an hour’s drive away. (607) was concerned both for herself and her elderly mother who was with her at the time, as she became increasingly unwell. When she arrived at the first hospital, she could not be admitted as there was no bed available, and so the delay getting treatment grew as she was sent to another hospital, by ambulance.

‘I thought he was going to give me an injection, but he referred me direct to the psychiatric SHO and so I was just waiting, I was wanting to have some medicine or treatment straightaway…I was deteriorating sort of quite rapidly and it was a strain…I suppose that’s a safety issue, the fact that there was a delay in treatment, but that’s the way things go, in hospital, it’s a door to needle time for somebody who’s suffering from MI [myocardial infarction] to give them the [medication] and I was just wishing for mental health problems there was a door to treatment time…they wanted to transfer me to another hospital because they didn’t have a bed, or there wasn’t an appropriate bed at the first hospital…and I was deteriorating further and that frightened me, I didn’t feel safe then, sort of felt very unsafe…when I arrived at the second hospital, I had completely lost touch with things’ (607)

(607) believed the situation could have been prevented by her receiving treatment more promptly through primary care services.

Situation (C): patient unsure if HCP had washed/ cleaned their hands

Of the 30 participants included in this analysis, only 3 said that they had asked, or attempted to ask, a health care professional to clean their hands before they touched them or carried out a clinical procedure. Most of those interviewed said they would assume that HCPs would do it ‘automatically’; several pointed out that it was difficult to be sure whether or not HCPs used alcohol dispensers if they were situated outside the room; and many participants reported that they would feel uncomfortable or embarrassed about asking a HCP to clean their hands.

Despite participant (202)’s professional background, her knowledge that health care professionals should clean their hands before coming into contact with patients, and the presence of posters encouraging her to speak up, she
clearly felt uncomfortable asking the nurse to use the alcohol rub; she ‘didn’t dare’ to pursue the matter with the nurse, whom she hardly knew, and blamed herself for not achieving the desired response from the health professional. In common with many study respondents, (202) could not be sure whether the HCP had cleaned their hands before coming into the hospital bay (see Synopsis 5)

Synopsis 5

Participant (202) was a qualified health professional in midlife, of white British origin, who had had surgery for breast cancer, and described her prior experiences as a hospital in-patient as generally positive, with the exception of a recent admission. (202)’s main or ‘greatest worry’ on going into hospital was the risk of acquiring an infection, as had happened previously to her after chemotherapy. Her description of herself was that she was not a complainer by nature; that she tended not to speak up about things because she would be embarrassed about making a fuss; that she would be more likely to speak up on behalf of other people; and that she did not believe her treatment would be affected in any way if she raised an issue. (202) described how she attempted to ask a nurse to use the alcohol rub before touching her, as urged to in the posters on display on the ward, but she was unsuccessful in her attempt, and too embarrassed to try again. She concluded that the nurse may have used the dispenser outside the door to the bay.

‘I forget now what one of the nurses came to do…whether it was changing my drip, or I don’t know what it was but he hadn’t used the alcohol and I made some mention about the posters that say, ‘if we haven’t used it, don’t be too embarrassed to ask’ and I obviously said something in such a clumsy way, meaning to say, ‘I haven’t seen you use the alcohol rub, will you please use it before you touch me’, and he completely misunderstood me and went away and brought me one, you know, a little dispenser back and said, ‘there you are, and put it on the table, and he still didn’t use it, and I thought, I didn’t handle that very well. So I didn’t dare say anything after that but that was the only time that particular nurse had anything to do with me… that was the nearest I think I got to saying, ‘please will you do what your posters say and use it’, but then again, he could have used the one outside the door, I don’t know, because on the whole I did see lots of evidence of staff using the alcohol rub coming in… I just didn’t do it very well’ (202)

(202) blamed herself for failing to convey her request to the nurse; if she could have been sure that the nurse had washed his hands, she would not have needed to ask.
Situation (D): patients suffered unnecessary pain

Two of the respondents (401, 408) who had undergone joint replacement operations reported suffering pain after their recent operations, which they attributed to inadequate monitoring of their analgesic infusions by nurses, and to the lack of a prompt response from staff when they first drew their attention to the situation by 'speaking up'. Participant (401) was being visited by his wife in hospital when his analgesic infusion stopped working, and she took the lead in speaking up on his behalf. Patient (408), an elderly lady of 78, was alone in hospital; she reported that nursing staff did not take her complaints of pain seriously, and it was only when she insisted that the anaesthetist come to check her infusion that it was noticed that it was blocked, and he offered her an immediate and unreserved apology.

Synopsis 6 presents extracts from the respondents' interview transcripts.
Participant (408)
'I was on a drip…but for over 2 hours, nobody noticed that the drip wasn’t running right, and I kept saying, ‘I’m in a lot of pain’…I was going mad with pain and…eventually I got a nurse to, I said ‘Will you get someone to check this for me, the anaesthetist or someone? There’s something wrong here’…My own anaesthetist, as soon as he had finished in theatre and he came down and put it right, and apparently it hadn’t been dripping…everything had been blocked up and nobody had noticed…I put me a fresh cannula in and started again, he was great…I just took over and said ‘I’m so sorry about this…I don’t know why nobody has noticed you haven’t been getting pain relief for over 2 hours, so obviously you have had a lot of pain that you shouldn’t have had and I can only apologise for that’ (408)

Participant (401)
‘they’re dreadfully short staffed. I mean at one point you were without morphine for how many hours, 5 hours without it, without your morphine drip being fixed and that was the second day, purely because nobody could come.’ (401’s wife)

‘…the bells were ringing from the other patients’ (401)

Interviewer: And did you raise somebody’s attention to that?

‘I did, he did, we told all the nurses, can you do something about this please…and they said, ‘Oh it’s alright love, his morphine has run out, and I said, ‘well, I think he’ll need some more doesn’t he, because it’s been like that since I came in at 4’ and this was about 6.30pm and eventually they came and said, ‘I can change it’ and he stood there, and I said, ‘well are you going to change it for him’, and he said, ‘I can’t do it on my own, I have to wait for a sister coming…and the next day they told you [401] off for not using your morphine…he said about the pain and they said, ‘well you should have used your morphine more’ and he said, ‘well, I couldn’t yesterday’ (Participant 401’s wife)

(401) and his wife believed he suffered unnecessary pain because his drip had not been monitored.
(408) thought her pain could have been prevented if her blocked cannula had been noticed and dealt with sooner.

In contrast to participants (401) and (408), respondent (406) described a situation which had occurred 14 years previously where he had endured post-operative pain because his ‘timidity’ prevented him from summoning assistance as he didn’t want to be seen as ‘a bit of a nuisance’. His recent positive experiences of being on a ward where the nurses had made it clear from the outset that he was to ask for help at any time meant that he thought he would take on a more proactive role in future.
'a lot's been learnt in 14 years on both sides…I had before a feeling as if I was reticent to call anybody…I’d feel like I’m a bit of a nuisance but I wouldn’t do that anymore because I realise at the time it was down to me to that and it was because of my timidity that I didn’t. But on this ward…they made it quite clear to you, don’t be afraid to ring us, ring us if you want to…because it’s sort of a two way thing isn’t it’ (406)

Situation(s) (E): patients prepared to ‘speak up’ in situations where they believe their own knowledge exceeds that of staff; staff are perceived as inadequately trained or inexperienced; patients believe clinical procedures are not being carried out correctly

Almost a third (9) of the 30 study participants reported ‘speaking up’ when they observed or suspected that a clinical procedure had been carried out incorrectly by health care professionals; the main reasons cited for such events were that staff lacked experience, training, appropriate qualifications, or that staff were not interested in doing their job properly. These acts of ‘speaking up’ reflected participants’ knowledge of how things should be done, because they had professional knowledge (for example, participant (508) was a qualified nurse) (see Synopsis 7), or because they had seen the procedure carried out many times. These actions also reflected the fact that patients were ‘keeping an eye’ on staff during the delivery of health care.

The reactions of health care professionals appeared to be the main determinant of the outcome of patients ‘speaking up’; in most cases, respondents reported that staff adopted a defensive attitude, so that the initial act of ‘speaking up’ escalated into a verbal or written complaint (as in the case of participant (605), (see Synopsis 8); frequently, patients who felt their initial concerns were dismissed or disregarded said that they abandoned any further attempts to pursue the matter, often because they were feeling too ill or vulnerable.

Amongst the study participants, mothers of children with asthma were most likely to describe situations where they ‘spoke up’ in a way which directly
challenged the decisions of health care professionals, in order to enhance the safety of their children. Based on their long-standing knowledge of their child’s condition, and intimate knowledge of the child as an individual, participants (302) and (303) were sure enough of their grounds to ‘speak up’ against the clinical judgement of health care professionals. In the two incidents described here (see Synopsis 9), their actions appeared to be warranted: (302)’s child was thought ill enough to require admission to hospital, while (303)’s action was supported by a nurse and senior doctor.

Synopsis 7

Participant (508) was a qualified specialist nurse who reported concerns about a recent admission on a general ward where she had received intravenous antibiotic treatment for an infection. One of her main concerns was that much of her care was provided by health care assistants, and she believed it was ‘of debatable quality’ because she felt their training was inadequate. During her interview, respondent (508) recalled that she ‘spoke up’ to a health care assistant (HCA) about the way in which he was carrying out a routine observation in her care (measuring her blood pressure). When she suggested to the HCA that he should not take her blood pressure on the arm with her antibiotic infusion, he said he would do it on her leg instead. (508) ‘spoke out’ again, to point out this would not be appropriate either, but the HCA insisted that he proceed. His response was so emphatic, that it raised doubt in (508)’s mind as to whether she were the one in the wrong; feeling very ill and vulnerable, she allowed him to go ahead, though she did check the point afterwards with a friend who was a doctor, and later included this incident in a letter of concern that she submitted to the Patient Liaison and Advice Service.

‘I sort of looked at him [the HCA] and said, ‘sorry I haven’t got any arms, you’re going to have to come back later’, and he said, ‘no, it’s OK I can do your blood pressure on your arm’. ‘No, you can’t’. ‘Yes, I can’. ‘No, you can’t.’ ‘I can, I’ve done it before.’ I said, I’m telling you, I’m a nurse, you do a blood pressure on an arm that’s got a patent infusion going you will blow the vein…’ so he said, ‘it’s OK, I can do it on your leg’. ‘No, you can’t.’ ‘Yes, I can.’ ‘You can do blood pressures on your leg if all the blood pressures are taken on your leg, but not if all the other blood pressures have been taken on your arm because the results will not be comparable. ‘Oh, it’s OK, I can do it.’ And I gave up at that point and he did it on my leg, and I said, ‘you need to record that on the chart that you’ve put it on a different part of the body’ ‘Oh, no I don’t…’ (508)

(508) attributed the situation to the HCA’s inadequate training for the task he was carrying out.
Participant (605) suffered from mental health problems and had had frequent stays in psychiatric hospitals. She described herself as a strong person who can normally stand up for herself, not afraid of authority; however she recognised that when she was ill she felt vulnerable and lacking in strength to ‘fight the system’. (605) recalled an occasion when she complained to a consultant psychiatrist about the nursing staff’s unwillingness to give her prescribed medicine at the correct time. After making a verbal complaint, which included the name of one of the nurses involved, (605) said she suffered recriminations from nursing staff. They also implied that she was overly sensitive due to her illness. In the end, (605) took her medicines at a time that was convenient to the nurses, as it was easier not to make a fuss.

‘if you asked for something, they [the nursing staff] would almost ignore you…they wouldn’t sort anything out for you, they made you feel so unimportant, and as if you were an absolute pain, it was partly the system’s fault in that they did have so much paperwork…my psychiatrist said I had particularly to have some medication at 8 o’clock, and one day it was given out at 10, because the take over [handover] time was between eight and nine…so I knocked on the door, that was the time they told me to ‘Go away’ and I was really quite distraught…I was very upset and afterwards they were a bit grumpy…and the next day…as soon as I knocked, it was different staff obviously and they were thinking, ‘Oh, God!’…you can hear…I could hear them saying something about me and they went and got the medication, but it was a nuisance to them, so eventually I did make a complaint to the psychiatrist because I was so angry, and she did take it very seriously and this particular nurse was reprimanded…when I came in in future she sort of would blank me and I felt sort of alienated by the others…so you feel awkward, so you think…I am just going to stick to the 10 o’clock because they can’t be bothered and I can’t take rejection, so I just left it, I didn’t bother any more…despite what the psychiatrist said…’(605)

(605) had not wanted to name the nurse concerned in her complaint, but had been told that she must so that it could be acted on.

‘I didn’t want to name the member of staff but she [the psychiatrist] said you have to, because I can’t take any action otherwise, but I felt awkward because they had another member of staff in there taking notes, which I found a bit intimidating…then it was known by everybody that I had made a complaint because there was another member of staff taking notes…’ (605)

(605) believed the situation could have been avoided had staff been responsive to her request.
Participant (302) described how she had called an ambulance for her son when she thought his asthma was becoming worse, but the paramedics believed that the child was not ill enough to require being taken to hospital.

‘he’s been really chesty, because I know what he is now, he has been in 9 times, so I know how he feels and what to look for symptoms…and the ambulance [paramedic] turned round and said ‘Oh, he looks healthy enough to me’…obviously they don’t know him…’I said, ‘I’m very sorry, but I know what he looks like and I know what I’m listening to, and he said, ‘Oh, well, you’ll probably go in but you’ll be coming back home, and he had to stay in’ (302)

Participant (303) related how she was prepared to ‘speak up’ to a ‘new’ doctor on the ward when she thought her child needed to receive his medication via a nebuliser in order to speed up delivery of the drug, and she described how she was supported in her act of speaking up by a senior doctor.

‘a new doctor had come in and he didn’t know my son’s situation, and I mean over the 9 years, I know straightaway he needs a nebuliser and I got really, really upset because he wasn’t listening to what I was saying…the registrar came in and said…his mother has told you he needs a nebuliser, give the child a nebuliser, and that made me feel a lot more comfortable…if they hadn’t said that, I would have kicked off, which I don’t often do, but when it’s my son’s health and safety…the registrar said, his mother knows more than we do how he is and she’s telling you this…he [the ‘new’ doctor] did apologise in the end’ (303)

In both instances, the parents believed the situation could have been prevented if the health care professionals had listened to and addressed their concerns.

**Situation (F): breakdown in communication relating to the interface between health care settings**

Around a fifth of those interviewed mentioned their concerns about a ‘safety gap’ that patients could fall into when they moved from one health care setting to another, brought about by poor communication. Patients were perceived to be especially at risk when they were discharged from hospital to primary care or community services, where follow up services were reportedly haphazard or non-existent due to a lack of pre-discharge planning, leaving patients in a care vacuum, and potentially at risk.
Faced with this situation, participants described how they had acted to reduce the risk of harm and to organise appropriate services, by contacting general practice and district nursing services, and seeking further information about medications. Participant (507) (see Synopsis 10) acted on behalf of her elderly mother; participant (408) had no-one to act on her behalf (see Synopsis 11).

Synopsis 10

Participant (507) provided a detailed account of how she needed to act to safeguard her elderly mother who was discharged from hospital without warning to her family, on two separate occasions. (507) described herself as someone who was confident, articulate and educated, who would be prepared to be proactive and ‘push things through’ though she stressed that she would try to avoid being confrontational in her dealings with health care professionals. On the first occasion, (507)’s mother had apparently been discharged to the care of the GP. The lack of communication with family meant that they had received no information about the many medications that the patient was given on discharge, including sedatives, which she was incapable of taking without supervision; her regular painkiller (morphine) had been stopped in hospital, without (507)’s knowledge. (507) was concerned that her mother’s safety and well-being were potentially at risk as family members were not given necessary information about her medications; her mother also suffered unnecessary pain due to the discontinuation of her analgesic drugs. (507) took a number of steps on behalf of her mother; she rang the GP surgery and organised a home visit; she checked on internet for information about her mother’s medication and she also went to the local pharmacist for further explanation about her medicines. Some time after her mother’s discharge, 507’s sister wrote to the hospital to complain, through PALS. (507) attributed the situation to a breakdown in communication between different parts of the health service; the situation could have been prevented if health care professionals had communicated relevant information to (507) as her mother’s recognised carer; the situation could have been ameliorated at various points, for example, if the general practitioner (or community nurse) had visited her mother at home soon after discharge.
Participant (408) was a widow aged 78 years, who said she had to ‘stick up for herself’ since her husband had died. After her operation on her knee, she was discharged from hospital without arrangements being put in place for her to have carers visit, or for her to have her stitches removed by the district nursing services. It also appeared that her GP was not aware that she had been discharged from hospital. Respondent (408) described how she had found it difficult to manage on her own at home at first after her operation, and how her leg had had become painful and inflamed, which she blamed on the stitches being left in too long. When she realised that no-one was coming to remove her stitches, she contacted the local community nursing services.

‘I mean it’s pretty hard trying to walk around when you can hardly bear to stand and make yourself a cup of tea even…I read a copy of a sheet after I had been home a while and it said on, ‘stitches should be taken out between 10 and 14 days’, and I’d been home 13 days, 14 days, and nobody had been near so I had to ring the nurses and ask them if someone could come down and take the stitches out… and this nurse said, ‘I’m sorry [name], we’ve had no instruction, we didn’t know anything about you. We didn’t know that we’ve to come and see you… we didn’t know you’d come out of hospital…so if I hadn’t rung them or I’d been too ill to ring them, what happens then?’

(408) attributed the situation to changes in the systems for organising social care and community nursing services, and to a breakdown in communication; the situation could have been prevented if the services had been notified of her discharge from hospital.

Situation (G): suspected or actual medication error

Many participants reported that they routinely checked medications prescribed in general practice to ensure that they received the correct drug, in the correct dose, and some, particularly patients with diabetes, mentioned participating in regular medication reviews.

Five respondents (101; 106; 203; 202, 511) made mention of double-checking with their doctor or a pharmacist on occasions when they suspected a mistake might have been made, and described the actions they took (more detailed discussion concerning the checking medication is included in Section 3).
Patient (101) took some tablets that she had been given back to the pharmacist to check them as they looked different from her ‘normal’ ones, and was told that the formulation had changed. Participant (106) discovered a dispensing error and returned the tablets that were not meant for her to the pharmacy. These actions seemed to be regarded as acceptable by both patients and health care practitioners, as a form of ‘checking with’ the health care professional. When participants were checking on the possibility of error related to the drug dosages prescribed by general practitioners, they seemed to perceive their activity as akin to ‘checking up on’ HCPs, an action they were willing to take.

In the case of participant (511), an error occurred in the delivery of tablets to her father (see Synopsis 12) and she acted by reporting it to the local pharmacist.
Participants indicated that it is more difficult to check medications received during a stay in hospital, and some said they were accepting of what was given to them. ‘I didn’t actually look at my bottle, I didn’t say, well, can I have a look’ (203). Two participants reported taking action when they suspected a possible error in their drug therapy when they were hospital in-patients.

Participant (509)’s wife refused to take the 4 antacid tablets she was offered, as she knew she should only take one tablet, until after the nurse double checked the dose; while participant (203) raised a query with the nurse about the order in which her chemotherapy drugs were being administered by one nurse, which differed from the previous five occasions, to be told that ‘Oh, well this is the way I am doing it’.

Participant 511 acted in the role of carer for her elderly father who depended on her help to manage his day to day affairs, and to be his ‘representative’ during encounters with health care services. She described how her father depended on her to check his medications when he suspected that perhaps a mistake had been made. In her account, participant 511 refers to obtaining assistance, and an apology from the pharmacist for the mistake made in the delivery of the drugs.

‘My dad used to have his tablets delivered to his sheltered housing, not this one, the one previously and the person who delivered it, delivered the wrong, the pack, the whole bag of medication to my dad. Heart medication was in it, all sorts of different medication, it wasn’t my dad medication… it was for other people in the flat next door. But because my dad looked at it and he said, ‘This is strange’, he need me to check it all…and it’s a good job he didn’t touch any tablet. I was horrified. When I opened the bag it wasn’t his medication so I dashed up to the pharmacy and the pharmacist and I told him about what happened, and he was horrified, and he was apologetic, you know, and he said, he’ll see the person concerned because if my dad, you know, and they don’t take in that, they could end up, ended up in trouble, yeah, so that’s my experience of the medications….’

Participant 511 attributed the mistake to an error on the part of the person delivering the medications to her father. The error could have been avoided if the person delivering the medicines had checked the identity of the person receiving them.
Situation (H): patient requires assistance from nurses

Participants described a number of incidences when they had ‘pressed the buzzer’ on the hospital ward to avert harm occurring either to themselves or to another patient. These situations included occasions when other patients were perceived as posing a safety threat, either to themselves or others; and when participants were concerned about the welfare of another patient, for example, if they were attempting to walk unaided when they required assistance, or if they thought they needed help with eating, or drinking fluids.

Respondents appeared more hesitant about pressing the buzzer to seek assistance for themselves, because they feared repercussions, or they did not wish to add to the workload of busy nurses, or because they thought a response from a health care professional was unlikely to be forthcoming.

Respondent (402) reported that her sheets were crumpled and she seemed at risk of developing ‘a sore bottom’; although she contemplated ‘buzzing’ for a nurse, she decided not to, as she felt her problem was ‘a bit petty’ and she didn’t want to ‘waste the nurses’ time. Her comment that ‘the bell is for if you need the bedpan or if there’s an emergency, not for sort of something that’s just happened’ is illustrative of a view expressed by many patients, that they should only ‘buzz’ for assistance when they were ‘in extremis’.

Situation (I): fear of potential harms associated with treatment

Six respondents reported that they had wanted to, or had withdrawn from, health care treatment as a means of avoiding situations which they considered might harmful to them, physically or psychologically.

Participant (401) refused to go into hospital when he had cellulitis for fear of ‘losing a leg’ to infection; participant (605) said she would not consider being treated in a psychiatric hospital unless she was ‘desperate’ because of the poor facilities and attitude of some staff; while participant (203) believed that
admission to the oncology ward could harm her psychological health, because of painful memories associated with her family members, as well as events that she had witnessed which had upset her (see Synopsis 13).

Three remaining participants reported that on various occasions they had not taken prescribed drugs which they had considered potentially harmful.

Five of the thirty interviewees mentioned that they had, or would, consider paying for private hospital treatment, primarily due to concerns about hospital acquired infections.

Synopsis 13

Participant (203) was a woman in her mid-fifties who had recently had treatment for breast cancer; close members of her family also diagnosed with cancer had died in the ward where (203) received her chemotherapy and was admitted for treatment for infection related to her chemotherapy. In order to avoid psychological distress to herself, because of her painful memories associated with the ward, and incidents which she witnessed there, respondent (203) delayed ringing the ward to arrange her re-admission for treatment for the infection.

'I knew myself I really should have rung…and the doctor played hell with me, she said, you don’t realise how dangerous it was [name]…it’s so distressing…and I just didn’t want to go in…there was this girl on the ward and it was this girl I saw on Friday going for her chemotherapy and they’d got silver blankets around her and all that and the noise that was coming from her was horrendous, so they wanted the side ward for her…so they rushed me out into the main ward so they could deal with her…she actually died…it was absolutely horrendous…I mean we’re there for chemotherapy aren’t we…and to experience that was awful, utterly awful. (203)

(203) thought the situation could have been avoided if facilities were available for patients to have chemotherapy in a separate area from the rest of the ward
Situation (J): dissatisfaction with level of service from provider leading to decision to withdraw

Two study participants (511) (see synopsis 14) and the daughter-in-law of (104) reported that they were motivated by perceived shortfalls in treatment to seek services from alternative providers.

The daughter-in-law of (104) was dissatisfied with the treatment and level of care that her mother-in-law was receiving from her general practitioner (for example, lack of regular medication reviews) which she considered could be detrimental to her well being. She suggested that her mother-in-law’s main reason for staying at the practice had been because she could communicate easily with the doctor in Punjabi. Participant (104)’s daughter-in-law persuaded her re-register at her own practice, where she was confident she would receive the level of care she needed, through regular reviews of her diabetes and management of her medicines.

Synopsis 14

Participant (511) discharged herself from a hospital ward because she was concerned that she was not receiving adequate treatment and because of the nature of the response from the health care professional when she reported her symptoms. After phoning her general practitioner, she was prescribed antibiotic treatment the same day, and her symptoms resolved.

‘I reported it to a younger staff nurse…in her 20s... I’m saying to her, look, I’ve got a urine tract infection’. She turned round and said to me and said ‘Oh, Mrs [name], you’ve just had a Caesarean and you’ve had a hard time. It took you nearly a whole week to come round’, which is true, was true, cause I did, I was poorly with that, ‘And I think it is all in your mind’. Well, I went mad. I says, ‘Right, go get me the ward sister, I’m discharging myself now. I’m going home and I’ll get my GP to give me some antibiotics’ (511)

Situation (K): sharing information with health care professionals

Sharing information with health care professionals was identified by respondents as an important way to alert health care professionals to potential
harms; for example, patients could tell staff about known allergies, or report new symptoms, or side effects from drugs. In synopsis 15, participant (304) describes her encounter with a nurse working on a paediatric ward when she tries to tell her about her child’s allergies.

Synopsis 15

Participant (304) was a young woman in her thirties who assumed a great deal of responsibility for her daughter’s care when she was at home, and who liked to be present with her child during hospital admissions; she continued to give her daughter medications when she was in hospital, an action which, she reported, could be interpreted by some nurses as ‘treading on their toes’. Participant (304) attempted to share information with a health care professional about her daughter’s known allergies to a particular type of cream and to sticking plasters; her daughter was acutely ill with asthma at the time, and (304) became angry at the response from the health care professional.

‘I said, that cream you are going to put on, she reacts to, so there’s two different types of cream and the other cream she didn’t seem to react to so much and she said to me ‘How do you know’. She [her daughter] couldn’t breathe, she was laid on a bed not able to breathe, she had oxygen on, and this young girl said to me, ‘How do you know?’ I said to her, she’s been coming here for 6 years and the cream irritates her…and I said, she’s also allergic to plasters, but she was going to put a plaster on, and the look I from her…I didn’t say anything because [name] was really ill, so I didn’t say anything, but you really want to scream at some of them and say, ‘why can’t you understand what I am telling you?’ …if I did speak up sometimes I’d probably get thrown out…but then you’ve got to because if they make a mistake and you can prevent it, you know, it’s like, do I have to say it?’

Other examples of information sharing cited by study participants are presented in synopsis 16
Section 2 Summary Points

- Participants’ reports suggest that they (or their family members) experienced a wide range of threats to their physical safety and psychological well-being when using health care services, and that they were prepared to act to protect themselves (or others) when certain circumstances prevailed.

- Perceived threats related to: medications; diagnosis; delays in referral; hospital cleanliness; perceived neglect of physical and emotional needs; poor communication; clinical procedures apparently incorrectly executed; inadequate facilities; threats to safety from other patients; administrative and systems factors.

- Participants recounted a variety of situations in which they had acted, or considered acting, to avoid error and avert harm, including situations in which they had ‘spoken up’ or considered speaking up.
Where the patient (or their representative’s) ‘speaking up’ met with an indifferent, defensive or hostile approach from the HCP, an increasingly acrimonious chain or ‘cascade’ of events was triggered, which usually culminated in one of two ways; either the patient (or their representative) ‘abandoned’ their attempt to obtain recognition of, or redress for, their concern; or they subsequently made a verbal or written complaint. This ‘cascade’ of events can be represented in a simple model (see below).

Model of ‘cascade’ of events triggered by patient ‘speaking up’

PATIENT PERCEIVES THREAT TO SAFETY/ SHORTFALL IN CARE

↓

PATIENT (OR REPRESENTATIVE) ‘SPEAKS UP’

ISSUE IS RESOLVED

ISSUE IS NOT RESOLVED

MORE CONFRONTATIONAL INTERCHANGE WITH HCP ENSUES

(usually emotionally charged)

PATIENT (OR REPRESENTATIVE) ‘ABANDONS’ ATTEMPT

PATIENT PURSUES MATTER VIA VERBAL OR WRITTEN COMPLAINT

AT RESOLUTION
3. PATIENTS’ (AND THEIR REPRESENTATIVES’) PERCEPTIONS OF THE VARIOUS ROLES THEY MIGHT PLAY IN ENSURING THEIR OWN SAFETY, AND POTENTIAL BARRIERS AND FACILITATORS TO THEIR INVOLVEMENT

(In what ways might differences in contextual circumstances influence patient actions? What kinds of actions might patients take? What are the likely barriers/ facilitators to adopting patient safety roles?)

While Section 2 of the report focuses on participants’ descriptions of their personal experiences of mistakes, errors, and potential harms related to health care use, and the actions they took, Section 3 highlights patients’ views of various patient safety roles and those contextual factors which might serve to promote or impede role enactment. There is, inevitably, a degree of overlap between these two sections of the report, but they may be regarded as complementary.

Section 2.3 (i) lays out detailed scenarios (with accompanying commentary) relating to (some) patients’ adopting a particular action (or actions) in a particular set of circumstances.

Section 3 (which follows below) includes a broader range of examples of role enactment referred to by patients in the context of talking about their views of adopting particular patient safety roles.

In the course of their interviews, patients (and their representatives) suggested and discussed a range of roles that they might adopt to ensure their own (or another’s) safety; additionally, they were asked by the interviewer to comment on specific roles, drawn from the literature, where these had not been mentioned spontaneously. Respondents were asked to say how they would feel about undertaking a particular role; and to suggest potential barriers to, and facilitators of, role enactment; in addition they frequently described incidences when they had adopted the role.
Participants’ views were elicited about a number of safety roles:

- Asking for clarification
- Asking a health care professional to wash/clean their hands
- Checking medications
- Feeding back individual experience of health care quality and safety
- Following instructions from a health care professional
- Ringing for results (for example, blood investigations, X-rays, scans)
- Sharing relevant information
- Seeking information
- Speaking up (for example, to express any concerns)

In general, participants wished to be involved in the promotion, enhancement and protection of their own safety with regard to health care through the adoption of patient safety roles. However, there was widespread recognition that various factors could impact on patients’ (or their representatives’) willingness or ability to take on such roles, relating to:

- characteristics of the patient (socio-demographic variables; personal characteristics; their current condition; point on the ‘patient journey’)
- anticipated or actual response from health care professionals
- level of challenge associated with role
- the context in which the role might be enacted

Participants’ views on specific safety roles, and the factors which facilitate or inhibit adoption of the roles, are discussed below.

**Role: Asking for clarification**

‘Asking for clarification’ was not spontaneously identified as a patient safety role by most of the study participants; their views of the role were elicited in response to a question from the interviewer. All but two of the interviewees (28 people) said that they would be willing to ask, or had asked, for
clarification about an aspect of their care or treatment. Specifically, they mentioned having asked for clarification concerning doctors’ advice or instructions; medical terminology; and the rationale underlying particular approaches to treatment.

‘sometimes when they use these medical terms and stuff I’ll say to them, what does that mean, could you speak English, and they do…and things that they do to him, I did ask once when he was tapping on the chest with his fingers and I said, what do you do that for…so I do ask a lot of questions when I don’t understand what they’re doing…’ (303)

The role of asking for clarification was viewed as one which potentially overlapped with the role of ‘speaking up’, or raising a query about a health care professional’s actions, which was viewed as posing more of a challenge to staff.

‘I think they definitely don’t mind you asking questions…just general chit chat, especially when you go for your first and second session [of chemotherapy]…that’s fine, but when you query, I did query later down the line…I felt they weren’t comfortable with that, I had actually challenged things’ (205)

Asking questions was viewed as a safety strategy by some respondents, allied to being vigilant, and taking and maintaining a measure of control over what happens to you during health care delivery.

‘Ask questions and be alert. It doesn’t always go down well with the nursing staff I should think to have a patient who’s asking awkward questions…’ (401)

‘if you’ve got questions or queries, don’t sit on it, always ask because you can put yourself in situations that could be potentially harmful by not speaking up’ (208)

Patients who indicated they asked a lot of questions could seem slightly anxious about the reaction their continual questioning might provoke in staff.
'I ask questions, I think they get sick of me asking questions all the time. But I want to know. I'm not an idiot. I want to control my life, I don't want them to control my life.' (106)

About a fifth of the study participants suggested that older people would find it more difficult than younger people to ask doctors, especially consultants, for clarification, because of the high esteem in which they held them.

‘I mean my mum and dad are educated, highly motivated people but he’s a consultant and to them, they’ve still got the old 20 years ago thing that a consultant is slightly higher than god, and what he says, you do…if you have that respect, will you ask and I don’t think a lot of people will.’ (508)

Elderly respondents did not support this view; they suggested that while they may have been in awe of doctors in the past, they had learnt to overcome such feelings; sometimes personal circumstances led to elderly patients’ asking questions on their own behalf where previously they might have relied on someone else.

‘I’ve learnt to talk to doctors more than I used to…at one time I wouldn’t have asked them anything…but I know now that I’ve got to stick up for myself…I’m on my own…I’ve got to say what I think or ask the question that is bothering me, otherwise I’ll come home wondering if I’ve done it right…’ (408)

Family members were viewed as a useful asset in asking for clarification. They could help with language translation and assimilation of information (participant (104), who could not speak English, was always accompanied to the diabetes specialist clinic by a member of her family to assist with clarification of information), especially when the patient was feeling ill, in shock when they heard their diagnosis, or anxious pre-operatively, when their mind might be ‘in turmoil’ (406).

Participants’ views and experiences of health care professionals’ response to them asking for clarification varied widely. In general, senior medical staff
(consultants and anaesthetists), and general practitioners, were said to make
time to answer patients’ questions and offer explanations; general nurses
were viewed more equivocally; while specialist clinical nurses appeared to be
regarded as playing an intermediary role in ‘interpreting’ information for
patients, particularly in relation to some of the complex drug regimes used to
treat breast cancer. These nurses were said to be relatively easily
contactable by telephone, and to have more time to talk to patients than ward
based nurses.

It was suggested that nowadays medical training produced doctors who are
more communicative with patients, and participants cited experiences of
hospital consultants using textbooks to explain details of procedures.

‘the younger ones, I have to say, they’ve learnt communication…my friends
who went to train as doctors were arrogant, they were of a certain sort, they
were intelligent but also very poor communicators’ (609)

‘I haven’t met a consultant yet who’s got difficult when I’ve asked for
clarification. In fact the last guy…he brought out this anatomy book to explain
to me…to make sure I understood what he was going to do in the
operation…he was willing to go into detail…he always gives the impression he
has all the time in the world, even though he is a very busy man…’ (402)

Views and experiences of asking hospital nurses for clarification were mixed;
some respondents suggested that nursing staff could regard questions as an
unwelcome intrusion into their routine, or suggested that they ‘talked down’ to
patients.

‘if they have got the time and are sat doing something with you where they
have to sit with you, that’s OK. But having to break them off and stop them
from what they are doing…you stop the system, stop the flow of things…’
(205)
‘a lot of nurses didn’t talk to you, they talked down to you, as if you’re the patient and you don’t know what you are doing…if you asked a question, they didn’t want to answer’ (408)

Parents of children who enjoyed a good relationship with nursing staff said the nurses would take time to offer explanations, often unasked (303); but where the relationship was not so good, the parent could find it difficult to ask. Parent (304), quoted below, said that she would find it easier to ask if nurses were more approachable.

‘I always say, you don’t mind me asking, and they say, no, not at all, that’s what we’re here for’ (303)

‘I just ask…sometimes it’s not comfortable…but I’ve learnt you just ask, I’ve learnt not to sit back…I’ve not done it in the beginning, and I’ve come away thinking, you know, I don’t know what they’ve said, so I’ve learnt just by past experience to ask’ (304)

Health care professionals who encouraged patients to ask questions and seek explanations, and who created opportunities for patients to seek clarification, were regarded as facilitative of the patient role; asking questions was regarded as a ‘two way process’; for questioning to be a successful strategy for patients, health care professionals must be ready to engage with them in providing answers.

‘I can ask the question, but whether I get the answer is another thing’. (203)

Summary statement: Study participants generally regarded ‘Asking for clarification’ as a comparatively easy safety role for patients or their family members (or representatives) to assume, and one which reportedly they actively engaged in.
Role: Asking a health care professional to wash/clean their hands

This was generally perceived as one of the most challenging of all the patient roles considered by study participants. Only 3 of the 30 respondents (303, 304 and 202) said that they had actually asked a doctor or nurse to wash or clean their hands using alcohol rub or gel before they carried out a clinical procedure or touched the patient.

Of the three participants who had asked, only one participant (303), reported feeling fully confident about asking staff to wash their hands. During her interview, participant (303) described herself as personally confident (‘I'm gobby, me’), mentioned that she enjoyed a good relationship with the staff on the paediatric ward where her child was frequently admitted (‘we can have a joke and stuff’), and showed an awareness of how infection may be transferred from one patient to another ‘I'm a qualified first aider myself so I know that you don't treat a patient after another patient without changing your gloves’.

Contrastingly, respondent (202), a qualified health professional, described herself someone who was ‘not a complainer’, the sort of person who gets ‘het
up’ about an issue, and thinks she should do something about it, and then doesn’t because she is embarrassed about ‘making a fuss’. When she attempted to ask a nurse, who was not well known to her, to wash his hands, her feelings of discomfort sabotaged her effort to articulate her request clearly, despite the posters on the hospital ward walls legitimatising her request.

‘I made some mention about the posters that say, if you think we haven’t used it, don’t be embarrassed to ask, and I obviously said something in such a clumsy way, meaning to say, I haven’t seen you use the alcohol rub, will you please use it before you touch me, and he completely misunderstood me…I didn’t dare say anything after that’ (202).

Respondent (304), also a mother of a child with asthma, had reported mixed experiences in her dealings with nursing staff on paediatric wards, and appeared wary of their attitude (‘some of them look down on you like why are you asking, you know, I’m a nurse, you’re not’). At two points in her interview, she had described some incidents where she felt her concerns for the safety of her child had been dismissed. Although uncertain of the response she might receive from health care professionals, (304) was aware that her request was justified; however, she displayed a degree of cynicism about the effect of posters on health care professionals’ behaviour.

‘the look you get, is like…like you’re asking them to build a new hospital for you…if I ask that nurse…she wouldn’t have a problem, but then if you get a nurse that just wants to come and do her work and go home, they have a problem…they just need to practice what they preach…it says all over the hospitals you can ask them to use that hand-wash’(304)

Amongst the remaining 27 participants, reasons given for not asking health care professionals to wash/clean their hands included:

- the assumption that they would already have done it

‘you shouldn’t have to ask…it should be second nature’ (406)
• patient has already seen the health care professional wash their hands

‘I can’t say I’ve ever seen a nurse or doctor not wash their hands’ (308)

• feeling uncomfortable or embarrassed about challenging professional behaviour, especially at the top end of the medical hierarchy

‘you could probably pick yourself out as an awkward patient...they’d probably think you were an old so and so, wouldn’t look on it very well...’ (401)

‘there’s almost an inherent accusation, ‘have you washed your hands?’, ‘are you coming near me clean?’ I think it would be difficult to do, especially... the higher up they go, the consultant marches in and stands there looking at you, you think, ummm, am I really going to say to him, have you washed your hands?’...I honestly don’t know if I would do it’ (508)

As health care professionals themselves, (508) and (607) suggested that staff might feel ‘on the defensive’ (508) if asked whether they had washed their hands, that asking could ‘get their backs up’ (607).

• fear of repercussions

‘you wouldn’t want to be in hospital knowing you’ve made an enemy by asking them to do something. They think you’re throwing your authority at them’ (408)

‘they might get narked and feel cross and that might influence the way they manage you...so they’ll be a bit more abrupt or something’ (607)

Four respondents expressed the view that posters and badges to encourage patients to ask staff to wash their hands might help them overcome their reluctance to ask. If they were to ask, participants said they would do so very politely, or in a light-hearted, jokey, non-confrontational way.
I think you would have to make a joke of it, you know, doctors says, unless you’ve done your hands, you know, try and pass it off lightly and not make it confrontational’ (401).

**Summary statement:** The majority of study participants regarded ‘Asking a health care professional to wash their hands’ as a challenging role which they would find difficult to fulfil.

**Possible facilitators:**
- personal confidence
- a perception of enjoying a good relationship with staff
- knowledge of the possible consequences of staff not washing their hands.

**Potential barriers:**
- assumption that staff would already have washed/ cleaned hands
- reluctance to challenge staff’s professionalism
- fear of repercussions
- posters regarded as ineffective in influencing health care professionals’ behaviour

**Role: Checking medications**

Patients’ expectations of how they might behave in this role appeared to vary according to a number of factors: the context in which patients received their medicines (hospital or primary care); the condition of the patient (how ill they were at the time); the presence of absence of a representative; and the number of drugs that the patient might be taking, were all cited as potentially affecting patients’ willingness and ability to assume and fulfil the role.

Participants’ descriptions of how they would check medications implied two forms of checking: ‘checking with’ (for example, checking with the pharmacist that you had received the correct drug); and ‘checking on’ (checking on professional competency), which seemed to be more surreptitious in nature.
Checking medications was viewed as an important aspect of their caring role by those participants in the study who were acting on behalf of others (mothers of children with asthma; spouses caring for ill wives and husband; children looking after elderly parents) (this is discussed separately in more detail below).

Patients receiving chemotherapy, those receiving drug treatment for severe and enduring mental health conditions, patients whose diabetes was controlled by medications, and patients undergoing joint surgery, all reported checking some aspect of their drug therapy. They reported checking for, and acting on:

- dispensing errors
- prescribing errors
- errors in drug administration
- side effects that they were not informed about by the prescriber

(1) Checking medications in the context of primary care

Dispensing errors
Six patients said that they would as a matter of course check any tablets that they received from a community pharmacist to make sure they had received the correct tablets, in the correct dosage; they said they knew what their usual medication looked like (colour and shape of tablets) and were familiar with its packaging; and that they would raise any queries directly with the pharmacist. Patients mentioned that they frequently drew on the knowledge of community pharmacists and they appeared to regard them as accessible, approachable and helpful.

In four cases (203; 511; 101; 106), respondents reported detecting dispensing errors; in three instances, they reported the error to a community pharmacist, while respondent (203) informed a district nurse of a mistake in the dispensing of heparin injections.
‘I took this bottle of tablets out and I thought, ‘what on earth are those?’ and they weren’t mine. So I phoned the chemist and I said, ‘you’ve given me somebody else’s tablets.’ ‘I haven’t, have I?’ Now whether it was the lady there who did it or whether it was him, I don’t know, but [name] took them back down…it was an extra bottle of tablets which weren’t mine. There was another name on it. We always check, but they weren’t mine’ (106)

Medication reviews
Some of the patients with diabetes and mental severe and enduring mental health problems reported participating in medication reviews, a form of ‘checking with’ health professionals.

Prescribing errors
During their interviews, three respondents each described an incident relating to what they thought might be a prescribing error; (106) said that methotrexate had been over-prescribed, an error picked up by her pharmacist who rang her (‘he knows us well, he’s very nice’); (202) believed a drug had been overprescribed by a doctor who was not her usual doctor (she checked with the pharmacist first, then got her own doctor to check the dose); and (406), who saw a locum doctor at his GP surgery, and was prescribed Ibuprofen, which he believed he should not have been given as he had been told by his usual doctor that it could interact with his anti-hypertensive medication. In these cases, the participants’ immediate reaction was to not take the tablets until they had made a check.

Regarding the methotrexate prescription, participant (106), (who said of herself that ‘I may be a pensioner but I’m not dotty’) said that she phoned her doctor afterwards about the error.

‘I told them in no uncertain terms that if I hadn’t been on the ball with the pharmacist they could have killed me!’ (106)
Side effects of medications
Some, but not all participants, were aware that they should have been routinely informed by health care professionals of potential side effects of their medications. In a minority of cases, where the HCPs had not fulfilled this aspect of their prescribing role, patients who were able (who had access to appropriate information sources; who had high health literacy) had taken on the role of checking for side effect of their medications.

“They never tell you any side effects [laughs] I have never been told about side effects, despite all the time I have been in the system… but I always read the little bits of paper that come inside the packet with it. My brother-in-law is a psychiatric nurse and he gave me this BNF book it is called, and so I always read it…it worked one particular time, because there was one particular mood stabiliser I was on and my hair was falling out, and I would get up in the morning, and there was all my hair on the pillow… and I looked it up and sure enough, one of the very bottom ones, and apparently if they are at the very bottom, they are very rare, was alopecia, and so I went in and I said, I am not taking this any more… this is a side effect’, and he said, ‘No, it’s not’, and I said, ‘It is, go and look it up in your book, and he went, ‘you are right, I’ve not come across that before, and I said, ‘I am not taking it any more’ (605).

(2) Checking medications in hospital

In the main, patients seemed to subscribe to the view that they should be able to rely on health care professionals to carry out checking of medicines on their behalf in hospital, and they appeared to be reassured when nurses carried out routine checks (for example, of their identity) prior to administering medications. A number of factors were suggested that might hinder patients from checking medications in hospital:

- lack of familiarity with the appearance of medication (the tablets you were being given looked different, but were in fact the same, as your usual tablets)
feeling too unwell to be fully aware of what you were being given
impractical/ impossible as a patient to check every injection, infusion, intravenous drug that was administered
feeling you were in a vulnerable position if you raised a query

Respondent (605) described her attempt to raise a query about the timing of the administration of a medication at a time when she was feeling ill and vulnerable.

Despite the potential barriers mentioned above, about a fifth of the sample of patients referred to incidents where they had carried out either covert or overt checking of drug therapy while hospitalised. For example, patients (402) and (406) both mentioned incidents where they had intervened to stop a nurse giving them an injection that was meant for someone else (mistaken identity); participant (509) had queried the dose of antacid medication she was being given in hospital; and respondents (203) and (205) had both raised a query with a nurse about the administration of their chemotherapy.
‘they were feeding something else, another sort of fluid or whatever it was into me, and I couldn’t remember them doing this before…so I thought, I am going to ask, I did…and they went to fetch some of the other chemo nurses, and they got my notes out…’(205)

(3) Patient representative participation in checking medications

Checking medications in hospital
Patients’ family members (and/ or their representatives) appeared to regard checking medications as an integral component of their overall role of acting on behalf of someone else, and it was one in which they actively engaged.

Three of the five mothers of children who were frequently hospitalised with asthma reported active involvement in checking their children’s medications, based on their extensive knowledge of, and familiarity with, the drug therapy for asthma. In some cases, for example, as described by participant (309), staff appeared happy for parents to assume this role; elsewhere however, the reactions of health care professionals as described by respondents (see the quotation from (304) below) implied concerns about role ambiguity or conflict.

Despite their active involvement, most of those acting on behalf of a spouse, child, or elderly parent expressed the view that responsibility for correct administration of medications should lie with health care professionals; and they pointed to the fact that they could not always be present in person to act as a checking mechanism.

Exceptionally, parent participant (309) said she preferred to ‘take over’ responsibility for administration of her child’s medicines while in hospital, which she felt she could do, as she had no younger children to look after. The general ‘busyness’ of the ward and her anxiety about agency staff who would not know her child as well as permanent staff were her reasons for giving the medicines herself.
‘I’ve never really left it up to the nurses, you know, if they come and give the medicine, I’ve always been like, I give it him myself, I’m quite used to his medication. I took over. If it was left to the nurses...I would be worried, because they’re so busy and they’ve got lots on their minds...he’s the youngest, I’ve had that time with him…if I had younger children then it might have been different…’ (309)

Family members (and/or representatives) stated that they checked:

- the physical appearance of medicines, to make sure they were the correct ones

‘once there were some other tablets there and I said, ‘what are these? and she said, they’re different to the steroids, they’re the same steroids, but it’s the sugar coated ones instead of the dissolvable ones’ (303)

- the administration of medicines

‘like if she supposed to have a steroid in the morning and it can be like a 3 day course or a 5 day course – on the 4th day, if I ask, does she need a steroid today, it’s like you’re interfering, like why, why do you want to know...some of them look down on you like, why are you asking, you know, I’m the nurse, you’re not.’ (304)

- possible allergic reactions

‘so they gave her it [an injection] and 5 minutes later...[name] said, Oh, I do feel warm and she was going bright red...absolutely burning up. So I went round to the doctor’s station and I said, excuse me doctor [name] is burning up’ (509)
Checking medications in the contexts of primary care and the interface between hospital/primary care

The role of the asthma specialist nurse, acting as a liaison between hospital and primary care, appeared to facilitate reconciliation of medications between the different health care settings, thereby relieving parents to some extent of the need to carry out checking procedures themselves.

‘his steroid inhaler...he was taking 250mgs at the hospital...and then it came down to 100mgs apparently the hospital said, they wrote to our GP but the GP gave 250mgs. So [name of asthma specialist] spotted that straightaway and we didn’t have any big problems’ (309)

Two respondents caring for elderly parents reported checking medications on their behalf, one in the context of primary care, and the other in relation to the interface between secondary and primary care.

Participant (511) described how she had had to intervene to prevent her aged father receiving a delivery of medications from a pharmacy to his sheltered accommodation that were meant for another resident, and which could have harmed him. In the case of respondent (507), her elderly mother had been discharged from hospital with various medicines, including sedatives, which she was incapable of taking without supervision, without any information being passed on to the family members who looked after her. Respondent (507), who described herself as confident, articulate and educated, with a job that allowed her some flexibility, was able to access the Internet to look for information about her mother’s medicines, contacted the GP to arrange a home visit to discuss the medicine regime, and went to see the local pharmacist for an explanation of the drugs and how they should be taken.

Summary statement: Patients’ behaviour reflected a willingness to take on the role of checking medications in primary care; however, they identified a range of factors which could limit their ability to assume this role in hospital, suggesting role transfer to health care professionals. Family members
assumed the role of checking medications on behalf of others with varying degrees of volition; their ability to check medications on behalf of someone else could be affected by their level of knowledge and their availability.

Possible facilitators:
- knowledge of your own (or another's) medications
- perception of health care staff as approachable (community pharmacists, your 'own' doctor)

Potential barriers:
- lack of familiarity with appearance of medicines
- limited knowledge of drug therapy
- feeling too ill in hospital to act
- anxiety about any repercussions if you raise a query

Role: Feeding back individual experience of health care quality and safety

(See also Section 4 of this report: Patients' awareness and views of reporting systems)

Participants’ views of the role of feeding back individual experience of health care quality and safety encompassed a desire to feedback positive as well as negative experiences of health care services, and to feedback in a manner that would be constructive for future learning. Overall, the role was regarded as potentially of value, as a means for patients to seek redress for perceived deficiencies in care or potential (or actual) breaches in safety, and for NHS learning, at local and national levels. However, patients expected and experienced multiple barriers to role enactment.

Patients’ views concerning this role related to five main areas: motivation for giving feedback; the kind of information that should be fed back; ways of feeding back individual experiences; acknowledgement from those
responsible for managing services that information fed back by patients is
given due attention and/or acted on; and potential barriers and facilitators to
role enactment.

(i) Patients’ motivation for giving feedback
Patient motivation for providing feedback of individual experiences appeared
to have three main drivers: firstly, a desire to seek a measure of redress,
usually in the form of an apology, for any perceived shortfall in care, adverse
event or error; secondly, a willingness to provide clinicians with information
that could be useful in improving the quality of care offered to all service
users; thirdly, a wish to prevent similar errors or adverse events occurring in
the future.

‘I felt satisfied with the reaction that I got back because the doctor did phone
me up and he did apologise to me, which was nice…’ (303)

‘if someone else can benefit from something you bring up, then it’s not a bad
thing…if it could make a difference to somebody else…then it is worth saying
something’ (208)

(ii) Perceptions of the kinds of information that should be fed back to health
care professionals
Participants indicated that they would welcome the opportunity to provide
feedback on their experiences of ‘routine’ care using patient suggestion
boxes, questionnaires, or comments forms that might be made available on a
hospital ward or in a general practice surgery, and that this kind of data could
enhance quality of care for all patients.

‘if they did a suggestion box type thing like saying, this could be improved by
doing such and such or might be a good idea if you did this…and then
somebody would empty the box and pass things onto whoever it’s relevant
to…’(308)
The majority of respondents said they would not report what they considered ‘minor’ mistakes to clinicians or to managerial staff, but that they would wish to bring to their attention any error or event which had, or potentially could have, resulted in harm, either to themselves or a family member.

Issues which respondents said they had wanted to report, attempted to report, or had actually reported, to clinicians, or service managers included: preventable post-operative pain (408; 401); preventable psychological harm (205; 203); inadequate discharge arrangements in place on leaving hospital (507; 408); development of pressure sores, in the patient themselves (401) and in an elderly parent during stay in hospital (511); clinical procedures not carried out correctly, linked to patient perception that health care professionals’ were inadequately prepared/ qualified to carry out task (508; 509); correct administration of medication not adhered to (605); unnecessary delay leading to deterioration in condition of patient (512); staff attitude (303; 509); perception of delayed referral in primary care (208)

(iii) Patients’ perceptions and views of feedback mechanisms and barriers and facilitators to feeding back individual experiences.

There was a widespread perception amongst study participants that having a senior clinician in a matron role in hospital wards, with the authority to effect changes in care delivery, would facilitate patients’ feeding back their individual experiences.

‘in the old days, at least once a day the Sister would come round and see everybody and you could speak to her’ (401)

‘I’d love to see the old fashioned Matron back’ (109)

Several of those interviewed said they would (or did) prefer to give feedback about errors or harms directly to the clinicians involved in the hope of achieving a speedier resolution of their concern or complaint or to promote learning ‘at the coalface’.
'I would report it [any concern] straightaway…it's no use leaving it and reporting it later…' (402)

'the final thing would be just to put something in writing like an official complaint, but I just wanted something more constructive in terms of giving feedback and getting to the right places, it's hard to give feedback there and then but I think that's the time to try and do it, and to say to the person…' (205)

Patients’ accounts of their experiences of attempting to give face- to- face feedback with clinicians were mixed; reported barriers were that it could be difficult to find the appropriate person to speak to, and/or that they met with a negative response when they tried to raise issues. For example, participant (507) described her feelings about trying to talk to staff directly about perceived shortfalls in communication when her mother was discharged from hospital.

‘the initial response was ‘you should have raised these issues at the time’, but who could we raise them with? Every time we went into the ward it was different people. We asked about the designated nurse scheme and one of the consultants told us they didn’t have that…which they nursing staff told me they did…the consultant at [name of hospital] was very obstructive…this sort of attitude, rather than trying to communicate with the family and work together…every question you put forward is met with a negative or rebuff, then you fall back to saying, how do you suggest we resolve this? How do you suggest we get to the bottom of this?’ (507)

For the most part, interviewees indicated that they viewed making a written, formal complaint as a last resort; this was a role which they were reluctantly to assume, though one they were willing it to adopt, if attempts to resolve issues face-to-face with health care professionals failed. A pattern was clearly discernible across the database of 35 interviews: the patient, or their family member or representative, initially raised a concern with an individual health care professional; the patient perceived the response to this as unsatisfactory;
the patient or their representative raised the matter again, this time more forcefully, and/or involving a more senior member of staff; if the response from the health care professional was again deemed unsatisfactory, the patient or their representative then made a decision to either ‘drop’ the concern, or to make a formal complaint.

‘they didn’t listen to us in the first place…he [participant 511’s father] was neglected and the negligence caused his skin to break down…I complained to the staff on the ward…they didn’t take much, any, notice…we had to contact PALs…after we make a complaint, that’s when they started to take action…before they did anything…’ (511)

Reasons given by participants for their unwillingness to make a complaint included a fear of repercussions, for both patient and health care professional (for example, being labelled as a difficult patient, or being ‘struck off’ a general practice list), allied to a disinclination to ‘name and shame’ individual clinicians. Some patients suggested that they should have the option of being able to make complaints anonymously, but many participants reported that they would be happy to put their name to any complaint they made.

‘I’ve heard people talking about they’ve complained about this doctor, [general practitioner] and they’ve been told, well, if you don’t like it, you can leave…why shouldn’t a patient complain without getting threatened that they can go somewhere else?’ (106)

‘we’re in a blame culture’ (208)

‘I know they were negligent, but I didn’t want to get anybody into trouble…I just wanted to bring to attention that these things had happened… (509)

‘I think you could give people the option to be anonymous or not. I would sign my name to it if I made a complaint’ (401)
Interestingly, participant (512) reported that while she had anticipated that she might experience a level of antipathy from hospital staff after making a complaint about staff at another hospital, in fact this did not occur.

‘I had to make them aware [that she had made a complaint]...they knew, but they didn’t say to me, ‘Oh, we know you made a complaint, they weren’t off with me at all, but I just said, you do know that I made a complaint and they said, ‘Oh, yes, and we were treated very well…’’ (512)

Interview accounts included detailed descriptions of patients’ experiences of making written reports about perceived deficiencies or errors in their care, and of the factors and processes which made this easier or more difficult.

In the first instance, patients said they might not be sure of their grounds for complaint, and several indicated that they would (or did) check with a trusted clinician, such as their general practitioner, about whether they should proceed with a formal complaint. A significant obstacle to role enactment reported by many interviewees was that they would not (or did not) know the appropriate person to whom they should address, or the procedure they should follow, to make a formal written complaint.

‘you’d perhaps go through your doctor and perhaps ask them what they suggest you should do...you’d have to find out who you’d have to report to’ (407)

‘there is more than one place to go to, how do you know which complaint goes to which place...there are so many bits of PCTs, so many bits of services that cover bits of the city...there probably aren’t any posters on the wall...so how do families know about it?’ (508)

In general, patients appeared to be fairly sceptical about whether feedback of individual patient experiences would be acknowledged and acted on, and most patients indicated that they would want to receive some kind of
assurance from those managing complaints systems that feedback would be valued and used as a basis for future improvements in service delivery.

‘paper filling in is fine as long somebody is actually going to read it and do something about it’ (208)

‘you’d want some feedback because otherwise it’s a waste of time on both sides and you don’t know if anything has come from it’ (408)

Knowledge of local reporting systems, such as the Patient Advice and Liaison Service (PALs) was limited or, in some cases, non-existent, and experiences of using it were variable. Of the thirty interviewees included in this analysis, six respondents (205; 303; 507; 508; 509; 511; 512) reported that they had used PALs. Three respondents (303, 511, 512) stated that they had been satisfied that their complaint had been dealt with in a timely manner and resolved satisfactorily through PALs, and they suggested that they would use the service again.

However, the remaining three participants (205; 508; 509) reported that their concerns had not been acknowledged or acted on through the PALs service. Of these three patients, participant (205), described feeling so frustrated and de-motivated by the experience that she dropped her complaint; participant (508) said she was resigned to the fact that her ‘letter of concern’ directed through PALs had been ‘acknowledged, filed and forgotten’; while participant (509) had persisted in bringing his concerns about his wife’s care to the attention of senior hospital management by writing to them directly to lodge a formal complaint. He commented that he was satisfied with the response because the signature indicated that the matters he had raised had come to the attention of the Chief Executive of the hospital, and each of the matters he had raised appeared to have been investigated or dealt with.

‘I made an appointment with him [the PALs representative] …so we can take some of these concerns forward…well, I never heard from him, two, three months went by, never heard from him…and the thing that was so
frustrating… I phone people up, I ask specific things, but people don’t get back to you… I let it go… I thought about the complaints, but I’ve left that alone…’ (205)

‘I did write a letter of concerns and I specifically said it was a letter of concern, not a letter of complaint and didn’t receive a response to that… next I had a message to ring the charge nurse on the ward who basically said that the health care assistants had had extra training and the bathrooms have been painted… to be honest, I don’t think anything has come of anything I said at all’ (508).

‘a lot of it has been taken on board… they looked at it thoroughly… the reply has gone into great depth… it’s gone to the top hasn’t it, the Chief Executive, it’s actually signed by him, it’s not for and behalf of…’ (509)

A significant number of participants suggested that feeling ill, emotionally vulnerable or ‘at a low ebb’ (202) due to a lack of energy because of on-going treatment regimes, had deterred them from raising concern or pursuing complaints; others reported that they decided not to raise concerns or make a complaint about incidents or events that had occurred in hospital once they had been discharged, and had resumed their usual activities.

Additionally, study participants suggested that certain groups of people would find it difficult to feedback their experiences of their care, for instance, people with dementia, or with mental health problems, or those whose language skills or formal education were limited, and that some of these people would require assistance to feedback their experiences.

Summary statement: Study participants appeared to regard feeding back individual experience of health quality and safety as an important role for patients to engage with (a) in order to seek redress for themselves (or a family member) and (b) because, potentially, the role enables patients to influence service improvement. However, they indicated that they would (or did) encounter a series of barriers to role adoption and fulfilment, and their
expectations and experiences of feeding back to clinicians or health care services complaints systems were often negative.

Possible facilitators:

- o patients invited to raise concerns about their care
- o health care professionals/ systems react to patients’ raising concerns in a manner which patients perceive as a fair response
- o patients concerns and complaints are acknowledged and acted on in a timely manner

Potential barriers:

- o patients lack knowledge of appropriate procedures for raising concerns or making a complaint
- o patients’ fear reprisals, for themselves, a family member, or ‘front-line’ clinicians
- o patients encounter apathy, defensiveness or hostility on the part of health care professionals or health service managers

Role: Following instructions from a health care professional

Following instructions from a health care professional was a role identified by less that a third (8) of the sample of interviewees, in response to a question from the interviewer along the lines of: ‘Do you think there are ways that patients can keep themselves safe when attending the doctor or going into hospital?’ Those who suggested the role stressed its importance.

Participants who mentioned this role spontaneously seemed to regard it as a role traditionally associated with patients, incorporating an implicit acceptance of health care professionals’ authority to issue instructions; their comments suggested that patients had a responsibility to follow instructions (unless they were unable to, for example if they were very ill) and that those who failed to do so might suffer consequences, with only themselves to blame.
'I've always regarded them [health care professionals] as the experts...and I think if they suggest a particular thing, then I do it unless I have some particular reason to doubt their ability and advice. But generally speaking, if they advise me to do something, I will do it. I think it is the patient's responsibility to do that.' (406)

'I think, if they say to a patient 'we don't want you to get out of bed yet, and this patient...is comos mentis...and this patient gets out of bed and falls, then personally I don't think it is the nurse’s fault.' (106)

Most of those who advocated that patients should follow instructions, or who said they had done so themselves, were older patients with diabetes or who were undergoing joint surgery.

Respondent (102) described how he closely adhered to instructions from his general practitioner and specialist diabetes nurse regarding the use of insulin injections in the regulation of his blood sugar levels; participant (407) said she had carried out exercises suggested by a health care professional during a pre-operative visit ‘by the book’.

Patients receiving treatment for breast cancer did not overtly identify the role of following instructions as a patient safety role, but it was clear from the interview accounts that they enacted the role, by checking for symptoms as instructed, and contacting specialist services if they noticed any signs of infection developing while they were receiving chemotherapy.

One of the parent respondents (303) seemed to regard ensuring that her child complied with clinicians’ instructions as one of the ways in which she shared responsibility for his care during hospital admissions.

‘the nurses can’t be there 24/7 with him at the bedside because there’s other patients to be seen...making sure that he is safe in the bed, making sure that he’s got his oxygen on...’ (303)
Perceived barriers to ‘following instructions’ related to both the health care professional and the patient: a lack of clarity in the instructions given, and an inability to remember them afterwards. Participant (302) discovered that her child had been using a steroid inhaler device incorrectly, because she had misunderstood instructions received from a doctor; patient (202) found she could not afterwards remember instructions given to her by a rheumatologist consultant about how to cut down her use of steroids, necessitating a phone call to the rheumatology specialist nurse to check.

Participant (101) suggested that health care professional could write instructions down in order to facilitate patients' remembering them, as she had requested her general practitioner to do.

Summary statement: ‘Following instructions’ was spontaneously identified by less than a third of those interviewed as a patient safety role; those who did mention it believed that patients had a responsibility to adhere to instructions carefully (as far as their condition allowed), or to suffer the consequences.

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<th>Perceived facilitators:</th>
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<tr>
<td>o instructions could be written down</td>
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<td>o family member (or representative) overseeing compliance with instructions</td>
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<th>Potential barriers:</th>
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<tr>
<td>o lack of clarity when instructions given</td>
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<tr>
<td>o patient’s inability to recall HCP’s instructions</td>
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Role: Ringing for results (for example, blood investigations, X-rays, scans)

All participants said they would consider carrying out this role, or that they had done so. The majority said that they would telephone within the time span suggested to them, that they would not ‘assume that no news is good news’
(203), though some reported they had only telephoned after encouragement from family members.

Respondents commented on obtaining results from their general practitioner’s surgery; from hospital departments; and from specialist services, such as from diabetic specialist clinics and a chemotherapy unit. Depending on the location, ringing for results was described as a relatively easy thing to do, or something that could be fraught with difficulty, resulting in a frustrating experience for patients and/or their family members and representatives.

Especially amongst older participants, there was a marked preference for obtaining the relevant information concerning tests and investigations from their doctor’s surgery, as it was considered comparatively easy to get through on the telephone to speak to someone, and the person on the other end of the telephone might be known to you. No-one appeared to like using automated telephone services.

‘our surgery is very good, you don’t tend to hang on the phone for too long and you don’t press 1 for this or press 2 for that, that awful set up’ (607)

A drawback cited was that the receptionist might not know whether the results of test could be released to the patient, or whether they should talk to the doctor, and it was suggested that perhaps results could be ‘flagged’ in some way to indicate what should be done.

Specialist services were rated highly in terms of accessibility and dependability; for example, mothers of children with asthma mentioned that they had been given individual telephone numbers of consultants and their secretaries, and of asthma specialist nurses, who they could depend on to ring them back if their call was missed. Some individuals using these services said that clinicians would ring them with test results, to reassure them that there was nothing to worry about, or to let them know of any abnormalities.
'It’s not very difficult for me because I have direct access to his doctor. I’ve got the doctor’s surgery number, his specialist’s number and you know, he said to me, phone anytime you need to know anything…and if I can’t get hold of him at one number, he’s given me another number to phone somewhere else…’ (303)

‘you leave a message and they’ll ring you. Sometimes I’ll ring up and I’ll say, how’s my bloods? I know if there was anything wrong they’d ring me, you know, but I like to know.’ (106)

In contrast, participants’ descriptions of ringing hospital wards or out-patients’ departments for results were couched in more negative terms, and suggested considerable levels of patience and persistence might be required. Barriers included not knowing your way around the system (who to contact, which department); difficulties getting through hospital switchboards; a dislike of answer-phones (leaving messages which are not returned); and being passed from one department to another. Reports of results getting lost in the system were not uncommon.

‘trying to get through on the [hospital] switchboard is extremely difficult. It’s alright if you’ve been told which department to ring…when they say ring, they should give you a number to ring’ (wife of participant 401)

‘I found the most frustrating and most difficult thing was results being passed from one department to another…I rang up and days and days went by and eventually what I did was ring the cardiology department…to see if the results had been sent from the scan and they said. ‘Oh no, we haven’t had any results yet…eventually what happened, was my wife…she’s a bit more forceful than me…got on the blower and she went right back to the beginning, have you sent those results, so the cardiologist said yes, we sent them within an hour of [name] leaving the ward’ (406)

**Summary statement:** ‘Ringing for results’ was a role that most of patients were willing to undertake, or had undertaken. Ringing for results from a
general practitioner's surgery, or specialist units or services, was considered substantially easier than ringing hospital departments, which could be fraught with difficulties.

Possible facilitators:

- being given a specific name or number to contact

Potential barriers:

- mainly systems related, for example, difficult to navigate through hospital switchboard and making calls between different departments

Role: Seeking information

Respondents appeared to regard the role of seeking information as key to keeping themselves safe and many said they actively sought information, both verbal and written, in a variety of ways, from a range of different sources.

Participants’ prime motivations in seeking knowledge seemed to be the desire to know more about their (or another’s) clinical condition, any treatment and investigations they were having, and information relating to medications.

This kind of information was viewed as necessary to enable patients to engage in safety promoting and enhancing roles and to underpin safety related decision making; for example, enabling patients to recognise and interpret clinical signs and symptoms of deterioration in themselves or others; aiding understanding to make informed choices between treatment options, or to select a hospital with low rates of infection; and furnishing patients with adequate levels of knowledge to challenge the clinical judgement of health care professionals when they suspected care or treatment was not as it should be.
Respondents reported that they sought information through verbal questioning of health care professionals (when they were given the time and the opportunity) and from reading materials they were given by health care professionals, acquired as part of their treatment plan (for example, booklets given to a patient with mental health problems during a routine visit by a community psychiatric nurse) or from information they sought for themselves (for example, articles from Internet websites, or books from libraries).

Use of computers to seek information
Active information seeking was often associated with access to computers and the Internet, but many of the patients spoken to, especially older patients, did not have such access, unless family members sought information on their behalf. These patients were therefore more reliant on information passed on to them by health care professionals during clinical consultations.

Patient (402) was one of several patients undergoing joint surgery who said she had tried to find information on the Internet relating to hospital acquired infection rates; her unsuccessful attempt led her to believe the information might have been ‘hidden away’.

‘I did try and find out of the web what the infection rate for hospital acquired infections were and although they waffled on a lot, I couldn’t find any exact figures for [name of hospital]...so I gave up in the end...’ (402)

Participants said they were most likely to make use the Internet at the point of diagnosis, when they felt their need for information was greatest, but when their ability to absorb information could be compromised by the shock of diagnosis; patients diagnosed with breast cancer described feeling overwhelmed and confused by the amount of information available on the subject on the Internet.

Patient (603) commented that she did not want to access information about her mental health condition from the Internet, as she might worry about the
prognosis unnecessarily; similarly, patient (607) said that she had ‘scared herself silly’ about some information she had found on the Internet, that she had completely got hold of ‘the wrong end of the stick’.

Patients cited instances when they turned to the Internet in the absence of information provision from clinicians. For example, participant (507) described trying to find information about the medications that her mother had been given on discharge from hospital, while respondent (202) said that she was unable to get information from doctors about the use of complementary or alternative medicine in the treatment of breast cancer. Internet users frequently cited difficulties in accessing information, assessing its validity and making decisions about its applicability. Participant (507), a highly educated professional, demonstrated her awareness of these issues.

‘because you haven’t been given the information and then you’ve got to try and find it, and I tend to try and stick to things which I think are reputable like NHS direct, because you can come up with quite spurious sites who’ve got an axe to grind…I think a reputable one is the Patient UK I think is one of them. I tend to look at 2 or 3 of them across the board. One of the latest tablets she’s been given was because she was having a lot of pain down her leg…well I looked the name of it on the Internet and it said it was being given for anti-depression…as a carer, it would be nice to know why the medication is actually being given…’ (507)

Seeking information from health care professionals
‘Human’ sources of information often seemed to be preferred by patients, either instead of, or in conjunction with, electronic sources; specialist clinical nurses (breast cancer, diabetes, asthma) were regarded as readily accessible, trusted and valued sources of condition-specific information, while pharmacists were perceived as a useful source of general information related to medications, as well as a first resort for specific inquiries. One advantage cited in using these ‘human’ sources was that patients could ask for clarification of any information they were unsure about. Participant (202)
described how she gathered information during the periods that her chemotherapy was being delivered.

‘some additional advice about managing that would have reduced my anxiety about the possibility of further infections…I think having intravenous chemotherapy was helpful because there was a nurse sitting there for at least half an hour and it was an opportunity to talk…’ (202)

Reading materials
Individual respondents from all clinical groups reported reading the leaflets that they received in the packaging of their medicines, where they could find information about the side effects of drugs that might not have been mentioned by the prescriber.

‘they never tell you any side effects of drugs [laughs] I have never been told about side effects, despite all the time I have been in the system, I have never been told about side effects, but I always read the little bits of paper that come inside the packet with it…’ (605, a patient with a long standing mental health problem)

Some respondents’ perceptions about potential barriers to information seeking were discounted by other patients, sometimes with help from family members; for example, patients without access to computers often said they could ask a son or daughter to retrieve information on their behalf; and a lack of English language reading skills did not seem to pose a barrier to accessing written information for participant (104), as family members were willing to take on the role of assisting her to access and assimilate information.

‘she can’t read this information that she needs one of the family member would look into [it] for her and read up and understand it…like when she goes to diabetic clinic, I explain to her…’ (daughter-in-law of participant 104).
Other potential barriers to seeking information cited by study participants included low level of or lack of literacy and an inability to understand medical terminology.

**Summary statement:** ‘Seeking information’ was viewed as a vital role by patients, integral to enabling them to promote and enhance their own safety.

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<tr>
<td>• health care professionals create opportunities for providing information to patients</td>
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<td>• assistance from family members (or representatives)</td>
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<th>Potential barriers:</th>
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<tr>
<td>• lack of access to computerised sources of information, including due to hospitalisation</td>
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<td>• low levels of literacy/health literacy</td>
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**Role: Sharing information**

Study participants suggested that in general, patients should, and would, take on the role of sharing information with health care professionals, unless they were incapable of assuming the role due to their condition (for example if the patient were acutely ill, or had dementia). Participants’ interviews revealed the kinds of information they expected to share with doctors and nurses: known or suspected allergies; side effects of prescribed medications; development of new symptoms; signs of deterioration in their (or another’s) physical or mental condition.

Some participants reported that in some circumstances, they encountered difficulties when they attempted to share information about their psychological and emotional needs for care with health care professionals. Respondents receiving treatment for breast cancer in particular expressed their desire to share this kind of information but found this difficult in a busy clinical environment; they said it was easier to access and talk to specialist clinical
nurses as they appeared to have more time. Participant (205) explained her wish to share her feelings about being diagnosed with breast cancer and having chemotherapy with the clinicians looking after her.

‘I tried to explain to them the thoughts about chemicals going into my body…that sort of freaked me out to the extent where I did get anxious before it…it was psychologically, nobody talks to you about that, they talk to you about the physical symptoms…but nobody talks to you about the mentally, psycholgically…the staff definitely haven’t got time to address that…I went over things [with the specialist cancer nurse] and we talked from an emotional point of view, and she tried to go over the results and the diagnosis and what options I had…’ (205)

The patient’s role in sharing information appeared to be viewed as synergistic with the role of the heath care professional; through information sharing, the patient could enable the health care professional to enhance their (or another’s) safety. For this to happen, respondents suggested that patients needed to be given opportunities to share information, and health care professionals needed to listen to the information and act on it, described by several respondents as a ‘two way process’. For example, an important aspect of sharing information reported by patients with mental health problems was to inform staff about the behaviour of fellow patients, perceived as a mechanism for keeping yourself and others safe.

‘if you have any bad experience from that person it is better to inform the staffs [sic], keep it in their knowledge, so that they can guide you and protect you…all these peoples [sic] they [health care professionals] may have encountered before, so it is better to give it in them, to their notice.’ (603)

Possible facilitators of information sharing identified by study participants included: the health care professional’s manner suggests they welcome information sharing; they provide the patient with an opportunity to talk; patient and health care professional have an established on-going relationship. A quotation is cited here from a single participant respondent (609), to
summarise these points, but many interviewees identified the similar facilitators.

‘my own GP has been wonderful...he knows how to communicate... every person on the mental health team has been first rate... I had a nice nurse come when I first had the bipolar disorder 3 years ago...a care plan was put in place very carefully it was a complete sort of two way process...and I saw this lady on a monthly basis and if needed to see her more, I'd got her phone number...I felt I was treated as a person... rather than a number (609)

An additional facilitator identified was for patients to write down information, particularly in relation to medications, which they could then present to health care professionals, to avoid items being forgotten.

‘when patients come into A&E...and they bring a list, because it’s carefully handwritten out or it’s the prescription, the counterfoil for the prescription, so you’ve got the exact dose and the exact frequency...that will help prevent errors...' (respondent 607, a qualified doctor).

With very few exceptions, patients said they could, and would, readily share information with general practitioners, who were perceived as receptive listeners.

‘Dr [name] is very polite and he’s very understanding to patient’s medical needs and he speaks to her in a level that she [speaker’s mother-in-law] can understand...he gives her time and his manner and the way he speaks is very good’(104)

Even with GPs, disclosure of some information appeared to be considered difficult.

‘when I first admitted to my GP that I’d got a breast lump, because I’d had it for a long, long time before I told anybody... ‘(202)
A range of potential barriers to information sharing were identified by study participants and are listed below, along with relevant quotations. Of these, the one that appeared to be regarded as the most significant was anticipation of, or actually meeting with, a negative response from the health care professional. Participants described not being ‘invited’ by the health care professional to share information and not being given the opportunity to do so; and they suggested that information given by patients was perceived as not acknowledged or acted on.

Potential barriers to sharing information identified by study participants:

- patient does not know what information is relevant

‘nobody had said, ‘Oh, this might happen to you, can you let us know, we need to monitor it…’ maybe there are things taken for granted by doctors and nurses that need to be pointed out to patients.’ (202)

- patient is unable or forgets to volunteer information

‘neither of my parents have got dementia or are senile but neither of them are as sharp as they were, they forget things…quite often they intend to say something or ask something but forget and often they’re told things and forget’ (507)

- cultural factors

‘…for example, Asian people, Pakistani people…the more they are getting integrated into society, they are knowing the ways of the society and they are getting used to it that you should not keep things to yourself and you should discuss it and when you discuss it a solution comes out…there is still people who need education…that they don’t keep their anxiety in, they’re worried to express it to medical people…this present generation of Pakistani, they
understand very well, but the older generation have communication problems…’ (102)

- lack of language skills (on part of patient or HCP); low health literacy

‘the high number of staff whose first language is not English and struggling to make myself understood and listening to somebody being admitted to the bed next to me and the nurse not understanding her…that made me think, has the nurse got that information down straight…’ (202)

‘if you are not well educated, possibly not very literate, if you don’t speak the language it can be quite difficult…’ (508)

‘some who maybe don’t understand, or can’t manage difficult medical words…’ (607)

- anticipated (or actual) response of health care professional perceived as negative: patients felt they were not listened to or given a chance to talk, or that the information they gave was not heeded or valued.

‘they wasn’t listening to me…that was probably the biggest complaint I had they wouldn’t listen to me so some of this information that they had [was wrong]…’ (602)

‘a lot of staff were just indifferent, totally indifferent…they don’t take anything on board, they are so busy nattering’ (605)

‘it was a little bit like standing in Top Shop, they were sitting there having a very interesting conversation about one of the husbands buying them flowers for Valentine’s day which was coming up and I sort of said, ‘hello, don’t mind me…’ (508)
'there have been occasions when it is very much a one-way, you know, they give you information then they expect you to go because they’ve got lots more patients…’ (205)

‘with the blood pressure…it was just a case of ‘I’m going to do it and that’s all there is to it’ and he didn’t appear to appreciate that I might actually know what I am talking about’ (508)

‘we did tell the doctor and the nurse about my dad’s condition and the tablets, the name of the tablets and everything…they had all the information…but they just didn’t seem to take any notice of it…most of all they didn’t listen to us in the first place…he came out with bed sores on his bum, on both his heels…I complained to the staff on the ward…they didn’t take any, much, notice…’ (511)

- patient may not know who the appropriate person is to share information with

‘I’ve phoned the cancer nurse and said, I don’t know if it’s your department or somebody else but I’ll tell you my problem and tell me where to go kind of thing…and that’s me, an educated person who happens to know the health care system…’ (508)

- patient confidentiality

‘[my mother] has already signed a letter at the surgery that myself and my sister can talk to the medical staff on all her medical details… you’ve got to have the authority to speak to people…my father certainly hasn’t written a letter for us to have authority to talk about his confidential records…it’s very much the male stiff upper lip’ (participant 507 accompanied both her parents during many of their medical consultations and episodes of hospital care).
• patient perception that information shared with one member of staff is not passed on to other staff

‘speaking to staff is useless I think to be honest…they change shifts and they don’t really pass the message on…’ (511)

Amongst the 30 participants included in this analysis, three (106, 208, 205) alluded directly to the extent to which patients ‘ought’ to be expected to assume responsibility for sharing information. Participant (106) suggested that health care professionals depended on patients to give them essential information to aid clinical decision making; respondent (208) implied that patients should take the blame for any consequences they might suffer if they did not disclose information fully; while respondent (205) expressed concern about the level of responsibility that might be associated with this patient role.

‘my rheumatology consultant says to me that the patient knows best how your body feels – they rely on you to tell them how you are feeling…he always says, the patient has to tell us if they’re feeling ill on the tablets or whatever…’ (106)

‘if you don’t tell them that you’re feeling a certain symptom or that you’re worried about something and then it does come out to be something else that you never told them, then you’ve got nobody but yourself to blame’ (208)

‘they made it clear that the onus is on you if you get symptoms, but I’d done the communicating. I’d contacted them but I just felt as if I was left to decide for myself, well, how urgent is it, how much do I push it…? (205)

Summary statement: Sharing information with health care professionals was viewed as a patient role which most participants were willing to assume, as far as they were able. The factor most likely to influence their willingness and ability to do this was the anticipated, or actual, response from the health care professional.
Role: ‘Speak up’ if your care does not seem as it should be

‘Speaking up’ about deficiencies in care was generally regarded as the most difficult role for patients to take on, as it was perceived as directly challenging of professional behaviour and authority, (thereby implying a lack of trust), and was associated with the possibility of confrontation with staff and repercussions for the patient.

Most people said they would find it easier to speak up on behalf of someone else than for themselves, that they would be strongly motivated to protect the safety and well-being of a child, parent, spouse or a fellow patient.

Study participants’ interviews suggested that the likelihood of patients or their family members ‘speaking up’ about any concern would depend on a complex interplay of factors relating to: the context of the situation; patients’ (or their family members’) socio-demographic/ biographic details and personal characteristics; patients’ physical or psychological condition; and their perceptions of the actual or anticipated response from health care professionals.

Respondents’ interviews included ‘rich’ descriptions of a wide range of situations in which they had attempted to ‘speak up’, or had ‘spoken up’, on behalf of themselves or another (see synopses in Section 3 of the report).

Factors identified in participants’ interviews that appeared to be influential in whether or not they would (or did) ‘speak up’ are discussed below.

- easier to ‘speak up’ on behalf of another

Many of those interviewed suggested that they would find it easier to ‘speak up’ on behalf of someone else than for themselves, because of a strong desire to act to protect others, whether the ‘other’ was someone they knew
and cared for, or a fellow patient on a hospital ward. This was borne out in their interviews, where they recounted numerous instances of them 'speaking up' when they considered someone else to be at risk of harm or neglect.

"generally speaking, I don’t find it [speaking up] easy…I have to screw myself up, but I think especially when it’s for somebody else, like for your own child or parent, it brings out your protective instincts’ (507)

'I’m just a kind of person that is aware of injustice and things but when it comes to myself I don’t make a fuss…I think I do on behalf of other people because that is part of my job, to advocate for other people…’ (202)

- contextual factors

Participants’ decisions about whether to not to ‘speak up’ about their concerns appeared to be linked to their perceptions of: the immediacy and gravity of any threat to safety; the seriousness of any shortfall in care; and the level of ‘busyness’ of the clinical environment.

Situations described in respondents’ interviews when they or their representative had ‘spoken up’ to avert potential harm or prevent errors, included instances of mistaken identity (wrong injection, wrong notes); delays in treatment, leading to marked deterioration of the patient; inadequate pain control, resulting in suffering unnecessary pain; and lack of nursing assistance, (for example, with mobility after an operation, with hygiene, nutrition and hydration) which could compromise well-being, privacy and dignity.

Patients (or their family members) reported that they were less likely to raise concerns with staff over matters that they considered ‘petty’ (406); or if they judged the clinical environment to be extremely busy, as they did not wish to deflect attention from other patients who might be in more need of care and attention.
'I was thinking, I wish somebody would come and sort my sheets out. But it did seem so petty to press the button and get a nurse to come and just do something like that. I suppose it wasn’t really petty because I was getting sore, but it just felt like a waste of their time really’ (402)

- socio-demographic/biographic details and personal characteristics

Participants suggested that patients’ (or their representatives’) willingness and ability to ‘speak up’ could be linked to a range of socio-demographic variables (age, gender, ethnicity, levels of education); biographical details (knowledge of their disease/condition; the point reached in ‘the patient journey’ (for example, whether newly diagnosed or living with an established condition); and personal characteristics (for example, level of personal confidence).

Patients’ perceptions of the impact of some of these variables on behaviour were often at odds with their interview reports of situations when they or others had acted by ‘speaking up’. For example, there was a widespread perception amongst participants that elderly people might find it more difficult to ‘speak up’ than others, because they would be more likely to be deferential towards doctors than younger people, and it was suggested that elderly people from minority ethnic backgrounds would be further disadvantaged by their lack of English language skills.

‘little old women, they’re quite content to take anything that the big surgeon or consultant says is gospel truth’ (402)

’both my parents…would never say ‘boo’ to a goose…whatever the doctor said, you just took it and you didn’t actually talk about issues, you just listened to what the doctor said…right, thanks doctor, out the way. But our generation have been encouraged to argue…that it’s your right to tell them when you think things aren’t quite going as they should be really.’ (609)
'our people are now second or third generation, they can speak [English] very well, so less and less a problem. But the older generation, they do still have problems, a communication problem' (102)

However, expectations that elderly people might be less willing to speak up than others did not accord with interviewees' reports of actual instances of ‘speaking up’ which frequently featured older patients in this role, nor with the views expressed by older people themselves.

Respondent (104), for example, a 71 years old Asian Pakistani woman, who did not speak English, managed to overcome language difficulties (by finding a nurse to translate for her) to ‘speak up’ forcefully on behalf of her young, English speaking daughter who, she felt needed urgent admission to hospital (see Section 2.3 (i), Synopsis 3, page 23).

‘I’d have no hesitancy whatsoever about speaking up’ (406, aged 72 years)

‘I stand up for my rights and so does he [her partner] but a lot of patients don’t’ (106, aged 64 years)

Similarly, participants’ expectations that it would be easier for educated, confident, articulate people to ‘speak up’ were not predictive of role behaviour; reported ‘scenarios’ in the interviews revealed that respondents with these characteristics could be deterred from ‘speaking up’ in various situations, for instance, when they were acutely ill, and feeling vulnerable; for example, respondent (202), a highly educated health care professional, felt too ill to ‘speak up’ about the lack of cleanliness of the toilets in the ward, while participant (205), a social worker by profession, had returned to the chemotherapy suite with a suspected infection, after treatment for breast cancer; finding herself ‘forgotten’ in the busy waiting area, she started to doubt her grounds for seeking attention from the staff, and to feel too upset to ‘speak up’.
‘I got an infection and I was quite poorly on the ward then and I think that probably stopped me from making comments on the state of the toilets’ (202)

‘I’m just sat there… and time went on and you could see how busy they were and everything… and then you start to think, is it that bad… and you begin to query that to yourself… maybe I’ll come back at the end of the day… I was feeling upset by then as well and I think it was this thing of feeling not knowing whether it was something to worry about, having to assert yourself and I didn’t feel great that day doing that anyway… ’ (205)

- biographical details

Participants undergoing treatment for breast cancer in particular suggested that it would be easier for patients to ‘speak up’ about their concerns regarding their treatment and care as they moved through an illness trajectory. Initially, it could be more difficult to ‘speak up’ because of the shock of diagnosis, and because knowledge was limited. Participant (205) described how, over time, as her knowledge increased and as she talked to other people with the same diagnosis, and listened to them ‘speaking up’ her own confidence in her ability to ‘speak up’ grew.

I had a lot of time to sit and observe… and notice… and because I was going for slightly repetitive treatment and if one person did it slightly differently to another person to me it would be noticeable, and I suppose as time went on, I felt I had to have my wits about me and be on the ball and assert myself… so yes, over time, I did begin to think about that more and ask questions or query… ’ (205)

Patients’ (or their representatives’) level of knowledge (for example, about a disease or condition, medications, routine clinical procedures) was considered an important factor in relation to decision making about whether or not ‘speak out’; some participants referred to this as being ‘sure of your grounds’. For example, parents of children with asthma seemed prepared to ‘speak up’ to challenge aspects of professional care-giving, on the grounds of being acutely
aware of small but significant changes in their child’s condition and also because of their often long term familiarity with asthma and its treatment; participant (302) was prepared to ‘speak up’ to challenge the decision of ambulance staff not to take her child to hospital, when she felt the child needed to be admitted, while participant (303) ‘spoke up’ to challenge a doctor about the appropriate way to administer a steroid.

‘the ambulance came and they said, ‘Oh, his stats are not very high…’and I said, well, I’m sorry, but I know what he looks like, and I know what he’s listening to’ (302)

‘a new doctor had come in, and he didn’t know my son’s situation, and I mean over the 9 years, I know straightaway he needs a nebuliser..’ (303)

Having a family member or other representative with you during health care encounters was considered facilitative of ‘speaking up’; they could be more alert to any deficiencies in care; could express concern on your behalf; or could support you in ‘speaking up’ for yourself.

‘it was fortunate that I was there and saw that it [intravenous infusion] wasn’t dripping. Some other poor person might not have had any visitors and she could have been hours and hours…with its not dripping, so that’s why I brought the subject up’ (509, who ‘spoke up’ on behalf of his wife).

- patients’ physical, mental and psychological condition

Participants emphasised that their ability and willingness to act in the role of ‘speaking up’ at any particular point in time would be directly related to their state of health (physical, mental or psychological) at that moment.

Suggested barriers to acting included: being very ill in hospital, and feeling vulnerable (‘you feel powerless in hospital’ (512)); feeling less than lucid after surgery (not ‘compos mentis’ (401)), or ‘in a fug of painkillers’ (202); suffering an acute episode of a mental health problem (‘we don’t need to take more
stress you know, because we are mentally ill, so it is not good to take more stress’ (603); or having a condition, such as Alzheimer’s disease, which would impair your ability to ‘speak up’ (609).

• anticipated or actual response from health care professionals

Several participants suggested that changes in society and within health care culture over recent decades should make it more acceptable for patients to assume a more active role in ensuring they received optimal care; although he subscribed to this view, participant (605) believed that de facto health care professionals did not welcome patients’ ‘speaking up’.

‘I think our generation have been encouraged to argue, which is so, so, important and I also think the important thing is that it is your right to actually tell them [health care professionals] when you think things aren’t quite going as they should be really.’

Interviewer: How do you think they react in general?

‘They don’t like it, because you can sense, ‘Oh, it’s him again’ (605)

Interviewees who were older, and those with mental health problems were likely to anticipate negative rather than positive responses from health care professionals if they were to raise concerns about their care or treatment by ‘speaking up’; by contrast, several of the parents of children with asthma anticipated a positive response, based on their perceptions of the good relationship they shared with the staff; views amongst other respondents were mixed.

Many participants drew a distinction between the responses they expected (and received) from doctors and nurses; anticipated (and actual) responses from nurses were described in more negative terms; (most) patients said they found it comparatively easy to raise concerns with hospital medical staff, as well as with general practitioners.
‘in those days, going back 60 years, doctors were gods, especially the top men, and even the staff daren’t talk to them,  But I’ve found it’s a much more relaxed atmosphere now. All the top men, the surgeons and doctors are all very agreeable…they talk to you, you seem to have a lot longer with them…’

(401)

Reasons cited by patients for not wishing to ‘speak up’ when they were in hospital included anxiety that they (or others) would be: ignored; rebuffed; labelled; insulted; told that their concerns were not real, but related to their illness; made to suffer repercussions; victimised; bullied. They also appeared anxious to avoid damaging any bond of trust between themselves and the health care professional (see relevant quotations below in Textbox 1).
Textbox 1: Patients’ perceptions of anticipated or actual responses from health care professionals

Ignored:
‘I used to feel as though I was ignored, they wasn’t listening… I mean there I am with bloody mania… and they’re not going to listen to me…’ (602)

‘I had been told by the psychiatrist to knock on the door at a certain time to have my medication earlier… and all they did was open the door and say ‘go away’ and close the door again’ (605)

Rebuffed:
‘generally speaking, I don’t find it easy if I am rebuffed, you know, I have to screw myself up… I try not to be confrontational’ (507)

Told concerns not real, but related to their illness:
‘when you have a mental health problem, you can’t really win… when you are mentally ill, and you are picking up signs, somebody could say, ‘It’s your illness’, and you are prone to that anyway…..’ (605)

Insulted:
‘you’re hallucinating…’ [nurse addressing patient] (509)

Labelled:
‘as I say, you do get labelled, I think I had one of the nurses say to me, ‘Oh well, you did find the chemo difficult… I felt a bit cross about something like that being said… I felt very judged’ (205)

‘you pick yourself out as an awkward patient’ (401)

‘I think some people would be frightened as being labelled a bother causer, a trouble maker. I think that makes people a bit careful as to what they are saying’ (406)

‘I was trying to say, this is why it’s happening, I’m not just being a bit picky’ (508)

Made to suffer repercussions:
‘because of the worry of the other staff, how she will behave [to] you, because she is permanent there, she is coming every night and how she can treat you… so you are worried…’ (603)

‘I think nowadays you have to hold your tongue in many cases. You very well could put yourself at risk of sort of being victimised because you’ve spoken out because that’s one thing professionals don’t like, is being criticised’ (401)

‘you think twice about it because you’re scared, you know, are they going to bully you for saying something’ (408)

‘she says that some people don’t speak because they fear they might not get the treatment that they would give because of them speaking, they might withhold, withheld that treatment’ (104)

Reluctance to break bond of trust:
‘I generally trust the professionals I deal with unless I’m given cause not to’ (507)

‘it leaves this thing of putting great trust in nurses and doctors and putting them up on a pedestal and not being… you couldn’t question that… you put an awful lot of trust in them…’ (205)
From many participants’ accounts of a range of situations where they had ‘spoken up’, it seemed that a negative response from a health care professional would usually lead to one of two outcomes: either the patient let the matter drop immediately, or they adopted a more confrontational approach to pursue the matter, which could lead to an increasingly hostile interchange between themselves and the health care professional. For example, participant (509) described the exchange that took place between himself and a nurse who had come to ‘flush’ a surgical drain that his wife had in situ after her operation, a procedure he had seen carried out a number of times.

‘she [the nurse] said ‘I haven’t done it before…all she had was one of the trays with the vial of saline solution in it. So I said, ‘Well, is that all you’ve got?’ She said, ‘How do you mean?…I said, ‘Well, you’ll need a syringe…you’ll need a key for the valve’. ‘How do you mean a key for the valve?’ I said,’ there’s a valve on it and you need a key to unlock it…it’s a valve that seals it.’ ‘You’re hallucinating, I don’t need a key’[nurse speaking]. I said, ‘You’ll need a key…and off she trundles to the nursing station and one of the other nurses said, ‘I’ll show you how to do it’…but she didn’t apologise you know…I was hallucinating!’ (509)

Anticipating, (or receiving), a positive response from the health care professional was the factor identified by most participants as most facilitative of ‘speaking up’. Respondents said they found it easier to ‘speak up’ if staff imparted the impression that they were approachable, were willing to take time to listen, and invited questions and queries; having a well established relationship with the health care professional, based on a relationship of trust, was described as a good foundation for speaking up.

‘I mean some of them from the word ‘go’, the first question you ask, ‘Oh, well, just a moment, it might just be the first word they say to you and that’s it for the course of everything they do…’ (203)

‘I mean we have quite a good relationship…so I do feel comfortable to say something and if it is something wrong, I would say it and they know I would,
because they always say to me especially the doctors…do you feel this, or do you want to say anything and they know I would and I feel comfortable speaking to them as well' (303)

‘in terms of encouraging the relationship with the medical profession as a patient, I just think sort of attitude and communication are the two main areas that are basic and can make all the difference’ (205)

Summary statement: Participants identified a range of factors that could impact on their willingness or ability to ‘speak up’ about concerns in their care; patients’ views about the (anticipated or actual) attitude and responses of health care professionals had a significant influence over whether or how they might ‘speak up’.

Main perceived facilitator:
- health care professionals take time to establish a rapport with patients and demonstrate a willingness to listen to, and address their concerns.

Potential barriers:
- ‘busyness’ of clinical environment
- patient is unable to ‘speak up’ (e.g., ill, feeling vulnerable, language difficulties)
- lack of underpinning knowledge of clinical condition
- patient unaccompanied by family member or representative
- fear of recriminations
- patient reluctant to ‘break trust’ with health care professional

3.1 Patient safety: roles and responsibilities

Study participants expressed a desire to become involved in a range of patient safety roles to varying degrees, dependent on factors relating to themselves, the clinical environment, the nature of their relationship with health care professionals, and the perceived level of ‘challenge’ associated with the role. These factors were perceived as potentially limiting the extent
to which patients (or their family members or representatives) could, or should be expected, to take responsibility for ensuring their own (or others’ safety) during delivery of health care services.

Many participants (in particular, parents of children with asthma) suggested that responsibility for ensuring safe delivery of health care could be shared between patients (and/or family members or representatives) and health care professionals.

Parent respondents reported that they assumed an active role in ensuring their child’s safety in making use of health care services in both community and hospital settings; they described how they monitored the child’s condition, accessed specialist advice and treatment in a timely fashion, commenced and administered medications appropriately, and, whenever possible, stayed with the child during hospital admissions to help ensure their safety. These respondents appeared to have a close relationship with the health care professionals looking after their children, and to have negotiated boundaries for sharing responsibility, based on a relationship of mutual trust.

‘it’s been a partnership really, the best thing is to work on it together…he [medical clinical specialist] says, you know her better than I do…if you see the first sign of her going down hill, you know exactly what to do…so I do…he knows I’ve known what she’s like for long enough…if she looks like she’s not coping, he knows that I’ll phone.’ (308)

‘they know he’s safe when I’m there, and I know he’s safe there when I’m not there’ (303)

The view of the majority of study participants was that ultimately, health care professionals, by virtue of their training and expertise, should be held accountable for ensuring patient safety, and that patients could not, and should not have to, be relied upon to act as a safety check in their own care.

‘if they are able to do so, I think people have to take a certain responsibility…I don’t think everything should be left to the nurses, but your medical care
should be…you should be able to feel your medical care is in the right hands as regards your tablets and things…’ (509)

‘as a carer and parent, you shouldn’t have that responsibility in hospital’ (512)

‘it’s [safety] their prime function and they should be doing all they can…’ (401)

Only one interviewee, respondent (205) expressed concern that in the current climate, when patient participation and involvement are being actively promoted, the burden of responsibility for safety could subtly be shifting from health care professional to patient.

‘I see it as a partnership in terms of going for a consultation with somebody who had got all that training and expertise and experience but acknowledging that everyone’s slightly different and that you do have some, you might not always be able to articulate it, but you do have some understanding about the workings of your body and how you function which could be quite helpful to that person…it’s more a partnership, I think that’s a good approach to have really. But I suppose it just worries me about this emphasis on the responsibility is with you. I can’t help but feel sceptical sometimes it’s a fine line between acknowledging that yes, you do have to take some responsibility about what you choose, treatment maybe, and what you share, your responsibility to tell as much as possible about your situation, your symptoms, whatever, but in terms of taking responsibility for about maybe your treatment or the outcome, I don’t know, I’m not quite sure, it just makes me cautious for some reason whether it’s hidden agenda or what, about putting the onus back on [patients]…maybe it’s just me being sceptical…’ (205)

Section 3 Summary Points

- In general, study participants wished to be involved in the promotion, enhancement and protection of their own safety with regard to health care through involvement in patient safety roles.

- However there was widespread recognition that various factors could impact on patients’ (or their representatives’) willingness or ability to take on such roles, relating to characteristics of the patient; the nature of their relationship with health care professionals; the level of
challenge associated with the role; and the context in which the role might be enacted.

- The view of the majority of participants was that, ultimately, health care professionals should be held accountable for ensuring patient safety, and that patients could not, and should not have to, be relied upon to act as a safety check in their own care.

4. PATIENTS' VIEWS ABOUT CONTRIBUTING TO REPORTING SYSTEMS

Section 4 of the report describes study participants’ views of contributing to reporting systems, under the following subheadings:

4.1 Patients’ views concerning NHS learning
4.2 Participants’ views about reporting systems that they are aware of and about those described by the interviewer
4.3 Types of issues that patients might consider reporting
4.4 Features of reporting systems that would make it more or less likely that patients would report

4.1 Patients’ perceptions of whether and how the NHS tries to learn from mistakes and situations in which patients are harmed in the course of healthcare

Study participants were ranged along a spectrum of opinion concerning whether the NHS learns from its mistakes and takes account of situations in which patients have suffered harm. At one end of the continuum stood respondents who said they ‘hoped’ that learning was on-going, and alongside them were respondents who quoted examples of areas where believed they had seen positive changes take place as a result of learning. At the other end of the spectrum were a smaller number of respondents who believed emphatically that the NHS did not learn from its mistakes; these individuals alluded to errors being covered up and the presence of a blame culture within
the NHS, and they drew on their own and/or others’ experiences to give examples of where they felt learning had not taken place. In between, stood several respondents who indicated that it would be difficult for them to gauge the extent of learning, as they had no way of knowing about it.

Quotations from three respondents illustrate positive views of NHS learning. As a practising doctor, respondent (607) referred to NHS learning taking place as a result of routine clinical governance processes, including investigation of patients’ complaints and audit of adverse events; respondent (203) seemed to think that the NHS would learn from mistakes in the same way that individuals learn; while participant (208) believed that some of the changes she had observed were the result of lessons learnt.

‘If say a health care professional has made a mistake then the people, the administrators or whoever it is who deal with the complaints, will take it to the relevant health care professional, so they’ll be aware that they’ve made a mistake, they’ve then got to try and explain themselves or put their side of the story’ (607)

‘I think everybody learns by their mistakes, they’ve got to, that’s life, that’s how we all, you think you’ve finished learning and then next week you’ll learn something else don’t you, and you think, ‘Oh, god. You never stop learning, do you?’ (203)

‘I think they try and learn, you know, like the MRSA, they’ve put hand cleaners on wards and they ask people to do it, even visitors. They do try and make a difference.’ (208)

Possible reasons suggested for a lack of progress in NHS learning were lack of funding to implement changes, tensions between managers and clinical staff, and the difficulties of effecting change in a large organisation.

Respondent (507) highlighted some of the difficulties associated with bringing about change in a large organisation like the NHS.
'I think the honest intention is there but it's a bit like trying to turn a tank around, isn't it, I think it takes a long time and you don't know whether it's happened or not...I think our national health [service] does try hard and we are lucky to have it' (507)

Asked whether he thought the NHS learnt from mistakes, participant (401) responded that 'the jury's out on that one'. He went on to describe how he believed that managerial interference, in the form of financial restraints, could hamper medical staff in their efforts to improve services, a point taken up by participant (308).

'when you criticise the national health [service] you've got to be careful that there are two sides to it. There's the administration and the medical, and to a degree I think they are both fighting each other...the medical people just want to get on with their job, there's too much interference and there's too much, you know, accounts are taken in...' (401)

'I think they're trying all the time to overcome problems and learn from things that have happened in the past, it's just unfortunate that the Government doesn't want to give them enough money to sort of fund these things' (308)

Amongst the respondents who felt the NHS did not learn from its mistakes, respondent (202) attributed her views to her general impression of how errors are handled in the NHS; respondent (304) referred to hearing of the same kinds of events 'again and again'; while respondent (605) echoed (304)'s views, and also described in some detail a failure in basic care delivery that has long been identified as detrimental to patient care (and highlighted recently as an area of concern by the National Patient Safety Agency) yet which remains widely unresolved within the NHS.

' I get the impression that there's probably quite a lot of cover ups of mistakes....I have a suspicion that in health services there's probably a lot of muddling over and hoping and keeping your fingers crossed' (202)
"I suppose they try to learn but they don't seem to differ. Nothing seems to get better. I mean they are good at what they do, they are helping people, but you still hear horror stories, the same kind of thing again and again. So if they're trying to learn, surely they'd stop, there wouldn't be as much" (304)

"I suppose you shouldn't believed everything that you see and read, but you talk about other people's experiences and the same thing seems to happen over and over again, you speak to somebody and they will say 'Oh yes, that happened to me, or that happened to my mother or daughter-in-law, and you think yes, it's still out there...I had a friend across the road whose wife got Alzheimer's or was it dementia, I'm not sure...but he had to go every day of the year and feed her, once a day, so he knew she had one meal, and sometimes he would be feeding other patients as well, and they still haven't learnt, they are still doing that, you know 12, 13 years ago, was happening, and here we are, I have a friend living across the road still doing that, all these years later" (605)

4.2 Views about reporting systems that participants are aware of and about those described by the interviewer

Overall, study participants were largely unaware of the existence of national reporting systems; they were more likely to say they had heard of, or had experience of using, local hospital complaints systems, such as Patient Advice and Liaison Service (PALS). None of the participants referred explicitly to having heard of reporting systems in general practice. Participants also referred to having used, or suggested, the introduction of questionnaires or 'suggestion boxes' as a means of measuring patient satisfaction with care on hospital wards. In some instances, respondents highlighted a need for the co-existence of local and national reporting systems in order to capture information about incidents as they occur in a specific local context, as well as information of a more general nature which would have wider applicability.
4.2 (i) Awareness of national reporting systems

Study participants revealed very limited awareness of current centralised reporting systems operating at a national level. It was generally agreed that such systems could be a valuable means of promoting learning within the NHS, as well as benefitting patients, as long as patients' reports were valued, monitored, and acted on.

Of the 30 study participants included in this analysis, only 2, participants (202), a clinical psychologist working in the NHS, and participant (607), a doctor, said they had heard of the Yellow Card reporting system, which allows voluntary reporting of suspected adverse drug reactions by health care professionals, and, more recently, by patients.

Similarly, only two participants appeared to have heard of the National Patient Safety Agency's National Reporting and Learning System; participant (603) who was a nurse working in a care home for the elderly; and participant (302) who said she had seen a leaflet about the National Patient Safety Agency during a hospital visit.

Of the 4 qualified healthcare professionals included in the sample, only one, (603), seemed to be aware of the NPSA's Reporting and Learning system.

Participant (508), a specialist nurse who recalled an incident in her clinical practice when she had mistakenly given a child an injection of insulin that had passed the expiry date, made no mention of making seeking advice from, or making a report to, the NPSA about the incident.

'I mean the incident with the little one who had the expired insulin, I told the mum exactly what I was going to do because the answer was I didn't know so I had to go and find a drugs company and find somebody in that company who would be able to tell me how much the drug would have degraded over time, what implications there would be for the child's care, what we should do about the dosage, all that kind of thing, and I said to the mum, this what I am
going to do and also there is a procedure to make sure that this gets investigated and it doesn’t happen again and I don’t know what it is but I’ll get back to you as soon as I’ve found out.’ (508)

Only one participant (607), a practising doctor, mentioned the routine use of incident forms to record adverse events in patient care.

4.2 (ii) Awareness of local reporting (complaints) systems

Three patients who did not know where or how to direct a complaint or concern about their care said they would seek advice from their general practitioner about who to report to, and to check that their concern was valid.

‘If I had concerns about my care I don’t know who I would go to. I think if I thought it was important enough I would probably check it out with somebody like my GP who wouldn’t have any direct responsibility for it, but just because I would want somebody to say, yes, you have got a point there, and it is worth making an issue of it… I would want somebody backing me up saying, yes, you’ve got a point there’ (202)

In contrast to an almost blanket absence of knowledge about national reporting systems, many, though by no means all, of the study participants demonstrated that they knew about local incident reporting systems in the form of hospital complaints procedures.

‘I had a word with somebody else, they said this Patient – I’ve forgotten his title but he’s like the patient liaison person that you can channel things through and they said maybe you need to talk to him on a one to one basis…’ (205)

Several participants highlighted their perception of the need for reporting systems to exist at both local and national level if safety issues were to be tackled effectively. If systems were in operation at both levels, problems could be resolved locally within the context in which they occurred, and where
there was a wider lesson to be learnt, it could be fed into a central reporting system.

‘the national point could be good because it could highlight something that is happening in various parts of the country but action has to be taken on a local basis I think, really you’d end up having to report it in two places to make sure it is covered… (507)

Patients with mental health problems and those with diabetes were least likely to say that they had heard of, or used, the Patient Advice and Liaison Service (PALS); amongst the other groups of patients were individuals who had had varying experiences of using the service, some positive and some negative.

Participant (512) appeared to have anticipated suffering repercussions when she informed ward staff that she had made a complaint via PALS.

‘I just made them aware that I’d made a complaint just in case somebody didn’t know and they all said, we know, but they didn’t come in and say, Oh, that’s her that made that complaint’ (512)

Local hospital complaints systems were viewed with a degree of scepticism by some participants who believed that complaints would not acted be on.

‘acknowledged, filed and forgotten’ (508)

‘I think they need to have somewhere to report to, because it won’t necessarily get moved up the line if you report something within a hospital, they are going to want to sit on it, because it doesn’t look good for them.’ (605)

‘I feel sceptical about that – I might be wrong about that but I think of it like rubberstamped – I don’t think it will get to the people I want to feed it back to…(205)
4.2 (iii) Participants’ preferences for face-to-face reporting

Mothers of asthmatic children were the participants most likely to say that they would prefer to deal with staff on a face-to-face basis rather than making use of a written reporting system, but individual patients from all the clinical groups indicated that they preferred to register a concern or complaint in this way (a), because you could ascertain whether your concern had been listened to, and (b), because there was the potential for a speedy resolution to the problem.

‘a form doesn’t mean owt. You could fill in a form any day you want, whereas if you talk to someone, you know that person is going to take notice of you and that person is listening to you about what your problem is and you’d think that person would go all the way and sort it out’ (302)

A perceived benefit of this approach was the opportunity it offered to address front line staff directly, coupled with the potential to move your complaint up the clinical or managerial hierarchy. Participant (308) said she would address initial concerns to the clinician in charge of the unit, but that she would also be prepared to pursue her concern at managerial level.

‘always face to face has to be the best answer because you’re actually putting your concerns to the people that need to know’ (609)

‘well, whoever was in charge of the unit and then take it to the Trust if it needed to go further…you have to be diplomatic about it, but in the same token, you want to make sure it won’t happen again…you need to make sure that the person who’s in charge of that particular person at the time, like the ward sister or whoever it happens to be needs to be aware this happened.’ (308)

Participants who were asked if they thought patients would be willing to be involved in feeding back concerns about their care to clinical and governance staff responded positively to this idea, with the proviso that the patients should
be able to exercise choice about whether or when to participate in such a scheme.

‘like coming from the horse’s mouth, from the patient, instead of going round and round, and you know, people adding things to what was originally started…I think if it came direct from the patient, I think they have better chance of correcting what had happened’ (303)

‘when I am mentally ill in hospital I couldn’t do it, no…but you could be on your getting well curve, so at that stage, yes…’ (605)

There were suggestions from three participants that learning could take place at a local level from routine measurement of patient satisfaction, in the form of questionnaire surveys or comments from patients about their experiences in hospital.

‘like when you go on holiday some of the tour operators say do want a form to ask what the hotel was like, was it clean, were the staff polite, something along those lines where you discover the day to day activities of the hospital, food…’ (401)

4.3 Types of issues patients might consider reporting

4.3 (i) Why do patients want to report mistakes?

Where study participants mentioned motivation for using national reporting systems, the main driver appeared to be the desire to prevent a similar occurrence of an error or harm in others.

‘I think they [accidents and near misses] should be reported because then…people can learn from it and also be aware of future situations occurring, you know, they can sort of make sure procedures are in place to avoid things happening again’ (308)
With regard to the use of local (hospital) complaints systems, patients’ interviews revealed that they were primarily seeking recognition of their concerns, to have them dealt with in a fair manner, to gain an apology where appropriate, and to prevent something similar happening to others. The prospect of gaining financial compensation did not appear to be uppermost in most participants’ minds; only three respondents referred to compensation or litigation issues.

Respondent (508) a qualified nurse with many years of experience, offered a summary of reasons why patients report errors at a local level which accorded well with what patients themselves said.

‘I think the reasons that people complain are probably very individual... in some complaints it’s that they want to be heard. In some complaints it’s that they don’t want it to happen to somebody else. I think that there are different reasons why people complain and to just say that people want compensation isn’t true. I suppose it just depends on what happened and how bad it was’.

(508)

4.3 (ii) What kinds of mistakes or safety issues would consider patients reporting?

The kinds of errors that most respondents said they would consider reporting were the ones they judged as ‘serious’, according to their perceptions of the degree of physical or psychological harm that might result. However, as can be seen from the quotation from participant (203), patients did not always seem to be aware of the safety implications of certain acts or omissions by health care workers.

‘If I felt really strong about it, then I would like to, but if it was just nit-picking and one thing and another like well, I didn’t see her wash her hands, or maybe not. But if it was something really serious, where you’ve seen an old lady drop out of bed or whatever and she didn’t get dealt with straightaway or something like that...’

(203)
Some participants believed that patients should report any matter that concerned them, no matter how trivial it might seem, as it could be important to somebody else’s well-being.

‘it’s not worth it if it’s niggling little things or petty little things…but if it could make a difference to somebody else who’s going to have the treatment or whatever after then, yeah, it’s worth saying something’ (208)

Errors that they described as ‘nit-picking’ would not be reported; indeed, patients implied that ‘minor’ errors, that is ones which did not result in serious harm, were to be expected, and that they should be tolerated or ‘forgiven’ (603) at the time they occurred.

‘I mean, for minor things, you just have to sort of agree and put up with it, as long as you can came out alright at the end of the day’ (401)

Most respondents talked in general terms about the kinds of errors or concerns they would report, assigned to the category of ‘serious’, such as medication errors, but a few mentioned specific examples of more ‘mundane’ undesirable events that were worthy of reporting, for example, being left to wait a long time for a bedpan; staff who behaved in an abrupt fashion towards you (401); or being left in pain (407).

Errors which had actually caused harm to participants seemed to be considered more likely to be reported than ‘near misses’.

4.4 Features of reporting systems that would make it more or less likely that patients would report

Features of reporting systems cited by participants as conducive to reporting included: high visibility; easy accessibility; incorporation of feedback mechanisms (including evidence that the information provided by patients is valued, monitored and acted upon); optional anonymity; and freedom from
repercussions, for both staff and patients. Implicitly, patients would be less likely to use a reporting system where these features were absent.

Visibility

Interviews revealed that many people were unaware or confused about how to report errors or concerns, and three participants (407, 309, 202) said they would need to seek advice from their general practitioner about how to proceed.

‘It should be advertised shouldn’t it? When you go, I mean, that should be part of the information you are given. That should be automatic to all patients really’ (609)

‘the trouble is now there are so many layers isn’t there, so many layers in the system even the hospital that you don’t know any more who’s really in charge and who you can really talk to. It’s not straightforward anymore.’ (407)

Accessibility

One participant mentioned that patients whose first language is not English could be prevented or deterred from participating in reporting systems because of the language barrier.

‘they don’t take it further. They just accept mistakes quietly because sometimes language holds them back to express themselves and things like that they should take them further’ (104)

Being able to access the reporting system easily was identified as important to patients at a time when they might be feeling at a low ebb.

‘it takes energy when you are having all this treatment as a patient, it depends what energy you’ve got as well at the time…’ (205)
‘a lot of people just can’t be bothered to report things’ (511)

Feedback mechanisms

Provision of feedback for people using any reporting system was identified as crucial by over half of those interviewed. Patients wanted to know that the information provided by themselves would be valued, monitored and acted upon; that it is to say, that it would not be ignored, dismissed, set to one side or ‘brushed under the carpet’ (202), in a time wasting process - ‘another tool in the administrator’s armour[y]’ (401)

‘paper filling in is fine as long as somebody is actually going to read it and do something about it…in a lot of cases, it’ll just get put over there’ (208)

‘I think whoever it was you were reporting to would have to adopt a means of indicating to you that information you were giving them was valuable…there’s nothing worse than saying something to somebody and them making a reply that reading between the lines they’re saying, I don’t know why you are bothering telling me this, you know, and I think it has to be acceptable that what you’re saying is valid’ (406)

‘…the impression I have sometimes is that things get brushed under the carpet…if I had the confidence to report something and thought it was worth making an issue about, I think I would want feedback about what had happened about it’ (202)

Anonymity

Opinion was divided as to whether participants would prefer reporting systems to be anonymous or not; some suggested that anonymity should be optional, according to the patient’s wishes. Interestingly, 3 of the 4 qualified health care professionals in the sample expressed a preference for anonymity if they were to use a reporting system, perhaps due to sensitivity about their dual status as patient and colleague.
‘I would like to report those two aspects [of her maternity care] anonymously so that health care professionals would change their practice so that it wouldn’t upset other people’ (607)

‘I assume there are things, you could report things anonymously and say, I’m aware that this has happened, I don’t want to say who I am, but can you please investigate’ (202)

Fear of repercussions

Participants’ main reason for preferring anonymity in reporting was a fear of repercussions, for the patient and/or for the staff concerned, if their identity were known.

‘I would probably initially want it to be anonymous, because I feel they do, it does react on you the system, because it will sort of put a little note on your thing, it’ll be a little such and such, you don’t know yourself, because I know these days you have access to our notes, but yes, I think it would be noted against you’ (605)

‘you don’t feel safe in reporting things, it’s like a witch hunt’ (402)

Having access to a central, rather than local, reporting system was perceived as advantageous as it was considered less likely to result in blame being assigned to individual clinicians.

‘so there’s not a blame culture but a learning [culture], and people don’t learn when they’re under stress or feel that it’s being complained about, so its’ sort of a no blame thing’ (607)
Section 4 Summary Points

- Opinion was divided amongst study participants about whether the NHS learns from its mistakes ranged along a continuum; around half of study participants said they thought positive changes occurred as a result of learning; others said they did not know how they could gauge whether learning occurred; while a minority held the view that errors were routinely covered up and that a ‘blame culture’ existed within the NHS.

- Overall, study participants were largely unaware of national reporting systems, and they had limited knowledge of local systems.

- Features of reporting systems cited by participants as conducive to reporting included: high visibility; easy accessibility; incorporation of feedback mechanisms; optional anonymity; and freedom from repercussions, for both staff and patients.

FINDINGS FROM FOCUS GROUPS

This section of the report, which describes the findings from the focus groups, comprises the following subsections:

1.1 Purpose of the focus groups
1.2 Focus group participants
1.3 Composition of the focus groups
1.4 Findings from the focus groups
1.5 Summary of findings
1.1 Purpose of the Focus Groups

Individual interviews were carried out with study participants in order to elicit detailed accounts of patients’ own experiences of health care, their perceptions of safety during specific health care episodes, their awareness of any errors or threats to safety in the course of their care, and examples of situations in which they acted, or considered acting, to help ensure their safety. By contrast, the emphasis in the focus groups was on a more general discussion about patients’ roles in ensuring the safety of health care.

Discussion in focus groups was supported by the use of illustrative vignettes (see Appendix 4.9), developed in part from interview data, which described health care situations in which patient safety might be compromised. In addition, a simple ‘roles exercise’, designed by the research team, based on findings from the interview data and relevant literature, was used to explore focus group participants’ views of patient safety roles.

The data from the patient and consumer groups was generated to serve as a ‘mirror’ or ‘foil’ for the interview data. By purposively employing an iterative approach to explore the two data sets, it is possible to compare and contrast the findings from each, in order to gain a greater depth and breadth of understanding of the phenomena under consideration than would have been possible from relying on either method alone.

1.2 Focus group participants

Focus groups were homogenous by clinical group within the six strategically chosen clinical groups. For each of the clinical groups, one focus group was held with patients recruited directly from health care settings, and the other group comprised participants from consumer or patient support groups. By deliberately sampling from consumer and support groups, we hoped to access a group of people who might be more likely to bring a more collective, as opposed to individual, experience to the project. In addition, we wanted to explore any particular differences in attitude and experiences of patients who
chose to be part of consumer or user groups and who are increasingly likely to be consulted about their patient experience and those who do not chose to take part in these groups.

1.3 Composition of focus groups

In total, 68 participants were recruited, of whom 19 were male and 49 were female; 64 participants were White British; 3 were of South Asian origin; 1 was Black Caribbean. Details of the composition of focus groups are given below.

**Patient Focus Group 1:** 5 participants (4 patients with diabetes, and partner of one patient) recruited via specialist diabetes service in primary care.

**Consumer Focus Group 1:** 9 participants, recruited from a local support group for people with diabetes, run by a specialist nurse in diabetes.

**Patient Focus Group 2:** 6 participants (women who had undergone treatment for breast cancer).

**Consumer Focus Group 2:** 4 members of a local support group (Bosom Pals) for people who have undergone treatment for breast cancer.

**Patient Focus Group 3:** 6 participants (parents of children with asthma).

**Consumer Focus Group 3:** 4 participants, parents of children with asthma who are members of a national support group (Asthma UK).

**Patient Focus Group 4:** 8 participants (7 people who had undergone joint surgery, and partner of one patient).

**Consumer Focus Group 4:** 5 members of a local support group, the Total Hip Replacement User Group (THUGS) (membership inclusive of anyone with any kind of joint surgery).

**Patient Focus Group 5:** 7 participants (patients (or their representatives)) who had made raised a concern or made a local complaint about their care.

**Consumer Focus Group 5:** 5 participants who had made a formal complaint about their (or a family member’s) care, and who were members of the national support group ‘Sufferers of iatrogenic Neglect’ (SIN).

**Patient Focus Group 6:** 5 participants, people with severe and enduring mental health problems.
**Consumer Focus Group 6:** 4 participants, patients with severe and enduring mental health problems who were members of the local branch of a national patient support group (Together, Working for Wellbeing).

Individual participant details can be found in Appendix 4.5. Participants who were also interviewed individually have two identifiers, a Patient Identifier, as well as a Focus Group Participant Identifier.

**1.4 Findings from the Focus Groups**

This section of the report will present findings from the focus group discussions relating to (a) participants’ views and perceptions of various patient safety roles, based on the ‘Patient Safety Roles’ exercise; and (b) synopses of situations where participants acted, or wanted to act to adopt patient safety roles; or where they made deliberate decision not to take on a particular role.

**Findings from the ‘Patient Safety Roles’ Exercise**

This exercise was designed to stimulate discussion amongst participants about specific patient safety roles. The patient safety roles on which the exercise was based are those advocated in the research literature, and they included roles that patients had identified or commented on during individual interviews held prior to the focus groups.

The exercise consisted of the following task: participants were asked to consider the set of patient safety roles listed below, and to discuss as a group whether they would classify each role as ‘easy’, ‘more difficult’ or ‘very difficult’ to fulfill. At the outset, the focus group facilitator (a member of the research team) stressed that they were no ‘right’ or ‘wrong’ answers, that we were primarily interested in hearing participants’ views of the roles, particularly their perceptions about those factors which would make it easy or difficult for them to adopt a role. The facilitator also invited participants who thought that their
views were different to those formulated by the majority of the group, to freely express their opinions.

The patient safety roles that participants were asked to comment on were:

- Ask a family member of friend to accompany you when you visit the doctor or go to hospital
- Ask questions about anything that you are not sure about
- Bring a list of your medications every time you visit the doctor or the hospital
- Challenge staff if you think they are doing something wrong
- Check any medications that you receive and ask questions if there are any that you are unsure about
- Check that a hospital has a good reputation before going in for surgery
- Follow instructions from doctors and nurses
- Learn as much as you can about your illness, condition, treatment and any tests that you might have
- Speak up if you think your care is not as it should be
- Speak up on behalf of somebody else if you think their care is not as it should be
- Talk to a surgeon about details of surgery
- When in hospital, ask everyone – caregivers and visitors – to wash their hands

Focus group findings concerning patient safety roles are presented below. Differences between the views expressed by participants in patient and consumer focus groups are highlighted.
Patient safety role: Ask a family member or friend to accompany you when you visit the doctor or go to hospital

In general, participants considered it a matter of personal preference as to whether or not they would, or did, ask someone, for example a friend, partner or spouse, to accompany them during encounters with health services.

Advantages cited were that the family member or friend could share necessary information with health care professionals, ask questions on your behalf, and absorb information that you might be too ill or upset to take in yourself – ‘what one misses the other catches hopefully’ (Participant 2, Patient Focus Group 1).

> ‘You’re up-tight, you’re worried as hell about what is happening to you. It’s your body that’s sort of packing in and falling apart at the seams…somebody else can listen in and later on say, ‘No, he didn’t say that at all’”

Participant 1, Patient Focus Group 4

However, significant perceived disadvantages were that the family member or friend could be adversely affected by knowledge of the patient’s diagnosis or treatment regime, resulting in an increase in anxiety for the patient; that their presence could undermine the patient’s own coping strategies; and that patients may wish details of their consultations with health care professionals to remain confidential. Participants who had undergone treatment for breast cancer expressed the view that health care professionals seemed to prefer them to be accompanied to appointments, in case they were to be given bad news.
Focus group participants with mental health problems commented that they would appreciate being accompanied when they were feeling ill, but that family members or friends might feel reserved or awkward about accompanying them because of the nature of their condition, or they might find it difficult to take time off work, in which case participants stated that might consider asking for an advocate from a support group such as the National Association for Mental Health (MIND), or their Community Psychiatric Nurse, to accompany them.

One participant in Consumer Focus Group 3, Participant 4, suggested that people of South Asian origin might be unwilling to allow even close family members to accompany them to health care consultations because of a disinclination to disclose medical problems.
Participants in Consumer Focus Group 5 were the only ones who suggested that it was ‘wise’ to take someone along to health care consultations, based on their prior negative encounters with health care professionals (HCPs) and they were the only group to suggest that HCPs were likely to resent patients being accompanied, particularly by a professional advocate.

‘coming from an Asian background and knowing other people in the Asian community, not everybody would want to talk about their problems to another person and that might be as close as a sister, they will be hiding everything...they will fear talking about it, leave alone...getting someone to come to the hospital is the most difficult thing for the Asian community...because it is a taboo subject to come across anything, maybe diabetes, maybe heart attack, maybe asthma, they don’t want to discuss these things, they want to keep everything under the shadow. If it happens to your daughter, no-one’s going to marry my daughter…it’s like a social and cultural aspect as well...so I would say, personally not for myself, but representing others in the Asian community, I would say that is very difficult’

Participant 4, Consumer Focus Group 3

‘I live on my own…and I’ve had professional advocates and they [health care professionals] have resented that, obviously that’s been written in my notes…’

Participant 3, Consumer Focus Group 5

Example of role enactment

Participants in Consumer Focus Group 1 discussed the benefits of taking someone along with them to health care consultations; they commented that they would find it ‘easy’ to ask someone to accompany them - participant 4 stated that she would be taking her daughter-in-law along to her next medical appointment with a consultant.
Patient safety role: Ask questions about anything that you are not sure about

Perceptions of how easy or difficult it might be for patients to ask questions were related to how ill the patient was (physical or mental illness); to individual socio-demographic characteristics (for instance, it was suggested that the elderly, or people who were ‘not quite with it’ or would find it difficult to ask, while other people might not want to know too much about their condition); to the immediate context (for example, a patient might feel more intimidated about asking questions in hospital than in the community); and to the attitude and response of the health care professional.

...there will be patients...who wouldn’t ask questions...
(1) No, my dad won’t...
(3) ...and there’s the thing about sometimes you don’t want to know, do you? Sometimes you don’t ask because you don’t want to know.
(4) I mean all these questions [patient safety roles] are based really as if you’ve got all your faculties and everything, obviously people who are not quite with it, so to speak, well, it’s going to be difficult for all these things, isn’t it?
(6) ...and people who are intimidated in that kind of situation, in hospital, you often are, aren’t you...so yes, as you say, the personality of the person...
(3) People can go to the extreme, can’t they, if they are sort of nervous of asking, they can almost get defensive and almost aggressive, it’s just that’s how they deal with it, rather than going timid and quiet…”

Extract from Patient Focus Group 5
Participants identified a number of barriers and facilitators to role enactment. Facilitators included writing questions down on a piece of paper beforehand; getting someone to ask questions on your behalf, such as a family member or your community psychiatric nurse; and belonging to a support group such as Asthma UK, which was said to instil confidence in patients.

The main barrier cited by focus group participants was the anticipated or actual response from the health care professional, linked to their ‘people skills’ and the time that they had, or made, available to talk to the patient. Participants in Consumer Focus Group 4 commented that it was harder to ask questions of nurses than doctors, as nurses were perceived as being too busy to talk to patients, whereas doctors could take time during ward rounds to answer questions.

‘It depends on the individual person… I would ask, now I would ask. Before I was in touch with Asthma UK I was totally different. OK, I would ask to a certain extent and then wait and let them say whatever they had to say and now after them saying something if I’m still not happy, I will have the guts to go out there and say, ‘Excuse me,… whatever…’’ Participant 1, Consumer Focus Group 3

(4) ‘if you’re not feeling so good, you’re not going to ask questions, are you? To be honest, you can’t think about the relevant questions… it’s going to go up and down like a yo-yo, depending on how we are…
(3) … and again, it’s dependent on how approachable the health care professional is… I think doctors are doing more in their training on the bedside manner and their approachability, but there are still the stuck up doctors…
(1) You’ve got the older one who are not very...
(4) … people skills, because it’s so vital isn’t it…’
Participants, Patient Focus Group 6
In general, focus group participants considered this to be an ‘easy’ role to carry out, and many, particularly parents of children with asthma, commented that they regularly took lists, often in the form of the duplicate form from a prescription, when they went to the hospital, though they said they would be less likely, or unlikely, to take a list of medications to an appointment with a general practitioner, as they would expect them to have a computerized record of their prescribed drugs.

A number of participants mentioned that they would have no need of a written list of drugs, as they knew exactly which medicines they themselves (or their family member) were taking at all times, though others commented that they were taking too many drugs to remember them all.
A potential barrier to this role, according to a participant in Consumer Focus Group 5, was that the patient’s list of medications might be disregarded by hospital based health care professionals, or that it was not valued by them.

Example of role enactment:

Participant 5, Patient Focus Group 6, described how the prescription which she had sent into hospital with her husband was lost, and she said that as a result he missed two doses of insulin that he should have had.

Patient safety role: Challenge staff if you think they are doing something wrong

Across the focus groups, this was perceived as the most difficult of all roles to enact; the notion of challenging a health care professional provoked a strong response from individual participants in both patient and consumer focus groups.
Within each group, however, were individuals who said they would, or had, challenged health care professionals, despite feeling uncomfortable about doing so.

Interestingly, and exceptionally, only patient participants in Patient Focus Group 3 (parents of children with asthma) suggested that they would find it ‘easy’ to challenge staff - Participant 6 commented that ‘we might not be representative of the whole population!’ (Participant 6, Patient Focus Group 3).

Discussion in the focus groups centred on a range of factors that participants thought likely to influence whether patients would challenge staff if they thought they were doing something wrong. Factors identified by participants included: patient (or their representative’s) personal characteristics; the patient’s physical or psychological health status; whether the patient was accompanied by a relative or representative to provide support; the anticipated or actual response of the health care professional; the gravity of the patient’s situation; the patient’s (or their representative’s) level of knowledge about their condition; cultural context (contrast between British and American cultural characteristics). These factors are reflected in the potential barriers and facilitators to role enactment identified by the focus group participants.
Potential barriers to role enactment

- Patient’s mental or physical condition deters them from challenging the HCP

(4) ‘sometimes when you’re in the unknown, and when you’re feeling a bit down, you just don’t have the energy to complain…’
(6) ‘…you just want to crawl off into a little hole…’

Participants, Patient Focus Group 6

- Patients lack appropriate knowledge base to challenge HCPs; it is difficult for patients to recognise when a health care professional is doing something ‘wrong’ as individual clinicians interpret and implement guidelines differently.

‘I’m not trained to do their job, who am I to tell them how to do what they’ve been trained to do?’
P2, Patient Focus Group 2

‘I think the word ‘wrong’ is always difficult in the medical profession, isn’t it? Because they, OK, they have guidelines and they have procedures but they all have different ways of practising medicine…they have different ways of treating the same condition…it’s difficult for us as non-medically qualified people’
P2, Consumer Focus Group 2

- Patients feel uncomfortable about raising any matter which might be seen as a criticism of staff’s professionalism

(6) ‘I have found it easier to question a medication and say ‘Why am I having this? What dosage? And to have a debate with the doctor about that. I found that easier to do than something like, ‘Will you use the hand gel, please?’
(2) ‘…because you are picking them up on something they should be doing as a matter of course’

Participants, Patient Focus Group
• Dislike of confrontation

(5) ‘I think it’s down to the [type] of person you are, because I don’t like any kind of confrontation, because that’s just the sort of person I am, quite shy’.

(2) ‘unfortunately when you do query something it can turn into very quickly like a confrontation. It depends on how the other person receives it…there are other incidences depending on the person [health care professional] where it has turned into like a confrontation and I’ve not intended it to be.’

Participants, Patient Focus Group 2

• Perception that challenging staff will not bring about a resolution of the problem

‘It is easy to challenge but not necessarily easy to get satisfaction.’

P2, Patient Focus Group 1

• Fear of consequences

‘there can be consequences in terms of how they deal with you and your level of care, it shouldn’t be like that…and they’d never admit that, but they do’

P1, Patient Focus Group 2

‘it should be possible to say to someone, ‘Oh, you’ve not done that quite right without actually feeling threatened that you are going to be labelled as a trouble maker or looked down upon’

P3, Patient Focus Group 6

‘carers, like as in relatives of people, they have a fear of speaking up because then think when they’re not there they [HCPs] take it out on people…they find it very difficult to challenge’

P3, Patient Focus Group 5
• Cultural characteristics

(4) ‘Are we [British people] all too polite, do we all stand back and if only we would stand up more for our rights, perhaps they [health care professionals] would take more notice…’

(3) ‘I think like you say, it’s something to do with intrinsic Britishness…we don’t complain…it’s hard to complain in a shop or anywhere else, so within a hospital…’

(4) ‘Whereas the Americans see it as so straightforward and they must take it as a straightforward issue where it’s ingrained into us not to complain…unfortunately’

Participants, Patient Focus Group 6

Possible facilitators of role enactment

• Personal confidence

‘It depends on the individual, if you’re a forceful sort of person then you are going to stand up for yourself, but then you get all the other sort of people who are more timid’

Participant 3, Patient Focus Group 4

• Patient adopts a polite approach

(1) ‘The method of challenging is quite important, if you are not too aggressive to start with you might get a bit further than if you…

(2) …If you ask politely the first time, the second time…

(3) Yes, things can be made easier by the way you approach the staff, for whatever reason. They might be doing something wrong because their mind is on something else or they might have had wrong instructions themselves.’

Participants, Consumer Focus Group 1

• Health care professional responds in a positive manner

‘There was a particular incident…and the immediate reaction of staff was so positive of, ‘That should not have happened, we will not let this happen again, we will deal with it’

P3, Patient Focus Group 6

• Patient has a good relationship with health care professional
Participant 1, in Patient Focus Group 1, felt able to ‘challenge’ the decision of one general practitioner to commence her husband on statins to treat high cholesterol with by checking with another doctor in the practice with whom they enjoyed a good relationship.

‘we stopped taking them, well, [name of husband, Participant 2] stopped taking them and we went back to see doctor [name], and doctor [name] said to us, ‘I see you’ve come off the statins [name], how are you feeling?’ Participant 1, Patient Focus Group 1

- Patient (or their representative) has extensive knowledge of their (or the patient’s) condition

‘it’s not easy, but it gets easier over time to challenge, that’s my experience’

P1, Patient Focus Group 2

(2) ‘…it’s knowing what’s wrong and what’s right…it’s easy to do once you know it’s wrong, but it’s knowing what’s wrong that’s the hard part…
(3) … and you only get that from knowledge and experience…’

Participants, Consumer Focus Group 3

- Patient has a family member or representative to accompany them

‘it’s a bit easier when you’ve got somebody with you…to back you up’

P1, Consumer Focus Group 4

- Patient perceives the situation as serious

‘I think when I felt they’re wrong, it’s usually a junior doctor and they’ve doing it according to some list or what they’ve been trained to do, or limited knowledge they’ve got and they don’t know any different and they decide to take a certain course of action, and you know because this needs to be done, and then it’s just a matter of saying, well actually, if you look at his notes, I think you need to talk to the consultant, I need you to be doing this now, and and this next, and this afterwards, and for me, I don’t find that hard, because we are usually in a life-threatening situation’

P2, Consumer Focus Group 2

A short extract from the transcription of the discussion amongst participants in Patient Focus Group 6 (patients with severe and enduring mental health problems) is included at this juncture for two reasons. Firstly, the extract
illuminates participants’ views of various factors that might influence their behaviour with regard to challenging health care professionals; secondly, it also illustrates how the dynamic nature of interaction between participants in a focus group can generate ‘rich’ data; within this short extract, every member of the focus group contributes to the discussion, using turn-taking, to underscore, expand, or contradict the previous comment.
I shall read out the first one… and it’s ‘Challenge staff if you think they are doing something wrong’.

It’s certainly not an easy one, as far as I’m concerned.

I think it’s quite difficult.

And, do you…? I’m going between more difficult and very difficult because, to some extent, it depends on, it would depend on how well I was feeling at the time. If I were feeling confident and reasonably well I’d probably put it in the more difficult category and if I were feeling really lousy, I think it would be very difficult.

My husband’s in hospital at the minute and I went yesterday and I noticed that the nurses are going around from patient to patient and they’re not washing their hands as they’re supposed to and his drip is empty and it’s now drawing blood out of his arm and you know, instead of dripping into him but I thought well, if you actually make a complaint, it’s worse for the patient, isn’t it really? So I just went politely along, I didn’t say anything about they weren’t washing their hands but I did say could they do something about his drip.

Yes.

It’s not easy. I think if you complain, your number’s marked and you’re a difficult patient.

I think I’ve a fear of that, so I’d probably class it as more difficult. That’s probably relating to my experiences in hospital where we used to live. I’ve recently had a spell in hospital here in [name of place] and actually was more relaxed with the staff, so probably would be heading towards the easier end. But again, it does depend on my frame of mind, the mood I’m in. When I’m very depressed, I think we’d be looking at very difficult. So I think I’d actually go from one end of the scale to the other depending on my mood, who I’m talking to, how well I know them.

I mean, I actually found here in [name of place], being able to speak on your [participant 3’s] behalf when you weren’t well that actually became quite easy because the staff were so approachable and positive and it wasn’t a question of complaining – more a question of bringing things to their attention that I thought they should know. But again, where we lived before, I couldn’t have, I couldn’t have done it because the attitudes were so different.

Yes, you’re right in what you say…

I think the attitudes are better now, yes, they’re better, and if you do raise something they are prepared to listen to you, yes…It has changed over the last few years.

But I think you’re right in what you’re saying; it depends on how you feel at the time, doesn’t it? And if you’re feeling pretty confident yourself, well, it’s going to get closer towards easier, although it’s still going to be more difficult.

Extract from Patient Focus Group 6
Examples of role enactment: ‘Challenge staff if you think they are doing something wrong.’

Two examples are given below, extracts from transcriptions of one focus group discussion (Patient Focus Group 2), where patient participants describe enacting the role of ‘challenge health care professionals if you think they are doing something wrong’.

In Example 1, the patient participant believed that the health care professional responded to being challenged in a positive manner on this occasion, though she commented that on other occasions when she had raised an issue, the situation had become confrontational, which she attributed to the response from the HCP.

Example 1

‘I had an incident where they were doing some chemo treatment, I had so many sessions, I think 12 – and there was genuinely was something they were doing, flushing something through and I couldn’t remember them doing this bag at all, and I sat there thinking, ’I can’t remember this, is this right?’; so I queried it, and to be fair, the chemo nurse, she was really good in this instance, she went off, she looked at the paperwork, she got another nurse to come as well, they went through it and I wasn’t made to feel as if I was challenging them as such. I was reasonably reassured about it. That was a good, more positive experience. But there’s other incidences depending on the person where it has turned into like a confrontation and I’ve not intended it to be. It’s just simply that they’re not used to people speaking up and asking a simple question even.’

Participant 1, Patient Focus Group 2

In Example 2, the patient stated that they had had to adopt an assertive stance in order to prevent the HCP doing something she perceived as wrong.
A further example, Example 3, describes how the mother of an asthmatic child (Participant 2, Consumer Focus Group 3) was prepared to challenge a doctor’s decision to ‘wait and see’ whether her child’s condition improved or deteriorated on admission to a hospital ward. Factors which appeared influential in role enactment in this case were the mother’s prior experience of seeing the child having a severe asthma attack; her knowledge of symptoms and treatment; recognition of the gravity of the situation; and a level of personal confidence which enabled her to persist with her challenge. In this particular instance, her action was ‘sanctioned’ by the specialist consultant.
Example 3

‘I remembered the occasion when he [her asthmatic child] was four… how quickly he had deteriorated…and I remembered that they had used Aminophylline and I knew Aminopylline was sort of an option, and he’s deteriorating so I said to the nurse, ‘I think you need to get the doctor now to assess [child’s name]. I think he’s deteriorating very quickly and I think you may need to think about Aminophylline’. and she rang the doctor, and he didn’t come within ten minutes so I said, ‘I meant now!’ You know, I really did mean now… [name] had been in hospital six times that year so he had been really poorly… so she did get the doctor and he came and said ‘What are the issues?’, and I said, ‘I think we need to think about giving [name] Aminophylline before he gets worse and we’re thinking about Intensive Care.’ And he said, ‘I don’t think we’re ready for Aminophylline yet, I think we can go another two hours. I’ll look at him again at 2 o’clock in the morning.’ So within the hour I decided I really wasn’t happy, so I called him back again within the hour and I said, ‘I’m actually telling you, I want to give him Aminophylline. It’s not a discussion point. I think you should give him Aminophylline now.’ And they’re getting all the lines ready and he agreed he would do that…and [name] goes into cardiac arrest in front of him. Heart stopped. I was right, and ever since then, it’s actually been written on [child’s] notes, ‘When Mrs [name] says she wants this, or he [child] is deteriorating, then listen to her’, and they [the specialist team] said, ‘you’ve got the best antennae… if you think he’s deteriorating, tell us’… and they’re brilliant. When we were in hospital this last time, I thought he was deteriorating enough to warrant Aminophylline and they gave him Aminophylline… and one of the consultants that looks after [child], I’ve heard him actually say to the students, ‘You mustn’t underestimate a mother’s knowledge and understanding of what is happening. You don’t have to ask her to qualify it. If she says she thinks they’re in pain or getting worse of whatever, you must… put that into your thinking and your diagnosis… because not every asthmatic presents in the same way…’

Participant 3, Consumer Focus Group 3

Example of non-enactment of role

In example 4, Participant 4, Consumer Focus Group 2, commented that she found it difficult to challenge staff when she was feeling anxious about seeing the oncologist for the first time after being diagnosed with breast cancer; it was her husband who pointed out that the consultant had the wrong set of notes.
Example 4

*the trouble is, you are so emotionally tied up with what is going on. I mean …my oncologist, he brought the wrong person’s notes up the first time I went to see him and he had somebody else’s notes with my name in front of him and it was my husband that said, ‘Those are not the right notes’.*  
Participant 4, Consumer Focus Group 2

Patient safety role: Check any medications that you receive and ask questions if there are any that you are unsure about

Participants in nine of the twelve focus groups classified this patient safety role as relatively ‘easy’ to carry out.

By contrast, participants in Consumer Focus Groups 4 and 6, and in Patient Focus Group 3, classified the role as ‘more difficult’ to enact. Participants in Consumer Focus Group 4 commented that patients were often not given information about medications that they were given in hospital, particularly about side effects, and nor were they given an opportunity to ask questions about them (see the short extract from the transcription of Consumer Focus Group 4 quoted below).
Participants in Consumer Focus Group 6 (people with severe and enduring mental health problems) suggested barriers to assuming and fulfilling the role were that patients might be perceived or labelled as ‘a nuisance’ by HCPs if they asked questions about medications; and that patients in hospital would be too ill to ask questions or to understand answers.

Parents of children with asthma in Patient Focus Group 3 reported that they would automatically check medications to make sure that their children were receiving the correct drugs, in the correct dosage, and they commented that their own knowledge of asthma medications enabled them to check with, or on, health care professionals’ prescribing and administration of medications.

(3) ‘You’ll get told, ‘You’ve got your tablets’, and that’s it.
(1) Yeah, ‘that’s what you are taking’
(2) I agree.
(3) That’s the answer you would get.
(5) Well, they came to me when I was in, in September with my back and everything and says, ‘Do you want painkillers?’ and I says, ‘Yes’. I think it was Codeine or something…so I was on these Codeine …I’m taking those for the pain, but what they didn’t say is…
(2) Side effects….
(5)…yes, the worse one was, you couldn’t go to the toilet. I was seven days before I could go to the toilet…now if somebody had said to me there’s a possibility that you’ll be lying in bed and you won’t go to the toilet for seven days…I wouldn’t have took those painkillers…had I known that could have been the side effect, I’d have put up with the pain.’

Extract from Consumer Focus Group 4

Participants, Patient Focus Group 3

(3) ‘you tend to just keep checking anyway, because that is what you do, even though they give it right there in front of you, you check the drug chart to make sure that it’s all been done in the right dose…’
(5) ‘it’s just second nature, you’re so used to doing it yourself…you’re just double checking to make sure what they are doing is right…’I mean once I went in and there was this new one, this Erythromycin, and I said to [her child] ‘You don’t take this! What’s this?’ [Child answers] ‘It’s a new one’. I said, ‘I don’t believe you’ and I took the file. ‘What’s this? Nobody’s discussed this with me.’ [Nurse replies] ‘We had to give it to him…Dr [name] will come and discuss it with you…’
However, the parent participants underlined that they regarded checking medications to be a health care professional, and not a parent, role.

‘I don’t think [parents should have to check], no, because it’s what they [HCPs] get paid for, they should be doing their job. We’re not there to say, ‘Here, you’re supposed to be doing this’

Participant 5, Patient Focus Group 3

This group of parent participants cited having a good relationship with staff, especially the specialist asthma nurse as facilitative of role enactment, while perceived major barriers were hospital staff, particularly agency nursing staff, not listening to parents; and parents lacking in personal confidence. The quotations below are all from participants in Patient Focus Group 3.

‘the doctor that [child] sees is really good and the specialist nurse, she’s brilliant, so between them two, we have a really good liaison between us, so I don’t find it difficult to check the medications…’ (Participant 5)

‘It is sometimes, when you’re in the hospital and you’re under their grounds, I think sometimes they don’t listen to you’ (Participant 1)

‘would you find it easy to be confident enough to ask questions?… I think that might be a problem for some people’ (Participant 6)

Participants, Patient Focus Group 3

Participants in Patient Focus Group 3 also described frequent changes to the names of medications as an impediment to role enactment, as can be seen in this brief extract from the transcription of their focus group discussion.

(5) ‘It doesn’t help when they keep changing the generic names for drugs…
(2) ‘…he started on Singulair and not it’s not Singular any more, its Montelukast..
(5) Yes, it gets confusing…’
(2) ‘If I get a different one from the chemist, I’ll say to the chemist, ‘Hey, this isn’t right’. ‘No, it’s the same one, it’s just a different name.’ ‘Right, I want the information on it. He’s quite good, my chemist, he’ll give me the information about it and say, ‘Look, it’s exactly the same thing, just the name’s changed.’

Participants, Patient Focus Group 3

Amongst the participants in the nine focus groups who classified the role of checking medications and asking questions as ‘easy’, the main facilitators cited were: being able to access pharmacy services (ringing the pharmacist
for advice, and participating in medication reviews undertaken by a pharmacist, mentioned particularly by participants with diabetes); knowing about your prescribed medications, for instance, by finding out information from the Internet, or by reading drug information leaflets; maintaining a written list of current prescribed medications as a useful means of checking that medications that you are given are the right ones, particularly in hospital; and engaging with health care professionals on occasions when they do give you information about prescribed drugs (for example, participants said that general practitioners would usually take time to give information about why they were prescribing particular medicines).

Barriers to role enactment cited by participants in the nine focus groups were that hospital nurses were perceived as not having time, or making time, to listen to or answer questions; and anticipated (or actual) negative responses to questions from health care professionals (nurses rather than doctors).

‘I’d say, ‘OK, right, what is that?’ ‘Oh, it’s antibiotics’ , ‘Yes, what antibiotics? What strength? Why are you running it that way? Why are you doing it in that order?’ And they did get a little bit annoyed sometimes…’
Participant 2, Patient Focus Group 5

Across all 12 focus groups, participants reported that they were given little or no information by health care professionals about potential side effects of medications, though in some cases patients accessed this information from elsewhere.
Examples of role enactment, and non-enactment

In Example 1, Participant 4, Patient Focus Group 1, described how she had been given aspirin on discharge from hospital; as she was taking warfarin, she had been cautioned by the ward sister that she should not take aspirin, and so she queried the prescription of aspirin with a nurse; participant 4 did not regard the response she received from the nurse as satisfactory, so she decided to not take the aspirin until she carried out a further check with her cardiologist.
In Example 2, participants commented that they had not asked any questions about the injections given in hospital because they had compete faith in the health care professionals looking after them. Participant 7 suggested that patients should not have to be responsible for checking their medications, and that patients should be given more information about their medicines prior to discharge from hospital.

Example 2

(7) 'you presume that they know what they are doing… I mean we used to get these injections into our tummies everyday, did you get the injection into your tummy, and I still don’t know why that was, do you know why?  
(1) I got them…  
(6) It was to stop you having blood clots…  
(1) Oh, that’s right…  
(6) It was a kind of warfarin [sic] type thing…  
(7) But it wasn’t until I came out that I actually found out…  
(2) The bruises… I’m going back, I want a refund!  
(3) Yeah, I didn’t know what them was for… they just said, ‘you’re having these injections’… I would have been like you and I would have accepted every tablet given to me by the doctor…’  
(7)…. I think we should not need to do some checking up… we shouldn’t need to check up… somebody should come, the day before you are coming out, and sit with you, for at least a quarter of an hour… that’s not a long time… it should be made a thing that they come and sit with everybody that leaves and then you would go home with a much better understanding of your own care afterwards…’

Participants, Patient Focus Group 4
In Example 3, Participant 4, Patient Focus Group 2, described how she raised a concern about the dose of herceptin she was being given in hospital, based on perception that the ‘bag’ of fluid being used to administer it was too big. Participant 4 reported that subsequent checking by the nurses revealed that she had been about to be given an incorrect dose of the drug.

**Example 3**

‘I had a bad experience with herceptin…the first one you have is something like 600 mls, I might have got that the wrong way round, a high dosage, and the second time I went, she was going to give me the same as the first time, and I checked and I said, ‘Is that right, that bag, because it looks quite large to me?, and she said, ‘Oh yes, it is, isn’t it?’ and they had to take that away and get a new one made up because they’d given me the wrong dosage, so every time I went then, I made sure it was a small bag and not a big bag…’

Participant 4, Patient Focus Group 2

Example 4 also illustrates an occasion when a patient suspected that they had been given the wrong dose of a medication in hospital. In this case, Participant 2, Consumer Focus Group 2, spoke up to query the dose of warfarin she was being given, and she reported that staff responded in a very positive manner.

**Example 4**

‘I’ve had several occasions during my emergency admissions, there was one, I was given the wrong dosage of Warfarin tablet and I knew it was the wrong one by the colour and I just challenged it and no problem with that….staff here were fantastic.’ Participant 2, Consumer Focus Group 2

**Patient safety role: Check that a hospital has a good reputation before going in for surgery**

Across the focus groups, this patient safety role was classified as ‘more’ or ‘very difficult’, to carry out, or even, in the words of one participant, ‘damn nigh impossible’ (Participant 1, Consumer Focus Group 4).
Most of the discussion in the focus groups centred on barriers to role enactment; similar barriers were identified across all the groups.

Few participants appeared to have actually checked the reputation of a hospital prior to having surgery, although some of those undergoing joint surgery, and women having surgical treatment for breast cancer, said they had attempted to check, with varying degrees of success. Within these two groups, some participants said they had checked the reputation of individual surgeons, by talking to patients they had already treated, or to family or friends who had connections with health care professionals through their work.

Potential barriers and facilitators are discussed under a series of headings below, illustrated by quotations from the focus group members.

Potential barriers to role implementation

- difficulty accessing and interpreting information

Participants appeared unsure about what kind of information they should be looking for; where they could find it; how to access it; and how to interpret it.

‘You know, good reputation, in terms of what?’ (P6, Patient Focus Group 2)

‘I think checking would be very difficult, for where do you go for the information?’ (P6, Patient Focus Group 3)

‘How do you do that…Google?’ (P4, Consumer Focus Group 3)

‘I don’t know what the procedure would be for checking. I know that they have league tables and things’ (P1, Consumer Focus Group 2)

Access to the Internet was regarded as the easiest way to get hold of relevant information, and lack of access was perceived as an obstacle.
Participants with well developed computer skills suggested that getting hold of information could be relatively easy, but that it could be difficult to make sense of statistical data; or to know whether or how organisation-wide data might apply to themselves as individual patients, or how much weight they should attach to it in comparison to other factors.

Comments from focus group participants revealed feelings of scepticism in relation to hospital data generated by the NHS; these views were prevalent in both patient and consumer focus group discussions.

Sequential quotations from participants in Patient Focus Group 3 and Consumer Focus Group 4 are reproduced here to illustrate this point.

(4) ‘What about the information…it’s not other people’s opinions, it’s a matter of what they [the government] put on there…’
(5) …Yes, it’s conjecture.
(6) …I don’t trust league tables because I think they are there to suit what the government wants to send out as a message’

Patient participants (Patient Focus Group 3)

(1) ‘The government put out a list every year, the national health puts a list out of your top hospital and your low ones….
(2) I’d take that with a pinch of salt…
(3) I was going to say, how near the truth is it?’

Consumer participants (Consumer Focus Group 4)

Unlike the majority of focus group participants, some of the members of
Consumer Focus Group 5, who had been dealing with hospital complaints systems over a number of years, revealed a sophisticated knowledge of hospital league tables, and other quality indicators, gained over time as they pursued individual complaints on behalf of themselves or their family members.

‘there’s a Doctor Foster database which can give you an indication and there’s a clinical risk management system set of standards… and obviously the health care commission’s reports which are not very precise but indicative, any health and safety improvement notices that you can see on the Internet, there’s databases related to disposal of clinical waste, because you are not just talking about your surgeon, it’s the whole system you are interested in… if a hospital has a CNTS level 1, it’s at the basic, it hasn’t got risk management in place. If it’s a 2, it’s reasonable, if it’s at 3, it’s the best you can get… Dr Foster will give you an indication that if you’ve got the choice between that hospital or that hospital… on the basis of that data, that’s the one to go to.’

Participant 2, Consumer Focus Group 5

- perception that patient choice was limited or constrained by other factors

Participants suggested that although they knew they were being encouraged to select a hospital provider on the basis of its official ratings in league tables, they would not know how they could act on that information to ensure they were treated according to their choice; moreover, they said the decisions they made would, de facto, be circumscribed by a number of other factors, some within and some outwith their control; for example, how they are feeling at the time that they must make a choice; feeling pressurised to make a choice; how quickly a bed might be available to them; the distance of a hospital location from friends and family, and whether or not the specialist or consultant whom they had been referred to worked in a particular hospital.
Facilitators of role implementation

The main facilitator of role implementation identified by participants was the role played by general practitioners in assisting them to select an appropriate hospital, either through the literature that they made available to patients visiting their surgeries, or verbally.

‘If you do know, do you have a choice? If you do know a hospital has good or weak ratings, are you actually in a position to do something about that? Can you choose to go to the good, better place, or can you avoid the less preferable option?’ (P2, Consumer Focus Group 3)

‘I think if I knew a particular area was renowned for fantastic knee surgery and I needed surgery and I wasn’t bothered about visitors or anything, I think yes, I would find it quite easy to say, No, I’d prefer to go there…if there were no other things to take into mind…’ (P3, Patient Focus Group 6)

‘When you are given that diagnosis [of breast cancer] you’re not thinking at the minute in time where I want to have my operation…you want to get it done now… (P4, Patient Focus Group 2)

‘on the spur of the moment, when the doctor’s saying, ‘I’m referring you, where do you want to go?’ How do I know?’ (P3, Patient Focus Group 6)

‘we had a choice of several hospitals within the area… I was drawn by the timescales… in actual fact it was a rubbish hospital, that was probably why we could get in there so quick…’ (P3, Consumer Focus Group 3)

‘transport is vital isn’t it, because if you’re going to be stuck twenty miles away, who’s going to be able to visit easily, you get no visitors if you’re stuck on a limb…’ (P4, Patient Focus Group 4)

‘well, I asked the doctor [general practitioner] before I went in if I could choose the hospital and he said, ‘Well, no, because you’re going to the hospital where your specialist is going to see you, it’s obvious, he’s not going to go to another hospital, so if you want to go to another one, you have to start again, and get another surgeon’, so really, you haven’t got a choice…’ (P6, Patient Focus Group 4)

‘I did pick up a leaflet at my GP’s surgery talking about you’ve got a choice of hospitals and it was actually telling you, you know, how to find the information… our surgery is pretty good. It has all these leaflets…’ Participant 5, Patient Focus Group 6
Older participants, mainly those in Patient Focus Groups 1 and 4, suggested that they would prefer to rely on their general practitioner or other health care professionals to suggest a suitable consultant surgeon.

‘Talk to people in the know, that’s the only way. There are publications that are put out… but you can’t always find out about individual surgeons. I mean, I’ve always said to doctor [name], ‘I need my cataracts doing, who’s the best guy that I can see?’ I also had a friend who used to work at [name of hospital] and I used to cross check it with her…and that’s the way I’ve checked, but not everybody can check that way.’ Participant 1, Patient Focus Group 1

Participants appeared to find it easier to check the reputation of an individual surgeon than a hospital reputation, and several of the patients undergoing treatment for breast cancer said they had done this.

‘Mr [name] offered to pass on previous clients… I’ll call them, previous patients. He said, ‘By all means, phone them and find out what they think of my work, so he was very, very open about it’ Participant 2, Patient Focus Group 2

Examples of role enactment

Two participants in Patient Focus Group 4 discussed their attempts to ‘check that a hospital has a good reputation before going in for surgery’.

Participant 3, Patient Focus Group 4, reported that he managed to find information about hospital acquired infections (HAIs) in local hospitals prior to his wife’s joint surgery.

Participant 5, Patient Focus Group 4, said she was accustomed to using the Internet but nonetheless described a fruitless attempt to find the information she wanted.
Patient safety role: Follow instructions from doctors and nurses

This patient safety role was classified as ‘easy’ to fulfil by members of the majority (nine) of the focus groups; however, participants in Patient Focus Group 5, and Patient and Consumer Focus Groups 6, perceived the role as ‘difficult’ or ‘more difficult’, which they attributed to issues of communication with, and lack of trust in, health care professionals (Patient Focus Group 5); to perceptions that it would be difficult to carry out the role when feeling mentally
unstable or ill (Patient Focus Group 6); and to perceptions concerning the nature of the relationship between patients and health care professionals (Consumer Focus Group 6).

Members of Consumer Focus Group 6 (people with severe and enduring mental health problems) expressed polarised views about their expectations of this patient safety role. Half of the group questioned the assumptions underlying the role, commenting that they would expect their relationship with health care professionals to be based on a partnership, rather than a paternalistic approach, whereby patients unquestioningly followed HCP instructions, and they suggested that as their knowledge of mental health problems increased, they would be less likely to automatically follow instructions. By contrast, remaining group members said they had been brought up to respect HCP expertise, not to question it.

A short extract from the transcript of the focus group conducted with patients with severe and enduring mental health problems (Patient Focus Group 6) illuminates their views about some of the barriers and facilitators to role enactment. As a group, they said they would find it more, or less, difficult to

```plaintext
'I wouldn’t automatically follow instructions, I would want to know the ins and outs of something. I wouldn’t expect to receive instructions. I would expect to receive a working partnership with a doctor or nurse and make decisions together about what we were doing. I certainly wouldn’t be following their instructions.’ (P1, CFG6)

'I find that personally quite difficult because I come from that generation where doctors were sort of up on a pedestal and they’re the experts who know everything…’ (P3, CFG6)

‘I’d be much like you. I was brought up sort of like the doctors tell you what to do, give you things and you sort of do it. For myself, I wouldn’t question what a doctor says to me’ (P4, CFG6)

‘What I’ve come to learn since I’ve had mental health problems is that it becomes self evident that the doctors and nurses don’t always know fully what they are about and there’s been instances where clearly some of the things, some instructions we’ve been given are clearly wrong, and I would question them, and I do, reluctantly at first…’ (P2, CFG6)
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Participants, Consumer Focus Group 6
carry out the role depending on how ill or well they felt, and that their ability to fulfil the role could be affected by short term memory loss (often associated with medication). Having someone accompany them to medical consultations to take note of any instructions, or being provided with written instructions, were some of the possible facilitators they identified. Like participants elsewhere, these participants identified a prior willingness to comply with HCPs’ instructions as integral to role fulfilment.

Extract from transcription of Patient Focus Group 6

(4) **Follow instructions from doctors and nurses.**
(2) I generally do. But sometimes I don’t want to.
(5) But when don’t you want to?
(2) When I’m actually at my rock bottom worst.
(4) Of course. Yes. But that’s…
(2) Or away with the fairies in the other direction.
(4) Yes, the two extremes.
(3) And they can be very confusing the instructions they give you, you go away and five minutes later you can have, ‘Now what was it?’
(4) Yes
(3) I know recently I’ve had a lot of problems with my memory so somebody actually wrote that down what they’d asked me to do, which was fantastic because…
(4) And that’s what they need to do.
(3) An hour later, I could look at it and think, ‘Yes, right, I can do that.’
(4) Because some people are able to take things in, take them home, go through them. Other people find it harder because they forget things or even they are not able to ask questions if they give you an instruction, you don’t fully understand it.
(2) …it’s not just understanding the instructions, it’s to do with compliance as well. Whether you are prepared to follow instructions.
(4) Do you visit your doctor yourself by yourself or do you tend to go quite often together?
(2) It depends…when I go with my friend, our friend, to visit the psychiatrist, I actually sit and take notes because she’s always anxious about her appointment so I sit and take notes and give her the notes.
(4) Well, that’s sensible.
(5) Wouldn’t it be more sensible if when somebody went to see their psychiatrist, he’s going to write a letter to your GP, if they actually wrote to you summarising what happened in the meeting and that would remind you, wouldn’t it?
(3) That links with feeling free to bring something up with the doctor, if you felt comfortable to say, ‘Could you just write that down for me?’ ‘Could you make a note of that?’ Then you could take it away yourself.
(1) I think they would be quite willing to do that if you asked them.
(4) Yes, it’s the asking.

Extract from Patient Focus Group 6
Patient participants in Focus Group 5, (Patient Focus Group 5), perceived the role of following instructions as ‘difficult’, due to two main factors: prior experiences when they had received ‘wrong’ instructions from health care professionals, or witnessed them being given to someone else; and barriers to communication between health care professionals and patients.

<table>
<thead>
<tr>
<th>Potential barriers to role enactment</th>
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<td>difficult to remember complex or verbal instructions</td>
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- ‘It’s easy if you if you can remember them once you have left the consulting room’
  Participant 4, Patient Focus Group 1

- ‘It depends how complicated they are’
  Participant 6, Patient Focus Group 3

Although members of nine focus groups classified this patient role as ‘easy’, they nevertheless identified an extensive range of potential barriers to role fulfilment, along with some possible role facilitators.
• asking for clarification of instructions may be interpreted as a challenge of professional authority

‘sometimes you don’t get the full instruction…if you’re instructions aren’t clear you can’t follow them…’
Participant 1, Patient Focus Group 1

• conflicting information

‘that’s fine if they are giving you clear instructions, but I’m a person who likes to understand why I’m doing something and…you’re made to feel you’re almost challenging their decisions if you just ask a simple question sometimes’
Participant 1, Patient Focus Group 1

• distrust of health care professional based on prior experiences

‘You can see three doctors…I wish they’d all speak the same language, and not give you three different tales…’
Participant 3, Patient Focus Group 2

‘I’ve learnt to distrust a lot of people after experiencing what I’ve experienced… I wouldn’t take it as read straightaway. I would do my own research…’
Participant 4, Patient Focus Group 2

• patient (or family member) is feeling unwell

‘if you are not 100% and they tell you to do these things’
Participant 3, Consumer Focus Group 4

Possible role facilitators

• health care professional gives clear, complete instructions and a full explanation
patient is willing to trust health care professional and to comply with instructions

‘if someone just comes and says, ‘You need to do that’, you don’t know what you’re doing, but if someone explains it properly to us then I think it is easier to follow…’
Participant 2, Consumer Focus Group 2

being given instructions in writing
‘if they give you a photocopy and a print out’ Participant 3, Consumer Focus Group 3.

family member of friend can promote role enactment

‘I’ve got a foolproof method, actually. I just tell my wife what the doctor says. You have to follow it then!’ Participant 7, Consumer Focus Group 1

feeling comfortable about asking for clarification

‘I just want to know why, it helps me to carry it out if I have confidence in why you are asking me to do that, some understanding…’
Participant 1, Patient Focus Group 1

fear of repercussions

‘You’re frightened to do anything else’ Participant 2, Consumer Focus Group 4
Examples of attempted and unsuccessful role enactment

In Example 1, Participant 1, Patient Focus Group 2, described her unsuccessful attempt to follow instructions to report side effects associated with her treatment regime.

Example 1

‘that just reminded me when you were talking about the chemotherapy, how insistent their instructions were initially, were insistent – any possible side effects, you feel unwell, I remember that. They stressed it, they were very clear. To me, they were very clear instructions – it was really important. And I tried to access that and feedback instructions and it was so difficult and I had to persevere, you know… it wasn’t easy, not at all.’ Participant 1, Patient Focus Group 2

Example of patient decision not to enact role

Example 2 relates to Participant 5, PFG6, a patient with mental health problems whose growing knowledge of her condition led her to question her treatment and to make the decision not to comply with prescribed medication.

Example 2

‘I conformed with them [instructions] for loads and loads of years because you know, they put me on lithium and that’s what made me like a zombie and I used to… I never questioned them in those days, but as I found out more about it, I mean those were the years everybody said were my zombie years, and I did nothing in the house, I used to be very creative, I did nothing the moment they put me on it. No knitting, no sewing, nothing. And then I read about it and it took me quite a few years to decide I wanted to come off it and with the reluctant agreement of my psychiatrist, we lowered the dose and the minute I was finishing it, he then slapped me out a prescription for something else and so I thought, ‘Well, this is the moment of truth’, so I just decided I wasn’t going to take it.’ Participant 5, Patient Focus Group 6
Patient safety role: Learn as much as you can about your illness, condition, treatment and any tests that you might have

Perceptions about how easy or difficult it would be to fulfil this patient safety role varied across groups, and between individual members within groups; across the groups the role was classified as ‘easy’ or ‘more difficult’; no group classified the role as ‘very difficult’ to fulfil.

Participants’ perceptions of the desirability of role enactment

Study participants in patient and consumer focus groups were in broad agreement that patients should, and would want, to learn as much as they could about their illness or condition, and any associated treatment and tests. However, participants who had undergone treatment for breast cancer (and some others) expressed the view that patients might not want to actively seek, or be given, too much information when newly diagnosed, before they had come to terms with their diagnosis.

Learning about your illness, condition, treatment and investigations seemed to be viewed by (some) participants in Consumer Focus Groups 5 and 6 as a necessary tactic for survival in the health care system; people with diabetes suggested that role fulfilment could benefit patients with diabetes by enhancing self management of their condition; while patients who had been recently diagnosed with breast cancer (along with some other participants) expressed the view that they would not (or did not want) too much information about their illness when first diagnosed, and that they would prefer to have learning spread over a longer period of time.
Information seeking behaviour

Patients with severe and enduring mental health problems, parents of children with asthma, and people who had made a complaint about their (or a family member’s) care appeared to be the most proactive information seekers, exploiting a wide range of information sources, including national and local patient support groups. Participants in focus groups composed of members who had undergone joint surgery, and those with diabetes, were more likely to report being the passive recipients of information provided by health care professionals; many of these participants reported that they lacked computer skills and access to the Internet. Participants in Focus Groups 2 and 3 commented that information provided through breast cancer and asthma specialist services was easily accessible and relevant, and they highlighted the verbal information received from specialist nurses as particularly valuable.
Internet use

The Internet was the information source preferred by those participants with on-line access, though there was widespread recognition of drawbacks to its use. The main advantage cited was the ease with which information could be obtained, but many more drawbacks to its use were mentioned; for example, being overwhelmed by the volume of material available; information obtained may pertain to a different cultural context; difficulty in understanding and interpreting information, and deciding on its relevancy; doubts about its veracity.
In general, participants without personal access to the Internet did not appear to feel particularly disadvantaged in terms of learning about their condition or illness and related treatments and tests. Some commented that they would be able to gain access to the Internet through a family member, or through a local library, and they said they could (and did) draw on alternative sources of information, which they seemed to find sufficient for their needs.

These other sources included information related to medications routinely provided in drug packaging; information and advice from specialist nurses; library books and books and condition-specific leaflets from health care providers; and many participants (particularly those undergoing joint surgery and those with diabetes) cited general practitioners and practice nurses as important sources of information.

‘I think the Internet is a saviour for patients’  (P1, Consumer Focus Group 5)

‘the Internet is brilliant. I just Googled bi-polar and all this gumpf came out so I printed it off, though I have to say it’s mainly American, very little English’ (P4, Patient Focus Group 6)

‘I’ve been very wary of some sites…some sites seem a bit, screwball.. I tend to try and stick to what I think is an authenticated site like NHS Direct or something like that. But even there you can get what seems like conflicting information and it’s very difficult trying to steer your way through it to get a clear picture’ (P6, Patient Focus Group 5)

‘I mean, you don’t know what you’re reading on the Internet, whether it’s true, it’s not necessarily true’ (P1, Patient Focus Group 6)

‘because you can think, all that is wrong with me, can’t you? Oh, the whole lot, when it [information on the Internet] is talking about the condition, not the person…or the information might relate to a disease in its most severe form rather than somebody who’s only just entered into it and perhaps might never get to that stage’ (P3, Patient Focus Group 5)

‘If you go on the Internet, you can frighten yourself into next week’ (P4, Consumer Focus Group 2)
Barriers and facilitators to role enactment

Focus group participants suggested that ideally patient learning should be a shared activity, a two way process between health care professional and patient, with shared responsibility.

During focus group discussions, various factors were identified which could promote or hinder this process.

Possible facilitators

- the HCP takes time to explain and checks for understanding
information should be tailored to suit different patients needs and preferences

Potential barriers

- HCP perceived as unapproachable, or as using ‘technical’ terms and language

- Perception that older people find it harder to request information than younger people
HCP does not take time to offer a full explanation

‘I think younger people find it easier to ask and we older people find it more difficult in some circumstances…we tend to accept.’

Participant 1, Consumer Focus Group 1

Patient not ready to seek or receive information

‘it’s dependent on the doctors you’re seeing or the nursing staff…some seem to give out a lot more information than others. Some doctors are very much ‘Oh, you’ve got bipolar disorder, thank you, good bye.’ Whereas others will actually take the time to explain what it is’

Participant 3, Patient Focus Group 6

Patient unable to assimilate information due to illness or condition, or low level of health literacy

‘everybody is different, some people might not want to know what’s going on and other people want to know’

Participant 3, Consumer Focus Group 2

‘sometimes you don’t want to know…for fear of the worst…’

Participant 5, Patient Focus Group 5

‘basically not putting the blame entirely on the hospital, more on yourselves…because you’re blanking it off slightly’

Participant 1, Consumer Focus Group 4

Difficult to access information when you are in hospital; perception that hospital nurses are unwilling or unable to impart information

‘People who have problems with either learning disabilities, mental health, whatever, they’re not always in that frame of mind to take on that information.’

Participant 3, Patient Focus Group 5

‘to some extent, I suppose it must depend on intelligence…’

Participant 3, Patient Focus Group 6
Perception that HCPs might regard ‘expert patients’ as threatening (reported only by members of Consumer Focus Groups)

Example 1

Participant 4 was a member of Consumer Focus Group 1 who described her attempt to ask a health care professional about a forthcoming investigation, which met with a negative response.

Example 2

Participant 2, Consumer Focus Group 5, explained how he had used the Internet to find information about side effects of antidepressant medication on behalf of a family member.
Example 3

One participant in Consumer Focus Group 6 said he had initially been given a wrong diagnosis and was motivated to find information when his diagnosis was revised.

‘...it really knocked me for six...I suddenly had to try to find some information. Nobody really told me what the major difference between schizophrenia and schizodefective disorder was and I am still a bit unclear because there are so many blurred edges...so I have tried to find for myself and what treatment and what tests I might need to have or whatever...’

Participant 2, Consumer Focus Group 6

Example 4

Participant 4, CFG6, highlighted some of the drawbacks cited by a number of participants in connection with using the Internet to obtain information - the difficulty of knowing whether or not information was relevant to a particular patient, and the possibility of the Internet engendering unnecessary anxiety.

‘I firmly believe in the old adage, a little knowledge is a dangerous thing for some people. My son, my younger son, had to go to hospital for some tests, he had to have a camera because he was vomiting and diarrhoea, had it for four months and he was really poorly, his girlfriend, partner, turned up, she went on the Internet, went on the symptoms – he's got bowel cancer! She had him convinced he had bowel cancer. He's just like me, he's just 'I'll worry about that if and when they tell me there's something wrong with me.' Touch wood, as it happened, the biopsy looks as if it's going to be fine but his girlfriend is in a terrible state over it’

Participant 4, Consumer Focus Group 6
Patient safety role: Speak up if you think your care is not as it should be

This patient safety role was classified as ‘more difficult’ or ‘very difficult’ by the majority of participants in all focus groups. Exceptionally, some members of the patient focus group comprising parents of children with asthma suggested that the role could be classified as ‘easy’, based on their perceptions of sharing a good relationship with the health care professionals looking after their children, their prior positive experiences of ‘speaking up’, and perceptions of themselves as confident individuals; however, not all group members were in agreement, and some suggested that while it might be easy to ‘speak up’, that was no guarantee of the desired outcome would be achieved.
Extract from transcription of Patient Focus Group 3 (parents of children with asthma)

(6) Yes? OK. **Speak up if you think your care is not as good as it should be. Or not as it should be.**
(2) I would.
(4) It’s very easy to do that.
(3) But you’re not always listened to, are you?
(1) That’s true.
(3) It depends who you are talking to.
(4) It’s easy saying it but it’s more are they listening to you or not. Listening to you, they sort of look at you as though they are listening to you but they don’t care what you have to say…
(3) Yes, it’s like, ‘what was the question?’ sort of thing, afterwards.
(2) Or I’ll go and fetch someone else to deal with it.
(1) I find it with the nurses more when you go in, yes. I find it most with the nurses because you’ll ask them questions and they’ll just went blank…as if I’m purple or something. You know they way they look at you? Yeah, sometimes they just do that.
(1) Yes, Sometimes they just do that… So you find it easy to deal with it but you might not get the results that you want.
(2) You see, I’m different because [name]’s grown up there so much so they’re like his family to him…
(1) Yes
(2) …and they know me once I walk in and if I come to the desk they’ll say, ‘Oh, what do you want?’ you know, and they know I won’t move until I’ve got the answer I wanted so I’m quite a determined person to get the right answer.
(1) Yes
(2) So I’m persistent on it, you know.
(6) So you find it quite easy to do?
(2) I find it very easy, yes.
(5) I’m like that with [name] actually.
(6) Put that down as an ‘easy’ one?
(2) Yes

Participants, Patient Focus Group 3
In general, there was an expectation amongst focus group participants that patients should not have to speak up about their care, that care should be provided that was of an adequate standard; at the same time, there was a widespread perception that care was often less than optimal, and participants said that they would be prepared to speak up (or had spoken) up, despite the many potential barriers to role enactment that they cited. In two of the focus groups, participants commented that they regarded speaking up as essential to staying safe in hospital, as a necessary ‘survival’ strategy. 

(1) ‘I think it is very much a personal thing…a characteristic of a person…
(4) …if they are willing to speak up for themselves…
(1) …some people can’t push…
(4)…I never used to, but I’ve learnt that I have to or else I don’t get what I need…’
Participants, Patient Focus Group 1

‘I mean, when you go into [hospital] you expect to get the care. You shouldn’t have to tell people…that the care that they give you is not quite up to the standard that it should be…but I think you should tell them, yes’
Participant 4, Patient Focus Group 4

(6) ‘you’ve got to see for yourself, haven’t you…you can’t just sit back and do nothing….
(8)…it’s a strange thing to say about hospital, but it really has got to be the survival of the fittest…’
Participants, Patient Focus Group 4

There was general agreement across the members of the focus groups that it was much more difficult to speak up about one’s own care than about the care of someone else, such as a family member or friend.
As indicated by their classification of the role of ‘speaking up’ as ‘more difficult’ or ‘very difficult’, focus groups members highlighted many more potential barriers than facilitators to role enactment during their discussions.

Possible facilitators of role enactment

As mentioned above, parent participants in Patient Focus Group 3 highlighted having a good relationship with health care professionals and a high level of personal confidence as potential facilitators of role enactment, factors also identified by other focus group participants, who suggested that confidence to speak up, and to not be ‘fobbed off’, was linked to the acquisition of knowledge and experience, which increased with the passage of time.

Perhaps surprisingly, having someone accompany you to provide support or provide back up, while you spoke up about your care, was not cited extensively as a potential role facilitator, although it appeared to be of great significance to those who mentioned it. (Contrastingly, many participants described occasions when their spouse or family member had actually spoken up on their behalf; participants also suggested that some (particularly elderly) people would find it very difficult to speak up for themselves, and would require someone else to do it on their behalf).
Interestingly, participants with mental severe and enduring mental health problems suggested the use of ‘advanced directives’ as a means of ‘speaking up’ about care that would be given at a future point, in an attempt to ensure care was given in accordance with the patient’s wishes during a period when they were acutely ill; however, most participants described their actual experience of using directives as similar to that of Participant 3, quoted below, that is to say, in their experience, directives tended to be largely disregarded by staff.

(1) No…what I’ve found with that kind of thing is sort of being able to split myself into an advocate for myself, so if I’m not well, I can say in advance, through an advance directive for example, what I want to happen and sort of facilitate them to look after me better.

(3) Yes, I’ve done that as well, done an advance directive…so that when I do become unwell, they could take that into consideration…but actually, most of the time, in my experience they haven’t done which has made me feel quite sad.

Participants Consumer Focus Group 6

Potential barriers to role enactment

Numerous barriers to role enactment were identified during focus group discussions relating to characteristics of the patient; characteristics of the health care professional; and the health care system.

Barriers relating to the patient

- lacks personal confidence
- patient feeling unwell; vulnerable; disempowered

(1) 'I would definitely speak up. I would find that easy.
(2) When you’re well.
(1) When I’m well. If I’m not well, I would find it very difficult which, interestingly, is the time I would need to speak up.
(2) Yes, that’s an interesting…is that a paradox?...I would agree with [name] that there are times when I feel well I would definitely speak up if I think my care is not as it should be, but if I’m unwell, you tend to...
(1) You can’t, can you?
(2) You’re not as able, are you?... so are we sort of saying that at a time when we perhaps most need to be able to speak up about our care, we’re less able to...

(2) With the mental health things, there are times when we are not well and we’re not able to express ourselves or reluctant to, or we lose insight and at that time, the doctor and the nurse or whoever else is dealing with you become all powerful. When you’re sectioned, your power’s virtually nil.’
Participants, Consumer Focus Group 6

(5) ‘It’s about being in a new environment isn’t it? You are unsure of yourself…you think everyone else is in charge, and you don’t feel as though you are in charge yourself as it were…
(6) …something like hospital is overpowering especially if anyone is a bit nervous’
Participants, Patient Focus Group 4

- reluctance to challenge health care professional’s expertise; desire to avoid confrontation

‘you’re actually blaming them, so it’s as though you’re saying they are doing it wrong…so that’s the reason it’s harder…the reason I find it more or less difficult is more or less because it’s more personal, I am caught in the front of a person, I am not blaming the system…it’s them I’m saying it about…you’re feeling embarrassed that you are actually saying it to a person, you’re not criticising a system, you’re criticising that person…’
Participant 7, Patient Focus Group 4
• fear of repercussions

“How brave are you feeling? How punished do you want to be?”
Participant 1, Consumer Focus Group 5

(1) Speak up if you think your care is not as it should be
(2) Well, that’s not easy, that’s for sure.
(1) It certainly is not easy. I mean, easy is out the window. It’s certainly difficult.
(3) The point is you’re frightened to speak up in case the nurse or the doctor take it out on you. Would you find it difficult to speak up?
(4) Not really, no, even though I am a little violet, I am sorry, but I would have to have my say’
(1) Right, but it wouldn’t be easy…?
(4) No, I suppose it wouldn’t….
(2) That’s right…I was frightened to speak up in case it was up against me…
(4) the first time I fell and broke my hip I was frightened to say a dickie bird…
(2) because they are all a clique…and one nurse did hold it against me….
(1) so certainly it varies from ‘more difficult’ to ‘very difficult’…”
Participants, Consumer Focus Group 4

Potential barriers relating to the health care professionals

• lack of communication due to language barrier

(8) ‘the nursing staff that are imported from eastern, probably now, eastern…
(6) from the Philippines…
(8) Eastern European, not having a full understanding of the language, because it is very easy for them to clam up when you ask them something, they don’t understand, they don’t fully grasp what you are on about…”
Participants, Patient Focus Group 4

• perception that HCP does not listen to, acknowledge or affirm the patient’s concern
‘and the other thing is if you have got something happening, whether it’s you’re in discomfort, pain or you feel sick or whatever, especially if you get nothing back when you tell that person, ‘I feel sick,’ if you know, if there’s no acknowledgement of your pain or discomfort, I think you’re left… personally I feel left, well, maybe I shouldn’t, maybe I should be able to tolerate this pain or, do you know what I mean? It’s that feedback that you don’t, you don’t get. So you’re left with it basically and then that affects the next time you want to speak up and ask them again, you know? Can I have something for my pain, or whatever, or is it normal to be feeling like this and…

(4) I bet we’re all so good at undermining how we’re feeling, is it, does it warrant the attention, I think I might have to have and I think you are undermined a lot by nursing staff.

(1) It’s unspoken, isn’t it? But if you seem to be the only one that’s asking for something and having to ask again and again, then, you know, your own mind starts ticking over like, you know, well, ‘Should I be able to put up with this?’ You just want some reassurance. Participants, Patient Focus Group 2

• negative attitude or response from HCPs

(8) ‘from the outset when you go in, let them know that you’re not a doddery old codger, and ask questions….

(3) I think you’re right, there is an attitude problem with a lot of youngsters, they take one look at you and they think, Oh, he’s 65 plus, he’s in the bin bag you know…you get this attitude, they think just because you are retired, so is your brain…they want to write you off…’

Participants, Patient Focus Group 4

‘when you start standing up against some of those staff, then your problems start. I’m sorry, they’re not all caring angels. They’re very far from it’

Participant 1, Consumer Focus Group 4

(6) ‘the attitude of the person you are speaking to. That can be very off-putting, can’t it? If there’s a particular sort of feeling of arrogance or superiority, something you feel perhaps worried about expressing your opinion.

(3) if people are dismissive…”

Participants, Patient Focus Group 5

Potential barriers related to health care system

• perceived busyness of clinical environment; staff shortages

‘I think it’s hard because of the general view that there’s not enough staff to go round and if you make demands on them does that mean somebody else is doing without?’ Participant 6, Patient Focus Group 2
The lengthy extract below, from the transcript of Patient Focus Group 5, is illustrative of the way in which some of the facilitators and barriers concerning the patient safety role ‘speak up if you think your care is not as it should be’ emerged during discussion within one group.

This extract also includes an example of role enactment on the part of Participant 2, herself a qualified nurse, who ‘spoke up’ (unsuccessfully) to ask a health care assistant not to use her leg to measure her blood pressure.

(3) Right then… leading up to: **Speak up if you think your care is not as it should be.**

(6) Yes, definitely.

(All): Yes, yes

(1) But that’s hard to do it for myself.

(3) For other people.

(1) I would find that hard for myself but easy if it was for somebody else. I would be better at it now because of my experience of the last three years but I’d still find it more difficult for myself than for somebody else.

(Several): Mmm

(6) I think I would. I think I probably would speak up for myself but I agree with you it would be easier on behalf of someone else. Definitely.
The thing is, I mean, when you go into a place like that you expect to get the care. You shouldn’t be… you shouldn’t have to tell people to, that’s not the care that you, the care that they give you is not quite up to standard that they should be so I think you should tell them, really, yes.

But it would be very awkward for people who haven’t got the confidence.

People would be very sort of withdrawn about their own care, probably.

And that’s if you can catch somebody long enough to actually tell them.

Yes, exactly.

Boils down to people’s temperament really, doesn’t it? Just how they… It also depends on the response you get.

Because when I was in, I had a health care assistant looking after me who told me quite easily that you can do a blood pressure on an arm that’s got a patent drip going.. ‘No you can’t. No you can’t. I’ve been a nurse for twenty-four years, do you want to argue the toss?’ I’d done it before and that’s the point when most people would shut up, he didn’t. He said, ‘Oh, I’ll do it on your leg.’ ‘No you can’t.’ ‘I can.’ ‘You can’t.’ And it kept going round in circles until, in the end, I said, ‘You’re not doing it, if there’s a problem, get the doctors to consult with me.’ And eventually he did want to do it on my leg and he did it on my leg and I just thought it’s a wasted result. Any doctor that looks at that result, it’s actually duff information.

I think the thing is as well, it’s almost like two levels, isn’t there? There’s having… being assertive enough to speak up but then following it through, raising your hand and saying, ‘Excuse me.’ It’s easy to be fobbed off but then it’s like I’m still not quite happy. I think that’s the…

I could argue the toss because I happen to know for a fact that someone else would say, ‘Oh well, he’s done it before, it must be right.’

It’s having the knowledge.

Yes, it is. But…

As long as you don’t expect too much, I mean, just reasonable care. If you’re demanding everything, well, fair enough, they’ve every right to get a bit impatient then but if it’s just generalised things that you expect, well, I think you should ask, yes.
There’s also the attitude of the person who’s, you know, you’re speaking to. That can be very off-putting, can’t it? If there’s a particular sort of feeling of arrogance or superiority, something you feel perhaps worried about expressing your opinion.

If people are dismissive.

Yes yes

I mean you want a bedpan and they’re really busy. Sit cross-legged. But yes,

What do we think then? **Speak up if your care is not as it should be.**

Again, it’s between ‘more difficult’ and ‘very difficult’.

Very difficult.

(Several): Yes

**Examples of role enactment**

**Example 1**: Participant 3, Consumer Focus Group 6, described how when she was ill, she would not have the appropriate level of insight required to speak up about her care, and she explained that to try to pre-empt this, she had drawn up an ‘advance directive’ as a means of ‘speaking up’ in advance of any treatment that she might be given. However, in her experience, staff tended to disregard such directives.

> ‘Well, I’ve just written an advance statement... although they’re not legally binding, the idea is that should you become unwell, and if there are certain treatments that you think have helped you in the past or certain things that you feel that you wouldn’t like them to administer again... then you can make an advance statement which, which in our hospital is attached to your notes... and although it’s not legally binding, it is hoped that people would look at that but I really don’t know whether they are taken into consideration very seriously. Like, for example, I think I’ve put as part of mine that I don’t want to be too drugged up because I’ve had experiences where I’ve been walking around like a zombie, that I really want to have as little medication. Enough medication to help but not to be overly drugged. And the other thing was I said that I didn’t, if at all possible unless I was sectioned again, then I would prefer not to have ECT again. But when I, when I have spoken to staff when I’ve been in hospital, oh, they’ve never mentioned the advance statement at all, so….'

Participant 3, Consumer Focus Group 6
**Example 2:** Participant (9), Consumer Focus Group 1, explained that he had been discharged from hospital after a heart attack and was taking the drug Atenolol, when he began to experience side effects. He went to his general practice and asked to be seen by a doctor urgently; he reported that he had to adopt a rather aggressive stance in order to convey the urgency of his situation to the surgery receptionist.

> ‘after I came out with the heart attack…they put me on one of the usuals, Atenolol to start with, and I started to seize up and I’d got as far as the surgery, going any further I couldn’t. My leg muscles had gone, my stomach muscles, just tightened up. So I managed to get in and as I’m there, ‘I’d like to see a doctor. I am not fussy which one, but it’s now’. And she [the receptionist] said, ‘What’s wrong?’ I said, ‘if I knew that I wouldn’t even bother telling you…I said, ‘I need a doctor, and now’’. She said, ‘Why?’ I said, ‘Have I got to make an appointment for another heart attack?’ And of course, that started it, she shot out and found me a doctor…’
> Participant 9, Consumer Focus Group 1

**Example of non-enactment of role**

**Example 3:** Participant 2 described how her perception of the level of busyness of the clinical environment in hospital initially inhibited role enactment; when she did press her bedside buzzer to report physical discomfort, and because she was feeling socially isolated, she reported that did not receive the response she hoped for.

> ‘I was confined to bed the first three weeks, I was in traction and I kept sliding down the bed, sheets are all crumpled and that. But they’re so busy, you’re frightened to…you ring the bell but nobody comes and when you’re in a wee room to yourself, you’re sitting there, you know, ‘I wish somebody would pass by, and give you a shout or something’.” Participant 2, Consumer Focus Group 4

**Patient safety role:** *Speak up on behalf of somebody else if you think their care is not as it should be*

The majority of focus group participants classified this patient safety role as relatively ‘easy’ to carry out. The exceptions were participants with diabetes
and those who had undergone joint surgery (in both patient and consumer focus groups) and members of Consumer Focus Group 2, who categorised the role as ‘more difficult’. The former groups of participants (in Patient and Consumer Focus Groups 1 and 2) said it would be (or was) ‘more difficult’ because they feared repercussions, for themselves, or for the person on whose behalf they might or did speak up. The latter group of participants (in Consumer Focus Group 2) said it could be difficult for them to make a judgement about whether it would be appropriate to speak up on behalf of somebody else.

Extract from transcript of Patient Focus Group 4

(7) 'I think it is more difficult because they tend to look at you as thought you are causing a bit of bother…
(6) Yeah, you get the blame for asking…
(7) …yeah, you spoil their easy life, well, they haven’t got an easy life, it’s making it more difficult for them, so I think it’s quite difficult to speak up…
(2) …on behalf of somebody else, yeah…
(7) because you’ve got to bite the bullet…
(3) yeah, cos you’re rocking the boat…
(2) it’s quite difficult, I’d say, that….
Facilitator: Harder than to speak up on your own behalf?
Chorus of voices: Oh, harder definitely….
Facilitator: Why is that?
(4) They tend to bully you for speaking out…they bully you afterwards, you’re deemed a nuisance…
(6) Yeah, ‘Don’t bother going to her, she’s always wanting something…’

Extract from Patient Focus Group 4
Where participants classified the role as ‘easy’, they described how they would (or did) find it much easier to speak up on behalf of someone else than for themselves, particularly for a close family member, but also for friends or other patients if they believed they were not being cared for as they should be. Focus group participants said they would be motivated to speak up by strong ‘protective’ instincts, and feelings of responsibility, especially in relation to speaking up on behalf of a child.
Amongst focus group participants there was a widespread perception that older people might need someone to speak up on their behalf, partly because they were perceived as unwilling to question or challenge health care professionals, and partly because they might see themselves as vulnerable to recriminations; these views were particularly marked amongst focus participants who were themselves of an older age, with reference to care delivered in hospitals.

‘If I think my wife isn’t getting the right treatment, I will move hell and high water to make sure she gets the right treatment’ (Participant 5, Patient Focus Group 1)

‘when my dad was in hospital…I had to speak out, and I think it’s only natural with your parents, you just want the best for them…I found that easy to do.’ (Participant 1, Patient Focus Group 2)

‘I wouldn’t be as pushy as that… [for yourself]. You’re more protective I think towards your own children…they’re more vulnerable’ (Participant 6, Patient Focus Group 3)

‘Certainly, when it’s your child you feel it is your responsibility with your child, invariably you are there because your child is sick and doesn’t have the capacity at the age they are at, doesn’t have the knowledge, doesn’t know what the baseline is or should be, so for me it’s a no-brainer’ (Participant 2, Consumer Focus Group 3)

‘I find that much more easy…I was able to speak up on [name’s] behalf when she was unable to speak up for herself. I’m able to speak up on behalf of the friend that I accompany. It’s much harder to speak up about myself. Again, there are times when my mental health is such that I would find it difficult to do but I would still, at that stage, find it easier to do for somebody else than for myself’ (Participant 2, Patient Focus Group 6)

‘they’re not comfortable with challenging things because that is not how they were brought up’ Participant 2, Patient Focus Group 2

‘they [the nursing staff] literally left her with her meal and she couldn’t eat…poor old soul…but I think that sums it up, she didn’t ring the buzzer because she didn’t want to be a nuisance [general murmur of agreement, ‘Yes, yes’]…if she thought she was being a nuisance, she probably thought she might be picked on or victimised for ringing it…’ Participant 8, Patient Focus Group 4
Potential facilitators and barriers to role enactment were identified across all 12 focus groups. Parent participants identified more facilitators than other participants in other groups, and patients who had undergone joint surgery, and those with diabetes identified more barriers.

Potential Facilitators

- easier to observe what is happening to someone else than to yourself
- high level of personal confidence
- (parent) participants considered it ‘legitimate’ to speak up on behalf of a child, and would expect a fellow parent to speak up on behalf of their child
- prior experiences of role enactment have been positive
- being sure of your grounds for speaking up
- having a good relationship with staff; aware of role boundaries

(7) ‘I find I see more things that are going wrong with other people’
(6) ‘you’re so busy being in the depths of self-pity you don’t notice for yourself’
Participants, Consumer Focus Group 1
being a member of a support group and/or having support from a specialist nurse

Perceived barriers to role enactment

- expectation that speaking up would not achieve desired outcome

1. “it’s easy to speak up for somebody else…”
2. “…but it’s not easy to get a result”

Participants, Patient Focus Group 1
• fear of repercussions

(7) ‘but to use my mum as an example, you find that if you want to speak up on behalf of somebody else they don’t want you to because they’re in there…I have to say that is why I did not speak up in my mother’s case…’
(4) ‘when you are not there, you don’t know what is going on…’
(1) ‘It’s quite intimidating…’

Participants, Consumer Focus Group 1

(4) ‘my aunt wouldn’t speak up for my uncle because she would be frightened in case they took it out on him’

Participant 4, Consumer Focus Group 4

• lack of personal confidence

‘I was pregnant and my daughter, she had to stay with my son, and she found it very difficult, because she was so…intimidated and she found it very difficult when she asked the nurses, they really knocked her down basically…she didn’t like it all…’

Participant 1, Patient Focus Group 3

(5) ‘I am sure there are some people who don’t feel they can speak for themselves…they need a spokesperson to do it for them’
(3) ‘…she may be a bit of a mouse’

Participants Patient Focus Group 3

• negative response from health care professional

(6) ‘I think it’s a lot to do with the reaction that you get the first time you speak up. If you get shot down, some people think, I’m not doing that again. Just live with it.’
(7) ‘some people just don’t really talk to you, don’t listen to you, they push you on to someone else’

Participants Patient Focus Group 3

Examples of role enactment

Example 1: Participant 8, in Patient Focus Group 4, pressed his bedside alarm on behalf of an elderly patient who had fallen out of bed.
Example 2: This example includes comments from participants in Consumer Focus Group 6 (people with severe and enduring mental health problems) that indicate that they would be willing to speak up on behalf of another person more readily than they would speak up on their own behalf. This extract includes a description of role enactment from Participant 1, of how a group of patients belonging to a patient support group took collective action to ‘speak up’ on behalf of another group member.

Example 2: Extract from transcription of Consumer Focus Group 6

Amongst the focus group participants, parents of children with asthma appeared the most likely to be willing to speak up, or to have undertaken the role of, speaking up on behalf of another (their asthmatic child). In the
examples of role enactment below (Examples 3, 4 and 5), three parents describe how they ‘spoke up’ when they suspected that their children’s care was not as it should have been.

**Example 3:** Based on her prior knowledge and experience of her child having the drug prednisilone, Participant 3 spoke up to query the dose prescribed for her child on a particular occasion (and subsequently checked the dosage with the specialist asthma nurse).

> ‘I’ve had this one [medication] before and I did query it because they wanted to give my son more Prednisolone than what he usually had. They wanted to give it to him for five days and he’s always had it for three and I queried it and they said, ‘No, no, it’s fine, we’ve changed the guidelines,’ ‘blah di blah. So I thought, ‘OK.’ So they sent us home and we’ve got a really good asthma nurse that he’s under so I still wasn’t sure so I phoned her up and they were wrong. He should have only had it for three days.’

Participant 3, Consumer Focus Group 3

**Example 4:** Participant 2, Consumer Focus Group 3 spoke up to query a medication being given to her child; in this case, she questioned the method of administration, based on her knowledge of the drug from previous experience.

> ‘I don’t know if any of your children have taken theophylline, it’s a medication used for asthma and there are various types of it but one type comes as a slow-release capsule, so it’s a little capsule and it’s got little grains in it and you swallow it and it’s slow release so it gives the drug over a period of time and my son was having a lot of difficulty swallowing this capsule because he was quite young at the time. So the nurse decided to break the capsule open and put it in milkshake, you see. And I could see they obviously did that with a lot of treatments kids won’t take and I just said to her, ‘You just can’t do that. That’s complete… the drug delivery of that drug is reliant on the capsule being in you know place. You can’t do that,’ and I felt that was sort of wrong, I suppose, that she was choosing to do something that if we hadn’t known any different could have been useless administration of drug which was supposed to get him out of hospital. But, again, that was only because I knew.’

Participant 2, Consumer Focus Group 3

**Example 5:** Like the other parents of children with asthma, Participant 1, Consumer Focus Group 3, spoke up to a health care professional about the
delivery of medication (Ventolin) to her child, and she also checked the
dosage prescribed with the specialist asthma nurse.

Example 6: Participant 1, Consumer Focus Group 4, described how he had
become accustomed to ‘speaking up’ on behalf of his elderly father, to warn
medical staff about his allergy to a number of antibiotics including penicillin.
Participant 1 reported that it was his perception that medical staff did not read
notes thoroughly.

Example of role non-enactment

Example 7: Participant 7, Consumer Focus Group 1, mentioned that he did
not speak up on behalf of his mother for fear that doing so might affect her
treatment in some way.
Patient safety role: Talk to a surgeon about details of surgery

Across the 12 focus groups this role was variously classified as ‘easy’ or ‘more difficult’; no group classified the role as ‘very difficult’ to carry out.

In some focus groups, participants commented that it would be easy to talk to a surgeon if they were given the opportunity, but they suggested that this might not (or was not) always be the case, either because the surgeon did not make themselves available, or because of the health care context, for instance, in cases of emergency rather than elective surgery.

'I would find the process of talking about it easy. Actually having a surgeon there, present, to talk about it is difficult. You know, how do you get hold of them?'

Participant 6, Patient Focus Group 2

'as an individual, whether they feel they should take time to talk to your patient or not...I asked him, I says, 'Well, why are you doing this when the other surgeons don’t do it?’ He says, ‘Because I believe in telling them, the patients, what exactly is going to happen and what could happen’, and he was very, very nice about it…'

Participant 4, Patient Focus Group 4

'I think the other thing is, it’s in what circumstances you are given the opportunity to talk to a surgeon. If there’s not time, if you’ve got, you know, you’ve had to go into Intensive Care, everybody’s rushing around, you’re not actually in the mood for having a discussion about the options. You just want them to do whatever it is they’re paid to do. Whereas, if it’s sort of an elective procedure and you get the chance and you’re more relaxed, you can sort of feel comfortable. So I think it just depends on the scenario.'

Participant 2, Consumer Focus Group 3

In focus groups where the role was classified as ‘more difficult’ a wide range of barriers to patients taking on the role were cited (discussed below).
Participants with severe and enduring mental health problems (in Patient Focus Group 6) said they would describe the role as ‘moveable’, that is to say, they suggested it could be easier or more difficult to carry out depending on certain characteristics of the patient (such as how well or ill they were feeling, or whether they were elderly, in which case they might perhaps be less willing to ask questions of a surgeon).

The majority of focus group participants expressed the view that they would expect (and would be given) an opportunity to talk to a surgeon about details of surgery, and that they would (or had) willingly engage(d) in any discussion to become more informed about their treatment. Exceptionally, Consumer Focus Group 5 participants suggested that they were unlikely to be given such an opportunity.

Most participants commented that surgeons would wish to inform patients of the details of surgical procedures and any associated benefits and risks as an inherent feature of good practice, and it was suggested that, in general, today’s surgeons were more skillful communicators than their predecessors.
However, there was widespread recognition that the communication skills of individual surgeons were bound to vary, making it more or less difficult for patients to express their views, ask questions, and understand the information that was being imparted to them. Participants indicated that surgeons need to be sensitive to the amount of information that patients would want at any one time, and that they should avoid using ‘technical’ language, viewed as a barrier to communication.

(1) Well, presumably they would explain it all.
(4) Well, you’d expect it, it’s good practice
(1) In my experience they go through it to the nth degree, to the point that it’s almost boring. Making sure that you understand and so on.
(3) They do and they also tell you nowadays, they go even further, they tell you all the risks involved and what to expect and what recovery…
(2) I think that’s something that’s improved a lot over the years, in my experience. My mother had to have an operation just two or three weeks ago and the amount of information they were giving out it was almost overload.
(3) I found that too and the same with the anaesthetist but I’m saying that’s a good thing.
(2) Not being critical, but there’s that much…a bit overpowering.

Extract from Consumer Focus Group 6

(3) ‘sometimes a surgeon will blind you with science and not actually…he’ll come out with all the technical terms and not actually explain…
(5) Yes, he’s explaining it but he knows very well that you are not going to understand.
(3) Or doesn’t accept.
(5) He’s just going through the motions.
(3) But others will give you a very thorough explanation – warn you about possible post-op problems or whatever. Again, I think it is dependent on the communication of the doctor or the surgeon.’

Extract from Patient Focus Group 6
Even where the time spent talking to a surgeon was limited, many participants indicated that they valued having an explanation from the surgeon who was going to operate on them because of the reassurance it offered.

Focus group participants drew attention to certain groups of patients who might find it difficult to talk to surgeon, for example, patients with learning disabilities, and those who depend on family members to act as carers. In these cases, it was suggested that the onus was on the surgeon to involve carers in talking about proposed surgery, and to attempt to communicate with people with learning disabilities in a manner that would enable them, as far as possible, to become involved in discussions about their treatment.
The majority of the potential barriers and facilitators to role enactment (talking to a surgeon about details of surgery) identified by focus group participants related to characteristics of: the patient (or their representative), the surgeon, and the health care context in which information sharing takes place; the nature of the information shared; and participants’ perceptions concerning their relationship with their surgeon.

Potential barriers to role enactment

- patient lacks personal confidence; does not have an established relationship with the surgeon; feels ‘overawed’ by the surgeon
patient lacks appropriate knowledge base to underpin informed discussion

‘I think the problem is that we’re quite so sort of limited as sort of lay people as to what questions we can raise with them really…we as lay people we don’t know if they’re giving us all the information…’ Participant 1, Consumer Focus Group 5

context in which information is shared is perceived as not conducive to patient involvement; (patients said they required time for consideration of information imparted from surgeon)
talking to more than one surgeon may result in patient receiving conflicting information

‘What I brought up when [name] came to see us was the fact that there was several… there was Mr [name] who was the main surgeon who treated [name of patient] and then each day there was a different registrar who came round so I think you saw about four or five different ones, didn’t you? And every one of them told a different tale and I said to this sister, I said, ‘Why is it that we don’t get the same story, you know, from every one of them?’ I said, ‘It’s just as if they don’t liaise with one another.’ And the sister said, ‘Well, to be quite honest,’ she said, ‘they don’t.’ She said, ‘I’ve got all the notes here but they never come and have a look at the notes. They walk around with the sister saying this and this and this but and they just don’t compare notes.’ That’s ridiculous, I mean, how they know what’s going off and what stage of recovery or any complications…’

Participant 4, Patient Focus Group 5

patients (particularly those being treated for breast cancer) might find it difficult to engage in the role at the point of diagnosis; language perceived as ‘jargon’ acts as a barrier to communication

(2) ‘I saw a surgeon when I was diagnosed and I have to say the surgeon I saw explained it and obviously I was I suppose in shock but I couldn’t understand the jargon he used. I want a discussion and he was open to… he was very rigid in his discussion, that’s what I remember and the jargon he used…’

(1) ‘yes, to me, he wasn’t a people person. He might have been very good at his job…’

Participants Patient Focus Group 2
Potential facilitators to role enactment

- Surgeon makes time to talk to patients; adopts an approachable manner; invites questions

‘Doctor [name] he was mine, he was very nice, very calm, very quiet, just ask a question and he will answer it…’ Participant 2, Patient Focus Group 4

‘Mr [name] is absolutely fantastic so he puts, no, as well as being gorgeous [laughter] but, he talks you through everything. Even turns up on a Sunday when you go in for like the night before for the operation. He comes and sees you in his own time, in civvies, and he looks even nicer. [laughter]... But he talks you through everything and if you had any queries or questions he would answer them and then the anaesthetists were exactly the same when they came round in the morning. It was no ‘Rush this, sign this.’ On some wards, when I had a portacath in, it was like down, waiting to be anaesthetised and I was signing to actually say OK to the operation or whatever, but with the big operation, he was absolutely superb.’ Participant 2, Patient Focus Group 2

‘I think that... the top person, they’re confident not just about the knowledge but they’re confident to speak to you whereas somebody else who’s still going through the process hasn’t got as much confidence and can see you asking questions as a bit of a challenge and they find it harder to deal with’ Participant 5, Patient Focus Group 5

- Intermediary (for example, specialist nurse) can act as ‘information broker’
Examples of role enactment

**Example 1:** Participant 4, Patient Focus Group 2, who had surgical treatment for breast cancer, appeared to think that the surgeon dealing with her case facilitated her role enactment.

‘Mr. [name] is wonderful isn’t he? I’ve spoken to him about reconstruction and he’s gone through everything and he’ll say, ‘Any more questions?’ You know, and he’s more willing to answer questions you put to him. They all vary, don’t they?’

**Example 2:** In this example, Participant 2, Consumer Focus Group 6, suggests that she was provided with an opportunity to speak to a surgeon about details of her son’s operation, and that she had the confidence to ask for further explanation if necessary.

Participants, Patient Focus Group 2
Example of non-enactment of role

Example 3: Participant 4, Consumer Focus Group 3, expressed the view that she was denied the opportunity to engage in a meaningful dialogue with a surgeon about a proposed course of treatment.

‘When I had a bad problem and I went to the doctor and to the surgeon, it was a matter of doing an out-patient surgery, just a big injection that they usually give, and not to have that, so I was given like not even five minutes to decide. Do you want it or don’t you? You know? Without going through the benefit, the drawbacks, the aftermath, whatever happens after that. So, surgery, some people are saying after that you could be like in a wheelchair or something like that, you know. So, nothing of that sort was explained … I just said yes and I got out of there… at the time I felt it was a most difficult thing, you know? They should have really sat me down with something, told me the pros and cons and here I was given five minutes to decide. ‘Do you want it, or you don’t want it?’ So I think that…that it gets more difficult.’ Participant 4, Consumer Focus Group 3

Patient safety role: When in hospital, ask everyone – caregivers and visitors – to wash their hands

Perceptions concerning how easy or difficult it would be to ask caregivers and visitors to wash their hands varied widely, both within and across the twelve (6 patient and 6 consumer) focus groups; the role was classified as ‘easy’ by focus group participants with diabetes, those who had undergone joint surgery and parents of children with asthma, while participants with severe and enduring mental health problems, and those who had raised a concern or
made a complaint about their care classified the role as ‘very difficult’ to carry out.

Focus group participants identified a number of factors that might influence anticipated or actual role enactment; these related to characteristics of the patient (or their representative); characteristics of the health care professional; patients’ (or their representatives’) perceptions of the nature of their relationship vis a vis health care professionals; and the context of care delivery. Overall, focus group participants suggested that there would be more barriers than facilitators to role enactment.

Participants’ perceptions of factors that might influence role enactment

Focus group participants suggested that the majority of patients would be disinclined to ask a health care professional, particularly a senior member of the hospital hierarchy, to wash their hands; in some instances, this was connected to a lack of personal confidence; in others, participants expressed anxiety that such a request might be interpreted as an implied criticism of professional standards, with possible repercussions for their care. Most (though not all) participants suggested that it would be easier to ask family members and other visitors to wash their hands than to ask health care professionals.

(1) ‘…whether you ask people to wash their hands or not is somehow bound up with their status in the sense that it is easy to ask family members and visitors….

(3)…and nurses…

(1)…and nurses, but….

(3)…but oncologists and surgeons….

(1)….oncologists and surgeons and senior doctors are more difficult’

Extract from Consumer Focus Group 2
Exceptionally, some Patient Focus Group 3 participants (parents of children with asthma) suggested that it would be harder to ask visitors to wash their hands than health care professionals; these participants argued that health care professionals know they ‘should’ wash their hands (and the parents said they would assume that they would do it routinely), while visitors might take offence at being asked.

‘I find it harder to say to visitors and people who come in and they’ve not noticed the signs or anything…with the doctors and nurses it is not so much of an issue…they do seem to do it routinely at the hospital we go to, but visitors, really ‘I just go to all that effort of coming’, and you know, ‘I notice when you came in you didn’t wash your hands, do you mind going to wash your hands’, I find that hard to say. Because if you are asking a doctor or nurse, they know that’s right so it’s not like you’re offending them in any way…visitors I find hard…’ Participant 2, Consumer Focus Group 3

There was variation between individual members in focus groups, and across the groups, as to whether or not health care professionals could be trusted to ‘automatically’ wash or cleanse their hands, before or after attending to patients, without the need for prompting from patients. Importantly, there was a shared perception across groups that patients should not, and realistically could not, be expected to take on the role of asking HCPs to cleanse their hands.
Patients with mental health problems, and those who had raised concerns about their care appeared more doubtful, or sceptical, than others about whether HCPs could be fully relied on to wash their hands. Participants with mental health problems expressed the view that it would be extremely difficult for patients to ask HCPs to wash their hands, due to a lack of personal confidence or fear of being ‘victimised’ in some way. They also pointed to the impracticality of patients attempting to ‘monitor’ whether staff washed their hands, and to the lack of hand-washing facilities in psychiatric hospitals by comparison with acute general hospitals.

Participants in Consumer Focus Group 5 (people who had made a complaint about health care delivery) classified this safety role as ‘very difficult’ to enact; while individuals indicated that they were willing to ask HCPs to wash their hands if they felt it necessary to do so, as a group, they were the most likely to anticipate an uncooperative or ‘hostile’ response to their request; like other participants, they highlighted the difficulty for patients of knowing whether or not HCPs had carried out the procedure prior to attending to them patients at the bedside.
Perceived facilitators of role enactment

The main facilitators of role enactment mentioned by focus group participants were a general heightened awareness of hospital acquired infections amongst patients and the public, and an emphasis within current health care culture on the promotion of hand-washing as a preventive measure, including the use of posters inviting patients to ask health care professionals if they have cleaned their hands. However, in general, participants appeared to think that potential facilitators were unlikely to counterbalance the many barriers mentioned during discussions.

‘I would have thought that now that it’s so sort of prevalent, you know, the whole discussion about how desperately serious it [MRSA] is, I would have thought that would have made it a bit easier… I can imagine sort of not so very long ago we would have been pretty reticent about it but I think that perhaps it would have been a bit easier now because people should have accepted it better.’ Participant 6, Patient Focus Group 5
Example 1: Example of (successful) role enactment

Example 1: Participant 1, who took part in Consumer Focus Group 1, was a retired pharmacist who described how she had addressed a nurse to ask her to wash her hands when she was about to attend to her infant grandchild who was ill in hospital. Participant 1 suggested that the nurse had forgotten to wash her hands due to a momentary lapse, possibly pre-occupied with the task in hand; she explained that the nurse immediately apologised and washed her hands. Participant 1 also commented that hand-washing was not being promoted as vigorously within health care culture at the time the incident occurred as is currently the case.

(8) ‘Do we find it easy, though, to actually ask someone, please go and wash your hands?
(1) I did. My grandson was in [hospital] when he was very tiny, in [name of hospital] and one of the nurses didn’t.
(4) And did you tell her?
(1) Yes…
(8) What was her reaction?
(1) ‘I’m very sorry’, and she did it immediately. She had come in quickly to do something and I said, ‘You haven’t washed your hands’, and she said, ‘I’m very sorry’, and she did it. And that was just fine, you know, she had a momentary [lapse]…it was when it was first becoming…
(4) I’m sure she was probably thinking about what she was coming to do…
(1) Come to do, yes, yes, for him…’

Extract from Consumer Focus Group 1
Example 2: patient attempts role enactment

Participant 4 described how she was ‘stumped’ when she asked a surgeon to wash his hands prior to carrying out the removal of stitches and he did not respond to her request; she went on to emphasise that while she was willing to ask HCPs to wash their hands, her experience led her to believe that her request would not necessarily meet with a positive response.

I asked the surgeon…if he’d washed his hands before taking stitches out and he just sort of stood there and said that was that, he didn’t do it, and I thought, what do I do, I need the stitches out…I would find it easy to ask them, but it’s the reception that I might get would be that the response would probably be hostile, that’s in my experience’ Participant 4, Consumer Focus Group 5

Example 3: patient makes the decision not to undertake role enactment

Participant 3 was a member of Consumer Focus Group 2 who had undergone surgical treatment for breast cancer. In this brief extract from the group discussion, she mentions that she raised the issue of her surgeon not using hand gel routinely with hospital management; she indicated that despite posters ‘inviting’ or ‘allowing’ her to challenge the surgeon not cleaning his hands, she found it too difficult to pursue the matter with him at a personal level, deciding instead to tackle the problem by reporting it to managerial staff.
Example 4: patient makes decision not to undertake role enactment

**Example 4:** Participant 5, member of patient focus group 6, commented that she felt too uncomfortable to ‘challenge’ the nurses attending her ill husband to ask them to wash their hands, although she had wanted to. Her comments revealed that she did not seem sure about when nurses should wash their hands prior to patient contact, and she implied that ‘agency’ nurses might be less likely to carry out the procedure than permanent staff.

‘Well, as I say, I went and… I noticed these, well, actually they were agency nurses. I noticed they were going but you see sometimes they are not actually touching the patient, are they? They’re only digging something in their arm but I mean when they were there, and I did feel like saying, ‘Shouldn’t you wash your hands, but I didn’t.’’ Participant 5, Patient Focus Group 6.
5.5 Summary of the findings from the focus groups

5.5 (i) ‘Roles exercise’

Focus group members expressed their views of 12 patient safety roles advocated in the research literature (see below) during participation in a group ‘roles exercise’ (developed by the research team) whereby they were asked, as a group, to classify each role as ‘easy’, ‘more difficult’ or ‘very difficult’ to enact. During the 12 focus group discussions (6 with patients and their representatives, and 6 with members of support or ‘consumer’ groups) participants identified barriers and facilitators to role enactment, and gave examples of situations when they had considered adopting, or had adopted various roles, or had decided against role enactment.

- Ask a family member of friend to accompany you when you visit the doctor or go to hospital
- Ask questions about anything that you are not sure about
- Bring a list of your medications every time you visit the doctor or the hospital
- Challenge staff if you think they are doing something wrong
- Check any medications that you receive and ask questions if there are any that you are unsure about
- Check that a hospital has a good reputation before going in for surgery
- Follow instructions from doctors and nurses
- Learn as much as you can about your illness, condition, treatment and any tests that you might have
- Speak up if you think your care is not as it should be
- Speak up on behalf of somebody else if you think their care is not as it should be
- Talk to a surgeon about details of surgery
- When in hospital, ask everyone – caregivers and visitors – to wash their hands

The findings from the 12 focus groups reflect wide variation in peoples’ views and experiences of patient safety roles, both within and between the six clinical groups (of patient and ‘consumer’ participants) who contributed to the discussions.
Overall, focus group participants were in favour of patients being actively involved in promoting their own safety, as far as they are willing and able. A significant finding however, was the lack of consensus regarding how ‘easy’ or ‘difficult’ it would be to adopt any one patient safety role, reflecting patients’ perceptions about the variability of the factors that could potentially affect their ability to be involved in measures to promote their own safety.

5.5 (ii) Perceptions of patient safety roles

Participants suggested that involvement in some roles would be a matter of personal preference (for example, the suggested patient safety role ‘Ask a family member or friend to accompany you when you visit the doctor or go to hospital’), and that involvement in others might not be desirable, even when they were judged as relatively ‘easy’ to carry out. For example, the patient safety role, ‘Follow instructions from doctors and nurses’ was classified as relatively ‘easy’ to carry out by members of nine focus groups, yet members of two focus groups (comprising people with severe and enduring mental health problems) commented that they would not wish to assume this role, as they would expect their relationship with health care professionals to be based on a partnership, rather than paternalistic approach, whereby patients unquestioningly follow HCPs’ instructions.

Amongst focus group participants, there was a shared perception that it would be very difficult to be involved in patient safety roles that required the patient to ‘speak up’ about deficiencies in their care, or to challenge a health care professional if they suspected a potential harm or threat to their safety. Reluctance to engage in these roles (which included asking HCPs to wash their hands) was based on participants’ perceptions that patients’ ‘speaking up’ could be interpreted by HCPs as representing an overt or implied criticism of their professionalism. The main barriers cited to adopting ‘challenging’ roles related to a desire to avoid personal confrontation with health care professionals, and anxiety about any potential repercussions that might result from ‘speaking up’.
There was widespread agreement that people would (and did) find it much easier to ‘speak up’ on behalf of another person (partner or spouse, child, parent, fellow patient) than for themselves, though fear of some kind of repercussion being suffered by the person receiving care was nevertheless cited as a potential barrier.

A perception that was widely shared was that elderly people would need someone to speak up on their behalf, especially when they were in hospital. However, this did not accord with the views of older study participants themselves, who said they would be prepared to ‘speak up’ on their own behalf, out of choice or necessity, and who gave examples of having done so, both in general practice and in during episodes of hospital care.

A major barrier to ‘speaking up’ identified by the majority of focus group participants was the perceived ‘busyness’ of the clinical (usually hospital) environment, linked to perceptions about staff shortages. Participants reported attempting to weigh up the importance of their own needs in relation to other patients’ when a ward was busy, and hesitating to ‘ring’ for a nurse for matters which they regarded as less urgent, with potentially negative consequences for their care (for example, patients undergoing surgical procedures did not report that they felt ‘sore’ in bed, because they did not want to divert busy nurses, and were therefore subsequently potentially at risk of developing a pressure sore).

Participants who said that they would be willing to ‘speak up’ about perceived deficiencies in care and/or potential errors and harms, included (some) parents of children with asthma. Their willingness to ‘speak up’ appeared to be associated with a number of factors:

- detailed knowledge of their child’s condition, medication and other treatment, gathered over a number of years, enhanced by information from specialist asthma nurses, and, (in some cases), membership of a patient support group (Asthma UK), which enabled the parent to feel
confident that they knew what ‘should’ happen (‘knowing your grounds’);

- the perception that a parent speaking up on behalf of their child is ‘legitimate’;

- positive experiences of ‘speaking up’ - parents’ said that often their decisions to ‘speak up’ were ‘sanctioned’ at a later stage by a senior medical clinicians;

- a perception of enjoying an established and ‘informal’ relationship with (particularly) nursing staff who are well known to the parent, and who know the parent as an individual;

- high level of personal confidence, and a willingness to be persistent and not easily ‘fobbed off’;

- knowledge of how the healthcare system ‘should’ work, and feeling confident in the clinical environment.

Patient safety roles which did not seem to entail potential for conflict with HCPs were not necessarily regarded as ‘easy’ to carry out. For example, the suggested patient safety role ‘Check that a hospital has a good reputation before going in for surgery’ was classified as ‘difficult’ by the majority of participants, partly because of reported problems with accessing and interpreting relevant information, but also because participants said they would wish to take other factors into account, besides the hospital’s reputation, when making a decision about choosing a hospital (for example, how far away the hospital might be located from friends and family).
5.5 (iii) Consumer perspective

Belonging to a support or ‘consumer’ group was regarded as enabling of patients becoming involved in keeping themselves safe. Participants suggested that group membership could lead to increased knowledge (for example, by providing patients with the opportunity to attend condition-specific courses and to receive relevant literature in a user friendly format); increase levels of personal confidence (through attendance at group meetings which allowed patients to draw on the experiences of others’); and by the provision of practical support, for example, in the form of advocacy, when required.

Participants in Consumer Group 5 (comprising people who had made an official complaint about their own or another’s care) appeared more sceptical than others that health care professionals would respond positively to patients’ adopting patient safety roles, especially where this involved patients ‘challenging’ the decisions or actions of HCPs.

5.5 (iv) Patient safety: roles and responsibilities

In general, focus group participants suggested that most patients would wish to assume responsibility for their own safety as far as they were able, but that their willingness or ability to do so could be affected by a wide range of variables, so that they could not (and should not have to) be relied on as a check in ensuring their own safety. These variables related to characteristics of the patient themselves, and their health status; the anticipated or actual response of the health care professional; and features of the wider health care system.

For example, participants suggested that many patients could (and do) routinely check medications that they receive in primary care for errors (such as dispensing errors), and that, therefore, in this context, patients play a role in ensuring their own safety; however, if the context ‘switches’ to a hospital ward, then focus group participants suggested that patients would be unlikely to be able (and should not be expected) to share responsibility with health care professionals for checking their medications.
In summary, there was general consensus amongst participants that ultimately responsibility for ensuring patient safety lies with health care professionals.
DISCUSSION OF THE QUALITATIVE FINDINGS

Summary of the study findings

Findings from the study revealed that patients (and their representatives) were largely unfamiliar with the specific term ‘patient safety’, though they grasped the broad concepts. Participants appeared to interpret the term in a broader sense than is commonly found in the literature, by subsuming notions of psychological as well as physical harm. Individuals with severe and enduring mental health problems were particularly concerned with the threat posed by other patients to their safety.

Overall, the majority of study participants appeared to think that errors are a common occurrence in health care (especially in hospital-delivered services) because health care treatments are inherently risky, and health care professionals are susceptible to error. Serious errors were viewed as occurring much less commonly than minor ‘mistakes’. Most people believed that health care professionals would generally attempt to cover up an error or mistake, depending on how serious the error was, and how the patient (or their representative) reacted when they learnt of the error.

People’s perceptions about the severity and frequency of error appeared to be influenced by the media and what they heard from friends and family. A particular concern, highlighted by many of those interviewed, was the possibility of contracting a hospital acquired infection (HAI). Inadequate staffing levels were identified as the main reason for safety failure in hospital, while poor communication was viewed as an important contributor to error in all health care settings, especially across the interface between care sectors, for example, between secondary and primary care.
Study participants reported that they (or their family members) had experienced a wide range of threats to their physical safety and psychological well-being when using health care services, and that they were prepared to act to protect themselves (or others) when certain circumstances prevailed.

Perceived threats to safety reported by those who took part in the study related to medications; diagnosis; delays in referral; hospital cleanliness; perceived neglect of physical and emotional needs; poor communication; clinical procedures reputedly inadequately executed; inadequate facilities; threats to safety from other patients; administrative and systems factors.

Participants described a range of situations in which they had acted or considered acting, to avoid error and/or avert harm. In most cases the action they took was to ‘speak up’ to a health care professional, to draw their attention to their concerns. Where the patient’s (or their representative’s) ‘speaking up’ to a health care professional was met with a ‘negative’ (indifferent, dismissive, defensive) response, a chain of events was triggered, usually described as confrontational, leading to one of two outcomes; either the patient (or their representative) abandoned their attempt to seek recognition or redress for their concern, or they subsequently made a verbal or written complaint.

In general, study participants appeared to be in favour of patients being involved in the promotion, enhancement and protection of their own safety through the adoption of patient safety roles. However, there was widespread recognition amongst both interview and focus group participants that various factors could impact on patients' (or their representatives') willingness or ability to take on such roles, relating to characteristics of the patient; the anticipated or actual response from health care professionals; the level of challenge associated with the role; and characteristics of the health care system.
Opinion was divided amongst participants about whether or not the NHS learns from its mistakes; about half of respondents thought that positive changes occurred as a result of learning, while others said they were unable to give an informed opinion, and a minority held the view that errors were routinely covered up and that a ‘blame culture’ existed within the NHS.

Study participants had limited knowledge of local reporting systems, and the majority were unaware of the existence of national reporting systems. Features of reporting systems cited by participants as conducive to reporting included: high visibility; easy accessibility; incorporation of feedback mechanisms; optional anonymity; and freedom from repercussions, for both staff and patients.

**Strengths and limitations of the study**

This in-depth, qualitative, exploratory study makes an original contribution to the field of patient safety research by providing empirical data relating to patients’ (and their representatives’) views of whether, how, and to what extent they wished to be involved in taking a role to ensure their own (or another’s) safety when using health care services.

A major strength of the study was the deliberate inclusion of a wide range of participants (drawn from 6 different patient and ‘consumer’ groups) in order to capture a broad range of views and perspectives from people with varying socio-demographic characteristics, whose diverse clinical conditions meant that had experience of using health care services in a wide variety of health care settings, often over long periods of time. Patients with severe and enduring mental health problems were purposively selected to participate in the study, as this group of patients are often overlooked in mainstream research.
On-going findings from the literature reviews undertaken in Phase 1 of the project fed into the development of aspects of the Phase 2 study (for example, development of the interview topic guide).

The study methods (individual interviews and focus groups) enhanced the comprehensiveness of the study findings. Depth interviews proved to be a highly effective way of exploring people’s beliefs and experiences in relation to patient safety roles, allowing the interviewer to probe and clarify responses in order to produce a rich data set that was grounded in the experiences of interviewees themselves. Individual interviews yielded highly detailed information on aspects of process (for example, on the nature of communication between patients and health care professionals) which contributed to identification of the ways in which particular beliefs or experiences were likely to influence behaviour.

The main purpose of the focus groups was to generate general discussion concerning the (68) participants’ views of patient safety roles, and focus group data served to complement and enhance the data gathered via the interviews in a number of ways. Firstly, use of the ‘roles exercise’ meant that data relating to focus groups participants expanded the data set, as they gave their views on a greater number of patient safety roles than interview respondents; secondly, the dynamic nature of the interaction in the focus groups, with evolving agreements and disagreements, consensus and conflicting viewpoints, resulted in both breadth and depth in the discussion of specific roles; thirdly, by using focus groups we were able to capture a ‘collective consumer’ perspective of patient safety roles; and, fourthly, discernible convergence of views about facilitators and barriers to role enactment across the focus group and interview data enhances the trustworthiness of the study findings.

The use of a theoretical framework (role theory) to underpin the study facilitated analysis and interpretation of the data by providing a useful ‘lens’ through which to focus on issues pertaining to role boundaries, ambiguities and conflict that can
result when patients adopt safety roles that may viewed by health care workers as representing a challenge to professional roles.

There are well recognised limitations to the qualitative approach used in the study. One of the obvious disadvantages is that it does not support the formulation of quantitative estimates of either the frequency or distribution of particular views or experiences within a population. The current study was designed in order to explore how patients’ desire to be involved in their care might vary according to health care setting, location, and in relation to patient demographics. It is feasible therefore, that findings from the current study could be used to usefully inform future survey work to investigate the significance of contextual and demographic variables in a quantitative fashion.

Due to the large amount of data collected, and the complexity of (particularly the focus group) data, analysis of the study data is currently primarily descriptive in nature, which imposes limitations on the generalisability of the study findings at this point in time. Whilst the analysis that has been undertaken enables us to meet the study objectives, and to comprehensively answer the research questions (as stated in the protocol), further analyses are possible. These will be carried out prior to the production of papers for publication in order to develop theoretical hypotheses (and to refine an explanatory model which we have already started to develop) from the data, which should allow for inferential and theoretical generalisation from the study findings.

**Alternative explanations for findings**

In considering alternative explanations for the study findings, the data have been examined from the stance that interview respondents may have sought to offer responses that they believed would be more socially acceptable, or ‘desirable’, while concealing their private views. To give an example, study respondents consistently said that their motivation for reporting potential or actual harms, or
deficiencies in care, would be to seek an apology or prevent a similar occurrence in the future, rather than because they would want financial compensation.

The likelihood of the researcher obtaining responses which the interviewee considers socially acceptable is greater where the interviewer does not develop a good rapport with the informant, and where the researcher asks general questions about health beliefs. By taking time to establish rapport with respondents (for example, visiting them in their own home, extending an invitation to a family member or friend to accompany the respondent during the interview) and by inviting interviewees to talk in detail about their own experiences of situations in which they had acted (or wanted to act) to guard their own safety, we believe we gained access to people’s ‘private’ views and accounts, as they described ‘real’ situations in which they themselves were the prime player.

Examination of the interview data set reveals that respondents were willing to share views and experiences of using health care services that cast themselves, and/ or health care professionals, in a ‘negative’ light, that is to say, they appeared willing to speak frankly when describing their views and experiences.

Data from focus group discussions requires careful interpretation because interaction within the group necessarily affects the data elicited, and the analyst needs to be alert to the effects of censoring (a member withholds potential comments), conformity (comments are tailored in accord with the member’s understanding of the leader and other group members) and ‘group think’ whereby people form their opinions partly in response to what has already been said (Carey 1995). During the analytic phase of the study the goal was to reach an understanding of the richness of the group data, while noting the effects of group dynamics, and the part played by dominant members in shaping the discussion. Segments of focus group data, which reflect the sequential turn-taking of individual group members, have been reproduced in the reporting of the findings.
from the focus group discussions in order to indicate how conclusions were drawn from the data.

A possible explanation for some interview respondents’ stated preoccupation with contracting a hospital acquiring infection (HAI) was the high level of attention given to HAIs, (particularly to Methicillin-resistant Staphylococcus aureus (MRSA), by the media during the period that the study was being conducted. However, information from these sources was discounted as ‘media hype’ by some participants, while those patients who were undergoing surgical procedures reported that they were given information about MRSA from health care professionals during attendance at pre-operative assessment clinics.

Meaning of the study

*Patients’ willingness and capacity to be involved in safety promoting activities*

Findings from the study reveal that patients may be willing to engage with the topic of patient involvement in patient safety and that they are likely to have broad understanding of the issues involved. Study participants expressed a desire to be involved in promoting and enhancing their own safety, but differed widely in their views about which patient safety roles they considered appropriate for themselves or others to adopt, and the circumstances in which patients should act to promote their own safety.

Participants indicated that their willingness and ability to adopt patient safety roles would be affected by a range of factors which related to themselves as individuals (including how ill or well they were feeling, and their emotional state); the nature of their relationship with HCPs; the gravity of the situation in which they found themselves; and features of the wider health care system. Because of the wide variability and unpredictability associated with these factors, it would appear that recommendations for consistent or blanket adoption of patient safety
roles may not be appropriate, and that patients can not, and should not be expected to, routinely adopt safety roles as means of acting as a safety check in their own care. While it seems that patients should not be relied upon as a check, many would be willing and naturally inclined to play a role in their own safety, if the context and the nature of the relationship with health care providers were appropriate.

Factors perceived as conducive to patient involvement in safety

Study participants highlighted the importance of the attitude and behaviour of health care professionals in facilitating their involvement in safety roles, and they suggested that the nature of the relationship that they shared with some health care professionals enabled them to feel comfortable about ‘speaking up’ about their concerns. They also stressed the importance of ‘knowing your grounds’, that is to say, having sufficient knowledge to feel confident about taking an active role in guarding your own (or another’s) safety; people said they needed sufficient information about their condition and its treatment to know what ‘should’ happen when care is administered.

Patients’ perceptions of a supportive and enabling environment were closely linked to the attitudes and behaviour of health care professionals. A facilitative environment was perceived as one in which staff:

- ‘invited’ patients to ask questions about their diagnosis, condition, investigations and treatment; took time to respond appropriately; were prepared to provide information that was relevant to the individual patient at that particular time point.

- gave patients ‘permission’ to raise concerns, and refrained from reacting in a dismissive, defensive or hostile manner; indicated to patients that their concerns would be listened to, acknowledged, and, if necessary, acted
upon; ensured that patients did not suffer any form of recriminations because they brought their concerns to the attention of staff.

- **responded to patients in a consistently positive manner.** Patients who met with a favourable response the first time they ‘spoke up’ suggested they were more likely to do so on future occasions.

Consequently, patients’ (and their representatives’) perceptions about the nature of their relationship with health care professionals appeared to be crucial in their decision making about whether, how and to what extent they might become involved in promoting their own safety. Where patients perceived that the relationship was positive, and that the health care professionals were open, communicative, empathetic and treated them with respect, they appeared more willing to ‘take the risk’ of ‘speaking up’ about their care, because they anticipated a positive responsive from the health care professional. The health care professionals with whom patients most frequently described sharing this kind of close, empathetic relationship were specialist nurses and their general practitioner.

Four short data extracts (also highlighted in the main body of the report) are presented in Table 4.2 below to illustrate the apparent effect on patients’ willingness to engage in safety related behaviour when they anticipate, or receive, a positive response from health care professionals.
Table 4.2: Extracts from interview and focus group data which illustrate the effects on patients of anticipated or actual positive responses from HCPs

<table>
<thead>
<tr>
<th>Extract</th>
<th>Participant/Group</th>
</tr>
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<tbody>
<tr>
<td>‘I had an incident where they were doing some chemo treatment...and there was... something they were doing, flushing something through, and I couldn’t remember them doing this bag at all, and I sat there thinking, I can’t remember this, is this right, so I queried it, and to be fair the chemo nurse, she was really good, she went off, she looked at the paperwork, she got another nurse to come as well, and I wasn’t made to feel as if I was challenging as such. I was reasonably reassured about it. That was good, a more positive experience. But there’s other incidences depending on the person where it has turned into like a confrontation and I’ve not intended it to be.’</td>
<td>Participant 1, Patient Focus Group 2 (women undergoing treatment for breast cancer)</td>
</tr>
<tr>
<td>‘The doctor that [her child] sees is really good and the specialist nurse, she is brilliant, so between the two we have a really good liaison, so I don’t find it difficult to check medications’</td>
<td>Participant 5, Patient Focus Group 3 (parents of children with asthma)</td>
</tr>
<tr>
<td>‘there was a particular incident and the immediate reaction of staff was so positive of ‘That should not have happened, we will not let this happen again, we will deal with it....’</td>
<td>Participant 3, Patient Focus Group 6 (patients with severe and enduring mental health problems)</td>
</tr>
<tr>
<td>‘I mean we have quite a good relationship [mother speaking about her relationship with staff on paediatric ward]...so I do feel comfortable to say something if something is wrong, I would say it and they know I would, because they always say to me, especially the doctors...’do you feel this?, or ‘do you want to say anything?’, and they know I would feel comfortable speaking to them as well...’</td>
<td>Interview respondent (303) (parent of child with asthma)</td>
</tr>
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Concluding summary

The study findings appear to suggest that patient involvement in patient safety could be enhanced by a shift away from the current emphasis on the prescription of specific patient safety roles, towards a focus on the provision by health care professionals of a broadly supportive environment in which patients (and their representatives) are routinely given information and encouraged to be actively involved in their own safety and to raise concerns, if and when they feel able, without fear of recriminations.
Implications arising from the study

Changes in the wider health care system would seem to be a necessary precursor to health care professionals being able to develop better relationships with patients. In particular, staffing shortages on general hospital wards appear to act as a major barrier to patients being involved in safety promoting activities. Study participants reported that often nursing staff in particular appeared to lack the time to respond to their requests for information or concerns about their care, and they indicated that when wards seemed particularly busy, they would try to avoid ‘disturbing’ nurses. Health care professionals need to be supported within the wider clinical environment in order to be able to offer patients the time and attention that might facilitate their involvement in patient safety activities.

A shift in emphasis towards HCPs being responsible for providing a positive, supportive environment that encourages patients to contribute to their own safety (according to their capacity and wishes) requires that HCPs are provided with opportunities to develop as effective communicators who are sensitive to the needs and concerns of individual patients.

Unanswered questions and future research

The current study relied on self reports from patients concerning their future or past behaviour in relation to the adoption of a range of patient safety roles, and we have no way of knowing how closely these reports matched, or would match, actual behaviour. The knowledge base about patient engagement in safety initiatives could be improved by ethnographic studies which focus specifically on patient-health care professional behaviour, and the contextual factors appear to be significant in influencing behaviour.

Our study focussed on the views of patients and their representatives, but did not include the views of health care professionals about patient involvement in
patient safety. A future study which might yield useful results with implications for practice might focus on health care professionals’ views of patient involvement in reporting their concerns directly to clinical staff, or to clinical governance groups.

Most of the people who took part in our study considered that the probability of the risk of them experiencing an error in their care would be much higher in hospital than in general practice, and the personal experiences they described of errors or potential harms related mainly to secondary care. Consequently, much of the data generated by the study pertains to patients’ perceptions of safety issues in connection with health care services delivered in hospitals.

Evidence about patient safety in primary care is generally lacking, and there is a dearth of evidence about patients’ views of the potential for them to be involved in safety initiatives within general practice. Recent changes in the ways that primary health care services are delivered mean that patients may be more likely to see different clinicians when they visit the surgery, and less likely to have an established relationship with a particular GP, which could potentially affect their willingness to engage in safety promoting activities. Further investigation into patient involvement in safety in primary care therefore seems warranted.
REFERENCES


Carey, M (1995) Comment: Concerns in the Analysis of Focus Group Data. *Qualitative Health Research* 5, 487


WORK PHASE THREE

CHAPTER FIVE:
ABSTRACT

Work Phase Three

A pilot study of an approach to enhancing safety involving individual patients feeding back their experiences to relevant clinical governance groups.

Background

Many patients are reluctant to adopt safety promoting behaviours because they fear this might have adverse consequences for their treatment and perceive that the current culture within healthcare is not receptive to patient reports of safety threats (Swift, 2001; Wachter, 2004). However, patient stories about their safety experiences have been identified as a powerful teaching tool and a stimulus for behaviour change (Sax, 2007).

Objectives

To design an approach that used patient stories to facilitate interaction between patients and healthcare professionals and to challenge professional norms about patient experience and involvement.
To evaluate this approach for feasibility, acceptability and perceived usefulness.

Methods

We designed and modified an exploratory approach that involved 5 patients feeding back their safety experiences while using NHS services to 5 clinical groups. We evaluated the approach through patient and clinical group feedback via post-intervention discussion, questionnaires, and a researcher diary.

Results

The intervention was largely evaluated by patients and staff as feasible, acceptable and useful. While staff had initial concerns about the appropriateness of the Clinical Governance Group (CGG) meeting as a forum for patient stories
and about patients being overawed by the setting, these concerns were not realised in practice and the stories stimulated discussion, reflection and pledges for action.

**Limitations**
Issues to be resolved include time and resource constraints in preparation of both patient and clinical groups. This intervention takes time to organise and CGGs have limited time for their workload. In addition, we found that some groups of staff were not receptive to this intervention due to pressure of work.

**Conclusion**
Clinical governance groups potentially provide a forum for patients and clinical teams to discuss and learn from stories based on safety experiences.
CHAPTER FIVE

A pilot study of an approach to enhancing safety involving individual patients feeding back their experiences to relevant clinical governance groups.

BACKGROUND

There are an increasing number of initiatives designed to stimulate patients’ involvement in promoting their own safety while using healthcare services. Phase 1 of this project has summarised current literature about patient roles and interventions, the effectiveness of those interventions where they have been evaluated and the willingness and ability of patients to be involved. The evidence suggests that many of these interventions have been proposed and implemented without consulting patients. Phase 2 of this project addressed that omission by generating new knowledge about patients’ views on their role in, and experience of, safety in healthcare settings. The call for proposals for this project called for the exploration of a promising intervention that involved patients. Drawing on the results from the primary research, which revealed a pivotal role for healthcare professionals in the facilitation of patient involvement, we chose to focus on this for the final component of the project (Phase 3).

There is evidence from phase 1 and phase 2 of this project that patients’ involvement in promoting their own safety is largely dependent on the reactions and attitudes of health care professionals to patient involvement. There is a perception by patients that the current culture within healthcare is not receptive to
patient reports of safety threats (Swift, 2001; Lozowski, 1993; Wachter, 2004) and that questioning or challenging healthcare professionals may have adverse consequences for patients’ individual treatment (Brown, 2006). This view is supported by experiences described by individual informants who participated in the primary research for this project and is likely to affect patients’ willingness and ability to raise concerns about safety. Doctors, nurses and allied healthcare professionals can give patients ‘permission’ to be involved in promoting their own safety by their manner, by giving time to patients and by inviting questions or comments or other kinds of involvement (Anthony, 2003, Duncanson, 2005, Cahill, 1998). We aimed to explore the potential for patient stories of safety experiences relayed to staff to impact on their culture and behaviour.

Changing the behaviour of healthcare professionals is a particular challenge (Cheater et al 2005). The belief that an individual can successfully change their behaviour or successfully achieve a goal is referred to as self-efficacy and this may be heavily influenced by cultural norms (Ajzen, 1980). The role of both self-efficacy and workplace culture in behaviour was illustrated by a recent study. Sax et al., (2007) examined the factors associated with norms and self-efficacy in the context of hand-washing in staff in a teaching hospital. They demonstrated that pressure from colleagues and the perception that colleagues had good adherence to hand-washing practices were independently associated with good individual adherence, as was the perception that hand-washing was easy to perform. Exposing a staff group to a patient’s story about their safety experiences
and subsequent discussion within the group may be a way of beginning to change the cultural norms associated with patient safety and patient involvement in safety promotion.

The use of personal experience is recognised as a powerful educational tool (Repper, 2004). It has been suggested that health professional learning tends to combine two approaches: experiential learning, which tends to be student centred; and accrualment of objective knowledge, which is teacher-led. There is some debate about the advantages and disadvantages associated with each approach, and it has been suggested that student capacity for the latter is limited (Wood, 1999). Two of the few studies which have assessed the effectiveness of patient involvement in health professional learning found that students displayed an improved ability to communicate and empathise with patients and were more likely to approach people as individuals (Wood 1999; Klein, 1999). In addition, an intervention where patients feed back their safety experiences could provide a forum, and establish a precedent, for open discussion of safety events and causes.

Clinical governance groups form part of many NHS Trusts’ clinical governance strategy through which healthcare organisations are accountable for continually improving the quality and safety of their services. This is achieved through monthly meetings of multidisciplinary clinical teams such as, for example, those providing services for children or older people. We chose to invite these
established groups to take part in the study as group members would have an awareness of quality and safety issues.

**Aims and objectives**

By attempting to facilitate interaction (between patients and health professionals) and challenge professional norms, this intervention aimed to impact directly on the prevalent healthcare culture. For the intervention, we asked patients to feed back, to a staff group, in person or on DVD (or a combination of both), their own experiences of safety and safety behaviours.

We evaluated this approach for feasibility, acceptability and perceived usefulness.

The specific objectives of Phase 3 of the study were:

1. To design an intervention that involved patients presenting their safety experiences to a group of staff of the relevant clinical team (for their healthcare experiences).
2. To identify patients and clinical teams who were willing to be involved in the design and piloting of this intervention.
3. To pilot and evaluate these approaches.
METHODS

Design
This was an exploratory study to investigate the feasibility, acceptability, usefulness (and any potential issues) of the implementation of an approach to patient involvement in safety promotion.

Ethics
Ethical approval for the study was obtained from an NHS Research Ethics Committee. Research Governance approval was obtained from the relevant NHS Trusts.

Setting
The study took place in both primary and secondary care and had three participating centres: an NHS Teaching Hospital Foundation Trust, an NHS regional general hospital Trust and an NHS Primary Care Trust. All three centres were in the North of England, United Kingdom.

Participants
Participants in this study included both patients (and/or their family/representative) and Trust staff who were members of clinical governance groups (CGG).
**Patient participants**

Patient participants who had already been recruited for Phase 2 of the project and who had indicated that they were willing to be involved in piloting an intervention were invited to take part. We recruited participants from a range of clinical groups who told their stories to staff members of a clinical governance group (Table 5.1). In one clinical group (adults with type 2 diabetes) the staff participants were attending Diabetes Team Educational Modules.

**Table 5.1: Participants recruited, clinical group and CGG group**

<table>
<thead>
<tr>
<th>patient clinical group</th>
<th>participants recruited</th>
<th>CGG</th>
</tr>
</thead>
<tbody>
<tr>
<td>adults with type 2 diabetes</td>
<td>1 patient with 1 family member</td>
<td>Diabetes Team Educational Modules Participants</td>
</tr>
<tr>
<td>women who had undergone treatment for breast cancer</td>
<td>2 patients</td>
<td>Oncology CGG</td>
</tr>
<tr>
<td>parents of children with asthma who had been hospitalised in the previous year</td>
<td>1 set of parents</td>
<td>Paediatric CGG</td>
</tr>
<tr>
<td>adults who had undergone a hip or knee joint replacement</td>
<td>1 patient</td>
<td>Orthopaedic CGG</td>
</tr>
<tr>
<td>adults who had complained or raised concerns about a safety issue</td>
<td>1 family member, 1 representative</td>
<td>Elderly care CGG CGG for Medicine</td>
</tr>
</tbody>
</table>
Consent

*Patients*

Patients who had taken part in phase 2 and had expressed an interest in phase 3 were sent written information about the study. A member of the study team then contacted these potential patient participants (at least 24 hours after they had received the information, but in most cases, after 7 days) to enquire if they understood the information that had been sent, had any questions and if they were interested in taking part. Patients who verbally expressed an interest in taking part (not an agreement to take part at this stage) were invited to attend a meeting with the project team to hear more information about the study. At this meeting potential participants were given further information and had the opportunity to ask questions. In addition, patients were asked if they were willing to take part and if so, written consent was obtained. It was also appreciated by the project team that participant ‘consent’ is an ongoing process. In view of that, we verbally checked with all participants, at each stage of the project, that they were happy to continue to take part.

*Staff*

Potential staff participants were informed about the study and they received information sheets at a meeting prior to implementing the intervention. They also had the opportunity to ask project team members questions about the study. Verbal group consent was then obtained for the intervention to take place at a subsequent meeting.
Interventions

The intervention was the patient story delivered in one of three different ways: face-to-face; by DVD; or a combination of DVD and ‘face-to-face’ to a group of staff.

Development of the intervention

Mindful of the need to build on past experience we developed this intervention with reference to the approach to appraising interventions developed as an earlier part of this project (Chapter One). This drew on a scoping review of literature about the involvement of patients in efforts to promote their own or others’ safety while using health services. The approach involves:

- identification of the ‘route(s)’ by which the intervention assumes patient behaviours might enhance patient safety
- identification of conditions that would need to be met for the patient to adopt the behaviours and make an effective contribution (this includes conditions relating to the patient and their family, the health professionals involved in their care, and the healthcare organisation/systems within which care occurs).
- examination of the support offered by the intervention and consideration of whether and to what extent it would ensure that the necessary conditions could be fulfilled (This is a context dependent examination)
- consideration of the potential negative effects of the intervention.
Figure 5.1 shows the appraisal of the proposed exploratory intervention using the approach developed:

Figure 5.1: intervention appraisal

**Example:** Patients tell a story about their safety experiences to a clinical team supported by staff to construct a story, to attend a team meeting and to take part in discussion after story

**Intended to prompt patients to:** help ensure that the problems and risks within healthcare systems are identified and reduced by providing feedback about experiences of health quality and safety

**Conditions to be met for patient contribution to be effective**

- the patient is able to construct and present a story
- the patient has access to clinical team
- the clinical team respond appropriately

**Questioning the support provided by the intervention**

- Is the patient adequately prepared for the intervention? *Patients may find the idea of standing up and telling their story to a group of clinicians daunting. They will need preparation for this and to know what to expect – details of venue and meeting size and composition. They will need help to write and hone their story*

- Is the patient supported throughout the process? *Patients will need support, not only for preparation, but also to negotiate access to a clinical team, to accompany the patient to meetings and to debrief after the story and discussion*

- Will the clinical team respond appropriately to the story? *Staff may need assurances that there is not a hidden agenda; and that the stories aim to be constructive rather than critical or singling out individuals for criticism. They need time and space to consider the story and this may not happen if the team is overstretched and pre-occupied with other matters.*

**Potential negative effects**

- If patients are not adequately prepared or supported or the clinical team are not responsive this may be a negative experience for them and staff
We worked with patient participants on an individual basis to develop the precise format and content of their stories. Because this was done on an individual basis, the process varied slightly, but occurred broadly as described in Figure 5.2.

**Figure 5.2: intervention flow chart**

**CGG meeting 1**: (researcher/s and CGG) presentation of project and intervention to CGG. Group consent obtained for researchers to return with patient. CGG collaborator identified.

**Patient meeting 1** (patients and researchers): Opportunity to discuss project. Viewing of ‘sample’ patient story. Patient agrees to take part/written consent obtained.

**Crafting the story** – (patient and researcher) a number of contacts refining the story. Contact may be face to face, by telephone or e-mail

**Patient meeting 2**: (patient, researcher/s and CGG collaborator) discuss content of story, format of CGG meeting and any questions about the study.

**Making the DVD**
patient comes to University to record DVD.

**CGG meeting 2**: (patient, CGG staff group and researchers) story presented followed by discussion

Patient requested to send final written copy of story to researcher
Meetings between patients and project team representatives took place at a location of the patients’ choice; in most cases this was their own home. The meeting between patient, researcher and CGG collaborator took place at the relevant Trust premises. Guidance was sought from reports of the experience of the use of patient stories by other staff teams, namely those at NHS Tayside and Royal Sussex County Hospital (O’Connor, 2007; Ottewill et al., 2006).

**Implementation of the intervention**

It was considered important that patients were adequately prepared for the experience of sharing their story with clinicians (Hanson, 2001; Gall, 1984; Spencer, 2000). The agreed format for the CGG meeting, patient input, room layout and expected staff numbers were discussed with the patient prior to the CGG meeting. Patients were also supported by a collaborator from the CGG, leading up to, and during the meeting. Researchers attended the meeting as observers and note-takers.

The implementation of the intervention at the CGG meeting was as follows:

- Collaborator who has liaised with the patient or patients introduced them to the CGG and acted as a support for them during the meeting if the patient had opted to deliver their story face-to-face.
• One or two patients told their story (from the pre-prepared script) or the DVD was played.
• CGG staff and patient(s), guided by the collaborator discussed the issues that arose in the patient story and the feasibility, acceptability and usefulness of the intervention.

Post-implementation of the intervention
Any travel expenses incurred by the patient were reimbursed. If patients had unresolved concerns, they were encouraged to contact the research team in the first instance. If patients needed help with issues raised by the process they were encouraged to contact a member of the clinical team or their GP.

Evaluation
At the discussion during the CGG meeting, evaluation by patients and staff was sought through guided prompts from the CGG collaborator about the acceptability, usefulness and feasibility of this intervention. The decision was taken not to audio record discussion following the intervention as recording might potentially have inhibited people from contributing. In addition, participants had the opportunity to complete a written evaluation form after the CGG meeting and these were returned to the project team.

The following data were collected:
• Written notes taken by researchers recording the discussion after the patient story at the CGG meeting.
• Short questionnaire distributed at the CGG meeting for staff participants to complete.
• Personal reflections about the process and experience by patient participants
• Researcher diary/field notes with reflection on the process.

Process
Three patients and two patient representatives, from four of the clinical groups interviewed, told their story to five different CGGs (Table 5.2). Five patients, (representatives or parents who originally agreed to take part) did not in fact participate. For four potential participants this was due to time constraints of the project, while the fifth person could not attend the CGG meeting on the date scheduled.
Table 5.2: details of participants, CGGs and presentation method

<table>
<thead>
<tr>
<th>participant</th>
<th>clinical group</th>
<th>CGG</th>
<th>presentation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (patient)</td>
<td>women who have been treated for breast cancer</td>
<td>Oncology CGG</td>
<td>DVD</td>
</tr>
<tr>
<td>2 (patient)</td>
<td>adults who have had joint replacement surgery</td>
<td>Orthopaedic CGG</td>
<td>face to face</td>
</tr>
<tr>
<td>3 (patient rep)</td>
<td>people who have raised or made a complaint about a safety related issue</td>
<td>Elderly Care CGG</td>
<td>face to face</td>
</tr>
<tr>
<td>4 (patient rep)</td>
<td>people who have raised or made a complaint about a safety related issue</td>
<td>Medical CGG</td>
<td>face to face</td>
</tr>
<tr>
<td>5 (patient)</td>
<td>people with severe and enduring mental health problems</td>
<td>Mental Health CGG</td>
<td>face to face</td>
</tr>
</tbody>
</table>

**Patient meeting 1 (patients and researchers)**

Concerns and discussion points at this initial meeting were: nervousness on the part of patients about presenting to a staff group, for some but not all; worries about the story being perceived as negative or criticism when, by and large, their overall experience had been positive; and worries, for one of the patients who had treatment for breast cancer, about re-living unpleasant experiences.

Most patients thought at this stage that they would like to tell their story face to face; one thought she would like to record the story on DVD but be present at the meeting for the response from the CGG.
CGG meeting 1 (staff and researchers)

Two of the CGG leads requested a face to face meeting with a researcher to discuss the intervention; for the other CGGs attendance at the introductory meeting was arranged by e-mail. Questions and concerns raised by the leads and at the introductory meetings were similar. All had initial concerns about the appropriateness of the forum for this feedback. They felt that as a group with experience of complaints and examination of untoward events the CGG had a good grasp of the ‘patient view’ and that this sort of feedback might be more useful for ‘grassroots’ staff.

In addition, all the CGGs were concerned about the effect of the experience on patients, that it might be too overwhelming. The CGGs were also anxious that patients might expect resolution of the issues they presented to the CGG and the consequences for patients of this expectation not being met.

Other concerns and comments from individual CGGs included resource constraints (from a newly formed group with a backlog of business); how stories about individual staff members might be dealt with and that it was just another opportunity for clinical staff to be blamed for things that were not their fault. Nevertheless all CGGs agreed that we could attend a subsequent meeting with a patient and hear their story.
One CGG offered to muster a higher proportion of ‘grassroots’ staff than would normally attend a CGG meeting – we indicated that we would prefer usual attendees. Another (time constrained) CGG did set up an extraordinary meeting for the project but with the usual attendees.

Crafting the stories

The stories were written by the participants after discussion with one of the research team. After discussion, researchers and patients agreed that they would prefer the security of a written script. Subject matter was drawn from the patients’ own interview for phase 2 of the project. The stories were then sent to and read through by one of the researchers. Suggested alterations included summarising points to reduce the overall length and clarification of salient points. These suggestions were usually acted on. Throughout, patients were concerned that their accounts should not be seen as critical but constructive, their motivation for taking part was to make things better, not to ‘pick holes’.

The stories took between 3 and 5 minutes to read out and took the form of a wider message illustrated by a specific incident. Examples of the stories are in appendix 5.1 but the themes were:

- different responses of healthcare staff to adverse events and how this affects patients
- the experience for a patient of receiving mixed messages from healthcare staff through their words and their behaviour
- how failure of staff on an acute mental health ward to take seriously a patient led to loss of trust and violence
- the experience of a poorly executed discharge for the daughter of a sometimes muddled elderly patient
- the importance of planning for healthcare interventions for patients with challenging behaviour

**Patient meeting 2 (patient, CGG collaborator, researcher/s)**

Prior to the CGG meeting patients met with the CGG representative who was to act as their support at the meeting. We had intended that this meeting with an identified support person from the clinical group would be reassuring for the patient and in fact it was perceived as such. It also served to reassure the CGG collaborator that it was not going to be problematic to present the story to the meeting. It also proved to be a useful forum for discussing perceived problems or worries. One patient, although keen to take part in the post story discussion, was concerned that her presence would restrict free exchange of views. The same patient was also concerned that the individual healthcare professional who was mentioned in her story would be at the meeting and how she and he might feel about that. Most patients indicated that they found this meeting useful and reassuring. One said that it meant she was much more relaxed than she would have been going into the CGG meeting and it served as clarification of the aim of the intervention as well as the wider function of the CGG.
CGG meeting 2 (patient, staff group, researchers)

For most of the CGG meetings the patient story was scheduled to be presented at or near the beginning of the meeting. For the acute trust CGG meetings the room was laid out as if for an outside presenter. This was daunting for the first patient to tell her story as she had to sit on a chair facing a ‘sea’ of faces. At subsequent meetings we asked the CGG representative to sit alongside the patient during her reading of the story and for the discussion following this.

All except one of the story and discussion sessions within the CGG meetings took around half an hour. The exception was the extraordinary meeting set up just for the intervention and, as there was no other business for the group, we agreed prior to the meeting to a longer discussion period. The discussion for all the meetings was recorded, in note form, by two researchers. Completed questionnaires (12 in all from 2 of the CGGs) were returned to researchers by a member of the CGG. One CGG member emailed researchers with comments.

Only one of the stories was delivered by DVD. There did not appear to be any lessening of the power of the story nor the amount of discussion later. However, the view of experience contributed by patients seemed to bring more depth and direction to the discussion as staff talked about problems and solutions, allowing the ideas to develop in a way that they did not without the ‘live’ patient contribution. For example: in one meeting, a staff member’s response to a detail of the story appeared to move responsibility for a problem experienced by the
story-teller away from the healthcare team but her recollection and description of
the experience shifted responsibility back to the staff group, as part of the health
and social care team aiming to provide a seamless service for patients and their
families.

All the patients who were present at CGG meetings took part in discussions and,
although some were initially nervous about presenting their story, did not show
any sign of being overawed or overwhelmed by the situation or any of the
individuals present. As the discussion went on they were quick to provide other
experiences which backed up their story, making it difficult for it to be dismissed
as a ‘one off’. Being present for the discussion meant that they were able to see
their story being taken seriously by staff and also had the opportunity to see the
staff point of view.

In some of the introductory meetings the researchers observed that participation
appeared to be dominated by higher status medical clinicians. This changed for
the CGG meeting with the patient present when participation was more
multidisciplinary and all ‘levels’ of staff contributed. This may have been because
the patient story was something everyone could relate to or the patient’s
presence may have introduced a degree of levelling of the power imbalance in
some clinical teams. For example, in one meeting the patient was able to
reinforce the feeling from the nursing team that a recent change to staffing
policies, disliked by doctors, was better for patients as well as nursing staff.
Post Meeting

The researchers and the patient left the CGG meeting and retired to an informal meeting over a cup of tea/coffee. This was an opportunity to debrief and identify any support needs of the patient. None were identified although this was still a useful discussion, summarising the main points, reflecting on staff responses and for most confirming the ‘worth’ of the exercise. For the one patient representative who told her story to a CGG who were less responsive, we were able to reinforce what she had recognised (that this group might have been more receptive at a different time) and reassure her that her delivery and story were not the issue.

We had originally intended to use the questionnaires for patients and staff but these were modified to be more staff focused and we substituted this debriefing session and a request for narrative feedback about the process from patients. This was provided by all but one of them and all of these reported that involvement in the project had been a positive experience for them.

RESULTS

Feasibility of the intervention

Time constraints were one of the biggest problems. Most of the patients also worked outside the home and, as CGG meetings were arranged during office hours and months in advance, had to attend during working hours or hope that the meeting coincided with free time. The intervention took twenty or thirty minutes out of a CGG meeting. For one CGG with a waiting list of business this
prompted an extraordinary meeting to facilitate their involvement in the study. For another it meant that, although we were offered the chance to attend at a later meeting, study time constraints meant that we did not conduct the intervention with that group.

Co-ordination of the meetings, crafting of the stories, supporting patients all took time and, if this intervention was adopted by a Trust or individual CGGs would demand a considerable commitment from a staff organiser.

Access to four of the CGGs was facilitated for this study by a medical director at the Acute Trust. This level of facilitation would be useful for any further exploration of or use of this intervention. For the two CGGs approached outside the Acute Trust access negotiation was more problematic, both in terms of identifying a suitable group to hear the story and gaining access to that group. For the mental health CGG access was finally gained through a member of the research project steering group and this was a prolonged but, ultimately, successful process. For the primary care group we had a willing collaborator and planned to incorporate patients feeding back two stories as part of a diabetes educational module. However, misunderstandings about the nature of the project meant that this was not a suitable forum and there was insufficient project time to negotiate another one.
The study team did attend several meetings where CGGs were clearly preoccupied by time and resource constraints. These groups found it difficult to engage with the stories and the project message, probably because organisational learning is not seen as a priority when clinical teams are worrying about where they will find space for the next patient.

**Acceptability of the intervention**

The concerns voiced by staff about ‘finger pointing’, the appropriateness of CGGs as a forum for this intervention and patients being overawed by the experience were not borne out. Patients appeared to have few difficulties with the story telling. The patient who was worried about re-living difficult experiences found that sifting through memories for a ‘suitable’ story was problematic but once she had identified a theme her anxieties went and she focused on telling the story. This patient completed a DVD as ‘backup’ as she thought she might be nervous about presenting face to face. The other patient participants, although most were nervous just prior to the meeting, were glad they had taken part. One said that it ‘wasn’t as nerve-racking as I thought it would be’. Although resolution of problems was not the aim of the intervention one patient commented that taking part, for her, ‘laid some ghosts to rest’. Most of the patients felt listened to and that staff were ‘genuine people who will do their best to change things’.

Two members of one CGG, which appeared to react positively to the intervention and made a number of proposals for change as a result of the story, raised some issues with the researchers after the meeting. They were concerned about the
‘agenda’ of the intervention and the importance of openness about this, and its representativeness of patient experience more widely. Some members of another CGG also had concerns prior to the meeting about the agenda of one team within the group. There were concerns that the patient story would be perceived as potentially divisive between staff groups by ‘backing’ the agenda of one team to the detriment of another. This experience suggests that it may be worthwhile, for this intervention, to have a collaborator within the CGG who was aware of the local context and could identify potential problems. This is not to suggest that difficult stories should not be heard but to recognise that being aware of and preparing for potential problems might ensure these stories are ‘heard’.

**Usefulness of the intervention**

**New insights**

Taking part in the post-story discussions gave patients access to information they would not normally have access to. For example: one patient representative found out the reason why the intervention which had been initiated as a result of her official complaint was no longer in use; another learnt about a new system of medical team organisation where doctors were physically ward based and she commented that this knowledge would make her feel safer in the ward. Patients also had the opportunity to hear about the constraints and restrictions experienced by staff. One patient was surprised by how interested staff were; another commented that staff listened and were not defensive.
Most of the story themes were not new to staff; what was new was the impact that these problems or staff behaviours have on patients. There were representations of care experiences that staff had not previously considered. The presence of a patient, in person, expressing their true feelings about an actual incident, moved health care professionals’ perceptions of the issues involved from the abstract to the concrete. The stories stimulated staff to think about how what they did or didn’t do might impact on patients. The stories also reminded staff that procedures and policies which were very familiar to them could be problematic for patients if they were not explained to them. Staff discussed these issues within the meeting and talked about potential solutions.

Neutral forum
Commenting on dealing with complaints, one consultant said that she often felt as if she didn’t know what patients and their families needed to make their experience better and this forum provided an opportunity to explore that. Another added that discussion of problems between patients, their representatives and staff via the complaints system was often hindered by defensiveness and entrenched positions and thus limited in its usefulness. This meeting provided an opportunity for open discussion without such hindrances.

Motivational aspects
One consultant said that he was re-motivated by the story he heard and the subsequent discussion. A patient said she left feeling empowered; just telling her
story made her feel that she had been heard by people who could be influential in improving services.

**Implications for changes to health care professional behaviour**

Although the project did not set out to monitor potential or actual change as a result of the intervention, staff did discuss potential practical responses to the stories and these are listed below. We did not return to see if any of these translated into action but this could be considered as a possible indicator/outcome measure for any future evaluation of this approach.

*Specific actions staff said they would take as a result of the patient story and discussion (staff role/s in brackets):*

- meet with colleagues and discuss the story and what they might do to avoid similar experiences for patients and their families (therapist team).

- re-instate an intervention designed to stop problems with discharge procedures which had fallen into disuse due to changes of ward location and staff turnover (pharmacist)

- have more face to face contact with patients (consultant surgeon)
• make more effort to ensure patients know their identity, by introducing themselves properly and remembering to wear a name badge (registrar)

• explore as a ward team a pre-discharge meeting for patient and relatives on an ‘as required’ basis (consultant geriatrician)

• make sure all patients and families are given instructions about how to use equipment provided for use at home (occupational therapist)

In several of the groups the story stimulated discussions where the group reflected on their behaviour and healthcare culture, these were:

• exploration of healthcare professionals’ reaction to an untoward event and the perceived tension between offering an apology and admitting liability. This included acknowledgement that there was a culture within healthcare of clinicians being afraid to take responsibility when things go wrong.

• suggestion that it might be useful for patients to have access to information about the structure of the medical team and their working practices

• acknowledgement of barriers that may impede patients ‘speaking up’, specifically the anxiety that they might be labelled as ‘difficult’.
DISCUSSION

What this project adds to current knowledge
Patient stories have already been identified as a potentially valuable tool in the education of healthcare professionals (Klein, 1999; Repper, 2004; Wood, 1999). Greenhalgh develops this further and highlights the ability of storytelling or ‘illness narratives’ to communicate to others the experience of illness; to help with diagnosis and the selection of treatment options; highlight the dilemmas faced by patients; generate new meaning and in some cases turn a bad experience into one which is more hopeful through exploration of what could and should have happened (Greenhalgh 2006; p. 14). This small scale pilot study has demonstrated that the use of patient stories to improve patient safety in clinical teams is feasible, acceptable and potentially beneficial. If found to be effective this intervention not only gives patients the opportunity to contribute to improving safety, but also opens new channels of communication between clinicians and patients, outside the constraints of both the complaints system and usual patient staff forums which can be governed by behavioural norms.

Limitations
Our patient participants were all female. We enlisted two men initially but, for various reasons, the intervention did not take place for their clinical group. It is
unclear whether male participants would have resulted in different issues arising in the study. It would have been useful and possible to ask CGG members if the nature of the discussion they had after the intervention was unusual for that forum and if so in what way.

We had aimed to present stories in three different ways, face to face, via DVD and a combination of the two. However, the patients who took part, although given the option to present in these different ways, were all keen both to tell their stories in person and to take part in the post story discussion. The patient who made a DVD did this as backup. When she was subsequently unable to attend, the DVD was played with her permission.

This intervention was facilitated by ‘outsiders’ (researchers) who had the advantage of an established relationship with the patients who presented the stories. The agenda was a research one, exploratory and potentially not as threatening to staff participants as a ‘learning’ one initiated and co-ordinated by a Trust staff member. There were concerns expressed by staff about who led the intervention and the potential for it to be used to further a particular cause or agenda. These concerns might be exacerbated if a Trust staff member rather than researchers acts as the patient support. In other Trusts who have adopted the use of patient stories for learning this has been co-ordinate by safety and risk managers (Ottewill et al., 2006; O’Connor, 2007)
were to be adopted as a widescale intervention, care would need to be taken to ensure the process was perceived as transparent to gain the confidence of all participants.

**Organisation**

Meeting arrangements were a time-consuming aspect of the project and involved many e-mails, and phone calls. Co-ordination of the intervention, support of the patient and gaining access to both CGG and patients could be achieved by a staff member from outside the CGG with knowledge of the healthcare system, the skills needed to support the patient and diplomatic skills to negotiate access to CGG meetings. A source of patients who have stories to tell could be those who raise concerns through the Patient Advice and Liaison System (PALS). Our experience of recruiting patients for this project from this source is that patients built up an ongoing relationship with the PALS co-ordinator while their concerns were being investigated. The ‘outsider’ could accompany the patient to the CGG meeting and help guide post story discussion if needed.

**Resource constraints**

Another problem was CGG time and clinical workload – one group could not give us time from a scheduled meeting and so arranged an extraordinary meeting, while another group was clearly under stress and not receptive to the story. This kind of situation cannot be predicted. However, it would seem sensible to try to avoid predictably busy periods, for example, when hospitals experience ‘winter
pressures’. (DOH, 1997). Likewise the time-tabled junctures for medical changeovers could be avoided for similar reasons; teams just getting used to each other and their new roles are possibly going to gain less from a patient story at the beginning of their allocation than when they are settled in.

**Future research**

Patient stories appear to be powerful tools which have the potential to influence and possibly change staff behaviour and perceptions of patient roles as well as fostering greater understanding between patients and clinicians. We had some evidence of members of groups who appeared to be committed to changes as a result of a patient story immediately after the intervention, but who then lost this commitment when they had time to reflect and perhaps discuss the issues with colleagues. Any evaluation of this approach would, ideally, need to include outcome measures of both immediate and lasting effects on safety. A possible study design might be a clustered randomised controlled trial, the cluster would be a clinical team and immediate outcome measures might be changes in safety culture (AHRQ, 2009); other outcome measures that might be considered could include any actions agreed by meeting (and executed); adverse event reporting by staff; serious adverse event occurrence and patient complaints. Less easy to measure but equally important might be any change in: response of staff to patient concerns; how safe patients feel; how involved patients feel in their care.
Issues raised by CGGs and patients prior to the intervention indicate that the intervention needs careful negotiation:

- Staff need reassurances that they are not going to be singled out for blame

- A collaborator within the group would help to avoid presenting patient stories to a group which is potentially not receptive, or to identify potential personality or faction clashes

- Patients need to be clear that the object of them telling their story is not to achieve resolution but to promote individual and organisational learning

- Care needs to be taken to make the process transparent so it is not seen as promoting one particular agenda

**Conclusion**

Patient stories are a feasible, acceptable and potentially effective method of enhancing patient safety through presenting patient safety perspectives to a pre-existing, multi-disciplinary group. Discussion with patients after the story was thought to be easy by staff, in contrast to the difficult communication experienced through the complaints procedure. The intervention stimulated reflective discussion in all staff groups. The advantages of using the CGG as a forum, and
not a specially convened staff group, are that this should help to embed patient safety in the existing clinical culture and not identify it as something separate from the existing clinical process. Significantly, it has the potential for helping to ensure that quality and safety improvement through clinical governance is truly patient centred.
REFERENCES


Repper, J., and Breeze, J., 2004 ‘A Review of the literature on user and carer involvement in the training and education of health professionals’, [http://www.shef.ac.uk/content/1/c6/01/34/62/Finalreport.pdf](http://www.shef.ac.uk/content/1/c6/01/34/62/Finalreport.pdf)


REPORT CONCLUSION

This three phased project set out to investigate how patients (and their family members and other representatives) might appropriately be involved in their health care to promote their own safety. The findings and implications of each phase have been reported in the previous chapters. In this concluding section we summarise the key findings in relation to our original objectives.

Phase 1 (objectives 1-3)

1. To develop a conceptual framework relating to patient involvement in patient safety, including a typology of mechanisms by which patients might contribute to their own safety.

2. To identify the strategies which have been considered or used to encourage patients to get involved in their care with a view to enhancing their safety, and to assess the effectiveness of these.

3. To investigate how the various types of reporting systems that have been developed to improve patient safety have solicited, received and used reports from patients and their representatives.

A scoping review allowed us to develop a conceptual framework that facilitated an analysis of interventions according to the ways in which they envisage patients contributing to their safety and the assumptions they make about patients’ willingness and ability to act. Whilst a large volume of literature was identified which described a broad range of interventions that had been suggested, and in some cases tried, to promote patient involvement in patient safety, few interventions had been rigorously evaluated. Overall there appeared to be little consideration of the mechanism of effect and of what conditions and
circumstances are required for patients to adopt safety roles, including willingness and ability to do so. In addition the literature revealed very little exploration of the negative effects’ of patients’ involvement in promoting their own safety.

Our systematic review of the relatively small number of studies that reported evaluations identified only limited evidence for the effectiveness of interventions designed to promote patient involvement in their care in order to enhance safety. In general the quality of the evaluations was poor, although we did find some evidence of improved safety outcomes through patient involvement, but only with respect to self management of anticoagulation therapy. Whilst the volume of research reporting high quality evaluations was comparatively small, a large body of literature was identified in our scoping review reflecting significant interest for involving patients in promoting their own and others’ safety.

We identified a number of systems that accept reports of adverse drug events, medication errors or more broadly defined safety incidents from patients. Relatively little has been written about the questions of how best to engage patients in these systems, but a few systems are collecting and using substantial numbers of patient reports of safety concerns/incidents.

Phase 2 (objectives 4-6)

4. To determine patients’ awareness of and concerns about health care safety.

5. To identify situations and ways in which patients or their representatives have acted to help secure their own safety.
6. To elicit patients’ views about the various roles they might play to ensure their own safety, about interventions to encourage or support them in playing those roles, and about their potential contribution to safety reporting systems.

The second phase of the project sought to generate new knowledge about patients’ views on their role in and experiences of safety in healthcare settings. We undertook individual interviews and focus group discussions with patients and patient representatives with experience of a variety of clinical settings. We found that in broad terms involvement in attempts to enhance safety was acceptable to patients and may have benefits. However most people were reluctant to think that their involvement should be relied on as a strategy for ensuring or enhancing their safety: there was a clear sense that the main responsibility for safety should lie with health care professionals and systems. Whilst people could identify with a number of roles through which they might enhance safety, there was little consistency amongst study participants on which roles they felt were appropriate for themselves or other patients, and the circumstances in which they thought they could be undertaken. Participants identified a range of factors which could influence whether patient roles in safety enhancement were adopted, including individual patient, health professional, and system characteristics. The importance of health professional behaviour and communication in facilitating patient involvement was particularly stressed. Whilst the views and experiences of people in the mental health group were in keeping with the other clinical groups, there was perhaps a tendency for people with a history of severe and enduring mental health problems to put a greater stress on their health status as a factor which influenced whether they adopted safety roles. If they felt unwell, particularly in respect of their mental health, they stated that they were more likely to be reluctant to take on such roles.
Phase 3 (objective 7)

7. To develop and carry out an initial developmental assessment of an intervention to promote patient involvement.

Phase 3 of the project piloted an approach to enhancing safety which involved individual patients feeding back their particular safety experiences while using NHS services to relevant clinical governance groups. We aimed to use the patient stories to facilitate interaction between patients and healthcare professionals to challenge professional norms about patient experience and involvement, and promote professional learning. This approach was developed on the basis of insights gained from phases 1 and 2 as to what might be an effective way of improving health care safety through the involvement of patients.

This small scale pilot involved 5 patients. It suggested that the intervention is feasible, acceptable and worthy of further study to investigate its effectiveness. However it should be noted that considerable effort had to be undertaken to support patients and staff during the planning and organisation of the meetings.

Phases 1, 2 and 3-implications

Practice

A central message from all three phases of the study is the importance of the health care professional and broader health care system in supporting patients to be involved in enhancing safety. Health care professionals need to be receptive and open to patient concerns and questions, and to facilitate patients’ attempts to be involved in their care. Brusque, dismissive or disinterested attitudes in the professional can inhibit patients from carrying out many of the roles that have been proposed as means by which they might enhance their safety. The nature of the patient-professional relationship would seem to be crucial in enabling patients to contribute to improvements in health care safety. A positive relationship in this regard makes a number of requirements of health care
professionals, including appropriate attitudes and communication skills. It also places requirements on health care systems to make it easier for professionals to enable patient involvement in safety, for example by ensuring that workload demands are reasonable. Given this, we would recommend that patient involvement in health care safety is better facilitated not by an emphasis on patient roles but by amending health care systems and supporting health care professionals to develop better relationships with patients. We can not “legislate” patient involvement in health care safety, but if patients feel more comfortable in their dealings with professionals then it is more likely that patient roles in enhancing safety will occur naturally as a matter of course, rather than as a response to an externally generated expectation.

**Future research**

Future research might usefully investigate the desirability and feasibility of implementing a shift away from recommendations that patients adopt particular roles or behaviours to promote their own safety towards efforts to facilitate more supportive professional behaviours and attitudes, and more supportive clinical environments. This might include research with health professionals to improve our understanding of their experiences of patients’ attempts to be involved in enhancing safety, and ethnographic studies of patient–professional interactions. Other research areas identified through this study include the development and evaluation of strategies to involve patients in the reporting of error and patient safety incidents, and a full scale evaluation of the intervention piloted in phase 3 where patients feed back their safety experiences to professional groups.

Finally whilst this study has collected data to identify points of contrast and commonalities across a diverse range of settings and conditions, there is a relative lack of data from primary care and future research could usefully investigate aspects of patient involvement in safety enhancement in this setting.
ACKNOWLEDGEMENTS

The PIPS research team would like to thank all the patients, their family members and representatives, who gave their time and views so generously to inform both phase two and three of this project. We would also like to thank all our clinical collaborators some who facilitated our contact with patients others who took part in phase three of the project. Without the support and co-operation of all those involved this project would not have been possible.

We would also like to thank Sandi Newby for her valuable contribution in the collation and production of the final report.
Appendices
Appendix 1.1 Search Strategy

1 Sources

Databases of Systematic Reviews
- Cochrane Database of Systematic Reviews (CDSR)
  Searched via The Cochrane Library at; www.thecochranelibrary.com
  Date searched: 21/08/06 (2006: Issue 3)
- Database of Abstracts of Reviews of Effects (DARE)
  Searched via the CRD internal database
  Date searched: 23/08/06

Databases of Controlled Trials
- CENTRAL
  Searched at via The Cochrane Library at; www.thecochranelibrary.com
  Date searched: 21/08/06 (2006: Issue 3)

Health Related Databases
- CINAHL
  Searched via OvidWeb: http://gateway.ovid.com/
  Date searched: 18/08/06 (1982 – August Week 2 2006)
- EMBASE
  Searched via OvidWeb: http://gateway.ovid.com/
  Date searched: 18/08/06 (1980 – 2006 Week 32)
- HMIC Health Management Information Consortium
  Searched via OvidWeb: http://gateway.ovid.com/
  Date searched: 18/08/06 (July 2006)
- MEDLINE
  Searched via OvidWeb: http://gateway.ovid.com/
  Date searched: 18/08/06 (1966 – August Week 2 2006)
- MEDLINE In-process & other non-indexed citations
  Searched via OvidWeb: http://gateway.ovid.com/
  Date searched: 18/08/06 (August 17, 2006)
- PsycINFO
  Searched via OvidWeb: http://gateway.ovid.com/
  Date Search: 18/08/06 (1967 to August Week 3 2006)

Social Care Databases
- Applied Social Sciences Index and Abstracts (ASSIA)
  Searched via CSA Illumina http://ca2.csa.com/
Date searched: 23/08/06 (1987 –2006)

**Economic Evaluation Databases**
- NHS Economic Evaluations Database (NHS EED)
  Searched via the CRD internal database
  Date searched: 23/08/06

**Databases of Reports, Conference Proceedings, Grey Literature**
- Agency for Healthcare Research and Quality
  Searched via http://www.psnet.ahrq.gov
  Date searched: 03/11/06
- Dissertation Abstracts
  Searched via DIALOG online
  Date searched: 30/08/06 (1861 – June 2006)
- Health Services/Technology Assessment Text (HSTAT)
  Date Searched: 22/11/2006
- Health Technology Assessment Database (HTA)
  Searched via the CRD internal database
  Date searched: 23/08/06
- Index to Theses
  Searched via http://www.theses.com/ (1716-present)
  Date searched: 14/09/06
- Inside Conferences
  Searched via DIALOG online
  Date searched: 30/08/06 (1993 – 29 August 2006)
- ISI Science & Technology Proceedings
  Searched via ISI Web of Knowledge at http://wok.mimas.ac.uk/ (1990-present)
  Date searched: 14/09/06
- ISI Social Science & Humanities Proceedings
  Searched via ISI Web of Knowledge at http://wok.mimas.ac.uk/ (1990-present)
  Date searched: 14/09/06
- National Technical Information Service (NTIS)
  Searched via DIALOG online
  Date searched: 30/08/06 (1964 – August Week 3 2006)
- Zetoc Conferences
  Searched via MIMAS at http://zetoc.mimas.ac.uk/ (1993-present)
  Date searched: 14/09/06

**Databases of Ongoing Research**
- Current Controlled Trials
Searched via http://www.controlled-trials.com/
Date Searched: 24/08/06

- Health Services Research Projects in Progress (HSRPROJ)
  Searched via http://www.nlm.nih.gov/hsrproj/
  Date searched: 21/11/2006

- National Research Register (NRR)
  Searched via http://www.nrr.nhs.uk/
  Date Searched: 24/08/06 (Issue 3: 2006)

- The Research Findings Electronic Register (ReFeR)
  Searched via
  Date Searched: 24/08/06

Patient Safety Organisations

- Australian Patient Safety Foundation
  Contacted: 08/11/06

- Consumers Advancing Patient Safety (CAPS)
  Searched via http://www.patientsafety.org
  Date searched: 13/11/06

- The Health Foundation
  Searched via http://www.health.org.uk/
  Date searched: 15/11/06

- Institute for Healthcare Improvement (IHI)
  Searched via http://www.saferhealthcare.org.uk/ihi
  Dates searched: 14, 15, 21/11/06

- Institute of Medicine of the National Academies (IOM)
  Searched via http://www.iom.edu
  Date searched: 15/11/06

- Joint Commission on Accreditation of Healthcare Organisations/
  International Centre for Patient Safety
  Searched via http://www.jcipatientsafety.org/
  Date Searched: 18/12/06

- National Patient Safety Agency (NPSA)
  Searched via http://www.npsa.nhs.uk/public
  Dates Searched: 6-9/11/06

- National Patient Safety Foundation (NPSF)
  Searched via http://www.npsf.org/html/bibliography.html
  Dates searched: 13&15/11/06

- Partnership for Patient Safety (p4ps)
  Searched via http://www.p4ps.org/resources.asp#6
  Date searched: 13/11/06

- Picker Institute
  Searched via http://www.pickereurope.org/
  Date searched: 15/11/06

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2 Search Strategies

Databases of Systematic Reviews

Cochrane Database of Systematic Reviews (CDSR)
Searched via The Cochrane Library at; www.thecochranelibrary.com
Date searched: 21/08/06 (Issue 3: 2006)
This search strategy retrieved 29 records;
#1 MeSH descriptor consumer participation explode all trees
#2 MeSH descriptor patient education, this term only
#3 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 involv*):ti,ab
#4 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 participat*):ti,ab
#5 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 view*):ti,ab
#6 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 attitude*):ti,ab
#7 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 role*):ti,ab
#8 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) next contribut*):ti,ab
#9 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) next reporting):ti,ab
#10 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 aware*):ti,ab
#11 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 concern*):ti,ab
#12 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 check*):ti,ab
#13 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 as partners):ti,ab
#14 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 partnership*):ti,ab
#15 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 engag*):ti,ab
#16 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 encourag*):ti,ab
#17 (promoting next (patient* or inpatient* or outpatient* or consumer* or
citizen* or public or carer* or caregiver* or user*)):ti,ab
#18 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 empower*):ti,ab
#19 ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 complain*):ti,ab
#20  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 educat*):ti,ab
#21  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 opinion*:ti,ab
#22  MeSH descriptor Adverse Drug Reaction Reporting Systems, this term
only
#23  MeSH descriptor Safety Management, this term only
#24  MeSH descriptor Risk Management, this term only
#25  MeSH descriptor medical errors, this term only
#26  MeSH descriptor diagnostic errors, this term only
#27  MeSH descriptor medication errors, this term only
#28  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 adverse):ti,ab
#29  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 safe*):ti,ab
#30  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 harm*):ti,ab
#31  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 unsafe*):ti,ab
#32  (risk* near/2 manag*):ti,ab
#33  (safe* near/2 manag*):ti,ab
#34  ((check* or monitor*) near/2 safe*):ti,ab
#35  (adverse near/4 reporting):ti,ab
#36  negligence:ti,ab
#37  negligent:ti,ab
#38  ((incident or error or errors or mistake* or safe* or harm*) near/2
report*):ti,ab
#39  ((professional* or worker* or dentist* or nurs* or doctor* or physician* or
surge* or pharmac* or human or practitioner* or psychiatrist* or psychologist* or
anaesthes* or anesthes*) near/2 (mistake* or error or errors)):ti,ab
#40  ((medical or diagnos* or treatment* or medication* or healthcare or care or
hospital* or system* or disclos* or past or previous) near/2 (mistake* or error or
errors)):ti,ab
#41  ((incident or error or errors or mistake* or unsafe* or safe* or harm*)
near/2 (detect* or prevent*)):ti,ab
#42  "miss":ti,ab
#43  "misses":ti,ab
#44  (err near/2 human):ti,ab
#45  #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or
#13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21
#46  #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32
or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or
#44
#47  #45 and #46

Database of Abstracts of Reviews of Effects (DARE)
This search strategy retrieved 81 records:

- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)involve
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)participat
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)view
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)attitud
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)role
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(w)contribut
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(w)report
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)aware
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)concern
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)check
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)(as(w)partners)
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)partnership
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(w)engag
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(w)encourag
- promoting(w)(patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)empower
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)complain
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)educat
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)opinion
- (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)adverse
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)safe$

s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)harm$

s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)(2w)unsafe$

s risk$(w)manag$

s safe$(w)manag$

s (check$ or monitor$)(2w)safe$

s adverse(4w)reporting

s negligence

s negligent

s (incident or error or errors or mistake$ or safe$ or harm$)(2w)report$

s (professional$ or worker$ or dentist$ or nurs$ or doctor$ or physician$ or surgeon$ or pharmaceutic$ or human or practitioner$ or psychiatrist$ or psychologist$ or anaesthetist$ or anesthesiologist$)(2w)(mistake$ or error or errors)

s (medical or diagnosis$ or treatment$ or medication$ or healthcare or care or hospital$ or system$ or disclosure$ or past or previous)(2w)(mistake$ or error or errors)

s (incident$ or error or errors or mistake$ or unsafe$ or safe$ or harm$)(2w)(detect$ or prevent$)

s near(w)miss

s near(w)misses

s err$(w)is(w)human

s s1 or s2 or s3 or s4 or s5 or s6 or s7 or s8 or s9 or s10 or s11 or s12 or s13 or s14 or s15 or s16 or s17 or s18 or s19

s s20 or s21 or s22 or s23 or s24 or s25 or s26 or s27 or s28 or s29 or s30 or s31 or s32 or s33 or s34 or s35 or s36

s s37 and s38

Databases of Controlled Trials

CENTRAL

Searched via The Cochrane Library at: www.thecochranelibrary.com
Date searched: 21/08/06 (Issue 3: 2006)

This search strategy retrieved 874 records:

#1 MeSH descriptor consumer participation explode all trees
#2 MeSH descriptor patient education, this term only
#3 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) near/2 involv$)
#4 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) near/2 participat$)
#5 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) near/2 view$)
#6  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 attitude*)
#7  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 role*)
#8  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) next contribut*)
#9  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) next reporting)
#10  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 aware*)
#11  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 concern*)
#12  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 check*)
#13  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 as partners)
#14  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 partnership*)
#15  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 engag*)
#16  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 encourag*)
#17  (promoting next (patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*))
#18  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 empower*)
#19  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 complain*)
#20  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 educat*)
#21  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 opinion*)
#22  MeSH descriptor Adverse Drug Reaction Reporting Systems, this term only
#23  MeSH descriptor Safety Management, this term only
#24  MeSH descriptor Risk Management, this term only
#25  MeSH descriptor medical errors, this term only
#26  MeSH descriptor diagnostic errors, this term only
#27  MeSH descriptor medication errors, this term only
#28  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 adverse)
#29  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 safe*)
#30  ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) near/2 harm*)
#31 (patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) near/2 unsafe*)
#32 (risk* near/2 manag*)
#33 (safe* near/2 manag*)
#34 (check* or monitor*) near/2 safe*)
#35 (adverse near/4 reporting)
#36 negligence
#37 negligent
#38 (incident or error or errors or mistake* or safe* or harm*) near/2 report*)
#39 (professional* or worker* or dentist* or nurs* or doctor* or physician* or
surge* or pharmac* or human or practitioner* or psychiatrist* or psychologist* or
anaesthes* or anethes*) near/2 (mistake* or error or errors))
#40 (medical or diagnos* or treatment* or medication* or healthcare or care or
hospital* or system* or disclos* or past or previous) near/2 (mistake* or error or
errors))
#41 (incident* or error or errors or mistake* or unsafe* or safe* or harm*)
near/2 (detect* or prevent*))
#42 “miss”
#43 “misses”
#44 err near/2 human
#45 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or
#13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21
#46 #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32
or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or
#44
#47 #45 and #46

Health Related Databases

Cumulative Index to Nursing & Allied Health (CINAHL)
Searched via OvidWeb: http://gateway.ovid.com/
Date searched: 18/08/06 (1982 – August Week 2 2006)
This search strategy retrieved 1254 records;
1 Consumer Participation/ (3886)
2 exp Patient Participation/ (25965)
3 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 involv$).ti,ab. (2414)
4 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 participat$).ti,ab. (1808)
5 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 participat$).ti,ab. (1808)
6 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 view$).ti,ab. (1232)
7 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 attitude$).ti,ab. (673)
8  (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 role$).ti,ab. (1278)
9  (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj contribut$.ti,ab. (78)
10 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj reporting).ti,ab. (286)
11 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 aware$.ti,ab. (822)
12 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 concern$.ti,ab. (1664)
13 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 check$.ti,ab. (154)
14 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 as partners).ti,ab. (28)
15 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 partnership$.ti,ab. (325)
16 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 engag$.ti,ab. (300)
17 (promoting adj (patient$ or inpatient$ or outpatient$ or consumer$ or
citizen$ or public or carer$ or caregiver$ or user$)).ti,ab. (118)
18 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 empower$.ti,ab. (612)
19 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 complain$.ti,ab. (730)
20 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 educat$.ti,ab. (6498)
21 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 opinion$.ti,ab. (452)
22 exp Patient Safety/ (17291)
23 Risk Management/ (3579)
24 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 adverse).ti,ab. (251)
25 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 adverse).ti,ab. (251)
26 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 safe$.ti,ab. (3911)
27 (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 unsafe$.ti,ab. (21)
28 (risk$ adj2 manag$).ti,ab. (1742)
29 (safe$ adj2 manag$).ti,ab. (277)
30 (check$ or monitor$) adj2 safe$.ti,ab. (223)
31 (adverse adj reporting).ti,ab. (202)
32 negligence.ti,ab. (822)
33 negligent.ti,ab. (278)
34 ((incident or error or errors or mistake$ or safe$ or harm$) adj2
report$).ti,ab. (804)
35  ((professional$ or worker$ or dentist$ or nurs$ or doctor$ or physician$ or 
surge$ or pharmaci$ or human or practitioner$ or psychiatrist$ or psychologist$ 
or anae$ or anethes$) adj2 (mistake$ or error or errors$)).ti,ab. (353)
36  ((medical or diagnos$ or treatment$ or medication$ or healthcare or care or 
hospital$ or system$ or disclos$ or past or previous) adj2 (mistake$ or error or 
errors$)).ti,ab. (2303)
37  ((incident$ or error or errors or mistake$ or unsafe$ or safe$ or harm$) adj2 
(detect$ or prevent$)).ti,ab. (744)
38  near miss.ti,ab. (68)
39  near misses.ti,ab. (75)
40  err is human.ti,ab. (68)
41  or/1-21 (43608)
42  or/22-40 (25322)
43  41 and 42 (1254)

EMBASE
Searched via OvidWeb: http://gateway.ovid.com/
Date searched: 19/03/04 (1980 – 2006 Week 32)
This search strategy retrieved 4179 records;
1  patient participation/ (865)
2  patient education/ (21343)
3  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 involv$).ti,ab. (23550)
4  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 participat$).ti,ab. (9002)
5  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 view$).ti,ab. (5779)
6  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 attitude$).ti,ab. (3463)
7  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 role$).ti,ab. (9561)
8  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj contribut$).ti,ab. (1423)
9  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj reporting).ti,ab. (1549)
10  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj aware$).ti,ab. (5108)
11  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj concern$).ti,ab. (10946)
12  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 check$).ti,ab. (1659)
13  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 as partners).ti,ab. (1113)
14  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
(patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 partnership$).ti,ab. (678)
15     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 engag$).ti,ab. (1151)
16     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 encourag$).ti,ab. (2849)
17     (promoting adj (patient$ or inpatient$ or outpatient$ or consumer$ or
citizen$ or public or carer$ or caregiver$ or user$)).ti,ab. (176)
18     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 empower$).ti,ab. (576)
19     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 complain$).ti,ab. (12159)
20     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 educat$).ti,ab. (12878)
21     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 opinion$).ti,ab. (2489)
22     drug surveillance program/ (5160)
23     Safety/ and exp patient care/ (3952)
24     Risk Management/ (8406)
25     exp medical error/ (17433)
26     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 adverse).ti,ab. (6830)
27     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 safe$).ti,ab. (15116)
28     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 harm$).ti,ab. (1725)
29     ((check$ or monitor$) adj2 safe$).ti,ab. (1755)
30     (adverse adj4 reporting).ti,ab. (1342)
31     negligence.ti,ab. (1007)
32     negligent.ti,ab. (307)
33     ((incident or error or errors or mistake$ or safe$ or harm$) adj2 report$).ti,ab. (4230)
34     (risk$ adj2 manag$).ti,ab. (6374)
35     (safe$ adj2 manag$).ti,ab. (2586)
36     ((professional$ or worker$ or dentist$ or nurs$ or doctor$ or physician$ or
surge$ or pharmac$ or human or practitioner$ or psychiatrist$ or psychologist$ or
anaesthes$ or anethes$) adj2 (mistake$ or error or errors$)).ti,ab. (1881)
37     ((medical or diagnos$ or treatment$ or medication$ or healthcare or care or
hospital$ or system$ or disclos$ or past or previous) adj2 (mistake$ or error or
errors$)).ti,ab. (8267)
38     (near miss.ti,ab. (355)
39     near misses.ti,ab. (145)
40     err is human.ti,ab. (67)
Health Management Information Consortium (HMIC)
Searched via OvidWeb: http://gateway.ovid.com/
Date searched: 18/08/06 (July 2006)
This search strategy retrieved 493 records;
1 exp user involvement/ (1344)
2 patient education/ (314)
3 patient information/ (1130)
4 exp consumer health information/ (1170)
5 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 involv$).ti,ab. (2751)
6 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 participat$).ti,ab. (947)
7 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 view$).ti,ab. (2026)
8 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 attitude$).ti,ab. (658)
9 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 role$).ti,ab. (1133)
10 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj contribut$).ti,ab. (91)
11 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 aware$).ti,ab. (447)
12 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj aware$).ti,ab. (447)
13 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 concern$).ti,ab. (974)
14 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 check$).ti,ab. (123)
15 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj as partners).ti,ab. (79)
16 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 partnership$).ti,ab. (512)
17 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 engag$).ti,ab. (180)
18 (promoting adj (patient$ or inpatient$ or outpatient$ or consumer$ or
citizen$ or public or carer$ or caregiver$ or user$)).ti,ab. (375)
19 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 encourag$).ti,ab. (97)
20 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 empower$).ti,ab. (464)
21 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 complain$).ti,ab. (325)
22     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 educat$).ti,ab. (968)
23     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 opinion$).ti,ab. (535)
24     patient safety/ (508)
25     exp safety measures/ (1443)
26     Risk Management/ (1314)
27     exp errors/ (484)
28     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 adverse).ti,ab. (99)
29     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 safe$).ti,ab. (1003)
30     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 harm$).ti,ab. (199)
31     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 unsafe$).ti,ab. (6)
32     (risk$ adj2 manag$).ti,ab. (1176)
33     (safe$ adj2 manag$).ti,ab. (215)
34     ((check$ or monitor$) adj2 safe$).ti,ab. (76)
35     (adverse adj4 reporting).ti,ab. (132)
36     negligence.ti,ab. (493)
37     negligent.ti,ab. (41)
38     ((incident or error or errors or mistake$ or safe$ or harm$) adj2
report$).ti,ab. (438)
39     ((professional$ or worker$ or dentist$ or nur$ or doctor$ or physician$ or
surge$ or pharma$ or human or practitioner$ or psychiatrist$ or psychologist$ or
anaesthes$ or anesthes$) adj2 (mistake$ or error or errors)).ti,ab. (139)
40     ((medical or diagnos$ or treatment$ or medication$ or healthcare or care or
hospital$ or system$ or disclos$ or past or previous) adj2 (mistake$ or error or
errors)).ti,ab. (381)
41     ((incident$ or error or errors or mistake$ or unsafe$ or safe$ or harm$) adj2
(detect$ or prevent$)).ti,ab. (231)
42     near miss.ti,ab. (20)
43     near misses.ti,ab. (52)
44     err is human.ti,ab. (8)
45     or/1-23 (13209)
46     or/24-44 (6043)
47     45 and 46 (493)
MEDLINE
Searched via OvidWeb: http://gateway.ovid.com/
Date searched: 18/08/06 (1966 –August Week 2 2006)
This search strategy retrieved 2729 records;
1     exp consumer participation/ (20642)
2     patient education/ (46093)
3     ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
(patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 involv$).ti,ab. (14953)
4  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 participat$).ti,ab. (7164)
5  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 view$).ti,ab. (3766)
6  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 attitude$).ti,ab. (3054)
7  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 role$).ti,ab. (4150)
8  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj contribut$).ti,ab. (504)
9  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj reporting).ti,ab. (1577)
10 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 aware$).ti,ab. (3254)
11 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 concern$).ti,ab. (8901)
12 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 check$).ti,ab. (921)
13 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 as partners).ti,ab. (40)
14 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 partnership$).ti,ab. (678)
15 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 engag$).ti,ab. (920)
16 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 encourage$).ti,ab. (1826)
17 (promoting adj (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$)).ti,ab. (235)
18 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 empower$).ti,ab. (734)
19 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 complain$).ti,ab. (9478)
20 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 educate$).ti,ab. (14179)
21 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 opinion$).ti,ab. (2180)
22 Adverse Drug Reaction Reporting Systems/ (2909)
23 Safety Management/ (6440)
24 Risk Management/ (9484)
25 medical errors/ (5515)
26 diagnostic errors/ (23058)
27 medication errors/ (5946)
28 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 adverse).ti,ab. (2506)
29 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 safe$).ti,ab. (8662)
30  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 harm$).ti,ab. (998)
31  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 unsafe$).ti,ab. (41)
32  (risk$ adj2 manag$).ti,ab. (5168)
33  (safe$ adj2 manag$).ti,ab. (1418)
34  ((check$ or monitor$) adj2 safe$).ti,ab. (1151)
35  (adverse adj4 reporting).ti,ab. (1264)
36  negligence.ti,ab. (1745)
37  negligent.ti,ab. (485)
38  ((incident or error or errors or mistake$ or safe$ or harm$) adj2 report$).ti,ab. (2404)
39  ((professional$ or worker$ or dentist$ or nurs$ or doctor$ or physician$ or
surge$ or pharmac$ or human or practitioner$ or psychiatrist$ or psychologist$ or
anesthesia$ or anesthes$) adj2 (mistake$ or error or errors$)).ti,ab. (1473)
40  ((medical or diagnos$ or treatment$ or medication$ or healthcare or care or
hospital$ or system$ or disclos$ or past or previous) adj2 (mistake$ or error or
errors$)).ti,ab. (8737)
41  ((incident$ or error or errors or mistake$ or unsafe$ or safe$ or harm$) adj2
(detect$ or prevent$)).ti,ab. (4427)
42  near miss.ti,ab. (431)
43  near misses.ti,ab. (179)
44  err is human.ti,ab. (133)
45  or/1-21 (130045)
46  or/22-44 (77331)
47  45 and 46 (2729)

MEDLINE(R) In-Process & Other Non-Indexed Citations
Searched via OvidWeb: http://gateway.ovid.com/
Date searched: 18/08/06 (August 17, 2006)
This search strategy retrieved 66 records;
1  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 involv$).ti,ab. (424)
2  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 participat$).ti,ab. (235)
3  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 view$).ti,ab. (104)
4  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 attitude$).ti,ab. (80)
5  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 role$).ti,ab. (126)
6  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 contribut$).ti,ab. (17)
7  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj reporting).ti,ab. (79)
8  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 aware$).ti,ab. (118)
9  ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 concern$).ti,ab. (316)
10 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 check$).ti,ab. (24)
11 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 partnership$).ti,ab. (36)
12 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 engag$).ti,ab. (44)
13 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 empower$).ti,ab. (27)
14 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 complain$).ti,ab. (257)
15 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 encourage$).ti,ab. (66)
16 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 empower$).ti,ab. (27)
17 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 complaint$).ti,ab. (257)
18 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 educate$).ti,ab. (358)
19 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 opinion$).ti,ab. (64)
20 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 adverse).ti,ab. (64)
21 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 adverse).ti,ab. (64)
22 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 safe$).ti,ab. (373)
23 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj2 unsafe$).ti,ab. (2)
24 (risk$ adj2 manage$).ti,ab. (220)
25 (safe$ adj2 manage$).ti,ab. (53)
26 ((check$ or monitor$) adj2 safe$).ti,ab. (41)
27 (adverse adj4 reporting).ti,ab. (54)
28 negligence.ti,ab. (31)
29 negligent.ti,ab. (9)
30 ((incident or error or errors or mistake$ or safe$ or harm$) adj2 report$).ti,ab. (110)
31 ((professional$ or worker$ or dentist$ or nurse$ or doctor$ or physician$ or surgeon$ or pharmacist$ or human or practitioner$ or psychiatrist$ or psychologist$ or anaesthetist$ or anesthetist$) adj2 (mistake$ or error or errors$)).ti,ab. (53)
32 ((medical or diagnosis$ or treatment$ or medication$ or healthcare or care or hospital$ or system$ or disclosure$ or past or previous) adj2 (mistake$ or error or
PsycINFO
Searched via OvidWeb: http://gateway.ovid.com/
Date searched: 18/08/06 (1967 to August Week 3 2006)
This search strategy retrieved 398 records;
1 client participation/ (610)
2 client education/ (2043)
3 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 involv$).ti,ab. (2880)
4 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 participat$).ti,ab. (2618)
5 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 view$).ti,ab. (1589)
6 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 attitude$).ti,ab. (2342)
7 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 role$).ti,ab. (1705)
8 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 contribut$).ti,ab. (124)
9 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 reporting).ti,ab. (317)
10 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 aware$).ti,ab. (1013)
11 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 concern$).ti,ab. (2276)
12 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 check$).ti,ab. (145)
13 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 as partners).ti,ab. (20)
14 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 partnership$).ti,ab. (210)
15 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 engag$).ti,ab. (848)
16 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$) adj2 encourag$).ti,ab. (606)
17 (promoting adj (patient$ or inpatient$ or outpatient$ or consumer$ or
citizen$ or public or carer$ or caregiver$ or user$).ti,ab. (83)
18 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 empower$).ti,ab. (347)
19 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 complain$).ti,ab. (783)
20 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 educat$).ti,ab. (3859)
21 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 opinion$).ti,ab. (1497)
22 safety/ (2583)
23 risk management/ (1182)
24 errors/ (4299)
25 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 adverse).ti,ab. (127)
26 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 safe$).ti,ab. (769)
27 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 harm$).ti,ab. (325)
28 ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or 
carer$ or caregiver$ or user$) adj2 unsafe$).ti,ab. (6)
29 (risk$ adj2 manag$).ti,ab. (1245)
30 (safe$ adj2 manag$).ti,ab. (225)
31 ((check$ or monitor$) adj2 safe$).ti,ab. (101)
32 (adverse adj4 reporting).ti,ab. (75)
33 negligence.ti,ab. (400)
34 negligent.ti,ab. (228)
35 ((incident or error or errors or mistake$ or safe$ or harm$) adj2 
report$).ti,ab. (4110)
36 ((professional$ or worker$ or dentist$ or nurs$ or doctor$ or physician$ or 
surge$ or pharmac$ or human or practitioner$ or psychiatrist$ or psychologist$ 
or anaesthes$ or anethes$) adj2 (mistake$ or error or errors$)).ti,ab. (472)
37 ((medical or diagnos$ or treatment$ or medication$ or healthcare or care or 
hospital$ or system$ or disclos$ or past or previous) adj2 (mistake$ or error or 
errors$)).ti,ab. (1134)
38 ((incident$ or error or errors or mistake$ or unsafe$ or safe$ or harm$) adj2 
detect$ or prevent$)).ti,ab. (945)
39 near miss.ti,ab. (74)
40 near misses.ti,ab. (51)
41 err is human.ti,ab. (16)
42 or/1-21 (23420)
43 or/22-41 (16249)
44 42 and 43 (398).

Social Care Databases
Applied Social Sciences Index and Abstracts (ASSIA)
Searched via CSA Illumina http://ca2.csa.com/
Date searched: 28/11/05 (1987 –2005)
This search strategy retrieved 114 records;
((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or
caregiver* or user*) within 2 (involv* or participat* or view* or attitude* or role*))
or ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) within 1 (contribut* or reporting)) or ((patient* or
inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver*
or user*) within 2 (aware* or concern* or check* or partners or partnership* or
engage* or encourage*)) or (promoting within 1 (patient* or inpatient* or
outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*)) or
((patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer*
or caregiver* or user*) within 2 (empower* or complain* or educat* or opinion*))
and ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) within 2 (adverse or safe* or harm* or unsafe*)) or
((risk* or safe*) within 2 manag*) or ((check* or monitor*) within 2 safe*) or
(adverse within 4 reporting) or (negligence) or (negligent) or ((incident or error or
errors or mistake* or safe* or harm*) within 2 report*) or ((professional* or
worker* or dentist* or nurs* or doctor* or physician* or surge* or pharmac* or
human or practitioner* or psychiatrist* or psychologist* or anaesthes* or anesthes*)
within 2 (mistake* or error or errors)) or ((medical or diagnos* or treatment* or
medication* or healthcare or care or hospital* or system* or disclos* or past or
previous) within 2 (mistake* or error or errors)) or ((incident* or error or error or
mistake* or unsafe* or safe* or harm*) within 2 (detect* or prevent*)) or (“near”
within 1 miss) or (“near” within 1 misses) or (err is human)

Economic Evaluation Databases

NHS Economic Evaluations Database (NHS EED)
Searched on CRD administration interface

Date searched: 23/08/06 (August 2006)

The same search strategy as that used for DARE was used and this retrieved
133 records.

Databases of Reports, Conference Proceedings, Grey Literature

Agency for Healthcare Research and Quality
AHRQ Patient Safety Network
Searched via http://www.psnet.ahrq.gov
Date searched: 03/11/06
A search for ‘patient involvement’ retrieved 1361 records of which 111 were
ordered.
Dissertation Abstracts

Searched via DIALOG http://www.dialog.com/
Date searched: 30/08/06 (1861 – June 2006)
This search strategy retrieved 176 records;
s patient(w)education
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)involv$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)participat$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)view$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)attitude$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)role$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)contribut$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)reporting
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)aware$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)concern$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)check$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)(as(w)partners)
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)partnership$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)engag$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)encourag$
s promoting(w)(patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or
car$ or caregiver$ or user$)
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)empower$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)complain$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)educat$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)opinion$
s (patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or
carer$ or caregiver$ or user$)(2w)adverse
Inside Conferences
Searched on DIALOG http://www.dialog.com/
Date searched: 30/08/06 (1993 – 29 August 2006)
The same search strategy as that used for Dissertation Abstracts was used and
this retrieved 26 records.

ISI Science & Technology Proceedings and ISI Social Science & Humanities
Proceedings
Searched via ISI Web of Knowledge at http://wok.mimas.ac.uk/ (1990-present)
Date searched: 14/09/06
This search strategy retrieved 1499 records.
TS=((patient* or inpatient* or outpatient* or consumer* or citizen* or public or
carer* or caregiver* or user*) same (encoura* or participat* or view* or attitude*
or role* or contribut* or reporting or aware* or concern* or check* or partners or
partnership* or encour* or encourage* or promoting or empower* or complain* or
educat* or opinion*) same (adverse or safe* or harm* or unsafe* or (risk* and
manag*) or negligence or negligent or incident* or error or errors or mistake* or
miss or misses))
TS=(err same human)
#1 or #2

National Technical Information Service (NTIS)
Searched via DIALOG http://www.dialog.com/
Date searched: 30/08/06 (1964 – August Week 3 2006)
The same search strategy as that used for Dissertation Abstracts was used and
this retrieved 592 records

Zetoc Conferences
Searched via MIMAS at http://zetoc.mimas.ac.uk/ (1993-present)
Date searched: 14/09/06
This search strategy retrieved 678 records;
“patient safety”

Databases of Ongoing Research

Controlled-Trials.com
Date Searched: 24/08/06
This search strategy retrieved 246 records, however, no records were deemed
potentially relevant so none were printed out.
(adverse or safe* or harm* or unsafe* or risk* or negligence or negligent or
incident* or error or errors or mistake* or miss or misses or err) and (patient* or
inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver*
or user*)

Health Services Research Projects in Progress (HSRPROJ)
A search for 'patient safety' retrieved 475 records and 16 were ordered.

**National Research Register (NRR)**
Date Searched: 24/08/06 (Issue 3: 2006)
This search strategy retrieved 303 records. 45 records were deemed potentially relevant and printed out.
(\text{adverse:ti or safe*:ti or harm*:ti or unsafe*:ti or risk*:ti or negligence:ti or negligent:ti or incident*:ti or error:ti or errors:ti or mistake*:ti or miss:ti or misses:ti or err:ti}) \text{AND} (patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*) and (involv* or participat* or view* or attitude* or role* or contribut* or reporting or aware* or concern* or check* or partners or partnership* or engag* or encourag* or promoting or empower* or complain* or educat* or opinion*)

**The Research Findings Electronic Register (ReFeR)**
Date Searched: 24/08/06
This search strategy retrieved 479 records. 10 records were deemed potentially relevant and printed out.
((\text{patient* or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*}) \text{and} (involv* or participat* or view* or attitude* or role* or contribut* or reporting or aware* or concern* or check* or partners or partnership* or engag* or encourag* or promoting or empower* or complain* or educat* or opinion*)) \text{and} (\text{adverse or safe* or harm* or unsafe* or risk* or negligence or negligent or incident* or error or errors or mistake* or miss or misses or err})

**Patient Safety Organisations**

**Australian Patient Safety Foundation**
Contacted organisation on the 08/11/06, no relevant patient involvement literature available.

**Consumers Advancing Patient Safety (CAPS)**
Searched via [http://www.patientsafety.org](http://www.patientsafety.org)
Date searched: 13/11/06
Browsed 43 resources/books, reports, and articles, and ordered 8.

**The Health Foundation**
Date searched: 15/11/06
Browsed 14 publication briefings and ordered 5.

**Institute for Healthcare Improvement (IHI)**
Searched via [http://www.saferhealthcare.org.uk/ihi](http://www.saferhealthcare.org.uk/ihi)
Dates searched: 14-21/11/06
Browsed 300 books & peer reviewed, and ordered 33.
Date searched: 15/11/06
Browsed 54 journal articles from 'Journalscan', Sept 2005 – July 2006, none were deemed relevant.

**Institute of Medicine of the National Academies (IOM)**
Searched via [http://www.iom.edu](http://www.iom.edu)
Date searched: 15/11/06
A search for 'patient safety' retrieved 47 records, of which none were relevant.
A browse of the 123 articles under the topics ‘healthcare & quality’ retrieved one potentially relevant article.

**Joint Commission on Accreditation of Healthcare Organisations**
International Centre for Patient Safety
Searched via [http://www.jcipatientsafety.org/](http://www.jcipatientsafety.org/)
Date Searched: 18/12/06
75 resource links were browsed and 14 articles ordered.

**National Patient Safety Agency (NPSA)**
Dates Searched: 6-9/11/06
Browsed 277 alerts, advice and publications, ordered 13 papers.

**National Patient Safety Foundation (NPSF)**
Dates searched: 13-15/11/06
A search for 'patient involvement’ retrieved 253, ordered 63 papers.

**Partnership for Patient Safety (p4ps)**
Searched via [http://www.p4ps.org/resources.asp#6](http://www.p4ps.org/resources.asp#6)
Date searched: 13/11/06
A search for 'patient involvement’ retrieved 17 records of which 7 were ordered.

**Picker Institute**
Date searched: 15/11/06
Browsed 42 patient and public involvement publications, and ordered 9.
### Appendix 1.2 Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADR</td>
<td>adverse drug reaction</td>
</tr>
<tr>
<td>A&amp;E</td>
<td>accident and emergency (department)</td>
</tr>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
</tr>
<tr>
<td>AORN</td>
<td>Association of Perioperative Registered Nurses (US)</td>
</tr>
<tr>
<td>DoH</td>
<td>Department of Health (UK)</td>
</tr>
<tr>
<td>FDA</td>
<td>Federal Drugs Agency</td>
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<tr>
<td>GP</td>
<td>General Practitioner (UK)</td>
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<tr>
<td>HCP</td>
<td>healthcare professional</td>
</tr>
<tr>
<td>ID</td>
<td>identification</td>
</tr>
<tr>
<td>INR</td>
<td>International Normalised Ratio (blood test of blood coagulation)</td>
</tr>
<tr>
<td>ISMP</td>
<td>Institute for Safe Medication Practices</td>
</tr>
<tr>
<td>IV</td>
<td>intravenous</td>
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<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organisations (US)</td>
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<tr>
<td>LVHHN</td>
<td>Lehigh Valley Hospital and Health Network (US)</td>
</tr>
<tr>
<td>MRI</td>
<td>magnetic resonance imaging</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service (UK)</td>
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<tr>
<td>NPO</td>
<td>Nil per os – (nothing by mouth)</td>
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<tr>
<td>NPSA</td>
<td>National Patient Safety Agency (UK)</td>
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<tr>
<td>NPSF</td>
<td>National Patient Safety Foundation (US)</td>
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<tr>
<td>NSAIDS</td>
<td>non-steroidal anti-inflammatory drugs</td>
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<tr>
<td>OTC</td>
<td>over the counter</td>
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<tr>
<td>PCA</td>
<td>patient controlled analgesia</td>
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<tr>
<td>RCT</td>
<td>randomised controlled trial</td>
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<tr>
<td>TB</td>
<td>tuberculosis</td>
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<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
</tbody>
</table>
## Appendix 1.3 Interventions identified from the review

<table>
<thead>
<tr>
<th>author</th>
<th>title</th>
<th>summary</th>
<th>ind/re p</th>
<th>intervention</th>
<th>categorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACOG Committee Opinion, 2005:USA</td>
<td>Partnering with Patients to Improve Safety</td>
<td>describes how physicians can actively involve patients in planning and delivering their care</td>
<td>ind</td>
<td>list of tips and resources for physicians to facilitate patient involvement</td>
<td>informing the plan, monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>ACOG Committee Opinion, 2006, USA</td>
<td>Safe Use of Medication</td>
<td>describes how clinicians can ensure that patients are well informed about their medication</td>
<td>ind</td>
<td>oral communication about medication written handout opportunity to ask questions list of medication documentation of allergies</td>
<td>Informing the plan, monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>ADA 2002: USA</td>
<td>Avoiding Insulin Errors</td>
<td>describes good practice for patients who are insulin users. ‘Patient Information’ sheet from American Diabetic Association</td>
<td>ind</td>
<td>information sheet about insulin safety</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Agoritsas 2005:Switz</td>
<td>Patient Reports of Undesirable Events During Hospitalisation</td>
<td>describes a study to estimate the frequency of undesirable events reported by 1518 recently discharged patients</td>
<td>ind</td>
<td>patient reporting of undesirable events while in hospital</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>AHA 2001: USA</td>
<td>Medication Safety Issue Brief: asking consumers for help</td>
<td>describes a number of interventions recommended by a consortium of stakeholders to reduce the risk of medication error through giving patients a list of questions they should ask about their medication and encouraging &amp; enabling staff to respond positively to patient questions.</td>
<td>ind</td>
<td>teaching consumers the questions they should ask about their medication medication review through chronic disease clinic pharmacist visit for patients starting medication from list that commonly cause problems</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>AHA 2003: USA</td>
<td>Medication Safety Issue Brief: Focusing on the Human Factor</td>
<td>describes the adoption of a human factors approach to hospital design and improving communication with patients and their families</td>
<td>ind</td>
<td>structured process for patient rounds in cardiac surgery unit involving patients and their families</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>AHC Media LLC 2002: USA</td>
<td>Proactive approach makes errors plummet</td>
<td>describes how patients can play a role in eliminating the potential for mistakes by being given a medication information pamphlet and taking part in surveys</td>
<td>ind</td>
<td>information sheet about medication safety surveying patients post discharge</td>
<td>informing the plan monitoring and safe delivery of treatment informing systems improvements</td>
</tr>
<tr>
<td>AHC Media LLC 2003: USA</td>
<td>Making patients part of the safety effort; tip sheet helps reduce medical errors</td>
<td>describes how healthcare institutions are teaching patients their role in safety.</td>
<td>ind</td>
<td>tip sheets for patients about being involved in their care sharing information about medication, allergies and adverse reactions asking questions making sure they understand instructions and treatment plans</td>
<td>informing the plan, monitoring and safe delivery of treatment</td>
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<tr>
<td>Author</td>
<td>Year</td>
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<td>AHC Media LLC, 2004: USA</td>
<td>Facility makes patients partners in safety efforts: Beaumont defined patients' role in safety</td>
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<tr>
<td>Anonymous, 2004 (ii): USA</td>
<td>Patient Safety Alert: Beaumont makes patients partners in safety efforts</td>
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<tr>
<td>Health and Wellness resource Center, 2004: USA</td>
<td>Beaumont makes patients partners in safety efforts: facility defined patients' role in safety</td>
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<tr>
<td>Beauregard &amp; Winkur, 2004: USA</td>
<td>Royal Oak Beaumont hospital: putting the patient in patient safety</td>
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<tr>
<td>Facility makes patients partners in safety efforts: Beaumont defined patients' role in safety</td>
<td>describes the patient safety brochure given to patients when they are treated at William Beaumont Hospital, Royal Oak</td>
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<td>Patient Safety Alert: Beaumont makes patients partners in safety efforts</td>
<td>ind</td>
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<tr>
<td>Beaumont makes patients partners in safety efforts: facility defined patients' role in safety</td>
<td>brochure for patients 'You and Your Caregivers: Partners in Safety' given to patients on admission, circulated to all physicians, distributed via community education programmes and stocked in waiting rooms</td>
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<td>Royal Oak Beaumont hospital: putting the patient in patient safety</td>
<td>informing the plan, monitoring and safe delivery of treatment</td>
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<td>AHRQ 2002:USA</td>
<td>Quick Tips- when getting a prescription</td>
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<td>lists questions that patients should ask when they are prescribed a new medication</td>
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<td>ind</td>
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<td>list of questions to ask when prescribed a new medication</td>
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<td>make sure you tell the prescriber the names of all your current medication</td>
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<td>any concerns you have about using your medication</td>
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<td>any allergies or adverse effects from taking any medication in the past</td>
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<td>arrange a follow up appointment to discuss any problems with the new medication</td>
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<td>any new prescriptions from any other doctors</td>
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<td>how you are feeling since starting the medication</td>
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<tr>
<td>informing the plan, monitoring and safe delivery of treatment</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>AHRQ 2000: USA</th>
<th>Improving Health Care Quality: a guide for patients and families</th>
</tr>
</thead>
<tbody>
<tr>
<td>guide which presents info and lists resources to help patients get better quality healthcare</td>
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<td>ind</td>
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<tr>
<td>recommendations for patients to help to improve the quality of their healthcare</td>
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<tr>
<td>informing the plan, monitoring and safe delivery of treatment</td>
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<tr>
<td>Source</td>
<td>Title</td>
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<tr>
<td>AHRQ 2000: USA</td>
<td>Twenty Tips to Help Prevent Medical Errors</td>
</tr>
<tr>
<td>AHC Media, 2003</td>
<td>Patient Fact Sheet: Twenty Tips to Help Prevent Medical Errors</td>
</tr>
<tr>
<td>Anonymous, 2003</td>
<td>On-line fact sheets provide patient safety education</td>
</tr>
<tr>
<td>AHRQ 2002: USA</td>
<td>20 Tips to Help Prevent Medical Errors in Children</td>
</tr>
<tr>
<td>AHRQ 2003: USA</td>
<td>Your Medicine: Play it Safe</td>
</tr>
<tr>
<td>AHRQ 2003: USA</td>
<td>5 steps to safer healthcare</td>
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</tr>
<tr>
<td>AHRQ 2005: USA</td>
<td>Having Surgery? What you need to know</td>
</tr>
<tr>
<td>AHRQ, 2005: USA</td>
<td>Web-based safety education curriculum incorporates suggestions from physicians, nurses and patients</td>
</tr>
<tr>
<td>Source</td>
<td>Title</td>
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<tr>
<td>AHRQ, Kaiser Family Foundation 2004, 2006: USA</td>
<td>Updates on Consumers' Views of Patient Safety and Quality Information</td>
</tr>
<tr>
<td>Albeck 1991: USA</td>
<td>Patient-Therapist Co-documentation: Implications of Jointly Authored Progress Notes for Psychotherapy Practice, Research, Training, Supervision and Risk Management</td>
</tr>
<tr>
<td>Alemagno et al 2004: USA</td>
<td>Using computers to reduce medication misuse of community-based seniors: results of a pilot intervention programme</td>
</tr>
<tr>
<td>Reference</td>
<td>Title</td>
</tr>
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<tr>
<td>Allen et al 2003: USA</td>
<td>What do consumers say they want and need during a psychiatric emergency?</td>
</tr>
<tr>
<td>Allen et al 2003: USA</td>
<td>What do consumers say they want and need during a psychiatric emergency?</td>
</tr>
<tr>
<td>Anonymous 2003: USA</td>
<td>New coalition of healthcare advocates unveils ‘Patient Safety Checklist’ and ‘Patient-Watch Hotline’ at press conference supporting registered nurse to patient ratios</td>
</tr>
<tr>
<td>Anonymous</td>
<td>Pre-testing patient safety tool helps ensure success</td>
</tr>
<tr>
<td>---</td>
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</tr>
<tr>
<td>Anonymous</td>
<td>Pre-testing patient safety tool helps ensure success</td>
</tr>
<tr>
<td>Anonymous</td>
<td>Safety concerns should not end with discharge</td>
</tr>
</tbody>
</table>

469
<table>
<thead>
<tr>
<th>Anonymous 2004: USA</th>
<th>Focus on Five: Five steps you can take to engage your patients in safety</th>
<th>describes how HCPs can involve patients in promoting their own safety. Includes:</th>
<th>ind</th>
<th>5 steps that HCPs can take to involve patients in promoting their own safety.</th>
<th>informing the plan monitoring and safe delivery of treatment informing systems improvements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>backing up written information with verbal explanation</td>
<td></td>
<td>encouraging patients to speak up if they have concerns</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>being receptive to patients expressing concerns</td>
<td></td>
<td>ask them to remind HCPs to wash their hands</td>
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<tr>
<td></td>
<td></td>
<td>issuing patients with safety promoting tools such as wallet cards listing allergies or a chart outlining scheduled care</td>
<td></td>
<td>being accountable - reporting errors and sharing with patient &amp; family</td>
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<td></td>
<td></td>
<td>bridging patient HCP gap by working with patient representatives at hospital management level</td>
<td></td>
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<tr>
<td>Anonymous 2004: USA</td>
<td>Missouri Commission on Patient Safety</td>
<td>report from a commission on patient safety in Missouri which met from September 2003 to May 2004 and produced a number of recommendations including establishing a consumer coalition to make the patient a more active, better-informed member of the healthcare team</td>
<td>rep</td>
<td>formation of a consumer coalition which will: conduct consumer research into patient needs for information and concerns about safety develop accessible educational materials disseminate information on how consumers can maintain their own safety make more safety relevant information available to consumers represent patient interests</td>
<td>informing systems improvements</td>
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<tr>
<td>Anonymous, 2004: UK</td>
<td>Safer Management of Controlled Drugs: information for patients</td>
<td>details the recommendations from the UK government in response to the Shipman report with regard to advice for patients and their reps about the safe handling of controlled medication in the home</td>
<td>ind</td>
<td>written and oral information about controlled medication and its special status delivered sensitively. The information should comprise: an accurate description of the drug advice about how to keep the drug safe advice to return any unused drug to the pharmacy</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Anonymous, 2004: UK</td>
<td>Plan targets patient reporting of adverse drug reactions</td>
<td>describes the pilot phase of a project to expand yellow card scheme that is used to monitor the safety of medicines in the UK. Patients will be able to report unexpected adverse effects of medication directly to the MHRA either on a yellow card or online</td>
<td>ind</td>
<td>yellow card reporting system</td>
<td>monitoring and safe delivery of treatment informing systems improvements</td>
</tr>
<tr>
<td>Anonymous, WHO 2005: UK</td>
<td>JCAHO alert gives new recommendations for PCA (patient controlled analgesia):</td>
<td>describes the new recommendations for selecting patients for PCA and teaching patients and family about the proper use of PCA</td>
<td>ind</td>
<td>written instructions for patients and families about the proper use of PCA and the dangers of PCA by proxy</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Anonymous, 2005: USA</td>
<td>Hospitals educate patients to reduce medical errors, improve patient safety</td>
<td>describes the work of two hospital groups to involve patients in the effort to improve patient safety within the health care system.</td>
<td>ind</td>
<td>instructional video and brochures that teach patients how to get involved in preventing errors staff trained to encourage patients to ask questions fall prevention programme internet access to institutional patient safety information bedside nurse handovers</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Source</td>
<td>Title</td>
<td>Description</td>
<td>Genre</td>
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<td>Anonymous 2006: USA</td>
<td>Partnering with Patients, family can improve safety</td>
<td>describes the development of a patient and family advisory council at the Dana-Farber Cancer Institute</td>
<td>rep</td>
<td>patient and family advisory council (PFAC)</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Anonymous 2006: USA</td>
<td>Preparing for National Patient Safety Awareness Week</td>
<td>describes one hospital's efforts in educating patients on safety issues focusing on effective communication</td>
<td>ind</td>
<td>patient safety fair with staffed information booths in hospital lobby. Information giving focused on: infection control patients being better informed medication safety patients taking part in their treatment planning</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Anonymous 2006: USA</td>
<td>Protecting yourself against medical errors</td>
<td>patient education guide from nursing journal adapted for ease of reading to 5th grade level</td>
<td>ind</td>
<td>patient education guide which aims to answer the questions: what are medical errors? how can I help prevent medical errors? how can I prevent errors at the doctors office? how can I prevent errors if I'm in the hospital?</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Ansell et al 2005: USA, UK, Denmark, Germany</td>
<td>Guidelines for implementation of patient self-testing and patient self-management of oral anticoagulation. International Consensus Guidelines prepared by the International Self-Monitoring Association for Oral Anticoagulation</td>
<td>describes guidelines developed after a critical review of the evidence which concluded that patient self monitoring and treatment gives several advantages including increased safety, and better quality of life</td>
<td>ind</td>
<td>guidelines for the provision of safe effective patient management &amp; patient self testing for oral anticoagulation</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Anselmi 2005: Italy</td>
<td>User centred design for the well-being: the pharmaceutical packaging</td>
<td>describes an approach to user involvement in developing medical products that aims to improve patient safety and healthcare quality. User centred design uses task analysis, questionnaires and user tests to develop consumer orientated products</td>
<td>rep</td>
<td>panel of patients/public testing medical equipment</td>
<td>informing systems improvements</td>
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<td>Anthony et al 2003: USA</td>
<td>The LVHHN Patient Safety Video: Patients as Partners in Safe Care Delivery</td>
<td>describes a video addressing 6 topics - or each outlines strategies that patients might employ or observations they might make to improve patient safety</td>
<td>ind</td>
<td>video given to patients pre-admission patients watch video which covers: treatment plan, falls, medication safety, surgical site ID, handwashing, discharge planning video gives patients permission to ask HCP video details strategies patients might employ to improve patient safety as collaborative members of the health care team</td>
<td>informing the plan monitoring and safe delivery of treatment invited</td>
</tr>
<tr>
<td>Anthony et al 2005: USA</td>
<td>Re-engineering the hospital discharge: An example of a multifaceted process evaluation</td>
<td>describes an evaluation of the hospital discharge process and recommends list of important themes to consider when re-engineering the process.</td>
<td>ind</td>
<td>patient education throughout the inpatient stay patient is given a discharge plan he/she can understand and has instructions about what to do if condition worsens patient assessed as at high risk of re-hospitalisation should be contacted after discharge</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Authors</td>
<td>Institution</td>
<td>Description</td>
<td>Collaboration</td>
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<td>Monitoring and Safe Delivery of Treatment</td>
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<td>Anthony et al 2005: USA</td>
<td>Lehigh Valley Hospital: engaging patients and families</td>
<td>describes the hospital’s efforts to engage patients in promoting their own safety alongside health care professionals</td>
<td>ind/rep</td>
<td>collaborating rounds involving patients and their families</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<td>patient safety video given to patients pre-admission</td>
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<td>patient representative on design group for paediatric intensive care unit</td>
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<td>patient safety suggestion boxes</td>
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<td>AORN and Ethicon Endo-surgery 2004: USA</td>
<td>New Campaign Urges Patients to Speak Up for Safer Surgery ‘Smarter Patient Campaign’ launches</td>
<td>describes a campaign to arm patients with information and knowledge of appropriate questions to ask before undergoing a surgical procedure</td>
<td>ind</td>
<td>five important questions that every patient should ask before surgery</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<td></td>
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<td>are there any other treatments for my condition?</td>
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<td>are there any other treatments for my condition?</td>
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<td>will a registered nurse be present in theatre during my surgery?</td>
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<td>will a registered nurse be present in theatre during my surgery?</td>
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<td>will reprocessed disposable instruments be used in my surgery?</td>
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<td>will reprocessed disposable instruments be used in my surgery?</td>
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<td></td>
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<td>am I receiving the right medication?</td>
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<td>am I receiving the right medication?</td>
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<td>how will the surgeon verify that he is operating on the right part of my body?</td>
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<td>how will the surgeon verify that he is operating on the right part of my body?</td>
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<td></td>
<td></td>
<td>booklet also provides general information about preparing for surgery, choosing a surgeon and what to expect during recovery</td>
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<td>booklet also provides general information about preparing for surgery, choosing a surgeon and what to expect during recovery</td>
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</tbody>
</table>
| AORN 2006: USA | AORN supports National Patient Safety Awareness week by issuing valuable safety tips | describes an initiative for perioperative nurses which lists tips for patients on how they can ensure their safety | ind | List of tips for patients:  
clean out your medicine cabinet of old and expired medication  
bring your medication to your doctor or pharmacist for review  
get copies of all your healthcare records and keep them in a safe place  
write down and carry with you a list of all your prescription and over the counter medications as well as any allergies  
write down and carry with you the names of all your HC providers and pharmacies  
identify an advocate who can accompany you and ask questions on your behalf  
talk to your family about what your preferences are for your healthcare in case you are unable to speak for yourself  
ask your hospital or HCP about patient safety and how communication and partnership between you can be improved  
communicate your healthcare safety concerns to your provider  
let your healthcare provider know with whom they should talk in case you are unable to speak for yourself  
informing the plan delivery and monitoring of treatment |
<p>| Arias et al 2003: Colombia | Surveillance of surgical site infections: decade of experience at a Colombian tertiary care centre | describes how patients were included in a protocol for surveillance of surgical site infections | ind | patients involved in monitoring the rate of wound infections after discharge from hospital | monitoring and safe delivery of treatment |</p>
<table>
<thead>
<tr>
<th>Arizona Cert 2006: USA</th>
<th>Patients' steps to safe medication use</th>
<th>lists five things that patients can do to avoid medication error</th>
<th>ind</th>
<th>list of five steps to safe medication use: take every medication, both prescription and non-prescription to every doctor's visit and discuss ask your physician to inform you fully about each prescription and ask how it may affect other medications you are taking ask what you should expect when you take your medication make sure you can read your physician's writing on the prescription and ask for written information about it insist that your pharmacist keep a computerised record of all your prescriptions and give you written instructions including a list of interactions with other medications inform your physician of any side effects you experience from medication including allergic reactions</th>
<th>informing the plan monitoring and safe delivery of treatment</th>
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</thead>
<tbody>
<tr>
<td>Aronson 1995</td>
<td>Confusion over similar drug names. Problems and solutions</td>
<td>describes ways in which patients can help to reduce the risk of medication errors due to the confusion of drug names</td>
<td>ind</td>
<td>recommendations for patients: they should educate themselves/be educated about their medication</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Aronson 2004: UK</td>
<td>Medication error resulting from the confusion of drug names</td>
<td>describes ways in which patients can help to reduce the risk of medication errors due to the confusion of drug names</td>
<td>ind</td>
<td>recommendations for patients: seek information about meds tell a new prescriber about all meds take meds along when consulting a prescriber/pharmacist</td>
<td>monitoring and safe delivery of treatment</td>
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<tr>
<td>Author</td>
<td>Title</td>
<td>Description</td>
<td>Strategies to Reduce the Risk of Medication Error:</td>
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<td>Author(s)</td>
<td>Title</td>
<td>Description</td>
<td>Indication</td>
<td>Key Points</td>
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<td>Aspinall et al 2002: USA</td>
<td>Improving adverse drug reaction reporting in ambulatory care clinics at a Veterans Affairs Hospital</td>
<td>describes a study in which direct patient and provider interviews yielded a significantly higher rate of adverse drug reactions (ADR) in an ambulatory care setting than a passive ADR reporting system. When ADRs reported, providers changed patient drug regimens in 34% of cases.</td>
<td>ind patients randomly selected by using last digit of social security numbers</td>
<td>patients asked a series of standardised questions about the medication they were taking and any adverse effects.</td>
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<tr>
<td>ASRT 2002: USA</td>
<td>Magnetic Resonance Safety</td>
<td>describes precautions to be taken by patients when attending for MRI scanning. Presented as 'patient page' in radiology journal.</td>
<td>ind information sheet about magnetic resonance safety</td>
<td>monitoring and safe delivery of treatment</td>
<td></td>
</tr>
<tr>
<td>Atkin et al 1998: Australia</td>
<td>The influence of information provided by patients on the accuracy of medical records</td>
<td>describes a study testing two interventions which aimed to improve the accuracy of doctor's information about their patients' medication.</td>
<td>ind Gp 1 medication record filled in by GPs - asked to bring to all consultations Gp 2 as above and also asked to bring all medication to each consultation</td>
<td>informing the plan monitoring and safe delivery of treatment informing systems improvements</td>
<td></td>
</tr>
<tr>
<td>Atkinson &amp; MacPherson 2001: UK</td>
<td>Patients' advocacy: The development of a service at the state hospital, Carstairs, Scotland</td>
<td>describes the setting up of an advocacy service at a secure unit and the tensions between empowering individual patients and ensuring the safety of all staff and patients.</td>
<td>ind advocacy service as a voice for disempowered patients within a maximum secure environment</td>
<td>informing the plan informing systems improvements</td>
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<tr>
<td>Author(s)</td>
<td>Year</td>
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<tr>
<td>Attilio</td>
<td>1996</td>
<td>Attilio 1996: USA Caring enough to understand: the road to oncology medication error prevention</td>
<td>describes how patients undergoing a course of chemotherapy can help to reduce the risk of medication error</td>
<td>ind</td>
<td>informed patients acting as the 'final barrier to preventing medical errors' monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Attilio</td>
<td>1997</td>
<td>Attilio 1997: USA Strategies for Reducing Chemotherapy-Related Medication Errors: Improving the Chemotherapy Prescribing, Dispensing and Administration Process and the Patient's Role in Ensuring Safety</td>
<td>describes strategies for improving medication safety in primary care and how patients can be involved in this</td>
<td>ind</td>
<td>open discussion between HCP and patient to reveal information about sensitivities and allergies, treatment preferences. Patient encouraged to read medication package inserts informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Avery</td>
<td>2004</td>
<td>Avery 2004: USA The way things should go: Part II</td>
<td>describes the use of a 'time out' procedure which involves the patient as the final check before surgery to make sure all agree the treatment plan</td>
<td>ind</td>
<td>surgical team and patient stop and take stock (via a checklist) prior to anaesthetic induction to make sure they all agree monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Avery et al</td>
<td>2002</td>
<td>Avery et al 2002: UK Safer medicines management in primary care</td>
<td>describes strategies for improving medication safety in primary care and how patients can be involved in this</td>
<td>ind</td>
<td>patient education medication error programme enabling patients to become knowledgeable consumers during their encounter with the health care system informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Awe &amp; Lin</td>
<td>2003</td>
<td>Awe &amp; Lin 2003: USA A Patient Empowerment Model to Prevent Medication Errors</td>
<td>describes the proposal for a patient empowerment model to help HCPs to see patients as part of the health-care team and decrease medication errors</td>
<td>ind</td>
<td>patient education medication error programme enabling patients to become knowledgeable consumers during their encounter with the health care system informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Author(s)</td>
<td>Year</td>
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<tr>
<td>Bachynsky 1986: Canada</td>
<td>Cost-benefit and cost-effectiveness in institutional pharmacy practice</td>
<td>describes the part patients can play in the reduction of medical errors. Recommends that patient awareness of pharmacists as a resource is improved through increased pharmacist counselling of patients both as an inpatient and prior to discharge, incorporating the patient into the therapeutic team</td>
<td>ind</td>
<td>medication counselling of patients by pharmacists</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Baum 2006: USA</td>
<td>A new look at informed consent</td>
<td>describes computer assisted informed consent which, the author argues, can enhance patient safety</td>
<td>ind</td>
<td>a computerised, automated consent process</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Beger et al 1999, 2000: USA</td>
<td>Self-administered medication packet for patients experiencing a vaginal birth</td>
<td>describes the implementation of a self-administered medication (SAM) packet to patients who have had a vaginal birth</td>
<td>ind</td>
<td>pharmacy prepares SAM packet. SAM packet includes medications, a tally sheet and medication information pamphlets which is given to the patient on admission by the nurse. Nurse educates the patient regarding the medications including amount and frequency. Patient signs permit patient takes medications and documents them on tally sheet. Nurse evaluates patient pain level and medication use on each shift.</td>
<td>monitoring and safe delivery of treatment</td>
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<tr>
<td>Author</td>
<td>Title</td>
<td>Summary</td>
<td>Indications</td>
<td>Monitoring and safe delivery of treatment</td>
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<td>Benjamin</td>
<td>Reducing medication errors and increasing patient safety: case studies in clinical pharmacology</td>
<td>describes what is known about medication errors and ways to prevent them using case studies to illustrate. To involve patients it recommends instructing patients to call if side effects occur and ensuring information giving and communication is good quality.</td>
<td>ind education of patients about medication, possible adverse effects and when to seek help</td>
<td>monitoring and safe delivery of treatment</td>
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<tr>
<td>Bersten</td>
<td>The Patient's Guide to Preventing Medical Errors</td>
<td>describes the patient centred approach recommended by the Institute of Medicine 'Crossing the Quality Chasm' and how this can improve patient safety</td>
<td>ind 10 patient partnership principles</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Bersten</td>
<td>The Patient's Guide to Preventing Medical Errors</td>
<td>describes the problem of medical errors, why they happen and what can be done to reduce the risk including partnering with patients and advice for patients about protecting themselves</td>
<td>ind information about medical errors and why they occur. detailed hints and tips about how patients can be involved summed up by: Beware Education Speak up Act Facts Error-free</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Author</td>
<td>Year</td>
<td>Country</td>
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<td>Intervention</td>
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<td>Beyth et al 2000: USA</td>
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<td>A multi-component intervention to prevent major bleeding complications in older patients receiving warfarin.</td>
<td>describes a RCT of a multi-component intervention to prevent major bleeding complications in older patients receiving warfarin. Two main components: Guideline-based consultation that assessed patient's indications for therapy and potential risk factors for warfarin-related bleeding. Patient education, coaching and self-monitoring of prothrombin time. Control patients received usual care</td>
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<td>Blennerhassett et al 2005: Australia</td>
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<td></td>
<td>Medication safety and patient participation: pharmacist, emergency department and beyond</td>
<td>letter to journal editor describing a resource available to patients called 'What to do with your tablets and medicines when coming into hospital'. This was developed when it was noted that patients didn’t know their own medication information on admission to the emergency department. a poster and pamphlet were developed, encouraging patients to bring all their medications into hospital and to all appointments with doctors, to know what medications they are taking and to keep an up-to-date medication list and to show it to relevant health professionals. Posters were put all over the hospital and the pamphlet in outpatient areas. informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Bonapace 2005: Italy</td>
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<td>User-centred approach in designing furniture for healthcare facilities</td>
<td>describes how collaboration between designers, human factors specialists and users can result in design of products that address both user and organisational requirements users and user representatives involved in gathering information throughout the whole product design process informing systems improvements</td>
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<td>Bouvenot 2001: France</td>
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<td>How to minimise therapeutic risk</td>
<td>describes a number of ways that risk can be reduced many of them involving patients personalised prescriptions information to patient about medication close relationship between the patient and prescriber informing the plan monitoring and safe delivery and</td>
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<td>Study</td>
<td>Title</td>
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<td>Informing the plan</td>
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<td>Brass et al 2003: USA</td>
<td>Label development and the label comprehension study for over-the-counter drugs</td>
<td>Describes a framework for over-the-counter medication label development</td>
<td>Ind</td>
<td>Guidelines for the development of labels for OTC medication which provide information to patients to ensure they use OTC medication safely</td>
<td></td>
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<tr>
<td>Brodell et al 1997: USA</td>
<td>Prescription errors: legibility and drug name confusion</td>
<td>Recommends ways that prescription errors due to poor handwriting can be minimised including educating patients about their medication</td>
<td>Ind</td>
<td>Educating patients about the name and purpose of all drugs being prescribed encouraging patients to bring their medication to each healthcare encounter</td>
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<tr>
<td>Brown &amp; Falloon 2000: UK</td>
<td>The incidence and reporting of adverse drug reactions in the Division of Psychiatry.</td>
<td>Describes a study that collected data on side effects/adverse effects experienced by patients commenced on newly marketing drugs in previous month. It found that both patients and HCPs under-report adverse drug effects and recommended medication discussion groups for patients to raise issues about their experience of taking medication</td>
<td>Ind</td>
<td>Medication discussion groups</td>
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<td>Monitoring and safe delivery of treatment</td>
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<td>Brown 2005: USA</td>
<td>Low literacy and medication safety: spreading the word</td>
<td>describes the development and implementation of a medication safety brochure that could be used by patients at varying reading levels</td>
<td>ind/re p</td>
<td>a medication safety brochure for low literacy readers was developed which aimed to reduce medication errors. A test group of adult learners identified pictures, symbols, graphics and key words that could convey messages to adults considered low literate or first time readers. Implemented across state and also available to download off web.</td>
<td>informing systems improvements</td>
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<td>Bruegman 2003: USA</td>
<td>Prescription for safety. Bedside program receives national attention</td>
<td>describes a patient bedside medication administration record (MAR) that has been implemented on a medical/surgical unit in a US hospital.</td>
<td>ind</td>
<td>bedside medication administration record (MAR). On admission to the unit the nurse takes a detailed health history and reviews the medications the patient was taking at home. The patient is given a copy of the MAR and when medications should be given. Patient also told by nurse to call a nurse if a medication is not given within an hour of its prescribed time.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Brushwood 1986: USA</td>
<td>Drug Information for Patients</td>
<td>describes the importance of giving information to patients about medication to minimise the potential hazards of drug use and emphasises the legal duty of healthcare professionals and facilities to do so</td>
<td>ind</td>
<td>information giving, verbal and written, about drug use and potential adverse effects by pharmacists, physicians and health care institutions</td>
<td>monitoring and safe delivery of treatment</td>
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<td>Author(s)</td>
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<td>Bryant et al 1991: USA</td>
<td>Effect of age on reporting of adverse clinical events</td>
<td>describes two surveys to determine the possible effects of age on reports by outpatients of adverse clinical events occurring after treatment with antibiotics or tricyclic antidepressants. One approach was staff initiated enquiry by phone, the other was patient initiated reporting by phone.</td>
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<tr>
<td>Bullman 2001: USA</td>
<td>Educate before you medicate: your lifeline for safe medication use</td>
<td>describes 3 steps patients can take to help ensure safe medication use from national Council on Patient Information and Education in Bethesda</td>
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<tr>
<td>Busch 2003: USA</td>
<td>Empowering patients to direct their healthcare</td>
<td>describes the assembling and use of a patient portfolio by a woman undergoing treatment for breast cancer containing all relevant past and current health information. This portfolio was taken to each encounter with HCPs</td>
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</tbody>
</table>

patients are invited to report adverse drug events by phone after treatment with antibiotics or tricyclic antidepressants either self-initiated or prompted by a HCP |

advice - 3 steps to help ensure safe medication use take part in treatment decisions follow treatment plan, watch for problems and get help solving them, series of questions to ask HCP or pharmacist about newly prescribed meds |

informing the plan monitoring and safe delivery of treatment |

informing the plan monitoring and safe delivery of treatment |

informing the plan |

informing the plan
<table>
<thead>
<tr>
<th>Authors</th>
<th>Title</th>
<th>Description</th>
<th>Ind/Rep</th>
<th>Notes</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Camins &amp; Fraser</td>
<td>Reducing the risk of healthcare associated infections by complying with CDC hand hygiene guidelines</td>
<td>Describes the launch and evaluation of a hand hygiene programme at a community hospital. Notes that patients and their families can contribute by asking HCPs if they have washed their hands.</td>
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<tr>
<td>USA</td>
<td></td>
<td></td>
<td>ind</td>
<td>Posters and badges worn by staff to encourage patients and their families to ask HCPs if they have washed their hands.</td>
<td>Monitoring and safe delivery of treatment.</td>
</tr>
<tr>
<td>Campbell &amp; Califf</td>
<td>Improving communication of drug risk to prevent patient injury: proceedings of a workshop</td>
<td>Describes a series of workshops that aimed to develop an agenda for research and education about risk and its management. Groups made up of representatives from the medical products industry, academia, consumer groups, regulatory authorities and the media identified increased involvement of patients and families as one of the potential solutions.</td>
<td>rep</td>
<td>Consumer involvement in workshops.</td>
<td>Informing systems improvements.</td>
</tr>
<tr>
<td>USA</td>
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<tr>
<td>Campbell</td>
<td>Listen to the Family</td>
<td>Describes a 'near miss' involving a missed diagnosis and follows with strategies put in place by one institution to prevent wrong site, wrong patient, wrong side errors and how patients are involved with this.</td>
<td>ind</td>
<td>Algorithms based on newly designed operative permit.</td>
<td>Monitoring and safe delivery of treatment.</td>
</tr>
<tr>
<td>2004: USA</td>
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<table>
<thead>
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<th>Author</th>
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<th>Title</th>
<th>Description</th>
<th>Indications</th>
<th>Outcome</th>
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<tbody>
<tr>
<td>Campbell &amp; Howie</td>
<td>1988: UK</td>
<td>Involving the Patient in Reporting Adverse Drug Reactions</td>
<td>describes a method for increasing the level of reporting of adverse drug reactions</td>
<td>ind</td>
<td>information leaflet encouraging patients to report adverse drug reactions to their doctor given at first repeat of their medication informing the plan monitoring and safe delivery of treatment informing systems improvements</td>
</tr>
<tr>
<td>Cantrell</td>
<td>2005: USA</td>
<td>A Double Dose of Caution</td>
<td>describes how healthcare institutions are using medication reconciliation programmes to try to reduce medication errors and adverse drug events</td>
<td>ind</td>
<td>patient maintains an accurate list of all current meds patient brings all meds to each consultation informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Carthey J</td>
<td>2005: UK</td>
<td>Thinking nationally, acting locally: the National Patient Safety Agency's approach to improving patient safety in the NHS</td>
<td>describes some of the work of the NPSA including the setting up of the national Reporting and Learning System and the Patient Safety Observatory. Also uses the example of methotrexate to illustrate ways in which the NPSA has tried to identify patient safety vulnerabilities and devise interventions.</td>
<td>rep</td>
<td>Patient Safety Alerts National Reporting and Learning System informing systems improvements</td>
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<tr>
<td>Caserta</td>
<td>1987: USA</td>
<td>It's a jumble - No; it's a maze - No; It's your client's medication shelf</td>
<td>describes a medication teaching resource pack available to homecare nurses to enable them to educate patients about their medication</td>
<td>ind</td>
<td>medication teaching resource pack informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Author(s)</td>
<td>Year</td>
<td>Location</td>
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<td>Patient Education</td>
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<td>Cassetta</td>
<td>1993</td>
<td>USA</td>
<td>Safe medication practices entail education of family, patients</td>
<td>Patient education about safe medication use</td>
<td>Monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Cheah &amp; Martins</td>
<td>2003</td>
<td>USA</td>
<td>Coumadin Knowledge Deficits: Do Recently Hospitalized Patients Know How to Safely Manage the Medication</td>
<td>Understanding assessment &amp; tailored education</td>
<td>Monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Cherian et al</td>
<td>1994</td>
<td>USA</td>
<td>ASA Abstract The National Medic Alert Difficult Airway/Intubation Registry: Patient Safety and Patient Satisfaction</td>
<td>Registry of individuals with a history of difficult airway/intubation</td>
<td>Informing the plan</td>
</tr>
<tr>
<td>Cimino et al</td>
<td>2000</td>
<td>USA</td>
<td>An evaluation of Patient Access to their Electronic Medical Records via the World Wide Web</td>
<td>Electronic medical records which can be accessed by patients as well as HCPs</td>
<td>Informing the plan monitoring and safe delivery of treatment</td>
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<td>Year</td>
<td>Location</td>
<td>Title</td>
<td>Description</td>
<td>Target Audience</td>
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<tr>
<td>1999</td>
<td>Australia</td>
<td>Clark et al.</td>
<td>Towards system-wide strategies for reducing adverse drug events describes the proceedings of a workshop focus group that produced recommendations for reducing adverse drug events within health services</td>
<td>Workshop comprising HCPs and consumers</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>1995</td>
<td>USA</td>
<td>Cleary</td>
<td>CAHP II</td>
<td>describes an ongoing project refining and evaluating the information available to patients about health care facility service quality and HCP performance</td>
<td>service quality information available for patients in a format appropriate for them</td>
</tr>
<tr>
<td>1995</td>
<td>USA</td>
<td>Cohen</td>
<td>Medication Errors. Aprotinin Injection. Beware: deadly reactions</td>
<td>describes possible severe allergic reaction to aprotinin particularly on 2nd time use. Gives advice to nurses to guard against this, including involving the patient through education and using a medical-alert bracelet.</td>
<td>recommends a number of safeguards so that it is known that the patient has received aprotinin once before. This includes, before discharge, teaching the patient and family about aprotinin and cautioning about the risks. In addition, patient should be told to obtain a medical-alert bracelet to notify future caregivers.</td>
</tr>
<tr>
<td>1996</td>
<td>USA</td>
<td>Cohen</td>
<td>Risk management of medical errors must include a careful look at the specific systems involved</td>
<td>describes ways in which the risk of medication error/adverse event can be reduced including educating patients about their treatment</td>
<td>advice given by HCPs to patients about medication use, handling &amp; storage</td>
</tr>
<tr>
<td>Author</td>
<td>Year</td>
<td>USA</td>
<td>Title</td>
<td>Summary</td>
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<td>Cohen 1996</td>
<td>Preventing medication errors in cancer chemotherapy</td>
<td>describes ways in which the risk of medication error/adverse event can be reduced for patients having a course of chemotherapy including educating patients about their treatment</td>
<td>ind</td>
<td>HCPs educating patients about their drug therapy and advising how they can protect themselves from medication errors</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Cohen 1997</td>
<td>Enhancing chemotherapy safety through medication system improvements</td>
<td>describes ways in which the risk of medication error/adverse event can be reduced for patients having a course of chemotherapy including educating patients about their treatment</td>
<td>ind</td>
<td>Pharmacists educating patients about their drug therapy and advising how they can protect themselves from medication errors</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Cohen 1997</td>
<td>Medication Errors. Insulin Lispro, it's a blur.</td>
<td>describes the similarity in labelling/packaging of two different types of insulin and how this may result in a medication error occurring. Gives advice on how to avoid such errors.</td>
<td>ind</td>
<td>Recommends that nurse educates the patient about the two types of insulin (Humulin N and Humalog) to avoid confusing the two, which are similar in packaging and name. Specifically: pointing out the similarity of name and importance of taking correct medication, explaining when to take each drug labelling or taping vials so patient can easily distinguish between them</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Cohen 1998</td>
<td>Medication Errors. Untapped help, &quot;nagging&quot; patients.</td>
<td>describes a study of patients checking HCP hand washing in four community hospitals. Article advocates employing patient checking to ID bands.</td>
<td>ind</td>
<td>Sticker worn by patient. ‘Did you check my ID band?’</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Cohen 1999: USA</td>
<td>ISMP Medication error Report Analysis 34</td>
<td>describes a number of drug errors which have been investigated and recommends how the risk of these errors/adverse effects could be reduced.</td>
<td>ind</td>
<td>advice given to HCPs to parents about the use and storage of syringes to administer liquid medication to their children</td>
<td>monitoring and safe delivery of treatment</td>
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<tr>
<td>Cohen 1999: USA</td>
<td>Medication Errors. The name game, inviting patients to play.</td>
<td>describes way for nurses to involve patients in verifying their identity before receiving drugs, procedures or treatments.</td>
<td>ind</td>
<td>recommends that facility protocols should involve alert patients in verifying their identity before receiving drugs, procedures or treatments patients should be taught to offer ID bracelet for inspection when anyone arrives with medications and insist on having it replaced if it's removed at admission patients should be advised to state full name, even if not asked, before accepting meds, procedures or treatments</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Cohen 1999: USA</td>
<td>Preventing medication errors in cancer chemotherapy</td>
<td>describes some errors that have occurred in cancer chemotherapy and makes recommendations to reduce the risk of error including educating patients and inviting patients to be part of the healthcare team</td>
<td>ind</td>
<td>keeping patient informed about their medication and treatment, giving patients tips on how they can help avoid error by making sure that their name band is checked, that they verify their identity before accepting treatment, that they observe staff double checking chemotherapy before administration</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Cohen 2001: USA</td>
<td>Medication Errors. Potential adverse responses, tell it like it is.</td>
<td>describes a survey of outpatients about how much they wanted to be told about potential adverse reactions to their medications. Most wanted to be told about all possible adverse reactions. Recommends educating patients about the most common adverse reactions and to urge that they report unusual feelings or symptoms.</td>
<td>ind</td>
<td>patient education about the most common potential adverse reactions to all their medications encouragement to report unusual symptoms after starting any new medication or after a dose adjustment of a current medication.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Cohen 2002: USA</td>
<td>Medication Errors. Giving children medication, teaching parents.</td>
<td>describes FDA publication 'How to Give Medicines to Children' and where it can be accessed on-line.</td>
<td>ind</td>
<td>FDA publication 'How to give medicines to children'. Includes easy-to-read tips including information on dosing dilemmas and which administration devices to use for which ages. Article highlights one of the tips in the publication that features illustrations emphasizing the need to remove syringe caps before administering the medicine.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Year</td>
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<td>Title</td>
<td>Description</td>
<td>Indication</td>
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<tr>
<td>2002</td>
<td>USA</td>
<td>Cohen</td>
<td>Medication Errors. Patient education, getting a read on literacy describes literacy issues/problems in US society and advises simple, straightforward instructions and written materials. ind patient information tailored to reading level</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>USA</td>
<td>Cohen</td>
<td>Medication Errors. Prescription for safety, take time to teach. describes a prescribing error. Recommends nurses to teach patients to always ask the prescriber the name of a drug being ordered and to talk with a pharmacist to make sure it's appropriate for their condition. ind patients encouraged to: ask prescribers the name of a drug being ordered talk with a pharmacist to make sure it's appropriate for their condition.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>USA</td>
<td>Cohen</td>
<td>Medication errors. Tips to avoid double dosing; patient instructions describes tips to avoid medication errors by making sure patient is well informed</td>
<td>keeping patient informed to avoid double dosing, making sure patients understand instructions</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>2005</td>
<td>USA</td>
<td>Cohen</td>
<td>ISMP Medication error Report Analysis 40 describes a number of drug errors that have been investigated and recommends how the risk of these errors/adverse effects could be reduced. ind advice given by HCPs to patients</td>
<td>monitoring and safe delivery of treatment</td>
<td></td>
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<tr>
<td>2007</td>
<td></td>
<td>Connock et al.</td>
<td>Clinical effectiveness and cost effectiveness of different models of managing long term oral anticoagulant therapy: a systematic review and economic modelling describes a review of the effectiveness of different ways of managing anticoagulant therapy including patient self management ind patient self management of anticoagulant therapy</td>
<td>monitoring and safe delivery of treatment</td>
<td></td>
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<tr>
<td>Author(s)</td>
<td>USA</td>
<td>Title</td>
<td>Description</td>
<td>Role</td>
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<tr>
<td>Connor 2002: USA</td>
<td>Multidisciplinary approaches to reducing error and risk in a patient care setting</td>
<td>describes the systems changes put in place at Dana-Farber Cancer Institute following a major drug error</td>
<td>ind/rep</td>
<td>adult patient and family &amp; paediatric advisory councils consist of 15 patients and family members who are involved in teaching medical students, patient care rounds, standing committees, risk management and planning</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Connor et al., 2002: USA</td>
<td>Multi-disciplinary approaches to reducing error and risk in a patient care setting</td>
<td>describes a programme to improve patient safety at Dana-Farber Cancer Institute including involving patients in design and planning</td>
<td>rep</td>
<td>patient representatives involved in design of new chemotherapy unit</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Consumers Union 2005: USA</td>
<td>Stay safe in the hospital</td>
<td>describes the problem of medical error and lists some strategies that patients may adopt to reduce the risk</td>
<td>ind</td>
<td>list of recommendations under the general headings of: infection protection preventing medication mix ups stopping surgical errors controlling your pain clear communication advice about how to select a surgeon and healthcare facility</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Cooper 2002: USA</td>
<td>CQC Notebook Reducing Medical Errors</td>
<td>describes progress on patient safety agenda since 'To err is human' and contains fact sheet which lists what patients can do to get safer healthcare</td>
<td>ind</td>
<td>fact sheet listing things that patients can do to get safer healthcare</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Author</td>
<td>Country</td>
<td>Title</td>
<td>Description</td>
<td>Target Audience</td>
<td>Outcomes</td>
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<tr>
<td>Corina 2005: USA</td>
<td>Errors from the consumer's perspective</td>
<td>describes how PULSE (Patients United Limiting Substandard and Errors in Healthcare) supports the victims of medical error and their families and the audiotape of guidelines and community education programmes produced by the organisation that aims to help reduce the risk of error and increase patient involvement in their care.</td>
<td>ind</td>
<td>audio taped guidelines for use by inpatients community education programmes to help people become better healthcare consumers and partners in their care</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Correa-De-Araujo 2005: USA</td>
<td>It's your health: use your medications safely</td>
<td>describes the differences between men and women's responses to medication. Provides a set of guidelines for women about their healthcare generally and medication safety especially</td>
<td>ind</td>
<td>guidelines for safe medication use for women</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Corso 1992: USA</td>
<td>Development of a questionnaire for detecting potential adverse drug reactions</td>
<td>describes a study which aimed to develop a database of adverse drug reactions based on patient questionnaires</td>
<td>rep</td>
<td>database of adverse drug events based on patient experience</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Coulter &amp; Ellis 2006: UK</td>
<td>Patient-focused Interventions, a review of the evidence</td>
<td>review of patient focused interventions with chapter 'Improving Patient Safety' grouped into: infection control initiatives adherence to treatment regimes direct patient reporting of adverse events equipping patients for safer healthcare preventing wrong site surgery</td>
<td>ind</td>
<td></td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Coulter 2002: UK</td>
<td>Ch 4 Managing care and ensuring safety: patient as care manager</td>
<td>describes ways in which patients can be involved in playing an active part in preventing mistakes and assuring their own safety</td>
<td>ind</td>
<td>patients are/should be involved in: helping to reach an accurate diagnosis choosing an appropriate treatment or management strategy choosing a suitably experienced and safe provider ensuring that treatment is appropriately administered, monitored &amp; adhered to identifying side effects or adverse events quickly and taking appropriate action reporting medical errors reporting post surgical complications</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Coulter 2006: UK</td>
<td>After Bristol: putting patients at the centre</td>
<td>describes and comments on the recommendations made by the Bristol Inquiry including ensuring patient safety by actively involving patient in their care. Recommended that patients know what to expect so that they can check things are going to plan, involving patient in the design of drug info leaflets, patients reviewing their notes and any correspondence about them, giving patients access to electronic records</td>
<td>ind/repeated</td>
<td>HCPs should give patients information about treatment plan patients should be involved in design of patient insert leaflet and packaging of medication patients should have access to medical notes, correspondence and electronic records</td>
<td>informing the plan monitoring and safe delivery of treatment informing systems improvements</td>
</tr>
<tr>
<td>Authors</td>
<td>Study Description</td>
<td>Methodology</td>
<td>Outcomes</td>
<td>Delivery and monitoring of treatment</td>
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<td>Cromheecke et al 2000: Netherlands</td>
<td>Oral anticoagulation self-management and management by a specialist anticoagulation clinic: a randomised cross-over comparison</td>
<td>ind</td>
<td>Self-management of anticoagulation. Underwent structured educational programme. Consisted of two, 2-hour sessions. First teaching session followed by 10 day trial period of measuring own INR. Second session learned and practised dosing regimen. A 24hour help desk was available to answer questions/assist with any problems. Controls: Anticoagulation management by specialised anticoagulation clinic.</td>
<td>delivery and monitoring of treatment</td>
<td></td>
</tr>
<tr>
<td>Cummings et al 1984: USA</td>
<td>The effect of clinical pharmacy services provided to ambulatory patients on hospitalization</td>
<td>ind</td>
<td>Drug therapy assessment, monitoring and patient education for all patients taking more than 7 medications daily</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
<td></td>
</tr>
<tr>
<td>Curry et al 2005: USA</td>
<td>Teaching Older Adults to Self-manage Medications: preventing adverse drug reactions</td>
<td>ind</td>
<td>Individualised assessment of older adults’ capacity to self-medicate safely &amp; introduction of interventions to facilitate this</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Study (Year)</td>
<td>Title</td>
<td>Description</td>
<td>Method</td>
<td>Intervention</td>
<td>Outcomes</td>
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<td>Daniv 1992: USA</td>
<td>The effect of instruction on comprehension and recall of prescription drug label information in older adults</td>
<td>Describes a study that investigated the effects of an educational programme for older adults in the correct use of prescription label information. Found that focused education helped patients remember knowledge about medication labelling and increased understanding of drug information.</td>
<td>ind</td>
<td>verbal and written instruction in interpreting and remembering drug label information from prescription labels</td>
<td>Monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Dassori et al 2003: USA</td>
<td>The Approaches to Schizophrenia Communication (ASC) Tool: Including the patient perspective in treatment</td>
<td>Describes the development of two checklists designed to capture the adverse drug effects of anti-psychotics. One list is completed by patient alone the other is completed by patient &amp; HCP together</td>
<td>ind</td>
<td>Checklist to facilitate discussion of adverse drug events experienced by patients taking anti-psychotics</td>
<td>Informing the plan, monitoring and safe delivery of treatment making systems safe</td>
</tr>
<tr>
<td>Author (Year): Location</td>
<td>Title</td>
<td>Description</td>
<td>Indications</td>
<td>Recommendations</td>
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<tr>
<td>David 2002: USA</td>
<td>Medication safety alerts describes how seamless care initiatives (making sure that continuity of care is maintained for patients across a variety of caregivers and their environments) contribute to patient safety by reducing the risk of medication error. Details how patients are involved in this list of recommendations to ensure that care is seamless including: encouraging patients to share relevant information with HCPs, encouraging patients to bring all meds they are taking, prescribed and not prescribed, to consultations, encouraging patients to use the same community pharmacist, alerting patients to the potential of HCP non-communication, encourage to take discharge summary to consultation, encourage patients to return any leftover medication, remind patients to take full course of antibiotics.</td>
<td>ind</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
<td></td>
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</tr>
<tr>
<td>Davidson et al 1991: USA</td>
<td>Principles for Treating Aggressive Patients in a Day Hospital: Balancing safety with patient autonomy describes intervention for managing aggressive acts by patients in a day hospital while both fostering patient autonomy and maintaining a safe environment.</td>
<td>ind</td>
<td>a variety of possible interventions for managing aggressive acts informing the plan informing systems improvements</td>
<td></td>
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<tr>
<td>Davis 1994: USA</td>
<td>Teaching Patients to Prevent Errors describes how patients can be educated about their medication including assessing their level of understanding, use of a regular pharmacist and maintaining a record of adverse drug reactions</td>
<td>ind</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Title</th>
<th>Description</th>
<th>Interventions</th>
<th>Improvements</th>
</tr>
</thead>
<tbody>
<tr>
<td>de Figueiredo 2001: Brazil</td>
<td>Adherence of Aids Patients to Treatment with Antiretroviral Drugs in a University Hospital: Difficulties Observed and Suggestions of Interventions</td>
<td>describes a study which found that those patients with less education were less likely to follow instructions about drug taking and more likely to make mistakes. The authors propose a pictorial information sheet and personalised drug administration chart for patients with poor understanding.</td>
<td>drug information presented pictorially individualised drug chart illustrated with drug labels (to correspond with labels on drug containers and detailing times &amp; ways to take medication (i.e. fasting))</td>
<td>informing the plan monitoring and safe delivery of treatment informing systems improvements</td>
</tr>
<tr>
<td>de Thurah 2004: Denmark</td>
<td>The effect of written and verbal patient education concerning the safe use of methotrexate in rheumatoid arthritis: the obstacles to optimal knowledge and degree of satisfaction</td>
<td>describes a cross-sectional study evaluating written and verbal information given to patients about the safe use of methotrexate.</td>
<td>evaluation of knowledge about safe use of methotrexate</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>De Villermay 1982: France</td>
<td>No prolonged use without adjusted explanations</td>
<td>describes the problem of patients, especially older patients, taking multiple medications and not being well informed about them. Recommends a number of ways to overcome this</td>
<td>patients informed about the medications they are taking patients advised not to take medication prescribed for others strategies for individual patients to self-medicate safely larger print &amp; clearer drug information provided by pharmaceutical companies</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Source</td>
<td>Title</td>
<td>Description</td>
<td>Intervention</td>
<td>Outcome</td>
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<tr>
<td>Devos et al 2006: Belgium</td>
<td>Safety first! Are patients and their relatives aware of the risks posed by the toxic medication they receive?</td>
<td>describes the development of information for patients and their families about the hazards posed by, and how to deal with, body fluids of someone undergoing a course of chemotherapy</td>
<td>information leaflets and posters to raise awareness among patients and their families/carers of the hazards posed by these body fluids and giving advice about measures to take to reduce the risk of harm</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Dick 1989: USA</td>
<td>Warning: take only as directed</td>
<td>describes ways in which home care nurses can help elderly patients to safely self-medicate</td>
<td>home care nurse reviews medication with patient paying attention to storage, reconciliation with latest physician list, how &amp; when taken</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>DiGiovanni et al 2003: USA</td>
<td>Patient Compliance in Avoiding Wrong Site Surgery</td>
<td>describes a study exploring a potential role for patients marking surgical sites prior to surgery to decrease the risk of wrong site surgery. Found that, despite explicit instructions some patients did not mark the extremity.</td>
<td>patients due to undergo foot/ankle surgery given instructions to mark the extremity not to be operated on with a bold NO</td>
<td>monitoring and safe delivery treatment</td>
</tr>
<tr>
<td>DOH/Design Council 2003: UK</td>
<td>Design for Patient Safety: A system-wide, design-led approach to tackling patient safety in the NHS</td>
<td>describes a perspective from the world of design to identify previously unrecognised opportunities for improving patient safety in the NHS</td>
<td>involving healthcare users at all stages in the design process both for buildings and systems</td>
<td>informing systems improvements</td>
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<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Description</td>
<td>Type</td>
<td>Additional Information</td>
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<tr>
<td>Doherty et al 2004: USA</td>
<td>The 10 most common prescribing errors: tips on avoiding the pitfalls</td>
<td>describes the most common prescribing errors and recommends ways to avoid them</td>
<td>ind</td>
<td>pre-treatment counselling of patients, informing patients of potential side effects, or symptoms to report, checking understanding of instructions, use of dosette boxes, finding out about allergies &amp; adverse reactions &amp; documenting this, asking specifically about over-the-counter medication, using open ended questions to facilitate the articulation of concerns, periodically asking patients to bring all their current medication to consultations</td>
</tr>
<tr>
<td>Dudley 1980: USA</td>
<td>Risk Management: The Patient Representative's Role</td>
<td>describes how the presence of a patient representative can not only increase patient satisfaction and reduce formal complaints but can also enhance patient involvement in promoting their own safety. Patient Representatives can act as advocate for patients when they do not feel they can question HCPs</td>
<td>ind</td>
<td>selected individual to act as patient representative, to respond to patient complaints and liaise with both patient/family and HCPs</td>
</tr>
<tr>
<td>Duncanson &amp; Pearson 2005: UK</td>
<td>A study of the factors affecting the likelihood of patients participating in a campaign to improve staff hand hygiene</td>
<td>describes a study which aimed to seek patient opinion on being asked to participate in a campaign to improve staff compliance with handwashing and to identify factors that may influence the likelihood of patients asking staff to wash their hands</td>
<td>ind</td>
<td>patients encouraged to ask HCPs to wash their hands before providing direct care</td>
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informing the plan delivery and monitoring of treatment
informing systems improvements
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<thead>
<tr>
<th>Author(s)</th>
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<th>Outcomes</th>
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</thead>
<tbody>
<tr>
<td>Edwards, R. &amp; Adams, D.W. 1982: USA</td>
<td>Clinical Pharmacy Services in Paediatric Ambulatory Care Clinic</td>
<td>describes the implementation of pharmacy services in a paediatric ambulatory care clinic.</td>
<td>ind</td>
<td>dedicated pharmacy service providing accessible information about disease states and prescribed medication with encouragement for patients to ask questions informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Egberts et al., 1996: Netherlands</td>
<td>Can adverse drug reactions be detected earlier? A comparison of reports by patients and professionals</td>
<td>ADR related questions received by a telephone medicines information service and ADRs received by a spontaneous ADR reporting system: a comparison regarding patients and drugs</td>
<td>ind</td>
<td>telephone medicines information service that aims to promote correct use of medicines and to identify problems related to medication use. Patients can anonymously and free of charge ask a pharmacist questions related to medication use. Initiated in 1990 in the Netherlands. Available Monday to Friday office hours. Pharmacist makes summary of each call and these are centrally collected into a database. informing the plan monitoring and safe delivery of treatment informing systems improvements</td>
</tr>
<tr>
<td>Egberts et al. 1997: Netherlands</td>
<td>Advising patients who seek alternative medical therapies</td>
<td>describes a proposed step-by-step strategy for conventionally trained medical providers and their patients to proactively discuss the use of avoidance of alternative therapies. This includes a discussion of patients’ preferences and expectations, maintenance of symptom diaries and list of questions for patient to ask alternative provider.</td>
<td>ind</td>
<td>a proposed step-by-step strategy for conventionally trained medical providers and their patients to proactively discuss the use or avoidance of alternative therapies. informing the plan monitoring and safe delivery of treatment</td>
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<td>Eisenberg 1997: USA</td>
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<tr>
<td>Reference</td>
<td>Program/Description</td>
<td>Country</td>
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<tr>
<td>Emblen 2004: Australia</td>
<td>Home Medicines Review. The how and why for GPs. describes a program of Home Medicines Review (HMR).</td>
<td></td>
<td>ind</td>
<td>Home medicines review (HMR) medication review of patients in primary care, involving their GP, community pharmacist and accredited pharmacist. GP initiates the review and the pharmacist visits the patient at home or at the pharmacy. The pharmacist assesses and educates the patient on the appropriate and safe use of medication.</td>
</tr>
<tr>
<td>Emlet 1988: USA</td>
<td>SRx: Medication Education Program for Seniors describes a medication education program (SRx) for senior citizens. This includes personal medication record booklet, theater education project, educational leaflets and training for caregivers.</td>
<td></td>
<td>ind</td>
<td>16 page personal medication record (PMR) containing information of medications, OTC drugs and other health information. theater project-plays/musicals/comedy acts which depict typical situations that can contribute to medication misuse. educational materials which inform about medication misuse and ways to prevent it training for caregivers on medication misuse and strategies for their prevention. Targets mainly professionals and caregivers of frail elders. advocacy- project expanded through the introduction of two state-wide legislative bills.</td>
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<tr>
<td>Author</td>
<td>Year</td>
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<tr>
<td>Fabregas</td>
<td>2006</td>
<td>USA</td>
<td>UPMC alert gives patients a voice in care Rapid Response Team activation by patients can mitigate errors describes an emergency alert procedure that can be triggered by inpatients and/or their family. The call brings an emergency team to the patient’s bedside. It was developed in response to the death of a child due to unrecognised complications. The intervention is intended to give patients and their families a way to get an immediate response to their concerns if other channels have failed.</td>
<td>ind</td>
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<tr>
<td>Feifer</td>
<td>2003</td>
<td>USA</td>
<td>How a few simple words improve patients' health describes the importance of health literacy for patient safety. Outlines steps that can be taken to bridge the health literacy gap.</td>
<td>ind</td>
</tr>
<tr>
<td>Feldman et al</td>
<td>2001</td>
<td>USA</td>
<td>The Role for Public Health in Reducing iatrogenic patient Injuries describes the role for public health in the patient safety movement including gathering data, designing interventions and increasing public awareness through education campaigns</td>
<td>ind</td>
</tr>
<tr>
<td>Authors</td>
<td>Study Title</td>
<td>Study Description</td>
<td>Method</td>
<td>Findings</td>
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<tr>
<td>Finkel et al 1982: USA</td>
<td>The current status of surgical second opinion programmes</td>
<td>Describes the practice of patients scheduled for surgery seeking a second opinion about appropriateness of the surgery. Concludes that although this is largely a cost containment exercise it should result in patients being better informed about the risks and benefits of their treatment and any possible alternatives facilitating his/her involvement in treatment decisions.</td>
<td>ind</td>
<td>surgical second opinion programmes informing the plan</td>
</tr>
<tr>
<td>Fisher et al 1987: USA</td>
<td>Patient-initiated post marketing surveillance: a validation study</td>
<td>Detecting adverse drug reactions in postmarketing surveillance: interview validity</td>
<td></td>
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<tr>
<td>Fisher and Bryant, 1990: USA</td>
<td>Post marketing surveillance: accuracy of patient drug attribution judgments</td>
<td>Describes a controlled trial of a patient-initiated monitoring system for adverse drug reactions versus staff initiated telephone monitoring. Results showed that patient-initiated reports closely matched those obtained from controls. Authors conclude that patient-initiated system could prove a promising complement to existing physician-based surveillance systems.</td>
<td>ind</td>
<td>patient-generated reports via telephone of 'adverse clinical events'. On collection of prescription a removable sticker gives a toll-free telephone number along with more details about how to report any new or unusual symptoms during the next two weeks. Free telephone reporting was available from 9am to 8pm Monday to Friday. At other times, answering machine available. Controls: Staff-initiated Interviews by telephone approx 2 weeks later.</td>
</tr>
<tr>
<td>Florida Healthcare Commission 2003: USA</td>
<td>POP (Paul O'Neil Pledge) Campaign Consumer Guide</td>
<td>describes the POP pledge campaign educating consumers to only accept prescriptions from their doctor only when they can read what is written</td>
<td>ind</td>
<td>patient wears a sticker when he/she visits a HCP stating that he/she will refuse to accept an illegible prescription</td>
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<tr>
<td>Fogg D 2002: USA</td>
<td>Custom packs; alcohol rubs; flash pans; sterilisation indicators; 'Speak Up' programme Speaking up saves lives</td>
<td>describes, as part of a clinical update bulletin, JACHO's 'Speak Up' program</td>
<td>ind</td>
<td>list of recommendations for patients including advice to: voice concerns and question until they understand pay attention to the care they receive &amp; check that they are given the right medication and treatment not make assumptions educate themselves about their condition ask someone to be an advocate for them know their medication use health care facilities with rigorous safety and quality standards take part in decisions about their care</td>
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<tr>
<td>Spillane 2002: USA</td>
<td>Care recipients urged to 'speak up' for safer health care</td>
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<td>JACHO, 2002: USA</td>
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<tr>
<td>Author</td>
<td>Source Year/Location</td>
<td>Title</td>
<td>Description</td>
<td>Occupation</td>
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<tr>
<td>Fordham</td>
<td>1993: USA</td>
<td>Patient education videos an excellent way to inform patients, avoid lawsuits</td>
<td>describes one surgeon’s production of customised videos for patients that introduce them to the staff and operating procedures of his office. He has also produced videos which detail operative procedures, outlining risks and benefits and convey the message that patients have responsibility for their own health and should ask if they don’t understand</td>
<td>Ind/Rep</td>
</tr>
<tr>
<td>Foreman J</td>
<td>2006: USA</td>
<td>To be safe, keep track of pills</td>
<td>describes ways consumers can reduce their chances experiencing a drug error</td>
<td>Ind/Rep</td>
</tr>
<tr>
<td>Forster 2006: USA</td>
<td>Can you prevent adverse drug events after hospital discharge?</td>
<td>describes a number of interventions which may be used to reduce the risk of adverse drug event for patients who have just been discharged from hospital</td>
<td>ind</td>
<td>recommendations to decrease risk of adverse drug event post discharge including: providing patients with an up to date list of their medication encouraging patients to bring all current medication to consultations with HCPs making sure patients know potential side effects of medication and how to respond if they experience them making sure patients know which medication requires regulation with regular blood tests and who is responsible for these making sure the patient is given a copy of the discharge summary to inform community HCP prior to GP notes being updated with copy from hospital</td>
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<tr>
<td>Four Leaf Enterprises and Partnership for Patient Safety 2005: USA</td>
<td>A DVD of and facilitator's guide for healthcare providers to using the consumer education film 'Things You Should Know Before Entering the Hospital'</td>
<td>provides background notes and resources for facilitators to use the consumer education DVD as part of an education session</td>
<td>ind</td>
<td>audio-visual presentation designed to increase patient awareness of medical error and give them information about what they can do to reduce the risk</td>
</tr>
<tr>
<td>Author and Year</td>
<td>Title</td>
<td>Description</td>
<td>Study Type</td>
<td>Outcomes</td>
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<tr>
<td>Foust 1996: USA</td>
<td>Maternity Education and Risk Management</td>
<td>Describes how prenatal risk assessment can help to identify women at high risk of birth complications so they can be targeted for interventions early in pregnancy</td>
<td>ind</td>
<td>risk assessment followed by risk reduction intervention delivered by an obstetric nurse. All women assessed in early pregnancy those at high risk of birth complications identified and assigned to obstetric nurse. Obstetric nurse remains in contact with woman throughout pregnancy, delivering an education programme and encouraging compliance with prescribed care by physician (i.e. bed rest). Informing the plan.</td>
</tr>
<tr>
<td>Fracica 2006: USA</td>
<td>Safety Checklist: keys to successful implementation</td>
<td>Describes the process of involving patients and their families in the review of discharge medication</td>
<td>ind</td>
<td>Pre-discharge review of medication by HCP, patient and family. Informing the plan, monitoring and safe delivery of treatment.</td>
</tr>
<tr>
<td>Francoeur &amp; Digiambatista 2001: Canada</td>
<td>Technical Considerations for Short Daily Home Haemodialysis and Nocturnal Home Haemodialysis</td>
<td>Describes education of patients having dialysis at home and how they should be involved in setting up the system</td>
<td>ind</td>
<td>Patient and family involvement in adapting system for use in patients own home. Technical training and manuals in a format easily understandable to the patient and family. Informing the plan, monitoring, systems improvements.</td>
</tr>
<tr>
<td>Fuchs et al 2003: Germany</td>
<td>Design of Package Inserts for Pharmaceuticals</td>
<td>Describes a study which surveyed 855 patients about their preferences for the ordering of information on medication package inserts</td>
<td>rep</td>
<td>Consultation of patients about ordering of information on drug package inserts. Informing systems improvements.</td>
</tr>
<tr>
<td>Gallin 2003</td>
<td>How to survive your doctor's care</td>
<td>Describes how patients can 'get the right diagnosis, the right treatment and the right experts for you'</td>
<td>ind</td>
<td>Book detailing how and why things go wrong in healthcare services and how patients might help prevent things going wrong. Informing the plan, monitoring and safe delivery of treatment.</td>
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<td>Reference</td>
<td>Title</td>
<td>Description</td>
<td>Indicators/ Examples</td>
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<tr>
<td>Gandhi et al 2003: USA</td>
<td>Creating an Integrated Patient Safety Team</td>
<td>describes the creation of a patient safety team as part of the patient safety strategy of the Brigham and Women's Hospital</td>
<td>use of patient focus groups for process improvement for quality and safety incorporation of complaints and concerns from patients and families into central data repository with reports from other areas and sources community lecture series for patients about medication safety, avoiding falls and communication patient safety video available in hospital television listings various audio-visual and printed materials for Patient Safety Awareness week informing the plan monitoring and safe delivery of treatment informing systems improvements</td>
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<tr>
<td>Garza 2001: USA</td>
<td>Courts Raise the Bar on Medication Error</td>
<td>describes the recommendations of the Physician Insurers Association of America after a number of cases where doctors have been held accountable for prescribing errors. These included providing information sheets for patients about commonly prescribed medications, informing patients of the name, dose, side effects interactions and reason for taking a particular drug and making sure that physician and patient discussed a newly prescribed medication at consultation</td>
<td>patient provided with information about medication in written and verbal form monitoring and safe delivery of treatment</td>
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<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Description</td>
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<td>Outcomes</td>
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<tr>
<td>Garza 2004: USA</td>
<td>Many Claims Involve Caregiver Communication Breakdowns</td>
<td>describes a number of system redesigns which obstetric practices could adopt to avoid lawsuits including equipping patients with an 'obstetric passport' containing updated medical information.</td>
<td>giving each patient an 'obstetric passport' which contains updated medical information to ensure that any HCP has all relevant information when patient presents to health care services</td>
<td>informing the plan</td>
</tr>
<tr>
<td>Gehring &amp; Ring 1999: USA</td>
<td>Latex allergy: Creating a safe environment</td>
<td>describes the signs and treatment of latex allergy including self-care practices for patients with suspect or known latex allergy.</td>
<td>medic-alert bracelet avoiding contact with latex informing employer &amp; HCP about allergy carrying pre-filled injectable ephedrine avoiding beta blockers which may potentiate allergic reactions carrying synthetic gloves and tourniquet arranging in advance for latex-safe medical and dental care</td>
<td>informing the plan</td>
</tr>
<tr>
<td>Gillespie 1995: USA</td>
<td>Five things you should know about medicine cabinets</td>
<td>describes common problems with medication storage at home and provides advice for pharmacists to give to patients when they are discharged.</td>
<td>advice for pharmacists to give to patients about medication storage &amp; use including: optimum temperature keeping them in their original containers finishing the course keeping meds with them when they travel</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Gillespie et al 2003: UK</td>
<td>Review of interventions for preventing falls in elderly people (Cochrane)</td>
<td>reviews a number of interventions, those which involve patients which are likely to be beneficial.</td>
<td>multidisciplinary, multifactorial health/environmental screening/intervention programmes a programme of muscle strengthening and balance training home hazard assessment and modification a programme of Tai Chi</td>
<td>informing the plan</td>
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<tr>
<td>Source</td>
<td>Study Details</td>
<td>Methodology</td>
<td>Findings</td>
<td>Implications</td>
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<tr>
<td>Glerup 1984: Denmark</td>
<td>The patient should self-administer medication whenever possible</td>
<td>ind</td>
<td>describes the use of dossette boxes for self-administration of medication introduced pre-discharge and continued at home</td>
<td>monitoring and safe delivery of treatment</td>
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<td>rep</td>
<td>describes the evaluation of a project to introduce the use of dossett boxes for medication self-administration prior to discharge</td>
<td>qualitative evaluation of intervention</td>
</tr>
<tr>
<td>Goldstein 2002: UK</td>
<td>Using IT to enhance patient safety</td>
<td>ind</td>
<td>describes how IT can help to enhance patient safety through reporting systems, improving care and educating patients</td>
<td>informing the plan</td>
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<td>on-line adverse event reporting use of interlinked IT systems for medication patient clinical records, investigation results, and decision support patient access to web-based information about their condition &amp; treatment &amp; quality measures for health care institutions and professionals</td>
<td>monitoring and safe delivery of treatment informing systems improvements</td>
</tr>
<tr>
<td>Gooday &amp; Hunter 2004: USA</td>
<td>Preventing falls and stump injuries in lower limb amputees during inpatient rehabilitation: completion of the audit cycle</td>
<td>ind</td>
<td>describes a 3 phase study which looked at the factors contributing to falls among recent lower limb amputees and evaluated an intervention to reduce the number of falls</td>
<td>informing the plan</td>
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<td>a number of interventions including notices placed around the ward to remind patients to transfer with care and teaching patients to transfer safely</td>
<td>informing systems improvements</td>
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<tr>
<td>Author</td>
<td>Title</td>
<td>Description</td>
<td>Intervention</td>
<td>Safety measures</td>
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<td>Gorman 1999: USA</td>
<td>Mixed-up meds</td>
<td>describes how easy it is for medicines to be confused by name or dose and recommends that patients need to know their medication as a safeguard against taking the wrong one.</td>
<td>ind</td>
<td>patient awareness of the colour and shape of the pills they are taking regularly, patient knowledge of both the generic and brand names, dose and dose schedule of their medication.</td>
</tr>
<tr>
<td>Gorski 2001: USA</td>
<td>Positive Inotropic Drug Infusions for the Patient with Heart Failure</td>
<td>describes how patients can receive infusions at home and how they should be involved in making sure the treatment is managed safely.</td>
<td>ind</td>
<td>education of patient or family member to manage infusion-giving competently, provision of checklists and flow charts indicating when outside advice/support should be sought.</td>
</tr>
<tr>
<td>Gosselin 2003: USA</td>
<td>Thermal wounds following heating pad use</td>
<td>describes the thermal wounds caused by heating pads used by patients with reduced sensation post mastectomy. Recommends that patients are informed about this and educated about how to manage post mastectomy pain without injuring their skin.</td>
<td>ind</td>
<td>education about the likelihood of reduced skin sensation post mastectomy, advice and support to manage post mastectomy pain.</td>
</tr>
<tr>
<td>Gray-Vickrey 1984: USA</td>
<td>Education to Prevent Falls</td>
<td>describes how patients can be encouraged to ‘fall proof’ their homes before they return after a hospital admission for a fall.</td>
<td>ind</td>
<td>an education session pre discharge to help patients identify potential hazards in their own home and interventions to reduce the risk of falling.</td>
</tr>
</tbody>
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informing the plan, monitoring and safe delivery of treatment
<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Title</th>
<th>Description</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Griffin 2003: USA</td>
<td>Safety Considerations and Safe Handling of Oral Chemotherapy Agents</td>
<td>describes how safe home administration of chemotherapeutic agents can be facilitated</td>
<td>ind</td>
<td>education and competency assessment of patient and family on giving/taking chemotherapy at home</td>
</tr>
<tr>
<td>Grissinger &amp; Kelly 2005: USA</td>
<td>Reducing the risk of medication error in women</td>
<td>describes how women can become more active in their own care and work with HCPs towards the goal of improving patient safety</td>
<td>ind</td>
<td>individualised written and verbal information about medication with assessment of understanding encouragement of patients to take part in treatment decisions and ask questions</td>
</tr>
<tr>
<td>Grissinger &amp; Kelly 2005: USA</td>
<td>Reducing the risk of medication error in women</td>
<td>describes how women can become more active in their own care and work with HCPs towards the goal of improving patient safety</td>
<td>rep</td>
<td>development of patient education material with focus groups to ensure that the materials are personally relevant &amp; culturally sensitive</td>
</tr>
<tr>
<td>Grissinger et al 2003: USA</td>
<td>The Role of Managed Care Pharmacy in Reducing Medication Errors</td>
<td>describes how pharmacists can play a more active role in medication error reduction through improving the patient education process</td>
<td>ind</td>
<td>a number of interventions to involve patients including patient education and involvement in their healthcare, particularly those identified as at risk of being affected by medication error</td>
</tr>
<tr>
<td>Grissinger et al 2003: USA</td>
<td>The Role of Managed Care Pharmacy in Reducing Medication Errors</td>
<td>describes how pharmacists can play a more active role in medication error reduction through improving the patient education process</td>
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<td>development of patient education material with focus groups to ensure that the materials are personally relevant &amp; culturally sensitive</td>
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<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Description</td>
<td>Methodology</td>
<td>Outcome</td>
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<tr>
<td>Guignard et al., 2004: France</td>
<td>Medication Errors in Primary Care: issues, prevention around the prescription and improvement of patient information</td>
<td>describes how a medication prescription can be used as a method of communication between the patient, the prescriber and the pharmacist and how this can help to minimise medication errors</td>
<td>ind</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Halstead et al 1999: Australia</td>
<td>Towards the safer use of warfarin II: results of a workshop</td>
<td>describes the output of a workshop which discussed ways to improve the management of the use of oral anticoagulants</td>
<td>ind</td>
<td>consumer education about the risks of anticoagulant therapy with targeted education for those at high risk of adverse events</td>
</tr>
<tr>
<td>Halstead et al 1999: Australia</td>
<td>Towards the safer use of warfarin II: results of a workshop</td>
<td>describes a workshop which discussed ways to improve the management of the use of oral anticoagulants</td>
<td>rep</td>
<td>a workshop comprising medical and nurse practitioners, pharmacists and consumers</td>
</tr>
<tr>
<td>Hanus 1992: USA</td>
<td>Improving Oral Anticoagulation Safety</td>
<td>describes new changes in monitoring warfarin therapy which can help to lower the risk of adverse event for patients taking this drug</td>
<td>ind</td>
<td>patient education combined with lower intensity anticoagulation</td>
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<thead>
<tr>
<th>Reference</th>
<th>Title</th>
<th>Description</th>
<th>Method</th>
<th>Example</th>
<th>Findings/Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harteker 2003: USA</td>
<td>Advances in Family Centered Care: partnerships for patient safety: profiles of four hospitals</td>
<td>describes the ways patients, families, parents and staff have formed partnerships for patient safety at four different hospitals</td>
<td>ind/re</td>
<td>patient safety steering committee - multidisciplinary group which includes a patient representative safety learning reports completed by family members if they sense a problem associated with a patient's care family advisory council use of patient and family stories to illustrate patient safety events quality Improvement subcommittee made up of equal numbers of parents and staff asking parents and families to be part of the hospital's safety culture and 'speak up' if they have concerns</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Harada et al 1999: Japan</td>
<td>Providing patients with written information helps them to be aware of and report adverse drug reactions?</td>
<td>describes a survey of patients about provision of patient-orientated information sheets on prescribed drugs. Until recently, in Japan information about prescribed drugs was limited; no patient medication instruction (PMI) or patient package insert (PPI) except for simple information leaflets of some particular drugs.</td>
<td>ind</td>
<td>patient-orientated information sheets in which symptoms and the degree of emergency of the ADRs that can occur were included for 220 drugs. The sheets avoided technical terms and a number was given for patients to call for further consultation</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Source</td>
<td>Description</td>
<td>Details</td>
<td>Method</td>
<td>Notes</td>
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<tr>
<td>Hartigan 2003: USA</td>
<td>Patient education: the cornerstone of successful oral chemotherapy treatment</td>
<td>Describes a programme of education for patients undergoing treatment with oral chemotherapy, a group who, typically, do not receive the same amount of teaching and monitoring as those receiving IV chemotherapy</td>
<td>Indirect</td>
<td>Patient education including: name of medication, dose &amp; dosing schedule, safe handling of medication and hazardous body fluids, relevant tests/investigations which should be completed prior to subsequent courses.</td>
<td></td>
</tr>
<tr>
<td>Hatlie 2004: USA</td>
<td>Consumers and the Patient Safety Movement: Past and Future, Here and There</td>
<td>Reflects at the time of the 5th anniversary of 'To Err is Human' on the involvement of consumers in the patient safety movement. Describes a consumer led workshop in 2003 which submitted a number of patient safety goals and the WHO Patients for Patient Safety Initiative</td>
<td>Reproductive</td>
<td>Consumer led workshop, expert patients defining and leading implementation of WHO objectives.</td>
<td></td>
</tr>
<tr>
<td>HCPro 2002: USA</td>
<td>Center around your patients to promote safety</td>
<td>Summary of a presentation by Susan Edgman-Levitan at the Annenberg VI conference which links patient satisfaction and patient safety. Patients can only be involved when they have emotional support, answers to their questions and physical comfort. Lists a number of ways patients might be involved</td>
<td>Indirect</td>
<td>Lists a number of ways to involve patients: standardised written medication information sheets, written discharge instructions, 'doc talk' cards to prompt questions that patients may not have thought of and encouraging them to question the unusual, asking staff to check their identity, asking clinicians if they have washed their hands.</td>
<td></td>
</tr>
<tr>
<td>HCPro 2003: USA</td>
<td>Briefings on Patient Safety Use Education to Boost Patient Involvement</td>
<td>excerpts from a new book 'Preparing your Patient Safety Programme for a JCAHO Survey' about using education to boost patient involvement. Contains sample of patient educational pamphlet</td>
<td>ind</td>
<td>book excerpt detailing how education can be used to boost patient involvement. Sample of patient education leaflet</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>HCPro 2004: USA</td>
<td>Eight quick tips to encourage patient involvement in care</td>
<td>list of tips given to patients admitted to Mount St Mary's hospital and Medical Centre Lewiston, NY.</td>
<td>ind</td>
<td>List of tips which are given to patients on admission or can be downloaded from the website: make sure you get the right treatment and right medication by the right HCPs. make sure staff have all of your important health information. Don't assume they know you take a certain medication or have a certain allergy educate yourself about your diagnosis, your treatment plan and your medications ask to have your treatment plan explained. This will help you to identify when something doesn't seem right ask a friend or family member to accompany you on visits and serve as your advocate participate in all discussions about your treatment. Your input is important always ask if you have any questions or concerns if you can't read a prescription ask for it to be clarified ask all HCPs if they have washed their hands before they touch you.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Source</td>
<td>Title</td>
<td>Description</td>
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<tr>
<td>HCPro 2006: USA</td>
<td>Suicide risk and patient involvement</td>
<td>Summing up of the JACHO 2007 National Patient Safety Goals. The goals for 2007 which involve patients are making sure that patients go home with an accurate medication list and encouraging healthcare providers to identify ways that patients can raise concerns about their healthcare and encourage them to do so.</td>
<td>ind</td>
<td>Patient Safety Goals issued by JACHO which healthcare institutions are required to meet. Medication lists given to patients at discharge. This should be a list of all the medication (over the counter as well as prescribed) taken by the patient not just that prescribed for the current inpatient stay should be given to patient and/or carer. Patients encouraged to report concerns about safety to health care provider via recognised pathway.</td>
<td></td>
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<tr>
<td>Healthcare Information Center 2005: USA</td>
<td>Low comprehension of consent forms creates a surge in medical errors</td>
<td>Describes ‘Safe Practices 10’ published by the National Quality Forum, which focuses on improving communication between health care providers and those patients with limited health literacy especially with regard to consent practices.</td>
<td>ind</td>
<td>Strategies to check patient understanding including ‘teach back’ where HCPs asks patients to recount information to demonstrate their level of understanding.</td>
<td></td>
</tr>
<tr>
<td>Health Services, Los Angeles County 2000: USA</td>
<td>Sending PharmD candidates to patients’ homes can avert potential medication problems</td>
<td>Describes a programme in which pharmacy students visit and review the medication of patients identified as at risk by home care nurses.</td>
<td>ind</td>
<td>Home visit from pharmacy student to review medication.</td>
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<tr>
<td>Study</td>
<td>Country</td>
<td>Methodology</td>
<td>Findings</td>
<td>Implications</td>
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<tr>
<td>Hecht 1974: USA</td>
<td>Improving medication compliance by teaching outpatients</td>
<td>describes a study in which 47 patients having treatment for TB were exposed to 4 levels of education about medication importance, characteristics, side effects, dosage and tips on ways to incorporate drug therapy into their everyday life</td>
<td>patient education including: name of medication, dose &amp; dosing schedule, ways to incorporate taking meds into daily life</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
<td></td>
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<tr>
<td>Hellier et al 2006: UK</td>
<td>Considering the impact of medicine label design characteristics on patient safety</td>
<td>describes the evidence, gathered from studies of food &amp; chemical labelling &amp; general warnings for the effectiveness of medication label design and its implications for patient safety. Notes that signal words, colour and typeface can be used to communicate the level of hazard but that care needs to be taken to minimise familiarity that may lead to habituation and less attention given to the message. In addition a balance need to be struck between avoiding cluttered labels and conveying all relevant information</td>
<td>guidelines for design of medicine labels informing systems improvements</td>
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<tr>
<td>Authors and Year</td>
<td>Description</td>
<td>Methodology</td>
<td>Results</td>
<td>Monitoring and Safe Delivery of Treatment</td>
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<tr>
<td>Hendee &amp; Turnbull 2001: USA</td>
<td>Improved patient safety through web based education</td>
<td>describes the proposed development of a standard method of patient safety education for providers, administrators and patients guided by patient safety experts and representative recipients</td>
<td>web-based and population specific patient safety continuing education with a supporting database on web-available patient safety resources</td>
<td>informing systems improvements</td>
<td></td>
</tr>
<tr>
<td>McKellar and Rutland-Brown, 2005</td>
<td>Using community medical auxiliary trainees to improve dose understanding among illiterate hospital outpatients in rural Nepal</td>
<td>RCT - participants were 50 hospital outpatients in rural Nepal. Intervention group given dose counselling by Community Medical Auxiliary On the Job Trainees versus control. Understanding assessed immediately after the intervention</td>
<td>intervention group given dose counselling by community medical auxiliary. Understanding of correct medication drug regimen assessed immediately after intervention</td>
<td>monitoring and safe delivery of treatment</td>
<td></td>
</tr>
<tr>
<td>Heral et al 2006: France</td>
<td>Education of the patient on anticoagulants: a quality management</td>
<td>describes an approach to educate patients about their illness and its management as part of their everyday life stressing the importance of the role played by the patient in the treatment process</td>
<td>patient education verbal &amp; written with evaluation of understanding</td>
<td>monitoring and safe delivery of treatment</td>
<td></td>
</tr>
<tr>
<td>Hermann 2002: USA</td>
<td>The Healthcare System - Strategies for Improvement - A Joint Commission Perspective</td>
<td>describes how patients can be involved in operation site marking within a wider overview of the Joint Commission Accreditation Process</td>
<td>patient and surgeon jointly identify and mark operative site pre-operatively</td>
<td>monitoring and safe delivery of treatment</td>
<td></td>
</tr>
<tr>
<td>Hill 2004: UK</td>
<td>Special Report: mental health. The NPSA's creation of a safer ward environment initiative</td>
<td>describes an NPSA initiative that hopes to improve patient safety in NHS inpatient mental health care settings</td>
<td>rep</td>
<td>six phase initiative over 2 years: build a picture, views from the frontline, developing, piloting, rolling out &amp; evaluating solutions. All stages involve input from service users.</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Hill et al 1988: USA</td>
<td>Reducing the incidence of falls</td>
<td>describes a programme to identify patients at risk of falls and implement interventions to reduce falls which included patient education</td>
<td>ind</td>
<td>individual patient education sessions to increase patient awareness of specific factors which make them more likely to fall and preventative measures to practice</td>
<td>informing the plan informing systems improvements</td>
</tr>
<tr>
<td>Hoffman et al 2003: USA</td>
<td>Bed safe: a bed safety project for frail older adults</td>
<td>describes a project to assess, provide interventions for and evaluate effects of these for patients at risk of falling. Pays particular attention to the reduction of the use of bedrails, which can cause injury though entrapment. This required a multi-disciplinary team of HCPs, technicians, patients and their families to work together to reduce the psychological dependence on the use of bedrails</td>
<td>ind</td>
<td>year long programme which included assessment, selection of alternatives to bedrails and evaluation of the intervention by multidisciplinary teams which included residents and their families</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Reference</td>
<td>Study Description</td>
<td>Methodology</td>
<td>Intervention</td>
<td>Outcomes</td>
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<tr>
<td>Horstkotte et al 1996:</td>
<td>Improvement of prognosis by home prothrombin estimation in patients with life-long</td>
<td>RCT</td>
<td>Self-management of anticoagulation versus management by home physician. Authors state that those in self-management group showed significant improvement in management of oral anticoagulants over the usual care group.</td>
<td>Home prothrombin estimation and adjustment of treatment received standardized training using CoaguChek system INR controlled by patients every third day controls: managed by the home physician without recommending an interval for these controls.</td>
<td>Monitoring and safe delivery of treatment</td>
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<tr>
<td>Germany</td>
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<td>Canada</td>
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<tr>
<td>Huang 1996:</td>
<td>Effectiveness of medication evaluation strategies for the elderly in the community</td>
<td>RCT</td>
<td>Individual or group patient education sessions</td>
<td>Patient education sessions either individual or group. All patients given a dossette box session included advice on: following instructions dosage dangers of consulting several HCPs about the same condition not storing meds on bedside table asking advice about taking meds from pharmacist not sharing medication sticking to prescribed medication completing the course checking the label.</td>
<td>Informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Reference</td>
<td>Title</td>
<td>Summary</td>
<td>Study Type</td>
<td>Outcomes</td>
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<tr>
<td>Hughes 2005 &amp; Edgerton: USA</td>
<td>First, do no harm: reducing paediatric medication errors</td>
<td>Describes how nurses can help to reduce the risk of medication error for paediatric patients by involving them and their family in treatment administration</td>
<td>Ind</td>
<td>Involving patient and family when administering medication to children, informing them of the name, dose, frequency and purpose of the medication, educating patient and family prior to discharge about current and new medication including route, correct use of any administration devices, potential side effects and when to contact HCPs.</td>
<td></td>
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<tr>
<td>Hugtenburg et al. 2002: Netherlands</td>
<td>Short Client Interviews at Repeat Prescription: a simple method to identify problems with the use of drugs</td>
<td>Describes a non-randomised study that involved asking patients if they had any problems with their medication when they presented for repeat prescription.</td>
<td>Ind</td>
<td>Patients asked about any problems with their medication on presentation for repeat prescription.</td>
<td></td>
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<tr>
<td>Hutcherson &amp; Gammon 1997: USA</td>
<td>Preventing Errors With Anti-neoplastic Agents: A Pharmacist's Approach</td>
<td>Describes how the pharmacist is in an ideal position to involve staff patients and their families in the prevention of medication errors involving anti-neoplastic agents</td>
<td>Ind</td>
<td>Education of patients and their families about the treatment plan and what to expect backed up by a chemotherapy calendar.</td>
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</tr>
<tr>
<td>Institute for Family Centred Care 1999: USA</td>
<td>Your Role in Safe Medication Use</td>
<td>guide for patients and their family with some suggestions about what they can do to ensure safe medication use</td>
<td>ind</td>
<td>brochure encouraging patients to: be informed about medication share relevant information about yourself with prescribers tell prescriber about any non-prescription medication when picking up new meds ensure you know how to take and what to expect check meds are what the doctor ordered follow instructions seek HCP help if you have a reaction follow storage guidelines in hospital: question anything you are not sure about ask what medication is for if a medication error does occur: ask what you should look out for keep asking if answers not satisfactory</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Institute for Family-Centered Care 2004: USA</td>
<td>Advances in Family Centered Care: Responding to HIPPA: Hospitals Confront New Challenges, Devise Creative Solutions</td>
<td>describes various ways that patient and family access to their records and charts can be facilitated and may help to improve safety and the tension between the free flow of information and safeguarding confidentiality</td>
<td>ind</td>
<td>discharge reports patient and family participation in multidisciplinary rounds reading and documenting in medical records for patient and parents shared access to electronic records</td>
<td>informing systems improvements</td>
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<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Brief Description</td>
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<tr>
<td>Isler 1977: USA</td>
<td>Teaching the elderly to avoid accidental drug abuse</td>
<td>Describes how nurses can help elderly patients to avoid making mistakes with their medication</td>
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<tr>
<td>Jaksevac-Miksa &amp; Curic 2002: Croatia</td>
<td>Ask about your medicines’ - Patient Education Project</td>
<td>Describes a project to improve patients’ knowledge of the medication they take and their awareness of the pharmacist as a resource</td>
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<tr>
<td>Jarernsiripornkul, N. Krska, J. Capps, P.A.G. Richards, R.M.E, Lee, A. 2002: UK</td>
<td>Patient reporting of potential adverse drug reactions: a methodological study</td>
<td>Describes a study which aimed to develop a generic method of enabling patients to report symptoms which they believe to be due to a particular prescribed drug</td>
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<tr>
<th>Indications</th>
<th>Actions</th>
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<tr>
<td>Teaching the elderly to avoid accidental drug abuse</td>
<td>Interventions to help elderly patients avoid making medication mistakes including: providing large print labels for medication bottles, teaching safety strategies, providing memory aids such as medication charts, looking with them at their day to day life and how this affects their medication use</td>
</tr>
<tr>
<td>The Patients' View: 2004 ISQSH National Survey</td>
<td>Patient survey</td>
</tr>
<tr>
<td>Ask about your medicines’ - Patient Education Project</td>
<td>Poster displayed in pharmacy, patient information leaflets and a sticker on the medication package to draw patients’ attention to the things they should know before starting a new medication: how the medication works when, how and how long it should be taken common contraindications what to do if you experience side effects patients encouraged to consult pharmacist if they do not know the answers</td>
</tr>
<tr>
<td>Patient reporting of potential adverse drug reactions: a methodological study</td>
<td>Questionnaire on which patients were asked to report any symptoms which they thought could be due to their medication (any one of nine identified drugs)</td>
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Informing the plan monitoring and safe delivery of treatment
<table>
<thead>
<tr>
<th>JCAHO 2002: USA</th>
<th>Help prevent errors in your care (for surgical patients)</th>
<th>brochure listing tips for patients to become active, involved and informed members of their healthcare teams to help make health care safe</th>
<th>ind</th>
<th>a brochure that can help patients prepare for surgery with tips on what to do before arrival, at the hospital and in the recovery room. It contains information about: checking that the surgical team uses the universal protocol to prevent wrong site, wrong procedure and wrong person surgery checking what they need to do prior to surgery bringing an advocate what to expect prior to the operation what to expect in the recovery room</th>
<th>informing the plan monitoring and safe delivery of treatment</th>
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<tr>
<td>JCAHO 2002: USA</td>
<td>Things you can do to prevent medication mistakes</td>
<td>brochure listing things patients can do to help prevent a medication mistake affecting them and their family</td>
<td>ind</td>
<td>a brochure that lists things patients can do to help prevent medication mistakes including: sharing information with prescribers about current meds, allergies and adverse reactions finding out about new medication making sure that they have the right medication taking medication as prescribed make sure staff check their identity before giving them any medication ask how long any IV medication should take to run out make sure you know about any new medication before you leave hospital a blank medication list for patients to complete, keep with them and show to HCPs</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>JCAHO 2002: USA</td>
<td>Three things you can do to prevent infection</td>
<td>lists 3 things that patients and the public can do to prevent infection</td>
<td>ind</td>
<td>poster/brochure listing 3 things that everyone can do to prevent infection: clean your hands, cover your nose and mouth when sneezing &amp; coughing, avoid/minimize close contact if you have a contagious/infectious illness</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>JACHO, 2004: USA</td>
<td>Focus on Five Practical Strategies to Involve Patients in Anaesthesia Safety</td>
<td>describes how HCPs can involve patients in the pre and post procedure phases of anaesthesia plan</td>
<td>ind</td>
<td>five strategies to involve patients in anaesthesia safety including: obtaining a full and complete history, physical examination continuing to listen for any comments from the patient about previous anaesthetic difficulties, giving patients the opportunity to speak, explaining risks and benefits of anaesthesia &amp; alternatives, inform the patient who will be monitoring them while they are anesthetised, describe the expected post anaesthetic pathway and advise when they should raise concerns with a HCP</td>
<td>informing the plan delivery and monitoring of treatment</td>
</tr>
<tr>
<td>JACHO 2004: USA</td>
<td>Sentinel Event Alert: patient controlled analgesia by proxy</td>
<td>describes the problem of unauthorised personnel (relatives, HCPs) administering patient controlled analgesia (PCA) 'by proxy' and makes a number of recommendations to prevent this including teaching patients and their families the correct use of PCA</td>
<td>ind</td>
<td>recommendations for safe practice including teaching patients about the proper use of PCA and the dangers of pressing the button for the patient. provide written instructions to family members place warning tags on all PCA delivery systems post warning signs in clinical areas where PCA systems are in use</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>JCAHO 2006: USA</td>
<td><strong>Patients as Partners: How to Involve Patients and Families in their own care</strong> publication from the Joint Commission which provides tips and advice on how to involve patients in their own care to improve healthcare quality and safety</td>
<td>ind</td>
<td>including patients in a culture of safety opening the lines of communication persuading and teaching patients to get involved understanding health literacy and improving informed consent assessing the education and involvement needs of special populations</td>
<td>informing systems improvements</td>
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<td>JCAHO 2002/2006 USA</td>
<td><strong>Speak Up: help prevent errors in your care</strong> RN news watch: professional update. National campaign urges patients to help reduce errors Care recipients urged to 'speak up' for safer health care</td>
<td>ind</td>
<td>a brochure that urges patients to: speak up if they have questions, concerns or don't understand pay attention to the care they are receiving educate themselves about their diagnosis, tests and treatment plan take an advocate to healthcare encounters know their medication use a health care facility which has undergone quality and safety evaluation participate in decisions about their treatment</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<td>Schiff, L., 2002: USA</td>
<td><strong>Unknown</strong></td>
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<td>Anonymous, 2002: USA</td>
<td><strong>Unknown</strong></td>
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<td>Anonymous, 2002: USA</td>
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<td>Jech 2000: USA</td>
<td>Med errors: a new approach to prevention</td>
<td>describes the problem of medication error and ways in which risk of this might be reduced</td>
<td>ind</td>
<td>patient education by HCP through drug information sites online through drug reference books patient advice encouraging patients to use the same pharmacy and to make sure online pharmacies are legitimate encourage them to keep an up to date list of all their medication and share it with HCPs encourage them to ask if they are concerned</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<td>Jensen 2003: Canada</td>
<td>Self-administered cardiac medication program evaluation</td>
<td>describes a CT of the effectiveness of a self-administered medication program for cardiology inpatients versus nurse-administered medication. Authors claim no differences between groups on medication adherence. Also claim intervention group performed significantly better than controls for satisfaction, medication errors and medication-related problems (note, no reproducible results available to substantiate claim re med errors and med-related problems).</td>
<td>ind</td>
<td>self-administered medication program. Consisted of two stages during which patients were monitored and given increasing responsibility over a two day time period. controls: nurse administered medications</td>
<td>monitoring and safe delivery of treatment</td>
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<tr>
<td>John 2005: USA</td>
<td>Preventing medication errors at home</td>
<td>describes the causes of medication error at home for the very old and very young and how the risk of harm may be decreased through patient and family education</td>
<td>list of strategies for HCPs to pass on to parents and caregivers including reading instructions looking out for the same active ingredient (e.g.: paracetamol) in over the counter medication make sure all caregivers communicate about medication use don’t rely on containers being ‘child resistant’ look at the concentration in liquid medication use accurate dosing implements use dosing devices provided with medication medication can be toxic if more than recommended dose is given medication for adults should not be given to children keep a list of current medication with you at all times know when to consult HCP look out for drug-drug or drug-food interactions don’t stop medication suddenly without advice ask if you are not sure don’t keep medication no longer in use do not share medication use a reminder system if it’s helpful do not overuse ‘as-needed’ medication informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Authors</td>
<td>Title</td>
<td>Description</td>
<td>Replication</td>
<td>Outcome</td>
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<td>Johnson &amp; Bament 2002: Australia</td>
<td>Improving the quality of hospital services: how diverse groups of consumers prefer to be involved</td>
<td>describes a study which asked over 2000 consumers about their preferences for participating to improve safety and quality in hospitals.</td>
<td>rep</td>
<td>face to face interviews, focus groups, telephone interviews in which consumers and representatives of consumer groups were asked about their views on involvement in public participation to improve quality and safety in the hospital.</td>
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<tr>
<td>Johnson 2000: USA</td>
<td>Improving outcomes in the elderly</td>
<td>Describes the problem of adverse drug events in older people and presents some approaches to reduce the risk of these events.</td>
<td>ind</td>
<td>verbal and written information about medication review of medication with patient provision of appropriate aids such as dosette boxes.</td>
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<tr>
<td>Johnson, Croft &amp; Crane 2001: USA</td>
<td>Counselling patients about drug allergies in the inpatient setting</td>
<td>describes a project in one hospital to improve allergy awareness of patients who had experienced a severe allergic reaction to a specific type of medication.</td>
<td>ind</td>
<td>individualised patient counselling by a pharmacist in appropriate language and at appropriate level. This is backed up by written information customised Medic ID bracelet which identifies the patient's allergies follow up phone call to ensure that bracelet had arrived and all patient's questions had been answered.</td>
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<tr>
<td>Jones &amp; Smith 1989: USA</td>
<td>Preventing Hospital Incidents - What We Can Do</td>
<td>describes a study which examined the relationships between selected variables related to hospital adverse events especially for elderly patients (which are mostly falls).</td>
<td>ind</td>
<td>education of patients about: their disease process and medication side effects which may affect their ability to walk safely strategies to avoid postural hypotension.</td>
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<tr>
<td>Kahn 1994: USA</td>
<td>The Patient-Staff Community Meeting: old tools, new rules</td>
<td>describes the use of the patient-staff community meeting as a tool to establish and maintain a therapeutic environment in a psychiatric inpatient unit with rapid turnover and acutely ill patients</td>
<td>ind</td>
<td>patient-staff community meeting - usually daily. Facilitated meeting to which all are encouraged to contribute</td>
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<td>Kane 2002: USA</td>
<td>Information is the Key to Patient Empowerment</td>
<td>describes the move to empower patients by making sure they have access to appropriate information about healthcare and the advantages of this including patients’ roles in the prevention of medical errors</td>
<td>ind</td>
<td>patient empowerment checklist as a list of questions and suggestions for a patient to determine if he or she has sufficient information to take responsibility for his or her care and to make responsible healthcare decisions: do you have a list of all your illnesses or conditions for which you sought healthcare including any therapies, treatments or medications received? do you check on your HCPs’ education and experience or your health care facilities’ experience? do you have a list of all your current prescriptions, over the counter medications and assistive devices? do you inform your HCP and Health care facilities of the treatments you are receiving at the time you seek services? do you ask questions when you do not understand something or if something confuses you? do you insist upon legible instructions from your healthcare professional or facility? do you know which healthcare facilities are covered and which HCPs or facilities are authorized by your health beneficiary</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Description</td>
<td>Ind</td>
<td>Additional Information</td>
<td>Issue</td>
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<td>Kanegan and Boyette, 2003: USA</td>
<td>How to Survive your Hospital Stay</td>
<td>'complete guide to getting the care you need and the problems you don’t'</td>
<td>ind</td>
<td>Book with two parts: 1. eight important ways to prepare for your hospital stay 2. the top ten risks: how to understand and avoid them Afterword: if you are hurt</td>
<td>Informing the plan Monitoring and ensuring safe delivery of treatment</td>
</tr>
<tr>
<td>Karash 2006: USA</td>
<td>Hospital patients need to be watchdogs too</td>
<td>describes 10 'overlooked issues' that can improve a stay in hospital</td>
<td>ind</td>
<td>list of recommendations: consult with your physician on issues such as the hospital’s reputation and expertise find out which doctor will be supervising your care in the hospital take an advocate bring a list of all medications you take and all allergies you have make sure the operation site is marked make sure you are given a discharge plan</td>
<td>Informing the plan Monitoring and ensuring safe delivery of treatment</td>
</tr>
<tr>
<td>Karch 2000: USA</td>
<td>Cutting it Close</td>
<td>recommendation for prescribers to advise patients that slow release tablets lose their slow release qualities if they are cut in half or the capsule removed to facilitate taking the medication</td>
<td>ind</td>
<td>giving patients written instructions with medication including, for those with sustained release medication, instructions not to cut or crush the tablets</td>
<td>Monitoring and safe delivery of treatment</td>
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<tr>
<td>Study (Year)</td>
<td>Title</td>
<td>Design</td>
<td>Description</td>
<td>Outcomes</td>
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<td>Kendall 2003: USA</td>
<td>Improving patient care with collaborative rounds</td>
<td>describes multi-disciplinary patient rounds at one hospital which involves patients and their family members</td>
<td>ind</td>
<td>patients and their families' active participation in the rounds process through listening to the treatment plan and review of medication and being asked if they think the plan is appropriate, achievable and if they think anything has been missed</td>
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<tr>
<td>Kennedy 1990: USA</td>
<td>The effectiveness of a self-care medication education protocol on the home medication behaviours of recently hospitalized elderly</td>
<td>describes a RCT to evaluate the effectiveness of a self-care medication education protocol for recently hospitalized elders. Authors claim that the intervention group showed significant increases in medication knowledge, medication administration skills and reduction in medication error rates compared to the control group.</td>
<td>ind</td>
<td>experimental group: assessment/evaluation for knowledge and skills for self medication, individualised teaching plan, written copy of discharge instructions, information about all medication, encouragement to record meds accurately and use reminder aids such as dosette box. patient contacted within one week of discharge to discuss any problems, ask questions. controls: Patients informed that in approx 30 days a nurse would contact them to schedule home visit to review medications. Assessment/evaluation for knowledge and skills for self-medication. Marked deficits in patient's knowledge or skills were reported to assigned staff nurse. No further intervention took place. In preparation for discharge the staff nurse is to clarify instructions regarding prescribed medications. Patient receives written copy of the discharge orders/instructions.</td>
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<tr>
<td>Kim &amp; Grier 1981: USA</td>
<td>Pacing effects of medication instruction for the elderly</td>
<td>describes a RCT to examine the effect of pacing education instruction on the learning of elderly clients.</td>
<td>ind</td>
<td>medication instruction at normal pace (Intervention 1) or slow pace (Intervention 2). Instruction included five areas: name of the drug, purpose, frequency, dosage and time of drug administration. Instruction was presented to the patients using audiotape and written learning material. Each patient received instruction for one prescribed medication and took approx 5 to 10 minutes. controls: not stated</td>
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<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Description</td>
<td>Study Design</td>
<td>Outcome</td>
<td>Improvements</td>
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<tr>
<td>Kivlahan et al 2002: USA</td>
<td>Developing a Comprehensive Electronic Adverse Event Reporting System in an Academic Health Center</td>
<td>describes the development of an electronic system to report, analyse and resolve adverse events relating to patient safety.</td>
<td>ind</td>
<td>adverse event reporting system open to patients and family as well as staff</td>
<td>informing the plan monitoring and safe delivery of treatment informing systems improvements</td>
</tr>
<tr>
<td>Klein 1991: USA</td>
<td>The Axis II Group: Treating Severely Characterologically Disturbed Patients</td>
<td>describes safety issues raised for HCP working with patients with severe personality disorder and ways of maintaining balance between autonomy and safety through therapeutic groups</td>
<td>ind</td>
<td>Axis II Group using psychodynamic orientation</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Kliger 2006: USA</td>
<td>Patient Safety in the Dialysis Facility</td>
<td>describes how mistakes in dialysis facilities should be recognised and learnt from preventing further mistakes. Patients should be involved by being responsible for maintaining an accurate updated medication list as well as sharing their thoughts about opportunities for improvement</td>
<td>ind/re</td>
<td>encourage patients to maintain an up to date medication list and share their thoughts about opportunities for improvement with facility providers and administrators</td>
<td>informing the plan informing systems improvements</td>
</tr>
<tr>
<td>Koertke et al 2001: Germany</td>
<td>International Normalized Ratio self-management after mechanical heart valve replacement: is an early start advantageous?</td>
<td>compares early onset self-management of anticoagulation therapy with conventional management by GP</td>
<td>ind</td>
<td>600 patients were randomised to either intervention or conventional treatment. Intervention patients were trained in self management 6-11 days after valve replacement surgery</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Koertke et al 2005: Germany</td>
<td>The Bad Oeynhausen Concept of INR self-management</td>
<td>describes the use of portable anticoagulation monitors by patients self-managing their anticoagulant therapy</td>
<td>ind</td>
<td>INR self-management</td>
<td>monitoring and safe delivery of treatment</td>
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<td>Koertke et al 2007: Germany</td>
<td>INR self-management permits lower anticoagulation levels after mechanical heart valve replacement</td>
<td>compares early onset self-management of anticoagulation therapy (narrow target range) with conventional treatment</td>
<td>ind</td>
<td>1818 patients were randomised to intervention or conventional treatment. Intervention patients were trained and then underwent an INR self-management examination. Those who passed received a coagulation monitor</td>
<td>monitoring and safe delivery of treatment</td>
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<tr>
<td>Kostopoulos 1985: USA</td>
<td>Reducing Patient Falls</td>
<td>describes the development of an assessment tool to identify those patients at risk of falls and strategies to reduce that risk including patient education</td>
<td>ind</td>
<td>patient education strategy recommending that they: rise slowly from sitting or lying know how to use walking aids safely wear properly fitting shoes open doors and go round corners cautiously pass water before taking a sedative</td>
<td>informing systems improvements</td>
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<tr>
<td>Kramer 2000: USA</td>
<td>Patient perceptions of the importance of maintaining preoperative NPO status</td>
<td>describes a study to evaluate the effectiveness of comprehensive NPO instructions on patients' perceptions of the importance of maintaining NPO status</td>
<td>ind</td>
<td>comprehensive NPO instructions including the rationale for adhering to preoperative NPO orders and stressing that personal safety was the most important reason for following the NPO instructions</td>
<td>monitoring and safe delivery of treatment</td>
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<tr>
<td>Authors</td>
<td>Title</td>
<td>Description</td>
<td>Method</td>
<td>Risk Assessment and Management of Risk Plan</td>
<td>Informing the Plan</td>
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<td>Kumar &amp; Simpson 2004: New Zealand</td>
<td>Application of risk assessment for violence methods to general adult psychiatry: a selective literature review</td>
<td>describes a review of the literature on the way risk has been conceptualised in different disciplines. Found 3 common key concepts and reviewed two main methods in use in psychiatry (actuarial and clinical). Concludes that there are benefits in shifting from risk prediction to assessment, management and reduction of risk and that this process should involve patients</td>
<td>ind</td>
<td>risk assessment and management of risk plan</td>
<td>informing the plan</td>
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<tr>
<td>Kuzel et al 2003: USA</td>
<td>Making the case for a qualitative study of medical errors in primary care</td>
<td>describes a proposal for a study which intended to use ‘reactor panels’ drawn from the community to meet and enhance data drawn from individual patient interviews providing further expansion of the lists of medical errors or assurance that saturation had been achieved</td>
<td>rep</td>
<td>recruitment of reactor panels from community who will be interviewed as a group</td>
<td>informing systems improvements</td>
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<td>Reference</td>
<td>Study/Context</td>
<td>Description</td>
<td>Indications</td>
<td>Improvements</td>
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<td>Langan &amp; Lindow 2004: UK</td>
<td>Living with risk Mental health service user involvement in risk assessment and management</td>
<td>describes ways in which service users may be involved in care planning and risk assessment.</td>
<td>ind strategies to involve service users in risk management: encourage service users to draw up advance directives so that their opinion about what works best for them can be taken into account give service users information about independent advocacy services be flexible about the number of people attending care planning meetings so service users feel able to be involved offer service users the support and preparation time for care planning meetings</td>
<td>informing the plan informing systems improvements</td>
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<td>Lange 2006: USA</td>
<td>Implanted device + MRI = trouble?</td>
<td>describes a case where a patient was permanently harmed by having an MRI scan because he had an implanted deep brain stimulator. Author stresses that patients who have such a device or have had in the past must alert all appropriate staff to this</td>
<td>ind alert or wallet card to highlight the importance of making radiology staff aware of presence of device patient or carer to ensure that all appropriate people are informed</td>
<td>informing the plan</td>
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<td>Leger et al 2004: France</td>
<td>Therapeutic information for patients receiving anticoagulants</td>
<td>Describes ‘Educ’AVK’ an education programme designed for patients starting oral anticoagulant treatment</td>
<td>ind Educ’AVK and education programme involving individualised patient education for self-management of treatment</td>
<td>monitoring and safe delivery of treatment</td>
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<tr>
<td>Author</td>
<td>Title</td>
<td>Description</td>
<td>Method</td>
<td>Improvements</td>
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<td>Lehman</td>
<td>Business coalitions get employers involved in improving patient safety</td>
<td>describes the National Business Coalition on Health's 5 step strategy to improve patient safety including developing and supporting consumer awareness of patient safety issues</td>
<td>rep</td>
<td>informing systems improvements</td>
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<tr>
<td>Lehmann</td>
<td>Quality use of medicines for people with diabetes</td>
<td>describes some of the potential medication errors that can occur for patients with diabetes. Lists ways in which these can be minimised including ongoing patient education and assessment of understanding.</td>
<td>ind</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<td>Leonhardt</td>
<td>Patient partnerships to improve safety</td>
<td>describes a project which aims to develop strategies and tools that can be used to engage patients and providers in medication management in the clinic and community setting</td>
<td>rep</td>
<td>informing systems improvements</td>
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<tr>
<td>Author(s)</td>
<td>Study Description</td>
<td>Methodology</td>
<td>Education and Communication</td>
<td>Monitoring and Safe Delivery of Treatment</td>
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<td>Levenson 2003: USA</td>
<td>Drug events may be more common in primary care than hospital patients</td>
<td>describes a study that found that a quarter of patients receiving prescriptions over a period of four weeks experienced one or more injuries related to medication. The researchers estimated that almost 40% were preventable. They go on to describe a web site at a Boston hospital which allows patients to access information about their medication and to e-mail clinicians about any problems.</td>
<td>education of patients about their medication website which allows patients to check their medication, get medication information and e-mail clinicians about problems with medication.</td>
<td>informing the plan monitoring and safe delivery of treatment.</td>
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<tr>
<td>Levesque &amp; Borg 2003: France</td>
<td>Anticoagulant clinic: a tool for reducing bleeding complications of oral anticoagulant treatment</td>
<td>describes the strategies employed to reduce adverse drug events for patients being treated with anti-coagulants including making sure that patients are involved in and well educated about their treatment.</td>
<td>anticoagulant clinics based on the principles of: education for all involved treatment individualised to patient sharing of information and regular contact between all in team (including patient).</td>
<td>informing the plan monitoring and safe delivery of treatment.</td>
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<tr>
<td>Ley, P. Jain, V.K, Skilbeck, C.E 1976: UK</td>
<td>A method for decreasing patients' medication errors</td>
<td>describes a randomised intervention to reduce medication errors among depressed patients by providing them with one of three versions of an information leaflet</td>
<td>information leaflets x 3 with different reading ease scores which gave patients information about name of drug, what to do if they forgot to take a dose and an explanation that the treatment would take time to take effect.</td>
<td>monitoring and safe delivery of treatment.</td>
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<tr>
<td>Li et al 2000: USA</td>
<td>Acetaminophen and ibuprofen dosing by parents</td>
<td>describes a study that aimed to discover the prevalence of and risk factors for inaccurate dosing with antipyretics of children by parents. Concluded that parent education about recommended dosage and improved labelling would probably reduce the incidence</td>
<td>ind</td>
<td>patient education improved labelling of paediatric medication</td>
<td>monitoring and safe delivery of treatment</td>
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<tr>
<td>Liang 2003: USA</td>
<td>Themes for a system of medical error disclosure: promoting patient safety using a partnership of provider and patient</td>
<td>describes how patients and providers can be involved in a system of medical error disclosure that is open and accessible and provides opportunity for learning. Also emphasises the need for patients to recognise that they have rights and responsibilities and suggests an agreement to be signed at the outset of care by the provider and patient</td>
<td>ind</td>
<td>healthcare partnership agreement which emphasises that medical care is complex, that patients are equal partners in care, that all will be done on the provider side to ensure that care is safe and effective and that they expect patients to speak up if they have concerns or issues.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Author &amp; Year</td>
<td>Title</td>
<td>Description</td>
<td>Indication</td>
<td>Additional Information</td>
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<td>Lilley &amp; Guanci 1998: USA</td>
<td>It Never Hurts to Check</td>
<td>describes a near miss medication event and emphasises the importance of educating patients about brand/generic names of medication and checking a medication name before taking it</td>
<td>ind</td>
<td>education of patients about brand and generic names of medication and the need to check a medication name before taking it</td>
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<tr>
<td>Lilley &amp; Guanci 1998: USA</td>
<td>A Prescription Refill Causes a Problem</td>
<td>describes a dispensing error that involved capsules of the same medication but different strengths, which look similar except for the dosage strength written on the body of the capsule. Authors recommend patient education to check the dosage imprint (if present), compare the previous tablets with new ones and look out for adverse effects including the symptoms of overdose</td>
<td>ind</td>
<td>education of patients about: checking dosage imprint on medication labels and tablets (if present) order prescription refill before old tablets run out and compare new tablets with previous be aware of the signs of overdose and look out for other adverse effects</td>
<td></td>
</tr>
<tr>
<td>Lipton 1982: USA</td>
<td>The Graying of America: Implications for the Pharmacist</td>
<td>describes the implications for pharmacy services of an aging population and strategies to avoid or minimize medication error</td>
<td>ind</td>
<td>medication information tailored to patient need use of safety promoting instruments (dosette boxes, large print labels, medication calendars) checking understanding of information</td>
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</tr>
</tbody>
</table>

informing the plan monitoring and safe delivery of treatment
<p>| Liu et al., 2004: USA | Development and evaluation of an integrated pharmaceutical education system | describes an integrated pharmaceutical information system which provides information about medication specific to individual patients' needs | integrated pharmaceutical information system which collects relevant information from a patient's electronic medical records and can provide pharmaceutical information specifically to meet that patient's needs | informing the plan monitoring and safe delivery of treatment |
| Loecher 2001: USA | Get out of the hospital alive: here's how to protect yourself from mistakes made in the name of medical treatment | lists a number of things patients can do to protect themselves from medical error | list of recommendations: find a good doctor - look at quality measures, interview potential candidates and, for surgical procedures, chose a surgeon who does it often play it safe - share information about the medication you are taking make sure you can read prescriptions and understand what any prescribed medication is for become an expert on your condition get a second opinion, pursue test results keep a copy of your records, check your chart find a good hospital - look at quality measures if you are having an operation - choose a hospital where the procedure is performed a lot take an advocate into hospital with you know your treatment plan question authority - anything that seems odd know the team who are providing your care, ask for their credentials get the surgeon to sign your op site ask staff if they have washed their hands before touching you make sure you have discharge instructions before you leave to interview a hospital ask - do you keep concentrated Potassium Chloride | informing the plan monitoring and safe delivery of treatment |</p>
<table>
<thead>
<tr>
<th>Lozowski et al 1993: USA</th>
<th>Parental intervention in the medical care of children with cancer</th>
<th>describes ways in which parents of children with cancer intervened to prevent or correct a medical mistake in their child’s treatment</th>
<th>ind</th>
<th>patient expert - parent corrected the staff regarding details about their child's care that the staff didn't know interpersonal negotiator - parent intervened because of staff attitude or style monitor of IV procedures - parent intervened regarding problems specifically related to IV procedures procedure historian - parent called staff's attention to incorrect or excessive procedures rescuer parent intervened to keep staff from giving the wrong treatment or an excessive amount of a drug</th>
<th>informing the plan monitoring and safe delivery of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ludwick 2004: USA</td>
<td>Surgical Safety: Addressing the JCAHO Goals for reducing wrong-site, wrong patient, wrong procedure events</td>
<td>describes an intervention to address the JACHO surgical safety goals at one hospital that could be implemented in other facilities. The intervention includes identity, surgical site and procedure identification by patient</td>
<td>ind</td>
<td>surgical verification procedure</td>
<td>monitoring and safe delivery of treatment</td>
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<tr>
<td>Author</td>
<td>Year</td>
<td>Country</td>
<td>Title</td>
<td>Description</td>
<td>Intervention</td>
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<td>Lynch 2004</td>
<td>UK</td>
<td>In safe hands</td>
<td>describes the piloting of and background to the cleanyourhands campaign organised by the NPSA</td>
<td>clean you hands campaign toolkit includes: bedside or clip on antiseptic hand rub dispensers posters and promotional material information leaflets that encourage patients to ask staff if they have washed their hands badges for staff that read ' clean your hands. It's OK to ask' advice on strengthening the role of ward housekeepers and modern matrons in promoting hand hygiene</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Maddock 2005</td>
<td>USA</td>
<td>Falls and Fitness: Translating Evidence into Clinical Practice: A Falls Prevention Programme for Community Dwelling Seniors</td>
<td>describes the development and implementation of a falls prevention programme for patients seen after a fall in the Emergency Department</td>
<td>falls prevention programme consisting of a 45 minute exercise circuit twice weekly for 6 weeks, geriatric medical assessment, home assessment and education by Occupational Therapist</td>
<td>informing the plan informing systems improvements</td>
</tr>
<tr>
<td>Magoon 2002</td>
<td>USA</td>
<td>Parents and medication errors</td>
<td>describes common errors made by parents when administering medication to their children and how these can be minimised</td>
<td>assessment of parental knowledge demonstration of measuring device evaluation of parental use of device drawing up of dosing strategy</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Mallik et al 2002</td>
<td>India</td>
<td>Liquid medication dosing errors: a pre/post time series trial in India</td>
<td>describes an intervention to determine if pharmacist education of parents improved the accuracy of liquid medication doses they gave to their children</td>
<td>two similar groups of children were prescribed antipyretic medication. Group 1 received standard care; Group 2 received standard care plus a syringe with a line across it at the correct dose mark and instructions on how to measure the dose by a pharmacist.</td>
<td>monitoring and safe delivery of treatment</td>
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<td>Author</td>
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<td>Description</td>
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<tr>
<td>Manno 2006: USA</td>
<td>Preventing adverse drug events</td>
<td>describes adverse drug events and their consequences. Recommends a number of ways to reduce the risk of adverse drug events including encouraging patient participation</td>
<td>shared decision making about treatment patient, family and carer education about medication including why they need them when they should take them how they should take them what adverse reactions to look out for when to call a HCP</td>
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<tr>
<td>Marsé et al 2004: Belgium</td>
<td>Management of adverse events and other practical considerations in patients receiving capecitabine</td>
<td>describes the use of an oral chemotherapy agent and highlights the need for patient involvement and education so this can be administered safely in the outpatient setting</td>
<td>patient education and explicit instructions about when to contact HCP</td>
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<tr>
<td>Martin 2000: USA</td>
<td>Medication Errors</td>
<td>describes two cases of medication error and goes on to document how health care institutions are reducing medication error in various ways including teaching patients about their medication</td>
<td>teaching patients about their medication: make sure they know the colours and shapes of all their medication encourage them to question HCPs if they are given an unfamiliar tablet provide them with information about books or websites where they can find information about their medication encourage them to keep an up to date list of their medication, both prescribed and OTC, any allergies or adverse reactions in the past encourage patients to use one pharmacy and to ensure this has a copy of the above list</td>
<td></td>
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<tr>
<td>Martin and Mead 1982: USA</td>
<td>Reducing medication errors in a geriatric population</td>
<td>tested three compliance improving strategies for older patients compared with a control group, only one significantly improved compliance and reduced medication errors</td>
<td>ind</td>
<td>100 older people were randomly assigned to one of four groups: Group 1 - control, standard treatment Group 2 - individualized instruction about correct medication use and how to incorporate into lifestyle Group 3 - coloured labels pasted to medicine bottles each corresponding to time of day and activity cue Group 4 - as group three with additional colour coded pill tray which they were taught to load from corresponding bottles Pills were recounted at 30 days</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Massachusets Coalition for the Prevention of Medical Errors, 2006</td>
<td>Know your medications for better health</td>
<td>tip sheet for patients advising them about medication use and other safety related behaviours</td>
<td>ind</td>
<td>learn about your medications read the label each time you take your medication never take anyone else's prescription medication treat medications like dangerous chemicals don't crush break or chew capsules or tablets unless instructed by your physician use only the cup or other measuring device supplied with the drug when administering liquid medication choose a pharmacy wisely inform your pharmacist or physician if you take any herbal or natural remedies or any other dietary supplements call your physicians office or pharmacy with questions during hospital stays ask about the medications you are receiving</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Author</td>
<td>Title</td>
<td>Description</td>
<td>Indications</td>
<td>Monitoring and safe delivery of treatment</td>
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<td>Matsuoka 2003: Japan</td>
<td>Simulation incision using an oil pen as a method of risk management</td>
<td>describes the use of an oil pen to mark the skin incision line for scheduled surgery on the day before surgery to prevent wrong patient, wrong procedure, wrong site surgery.</td>
<td>surgical incision line is drawn with an oil pen on the day prior to surgery as part of the pre-operative information session.</td>
<td>monitoring and safe delivery of treatment</td>
<td></td>
</tr>
<tr>
<td>McCabe 1984: UK</td>
<td>Getting the right prescription</td>
<td>describes interventions implemented by a community nurse after noticing non-compliance or adverse effects from the multiple medication taken by elderly patients.</td>
<td>advice and education about: what the drugs were for when was the best time to take them what sort of side effects to look for how to control them if the drug was essential symptoms to report to their GP.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
<td></td>
</tr>
<tr>
<td>McCarthy &amp; Blumenthal 2006: USA</td>
<td>Committed to safety: one of 10 patient safety initiatives: collaborative rounds at Concord Hospital</td>
<td>describes the collaborative multidisciplinary rounds at Concord Hospital involving patients who have undergone cardiac surgery.</td>
<td>10 minute briefing with all members of cardiac surgery team at patient’s bedside with patients and family being encouraged to participate.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
<td></td>
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<tr>
<td>McCloskey and Bulechek 1996: USA</td>
<td>Teaching: prescribed medication (book section)</td>
<td>lists instructions to be given to patients to help them safely self-medicate.</td>
<td>list of 29 instructions to prepare a patient to safely self medicate.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
<td></td>
</tr>
<tr>
<td>McCollum 1978: USA</td>
<td>Hospital system works to ensure risk management, quality of care</td>
<td>describes a health care corporation’s approach to risk management including patient education.</td>
<td>patient education via audiovisual media shown to patients advising them what to expect during their stay, how to help to take care of themselves and what precautions should be taken to ensure their optimum care.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<td>Author</td>
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<td>McGoodwin</td>
<td>Self-reported therapeutic errors to a poison control centre</td>
<td>describes a study of self-dosing errors and their causes compiled from reports to a poisons centre over one year (2001). Provides a number of recommendations to reduce the risk of error.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<td>2003: USA</td>
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<tr>
<td>McGovern</td>
<td>10 Golden Rules for Administering Drugs Safely</td>
<td>lists the rules nurses should follow when administering medication including teaching patients about their medication and taking a drug and allergy history.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<td>1992: USA</td>
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<tr>
<td>McKibben</td>
<td>Ensuring rational public reporting systems for health care-associated infections. Systematic literature review and evaluation recommendations</td>
<td>describes a review of the effect of publicly available figures for health care associated infection on service improvement. Found that the evidence is inconclusive and calls for rigorous evaluation.</td>
<td>monitoring and safe delivery of treatment</td>
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<tr>
<td>2006: USA</td>
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<tr>
<td>Authors</td>
<td>Description</td>
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<td>Monitoring and safe delivery of treatment</td>
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<td>McMahon et al 1997: USA</td>
<td>Parents can dose liquid medication accurately</td>
<td>intervention one: parents given verbal instructions and a demonstration of antibiotic dosing plus a syringe intervention two: parents given verbal instructions and a demonstration plus a syringe with the correct dose marked on it control: given verbal instructions only</td>
<td>monitoring and safe delivery of treatment</td>
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<tr>
<td>Meadows 2003: USA</td>
<td>Strategies to reduce medication errors</td>
<td>consumers can be informed by: knowing what kinds of error occur finding out what medication is and what it's for finding out how to take the medication keeping a list of all medication and sharing this with prescribers asking if in doubt</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Meyer &amp; Arnheim 2002: USA</td>
<td>The power of two; improving patient safety through better physician-patient communication</td>
<td>list of recommendations for physicians to follow to facilitate patient involvement put patients at ease be explicit in instructions prompt the fullest answers co-ordinate patient care work together</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Miglietta et al 2004: USA</td>
<td>Computer assisted communication for critically ill patients: a pilot study</td>
<td>Life Voice computer communication system activated by eye blinking or touching</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Authors</td>
<td>Country</td>
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<td>Miles 2004: New Zealand</td>
<td></td>
<td>Bridging the chasm: a professional college's role in quality</td>
<td>describes the work of the Royal Australian and New Zealand College of Psychiatry to ensure quality care and reduce the risk of medical error. Their efforts include patient and family representatives at board level, patient and caregiver input in the curriculum and complaints process. The report recommends that this involvement be increased.</td>
<td>rep inclusion of patient representatives at board level and in all areas of the college informing systems improvements</td>
<td></td>
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<tr>
<td>Miller 1995: USA</td>
<td></td>
<td>The adverse drug reaction: a clinical opportunity for pharmacists</td>
<td>describes the development and evaluation of an adverse drug reaction protocol which involves the patient both in the initial assessment and then through the patient carrying a card which details the reaction for other HCPs</td>
<td>ind adverse drug reaction protocol informing the plan</td>
<td></td>
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<tr>
<td>Miranda et al 2005: USA</td>
<td></td>
<td>Speaking plainly: communicating the patient's role in health care safety</td>
<td>describes the development and testing of the patient fact sheet 'Five Steps to Safer Health Care'</td>
<td>rep focus groups of patients to identify persuasive error prevention messages informing systems improvements</td>
<td></td>
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<tr>
<td>Monk 2002: USA</td>
<td>Medical errors kill, injure SC patients</td>
<td>describes a number of cases where medical error has allegedly led to patient death in South Carolina. Provides a list of tips for patients to follow to help prevent mistakes</td>
<td>ind</td>
<td>list of tips such as: speak up, be informed, choose the most appropriate HCP &amp; facility, chase up results, get the right investigations, share relevant, personal information, (including illegal drug use), take backup, avoid hospitals at weekends, holiday time and at night if possible, label body prior to surgery, make sure you can read a prescription, make sure med you are given is what you were prescribed, take advocate</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<td>Monnier et al 2003: France</td>
<td>Evaluation of drug therapy knowledge after pharmacy counselling</td>
<td>describes the problem of information poor patients due to a number of factors (poor explanation generally, individual patient characteristics, no information given on discharge) and the strategies developed by a transplantation service to overcome these problems</td>
<td>ind</td>
<td>structured consultation with a pharmacist which comprises: assessment of patient's current knowledge review of all medication supplementation of knowledge assessment of understanding of information given written individualised drug administration plan with contact numbers for pharmacist</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Morath 2003: USA</td>
<td>Changing the healthcare culture: the consumer as part of the system of care</td>
<td>describes how consumer demands are driving up the quality of healthcare and documents a number of initiatives where HCPs, patients and their families have worked together to improve the safety of care</td>
<td>ind/re</td>
<td>family focus groups to develop policies to improve safety at a children's healthcare institution policies developed by family focus groups to improve safety collaborative patient rounds in New England making healthcare knowledge accessible to consumers</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Motluk 2000: USA</td>
<td>Someone to watch over you</td>
<td>describes an intelligent system personal electronic companion or 'guardian angel' to manage individual's care from cradle to grave.</td>
<td>ind</td>
<td>electronic medical record accessible to an individual and others he/she chooses.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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</table>
| Murie, 2003: UK | Amiodarone monitoring: Involving patients in risk management  
Developing an evaluated patient-mediated intervention for monitoring amiodarone therapy | describes the development and evaluation prior to use of a booklet for amiodarone monitoring in primary care by a GP practice patient participation group | rep | self report questionnaire and focus group discussion | informing systems improvements |
| Murie 2005: UK | Amiodarone monitoring: Involving patients in risk management  
Developing an evaluated patient-mediated intervention for monitoring amiodarone therapy | describes the development and evaluation prior to use of a booklet for amiodarone monitoring in primary care by a GP practice patient participation group | rep | self report questionnaire and focus group discussion | informing systems improvements |
<p>| Nabeshima 2002: Japan | Outpatient pharmaceutical care: warfarin classroom | describes the evaluation of an educational intervention of patients taking a course of anticoagulant therapy | ind | warfarin classroom an educational intervention to provide information to patients about their treatment and how to minimise the risk of adverse events | monitoring and safe delivery of treatment |
| Nabeshima et al 2002: Japan | Outpatient Pharmaceutical Care: Warfarin classroom | describes a programme which provides information about warfarin to outpatients | ind | warfarin classroom where pharmacists counsel patients about the importance of compliance, the food-drug reaction, the drug-drug reaction | monitoring and safe delivery of treatment |</p>
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<tr>
<th>Source</th>
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<th>Description</th>
<th>Individually</th>
<th>Group</th>
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</thead>
<tbody>
<tr>
<td>Neafsey 2002, 2003: USA</td>
<td>Interactive personal technology education programme decreases adverse medication events</td>
<td>describes a medication education system, designed for older adults, which is accessed on a laptop computer through touch-screen technology. Evaluation of the system showed that it was well received by patients and reduced self reported adverse medication behaviours better than a well designed booklet</td>
<td>ind</td>
<td>computer based, interactive personal education programme 'avoiding medicine conflicts'</td>
</tr>
<tr>
<td>NICE 2003: UK</td>
<td>Infection Control Prevention of healthcare associated infection in primary and community care</td>
<td>infection control guidelines for those giving or receiving care at home</td>
<td>ind</td>
<td>clinical guidelines to be followed to help prevent healthcare associated infection: hand washing using protective equipment disposing of sharps care of urinary catheters</td>
</tr>
<tr>
<td>Nicholas 2005: USA</td>
<td>Towards Safer IV medication administration</td>
<td>describes the potential for serious medical error when administering IV medication. Recommends various strategies including providing information to patients and their families about safe practices</td>
<td>ind/re p</td>
<td>provision of information for patients and their families about their IV medication and safe practice involvement of patients and families in the development of educational material</td>
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<td>Source</td>
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<td>Norman et al 1995: USA</td>
<td>Computer-assisted quality improvement in an ambulatory care setting</td>
<td>describes a system which aims to improve quality of care for patients in the community by producing worksheets at each patient visit which provide reminders for both physician and patient</td>
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<tr>
<td>NPSA, 2003: UK</td>
<td>Patients to have a new role in improving methotrexate safety says NPSA</td>
<td>describes NPSA measures to reduce adverse events associated with methotrexate treatment.</td>
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<tr>
<td>NPSA, 2004: UK</td>
<td>Towards the safer use of oral methotrexate</td>
<td>describes the thinking and process behind the oral methotrexate safety alert, outlines the evidence for recommendations and provides advice for implementing the actions within the alert. Examples of documentation. Patients were involved at all stages.</td>
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<tr>
<td>NPSA 2004: UK</td>
<td>Patient Briefing: clean hands help to save lives</td>
<td>safety alert issued by NPSA</td>
<td>patient briefing detailing the part patients can play in improving hospital staff hygiene practices</td>
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Template and core content for patient diary |

NPSA: UK |

Towards the safer use of oral methotrexate |

Methotrexate Patient Information Leaflet |

Patient held monitoring and dosage record |

Patient briefing detailing the part patients can play in improving hospital staff hygiene practices |

Monitoring and safe delivery of treatment |

Informing the plan monitoring and safe delivery of treatment |

Making systems safer |

Informing systems improvements |
<p>| NPSA 2005: UK | Building a memory: preventing harm, reducing risks and improving patient safety | describes the Patient Safety Observatory provides information from the National Reporting and Learning System (NRLS) and shows how it is used. This system was developed with input from, among others, patients and patient groups | rep | National Reporting and Learning System developed with input from patients and patient groups | informing systems improvements |
| NPSA 2005: UK | Patient Briefing: correct site surgery - making your surgery safer | safety alert issued by NPSA | ind | patient briefing detailing the agreed standard way of marking the operation site prior to surgery | monitoring and safe delivery of treatment |
| NPSA 2005: UK | Patient Briefing: improving emergency care for patients who breathe through their neck | safety alert issued by NPSA | ind | patient briefing detailing the problem and the steps taken by the NPSA to overcome this | monitoring and safe delivery of treatment |
| NPSA 2006: UK | Patients urged to 'please ask' about their healthcare | Top ten tips for safer patients | ind | Please Ask' campaign Top 10 tips Find out all you can about your condition and treatment Ask the doctor to explain any treatment options that are open to you including the risks If you are not quite sure what a doctor or nurse is saying ask them to repeat it If you are allergic to anything make sure HCPs know about it Always read the instructions that come with Medication Check the details of any consent form before signing it Ask questions for others if they have trouble speaking It's important that staff have the correct information about you. You may be asked to confirm your name a number of times If you are pregnant or think you might be tell HCPs before you have any treatment or x-rays It's OK for you to ask doctors or nurses if they have washed their hands before treating you | informing the plan monitoring and safe delivery of treatment |
| NPSA 2006: UK | Patient Safety 2006 | DVD of conference proceedings. | rep | involvement of patients and patient stories to inform policy and practice | informing systems improvements |
| NPSF 2002: USA | Patient Safety: Your Role in making Healthcare Safer | video and pamphlet illustrating, through scenarios, how patients might be involved in making healthcare safer. 1. Older woman and her daughter initial consultation with specialist 2. Mother and her daughter prior to the child's surgery 3. Man in A&amp;E after trauma | ind | video showing, via 3 different scenarios, how patients can be involved in making healthcare safer pamphlet with written reinforcement of video message talk to your doctors, nurses &amp; pharmacists ask questions don't be afraid that you will bother or insult HCP ask a family member to come with you as an advocate answer all questions about your health as truthfully and completely as possible bring along your current medication be sure to mention all allergies and sensitivities write down the names of all the medications you will receive in the hospital check that the medicine you are about to take matches with what you have written down be sure you understand your discharge instructions before you leave the hospital or clinic | informing the plan monitoring and safe delivery of treatment |
| NPSF 2003: UK | National Agenda for Action: Patients and Families in Patient Safety Nothing About Me, Without Me | describes the NPSF initiative to involve patients and families in systems and patient safety programmes | rep | road map for action in four areas as a call to action for health care providers: education and awareness building a culture of patient and family centred patient safety research support services | informing systems improvements |</p>
<table>
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<th>Source</th>
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<th>Description</th>
<th>Target</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPSF 2003: UK</td>
<td>Consumer Fact Sheet: the role of the patient advocate</td>
<td>describes the role of a patient advocate, formal and informal</td>
<td>ind</td>
<td>advice for patients about the use of advocates</td>
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<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>NPSF 2003: USA</td>
<td>Consumer fact Sheet: preventing infections in the hospital</td>
<td>lists what patients can do to protect themselves from infection in hospital</td>
<td>ind</td>
<td>fact sheet planning ahead for surgery whilst in the hospital following surgery</td>
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<td>informing the plan monitoring and safe delivery of treatment</td>
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</table>
| NPSF 2003: USA | Consumer Fact Sheet: What You Can Do to Make Healthcare safer | lists what patients can do to make healthcare safer | ind | fact sheet become a more informed healthcare consumer  
keep track of your history  
work with your doctor and other healthcare professionals as a team  
volve a family member or friend in your care  
follow the treatment plan agreed upon by you and your doctor |
|         |                                                                      |                                                                             |        | informing the plan monitoring and safe delivery of treatment           |
| NPSF 2003: USA | Consumer Fact Sheet: Safety as you go from Hospital to Home  | lists what patients can do to make the transition from hospital to home safer | ind | fact sheet covering:  
medicine for home follow-up appointments  
home health services  
taking care of yourself when you get home |
|         |                                                                      |                                                                             |        | informing the plan monitoring and safe delivery of treatment           |
| Odom-Forren 2006: USA | Preventing Surgical Site Infections | guidance for nurses to help prevent surgical site infections including involving patients by giving them post-operative advice | ind | advice issued on discharge after a surgical procedure:  
keeping warm by having hot drinks, wearing enough clothes and increasing room temp looking out for and responding to signs of surgical site infection |
<p>|         |                                                                      |                                                                             |        | monitoring and safe delivery of treatment                            |</p>
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<tr>
<th>Reference</th>
<th>Title</th>
<th>Abstract</th>
<th>Study Type</th>
<th>Intervention Type</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Oermann et al 2003: USA</td>
<td>Using the web to improve seniors' awareness of their role in preventing medical errors</td>
<td>describes the development and evaluation of an educational intervention aimed at increasing the awareness of older people of their role in preventing medical errors. Found that the web-based intervention did increase patient knowledge</td>
<td>ind</td>
<td>web-based educational intervention</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<td>Oermann et al 2003: USA</td>
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<td>rep</td>
<td>development and evaluation of web-based educational intervention</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Oermann et al 2005: USA</td>
<td>Using web sites on quality health care for teaching consumers in public libraries</td>
<td>describes a project which educated patients about quality care and patient safety using websites evaluated for quality of information</td>
<td>ind</td>
<td>patient information websites evaluated for quality</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Description</td>
<td>Method</td>
<td>Educational Material</td>
<td>Improvement Focus</td>
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<tr>
<td>O'Keefe, Shaindlin &amp; Eagan (1997: USA)</td>
<td>Patients require safety education regarding polio vaccine</td>
<td>Describes the problem of exposure of immuno-compromised patients to the live polio vaccine and provides details of a fact card given to such patients about how they can avoid this</td>
<td>ind</td>
<td>Educational fact card which provides instructions for immuno-compromised patients to follow</td>
<td>Informing the plan</td>
</tr>
<tr>
<td>O’Neill et al (2004: USA)</td>
<td>Patient misidentification in a pediatric emergency department</td>
<td>Describes a case of mistaken identity at an A&amp;E department and the policies and procedures implemented to reduce the risk of it happening again</td>
<td>ind</td>
<td>Patient and family encouraged to alert staff to a lack of patient ID bracelet or incorrect information on an ID bracelet</td>
<td>Monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Ottewill et al (2006: UK)</td>
<td>Using patient and staff stories to improve risk management</td>
<td>Describes the way staff and patient stories have been used to learn from medical errors</td>
<td>ind</td>
<td>Staff education through patient stories of the experience of being a victim of medical error</td>
<td>Informing systems improvements</td>
</tr>
<tr>
<td>Pane et al (1991: USA)</td>
<td>Notifying patients of adverse drug reactions</td>
<td>Describes a programme at Grand View Hospital to report adverse drug reactions and counsel patients to reduce the risk of them happening again</td>
<td>ind</td>
<td>Medic alert consultation contrast dye reaction card</td>
<td>Informing the plan</td>
</tr>
<tr>
<td>Parish et al (1983: UK)</td>
<td>The elderly and their use of medicines</td>
<td>Describes some of the reasons for adverse medication events for elderly people and some ways to reduce the risk of events including presentation and packaging, use of dosing aids and patient education</td>
<td>ind</td>
<td>Better presentation and packaging dosing aids patient education</td>
<td>Informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Reference</td>
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<td>Description</td>
<td>Indications</td>
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<td>Parkman 2001: USA</td>
<td>Polypharmacy, herbal therapies, and elders</td>
<td>describes some of the issues raised when elderly patients are taking multiple prescribed medications as well as herbal products. Lists safety advice for older people taking herbal therapy.</td>
<td>Indicate herbal therapy safety advice for elders contact HCP if you are experiencing symptoms do not use herbs to delay treatment from traditional HCP follow the prescribed doses make sure ingredients are standardised 'natural' does not necessarily mean harmless never ignore symptoms purchase herbal remedies from a reputable source read labels carefully tell &amp; pharmacist all medication you are taking use same pharmacist for all dispensing</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Pasero &amp; McCaffery 2005: USA</td>
<td>Authorized and unauthorized use of PCA pumps</td>
<td>describes the issues that are raised when patient controlled analgesia stops being patient controlled and suggests strategies such as nurse controlled or family controlled analgesia.</td>
<td>Indicate tips for the safe use of PCA pumps if patient unable to press the button a nurse or designated family member may be instructed in the safe use of PCA monitoring regular evaluation.</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
<td></td>
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<tr>
<td>Patrick et al 1999: USA</td>
<td>A standardized assessment and intervention protocol for managed risk for falls on a geriatric rehabilitation unit</td>
<td>describes the tailored intervention protocols implemented on a geriatric rehabilitation unit for patients assessed as being at risk for falls.</td>
<td>Indicate tailored to need but includes: safe strategies to compensate for functional impairment taught to patient &amp; family compensatory strategies for balance and other deficits safety teaching.</td>
<td>informing the plan informing systems improvements</td>
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<tr>
<td>Authors</td>
<td>Title</td>
<td>Description</td>
<td>Method</td>
<td>Examples</td>
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<td>Paul et al. 2002: UK</td>
<td>Patient Information: involving the user group</td>
<td>Describes a project to improve the provision of patient information at an acute UK trust. This involved the project staff interviewing and surveying patients to ensure the information was developed according to their needs.</td>
<td>rep</td>
<td>Surveys and interviews with patients, involvement of patients in groups with staff undertaking ongoing review and updating of patient information</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Peck 2004: USA</td>
<td>Report to the Agency for Healthcare Research &amp; Quality from the Consumer-Led Workshop to Advance Patient Safety</td>
<td>Describes a consumer-led workshop made up of health consumers and non-consumer stakeholders over three days which aimed to produce a vision, a mission, goals and an action plan and to create a partnership with other stakeholders to improve healthcare safety.</td>
<td>rep</td>
<td>A consumer led workshop comprising health consumers and non-consumer stakeholders</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Pereles et al., 1996: USA</td>
<td>Evaluation of a self-medication program</td>
<td>RCT of self medication in 51 elderly inpatients versus nursing administration.</td>
<td>ind</td>
<td>Intervention group enrolled on a self-medication programme control group medication administered by nursing staff</td>
<td>Monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Phelan 1996: USA</td>
<td>Self-administration of medication by patients and family members during hospitalization</td>
<td>Describes a self-administration medication programme in a nursing unit and review of medication error using this method. Found that this was a safe and effective method of administration.</td>
<td>ind</td>
<td>Self-administration of medication independently or supervised by care partner</td>
<td>Informing the plan informing systems improvements</td>
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<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Description</td>
<td>Informing</td>
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<td>Piotrowski et al 2002: USA</td>
<td>The Safety Case management Committee: Expanding the Avenues for Addressing Patient Safety</td>
<td>describes the development and work of the Safety Case Management Committee at the Ann Arbor Healthcare System which is made up of healthcare managers, front line workers and a consumer representative and aims to develop thematic approaches to improving major systems triggered by unsafe or risky incidents</td>
<td>rep</td>
<td>Safety Case Management Committee informing systems improvements</td>
<td></td>
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<tr>
<td>Polk 1994: USA</td>
<td>Drug interactions with fluoroquinolone antibiotics and patient education</td>
<td>describes the interactions that may occur between fluoroquinolone and other medication/food and the instructions that should be given to patients to help prevent or minimise adverse drug events</td>
<td>ind</td>
<td>patient instructions on package insert informing the plan monitoring and safe delivery of treatment</td>
<td></td>
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<tr>
<td>Ponte 2004: USA</td>
<td>Linking Patient and Family Centred Care and Patient Safety: The Next Leap</td>
<td>describes patient safety rounds at Dana-Farber Cancer Institute</td>
<td>ind</td>
<td>patient safety rounds informing systems improvements</td>
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<tr>
<td>Author(s)</td>
<td>Year</td>
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<tr>
<td>Ponte 2004: USA</td>
<td></td>
<td>Linking Patient and Family Centred Care and Patient Safety: The Next Leap</td>
<td>describes the work at the Dana-Farber Cancer Institute to involve patients and their families in all aspects of care and care processes through the establishment of patient and families advisory councils for both adults and children. Lists a number of patient initiated projects at the Institute and details patient safety rounds</td>
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<tr>
<td>Ponte et al 2003: USA Runy: USA, 2005</td>
<td></td>
<td>Making Patient-centered Care Come Alive: achieving full integration of the patient's perspective 25 things you can do to save lives now</td>
<td>describes how managers at the Dana Farber Institute have incorporated patients' interests in their development of safe care practices as part of their patient centered model of care.</td>
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<tr>
<td>Porter et al 2005: USA</td>
<td></td>
<td>Parents as partners in obtaining the medication history</td>
<td>describes a study which compared the accuracy and completeness of medication history obtained from parents and HCP in the emergency department</td>
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<tr>
<th>Role</th>
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<tr>
<td>rep</td>
<td>patient and family advisory councils</td>
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<td>ind</td>
<td>A representative from the Patient and Family Advisory Council sits on most committees at the Dana Farber Institute</td>
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</tbody>
</table>

<p>| | informing systems improvements |
| | informing the plan |</p>
<table>
<thead>
<tr>
<th>Punekar 2003: USA</th>
<th>Development and validation of a patient medication risk reduction behavior scale and application in a managed care population</th>
<th>RCT of a medication risk reduction behaviour programme in 2000 members of a drug benefit plan</th>
<th>ind</th>
<th>participants given: a brochure with a list of tips for safe medication use a wallet card with space to record medication a set of questions to ask their doctor</th>
<th>monitoring and safe delivery of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quinn 2003: USA</td>
<td>Infusion devices: understanding the patient perspective to avoid errors</td>
<td>describes a study to detect the causes of problems with infusion devices and identify ways of preventing errors. It makes a number of recommendations including giving patients more information about infusion devices</td>
<td>ind</td>
<td>patient information about infusion devices in general and their device and infusion specifically: why it is necessary how it operates how long it would be needed dosage likely problems details of the pumps use warning about alarms, air bubbles and backtracking blood in the tubing</td>
<td>monitoring and safe delivery of treatment informing systems improvements</td>
</tr>
<tr>
<td>Quirk et al 2005: USA</td>
<td>Risk management by patients on psychiatric wards in London: an ethnographic study</td>
<td>describes a study which explored how patients on an acute psychiatric ward use various strategies to maintain a safe environment for themselves when faced with the threat of assault or sexual harassment from interactions with other patients on the ward</td>
<td>ind</td>
<td>strategies to manage risks posed by interaction with other patients on an acute psychiatric ward including: avoiding risky situations or individuals de-escalating potential risky situations seeking safety interventions by staff or increased surveillance protective involvement with other patients</td>
<td>informing the plan informing systems improvements</td>
</tr>
<tr>
<td>Author</td>
<td>Title</td>
<td>Description</td>
<td>Ind</td>
<td>Advice to Patients</td>
<td>Informing the Plan, Monitoring, and Safe Delivery of Treatment</td>
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<tr>
<td>Ragone &amp; Lando 2002: USA</td>
<td>Errors of insulin commission?</td>
<td>describes the errors which can affect patients who are treated with insulin and makes a number of recommendations to help reduce the risk of this occurring</td>
<td>ind</td>
<td>advice to patients about insulin use including: correct storage knowing what type of insulin they use checking injection technique sick day rules checking that the insulin dispensed is the one prescribed</td>
<td>informing the plan, monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Ramosz 2000: USA</td>
<td>Educate Then Medicate</td>
<td>describes the problem of medication errors, what causes them and how they can be avoided including by educating patients</td>
<td>ind</td>
<td>patient education: encouraging patients to share information about their medical history, all medication taken and any previous adverse reactions all HCPs reviewing medication with patients, describing how to take and potential side effects encouraging patients to know their medication, to check the label before taking and to maintain an up to date list of their medication advise not to take medication prescribed for others</td>
<td>informing the plan, monitoring and safe delivery of treatment</td>
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<tr>
<td>Raths, D. 2006: USA</td>
<td>Gateway to success</td>
<td>describes the use of web-portals in healthcare, including as a tool for patients to be involved in promoting their own safety</td>
<td>ind</td>
<td>PatientSite portal which gives patients online access to health records, clinicians reports, lab results, appointments, medication records and medical advice</td>
<td>informing the plan, monitoring and safe delivery of treatment</td>
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<tr>
<td>Author</td>
<td>Title</td>
<td>Describes</td>
<td>Ind</td>
<td>Machine and Information Booklet Design which takes account of range of potential users</td>
<td>Monitoring and Safe Delivery of Treatment Informing Systems Improvements</td>
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<td>Reid &amp; Sawyer</td>
<td>The Human Factors Implications of Peritoneal Dialysis: Cycler Overfill Incident Reports</td>
<td>describes the problem of overfill for patients undergoing peritoneal dialysis and how the risk of this might be minimised though design of equipment and instruction booklets which considers the range of potential users.</td>
<td>ind</td>
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<td>Reiling</td>
<td>Creating a Culture of Patient Safety through Innovative Hospital Design</td>
<td>describes the design of a hospital that focused on patient safety. The process involved patients and families in the design process through focus groups that reviewed plans, viewed and evaluated the mock-up patient room. In addition the design included facilities for families to stay overnight and to enable patient, family and staff access to medical information at the bedside</td>
<td>rep</td>
<td>patient and family representatives involved in the design process</td>
<td>informing systems improvements</td>
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<tr>
<td>Ridley 2003: UK</td>
<td>Dangers need to be pointed out</td>
<td>describes the dangers of EpiPens in inexperienced hands and recommends that prescribers ensure that patients and their families are instructed in the correct administration and handling of the EpiPen</td>
<td>ind</td>
<td>verbal instruction for patient and anyone who might be required to administer adrenalin prescriber should be satisfied that device will be used correctly</td>
<td>monitoring and safe delivery of treatment</td>
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<td>Rindfleisch 2005: USA</td>
<td>La Crosse medical centers take aim at mistakes with safety initiatives</td>
<td>describes the efforts by La Crosse healthcare institutions to improve patient safety including asking patients to play an active role</td>
<td>ind</td>
<td>list of recommendations for patients: keep an up to date list of medications, allergies or adverse reactions and inform all HCPs treating you about them ask about medications you are given in hospital. Make sure they are for you. Make sure your ID is checked before you are given medication. speak up if you have concerns take an advocate to healthcare encounters</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Robinson &amp; Nash 2000: USA</td>
<td>Consumers’ role in patient safety</td>
<td>describes the many interventions recommended for patients to play a role in enhancing their own safety and argues that there is evidence to suggest that most patients are capable of only limited involvement because of their limited understanding of the reasons for medical error. The author recommends that attempts are made to involve patients in processes that directly relate to them such as medications, operations and lab results with the aim of switching the focus from individual blame to processes of care.</td>
<td>ind</td>
<td>involving patients directly in: medication review right site, right operation, right surgery checks lab result chasing</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Rogers et al 2006: USA</td>
<td>Reconciling medications at admission: safe practice recommendations and implementation strategies</td>
<td>describes the medication reconciliation process, patient’s and their families roles in this process and how it can help to reduce the risk of medication error</td>
<td>ind</td>
<td>checking accuracy of information about medication with patients and their families</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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<tr>
<td>Author(s)</td>
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<td>Roizen &amp; Oz 2006: USA</td>
<td>You, the smart patient: an insider's handbook for getting the best treatment</td>
<td>book written by two doctors in conjunction with the Joint Commission to show patients how to take control of their own healthcare</td>
<td>ind</td>
<td>book which patients can buy to help them navigate the healthcare system includes chapters on: making sure that HCPs have all relevant information (tips on how to recognise what is relevant) finding an appropriate HCP and healthcare institution medication safety getting a second opinion details of the patients' bill of rights considering alternative therapies</td>
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<tr>
<td>Rome 2002: USA</td>
<td>Developing a fall-prevention program for patients: making it everyone's business</td>
<td>describes the development, implementation and evaluation of a falls prevention programme at a medical centre</td>
<td>ind</td>
<td>falls prevention programme informing the plan informing systems improvements</td>
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<tr>
<td>Roper 2003: Australia</td>
<td>Consumer perspective employment in the psychiatric service system: a Victorian view on safety issues.</td>
<td>describes the issues and dilemmas faced by consumers of mental health services being employed to provide their perspective on safety within the service and in research departments</td>
<td>rep</td>
<td>employed consumer representatives within the mental health care system informing systems improvements</td>
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<td>Roth 2004: USA</td>
<td>One hospital's approach to sided surgery identification</td>
<td>describes the implementation of a sided surgery identification programme at a healthcare institution.</td>
<td>ind</td>
<td>sided surgery identification process monitoring and safe delivery of treatment</td>
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<tr>
<td>Author(s)</td>
<td>Title</td>
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<td>Ruder, D., 2002: USA</td>
<td>Patients and families make a difference at Dana Farber</td>
<td>describes the work at the Dana-Farber Cancer Institute to involve patients and their families in all aspects of care and care processes through the establishment of patient and families advisory councils for both adults and children.</td>
<td>rep</td>
<td>patient and family advisory councils informing systems improvements</td>
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<tr>
<td>Ruelas 2006: Mexico</td>
<td>Citizens' Quality Councils: An innovative mechanism for monitoring and providing social endorsement of healthcare providers' performance</td>
<td>describes the establishment of citizen groups to monitor quality indicators of health providers as part of the 'National Crusade for Quality in Health Services'.</td>
<td>rep</td>
<td>Citizen Endorsement Groups monitoring quality at healthcare institutions promoting patients' rights informing systems improvements</td>
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<tr>
<td>Ruland 2004: Norway</td>
<td>Improving patient safety through informatics tools for shared decision making and risk communication</td>
<td>describes how informatics tools can support shared decision making and risk communication and thereby play an important role in enhancing patient safety.</td>
<td>ind</td>
<td>informatics tools to support shared decision making and risk communication informing the plan</td>
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<tr>
<td>Ryan et al 2002: USA</td>
<td>Experience with adverse drug reaction reporting program in a neurology speciality clinic</td>
<td>describes an adverse drug reaction reporting program which gathered reports from clinicians, patients and pharmacists</td>
<td>ind</td>
<td>adverse drug reaction reporting system informing the plan monitoring and safe delivery of treatment informing systems improvements</td>
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<td>Sandroff 2004: USA</td>
<td>Protecting yourself from medication error</td>
<td>describes a study by the US Pharmacopeia of medication error and provides a list of tips for individuals to follow to reduce the risk of medication error</td>
<td>list of tips: maintain an up to date list of all your medication, remind your HCP of all medications, including OTC &amp; herbal, you take if your regular medication looks different ask why make sure the right medication has been dispensed know what to do if you miss a dose store medication in the original container if you are staying in a healthcare facility: state your name before taking any medication ask the name of the medication you are being given note regular medication times and ask if any are missed remind HCP if you have any allergies ask a friend or family member to help with monitoring your meds</td>
<td>informing the plan, monitoring and safe delivery of treatment</td>
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<tr>
<td>Sansivero &amp; Murray 1989: USA</td>
<td>Self management of chemotherapy at home</td>
<td>describes the development, piloting and evaluation of an information booklet for patients who were receiving continuous infusion chemotherapy at home</td>
<td>booklet 'Safe Management of Chemotherapy in the Home'</td>
<td>informing systems improvements</td>
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<tr>
<td>Source</td>
<td>Title</td>
<td>Description</td>
<td>Methodology</td>
<td>Setting</td>
<td>Outcomes</td>
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<tr>
<td>Santell and Hicks 2005: USA</td>
<td>Medication Errors Involving Paediatric Patients</td>
<td>Describes the type, scale and causes of medication errors involving paediatric patients. Makes a number of recommendations to minimise the risk including involving parents and families of paediatric patients.</td>
<td>Individually</td>
<td>Parent and family education about medication. Parents and families as information resource for HCP. Parents and families act as a check for safe drug admin by HCP.</td>
<td>Informing the plan, monitoring and safe delivery of treatment.</td>
</tr>
<tr>
<td>Sarudi 2001: USA</td>
<td>A Commitment to Safety</td>
<td>A toolkit for healthcare institutions to prepare for the JCAHO's new patient safety standards. Includes involving patients by explaining to them the anticipated and unanticipated outcomes of treatment and, through patient and staff education, encouraging them and facilitating their involvement in promoting their own safety.</td>
<td>Individually</td>
<td>Patient safety toolkit which includes recommendations on how to involve patients in patient safety. Actions for patients might be: share with HCP information about medication, allergies and adverse reactions. Ask for written information about possible side effects. Choose a hospital with experience of treating your condition. Ask a relative of friend to be an advocate. Make sure written prescriptions are legible. Ask for a plan before being discharged home.</td>
<td>Informing the plan, monitoring and safe delivery of treatment.</td>
</tr>
<tr>
<td>Author</td>
<td>Title</td>
<td>Description</td>
<td>Indications</td>
<td>Outcomes</td>
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<tr>
<td>Sass 2003: USA/Germany</td>
<td>New Options for Health Care Policy and Health Status Insurance: Citizens as Customers</td>
<td>argues for fundamental changes in the way health care systems operate, moving away from disease management to a situation where consumers are supported to manage their own health care throughout their lives with varying input from HCPs. Emphasises that the improvement of health care literacy is vital for this.</td>
<td>ind</td>
<td>eight health care rules for the lay person including recognising the risks and limitations of medical interventions, finding educated and trustworthy HCPs and developing healthcare competency and responsibility</td>
<td></td>
</tr>
<tr>
<td>Sawicki 1999: Germany</td>
<td>A structured teaching and self-management program for patients receiving oral anticoagulation</td>
<td>describes a trial of self-management of anticoagulation versus usual care via primary care physicians. Found that self management by patients led to better anticoagulant control and improved quality of life</td>
<td>ind</td>
<td>anticoagulation self-management</td>
<td></td>
</tr>
<tr>
<td>Scalise 2003: USA</td>
<td>Watch Yourself: Five steps to safer healthcare</td>
<td>describes AHRQ's poster 'Five steps to safer healthcare'. Being distributed by the American Hospital Association to healthcare providers around the USA</td>
<td>ind</td>
<td>poster 'Five Steps to Safer Healthcare' which encourages patients to: ask questions get the results of any tests they have keep and bring a list of all medication to each healthcare encounter talk to their doctor about which hospital is best for their health needs make sure they understand what will happen if they need surgery</td>
<td></td>
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</table>

Anonymous 2003: USA | Watch Yourself: Five steps to safer healthcare | describes AHRQ's poster 'Five steps to safer healthcare'. Being distributed by the American Hospital Association to healthcare providers around the USA | ind | poster 'Five Steps to Safer Healthcare' which encourages patients to: ask questions get the results of any tests they have keep and bring a list of all medication to each healthcare encounter talk to their doctor about which hospital is best for their health needs make sure they understand what will happen if they need surgery |

informing the plan monitoring and safe delivery of treatment

monitoring and safe delivery of treatment

informing the plan monitoring and safe delivery of treatment
<table>
<thead>
<tr>
<th>Author</th>
<th>Title</th>
<th>Description</th>
<th>Participants</th>
<th>Monitoring and safe delivery of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schnipper 2006: USA</td>
<td>Role of pharmacist counselling in preventing adverse drug events after hospitalization</td>
<td>RCT comparing pharmacist medication counselling of 92 inpatients with usual care by ward staff</td>
<td>ind participants on a general medical ward were given medication counselling by a pharmacist</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Schwartz 1975: USA</td>
<td>Safe, self-medication for elderly outpatients</td>
<td>describes how medication error or other adverse medication event can occur for older patients and how this might be avoided</td>
<td>ind assessment, review and education</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Schwartzberg 2002: USA</td>
<td>Low Health Literacy: What do your patients really understand?</td>
<td>describes how low health literacy in patients is linked to poor health, more hospitalisation, low compliance and medical errors. Recommends that giving patients instructions involves checking understanding and lists ways to achieve this</td>
<td>ind list of 'simple ways to improve health literacy and patient communication' improve verbal communication modify written language create a shame free environment use available resources</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Senst &amp; Johnson 1997: USA</td>
<td>Latex allergy</td>
<td>describes latex allergy, how it is diagnosed, methods for preventing reactions and reducing exposure including education, use of medic-alert and allergy bracelets.</td>
<td>ind education medic-alert bracelet</td>
<td>informing the plan</td>
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<tr>
<td>Reference</td>
<td>Title</td>
<td>Description</td>
<td>Individuation</td>
<td>Outcome</td>
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<tr>
<td>Shaw et al 2004: UK</td>
<td>Adverse events reporting in English hospital statistics: Patients should be involved as partners</td>
<td>describes how involving patients as partners in decisions about and management of drug treatment acts as a safeguard against errors</td>
<td>ind</td>
<td>open discussion of medication by HCPs &amp; patients fold out, credit card sized record card for listing medication. 'Ask about Medicines' promotion to encourage partnership between medication users, carers and HCPs informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Siderov 2005: Australia</td>
<td>What's in a name? Lack of pronunciation in Consumer Medicine Information</td>
<td>describes a review to determine if drug information inserts contained a pronunciation guide as mispronunciation of a medication name can lead to erroneous prescribing</td>
<td>ind</td>
<td>pronunciation guide on medication pack inserts informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Siebenhofer et al 2003: Austria</td>
<td>Systematic Review of studies of self-management of anticoagulation</td>
<td>reviews four studies of anticoagulation self-management. Concludes that self management of anticoagulation achieved better control and higher quality of life scores than management by primary care physician</td>
<td>ind</td>
<td>anticoagulation self-management monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Siebens &amp; Randall 2005: USA</td>
<td>The Patient Care Notebook: from pilot phase to successful hospital-wide dissemination</td>
<td>describes the development and implementation of a patient care notebook which patients take with them to encounters with different HCPs</td>
<td>ind</td>
<td>patient care notebook containing both general and personalised information which can be taken to different care settings informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Author</td>
<td>Title</td>
<td>Description</td>
<td>Induction</td>
<td>System Impact</td>
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<tr>
<td>Simpson 1980: New Zealand</td>
<td>Medication and the elderly, the nurse’s role</td>
<td>describes the problem of adverse drug events for older people and how the risk of these might be reduced through education</td>
<td>ind</td>
<td>education assessment of ability to safely self medicate</td>
</tr>
<tr>
<td>Singh et al 2005: USA</td>
<td>Computer visualisation of patient safety in primary care: a systems approach adapted from management science and engineering</td>
<td>describes the development of a model, using a systems engineering approach, for understanding the causes of error in primary care. Patients could be helped to understand their role within this system so empowering them to advocate for themselves.</td>
<td>ind</td>
<td>model for understanding causes of error in primary care accessible to patients</td>
</tr>
<tr>
<td>Sipilainen 2005: Finland</td>
<td>Design of a washroom and WC for healthcare facilities</td>
<td>describes the design of a washroom and WC to fulfil the requirements of different users of healthcare facilities</td>
<td>ind</td>
<td>consultation with HCPs, carers and patients on design and evaluation of washroom &amp; WC</td>
</tr>
<tr>
<td>Sirio 2005 (ongoing): USA</td>
<td>Enhanced patient safety intervention to optimize medication education</td>
<td>describes an ongoing project to evaluate the hospital wide implementation of a multi-modal patient medication education system</td>
<td>ind</td>
<td>medication education programme</td>
</tr>
<tr>
<td>Sivertsen &amp; Fletcher 1982: USA</td>
<td>Assisting the elderly with drug therapy in the home</td>
<td>an assessment guide for HCPs to use in patient’s homes to help reduce the risk of adverse medication event</td>
<td>ind</td>
<td>assessment, review and education</td>
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<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Title</th>
<th>Description</th>
<th>Indicators</th>
<th>Monitoring and Safe Delivery of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slaninka &amp; Galbraith 1998: USA</td>
<td>Healthy endings: A collaborative health promotion project for the elderly</td>
<td>describes a health promotion project where the objectives included safety</td>
<td>ind weekly health promotion programmes covering topics such as: health screening, exercise, medication compliance and safety</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Smetzer 2001: USA</td>
<td>Medication Error Prevention Techniques for the Bedside Nurse</td>
<td>describes techniques which may be adopted by nurses to reduce bedside medication error including enlisting the help of patients</td>
<td>ind reminding patients that anyone giving them tablets should check their identity first enlist the help of pharmacist to educate patients about their medication, dosing schedule and any potential adverse effects</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Smith 2005: USA</td>
<td>Patient Safety: the case manager</td>
<td>describes the patient safety movement, the scale of medical errors and what case managers can do to reduce the risk of medical error for their patients</td>
<td>ind education review of medication encouragement to speak up &amp; question</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Spath 2002: USA</td>
<td>target: patient safety</td>
<td>describes the revised Joint Commission patient safety standards and what health care organisations need to do to meet them including partnering with patients and families</td>
<td>ind partnering with patients and families to improve the standard of healthcare by: checking patient ID with them prior to giving meds tell patients what to look out for after a procedure or medication make sure everyone on the patient’s team is well informed let patients know how they can help to prevent medical error</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
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</table>
Can you hear me now? Providers must give patients a voice in efforts to reduce medical error. Spath 2003: USA

<p>| Spath 2003: USA | Can you hear me now? Providers must give patients a voice in efforts to reduce medical error | describes how patient involvement in reducing medical error requires facilitation from HCPs and change in health care organisational culture. Lists things patients can do to contribute to healthcare safety and describes a number of ways these tips can be presented to patients including brochures, videos and via the internet | ind list of tips for patients: remind HCPs to check identity, speak up if you think you have been confused with someone else, share relevant information with all HCPs, ask questions about treatment &amp; discharge plan, remind HCPs to mark op site, find out why tests/treatments are needed, ask for help getting out of bed, inform HCPs about reactions to meds, speak up if you are concerned | informing the plan monitoring and safe delivery of treatment |
| Starr 2001: USA | Protecting your patients from medical errors | describes the problem of medical error for children being treated in and out of hospital and details actions that can be taken to reduce the risk including a guide for parents. | ind | guide for parents: be a member of the healthcare team share information about your child's current medication, allergies and adverse reactions make sure you can read any prescriptions written for your child make sure you understand what a prescribed medication is, how it should be taken, what it is for and what side effects it may cause clarify instructions on drug labels ask about measuring devices choose a hospital which has experience treating your child's condition ask HCPs coming into contact with your child if they have washed their hands ask for a discharge plan speak up make sure someone is in charge make sure all HCPs have relevant info about your child enlist help if you have any doubts about your ability to advocate for your child more is not always better if your child has had a test find out the result learn about your child's condition informing the plan monitoring and safe delivery of treatment |</p>
<table>
<thead>
<tr>
<th>Stewart 2000: Canada</th>
<th>Preventing medication errors</th>
<th>describes the patient's role in preventing medication error includes a list of recommendations for patients</th>
<th>list of recommendations: maintain an up to date list of all medication you are taking including herbal &amp; OTC. Include any allergies and adverse reactions. Share with HCPs make sure you know the name, purpose and dosage instructions of any medication before you leave the doctor's office be aware of the brand and generic name of your medication raise concerns if your medication looks different, if you experience any unexpected side effects read the label before you take the medication check the doses and active ingredients of non-prescription drugs ask about medications you are given in hospital, if you are not well enough ask someone to go with you and act on your behalf</th>
<th>informing the plan monitoring and safe delivery of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storr, J. Hookway, J. 2005: UK</td>
<td>Preventing infection in hospital - should patient involvement be central to current hand hygiene strategies?</td>
<td>describes a pilot project to inform the implementation of the NPSA's 'cleanyourhands campaign'</td>
<td>patients encouraged to ask HCPs if they have washed their hands before touching them</td>
<td>monitoring and safe delivery of treatment informing systems improvements</td>
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<tr>
<td>Author</td>
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<td>Indicators</td>
<td>Notes</td>
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<tr>
<td>Stucky, 2003: USA</td>
<td>Prevention of Medical Errors in the Paediatric Inpatient Setting</td>
<td>Describes the published guidelines available online with a section for parents describing how they can help to prevent medical errors during their child's hospital stay</td>
<td>Indirectly parents are advised to: share relevant information with HCPs about allergies, adverse reactions, other medication, any complementary therapies or alternative medicines, any difficulty taking medication, make sure they know the names of their child's meds as well as the dosing regime, strengths, any possible adverse effects, check that HCPs have checked their child's identity before administering any meds, ask questions about the purpose of each med to be used</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Sung et al 2006: USA</td>
<td>Direct reporting of laboratory test results to patients by mail to enhance patient safety</td>
<td>describes a study to assess the interest of physicians in the provision of direct lab reports to patients by mail. Physicians expressed interest in this intervention especially as they thought it would reduce workload &amp; ensure important results were not missed. However, they were concerned about frightening patients and that they would seek unreliable information (e.g.: online) to explain results</td>
<td>Indirectly direct reporting of test results to patients by post</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Tahan 2005: USA</td>
<td>Identifying and reducing risk of medical errors</td>
<td>describes case management as a process to reduce or prevent the risk of medical error</td>
<td>ind</td>
<td>case manager acts as advocate for patient and family and encourages them to speak up, question and be involved</td>
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<tr>
<td>Thompson 1982: USA</td>
<td>Teaching the client about anticoagulants</td>
<td>describes an education programme for patients taking anticoagulants</td>
<td>ind</td>
<td>education programme for patients taking warfarin includes advice about: diet medication schedule bleeding bruising medication storage missed doses drug interactions when to contact HCPs sharing info about medication with other HCPs preventing injury patients are given a calendar where they can record doses taken as well as blood results</td>
</tr>
<tr>
<td>Traynor 2003: USA</td>
<td>Adverse events occur after hospital discharge, study finds</td>
<td>describes a study that revealed that one in five patients suffer adverse events within 5 weeks after discharge. Recommends strategies to remedy this</td>
<td>ind</td>
<td>educating patients about their drug therapy prior to discharge monitoring patient progress after discharge possibly with a follow-up call from a pharmacist to review medication</td>
</tr>
<tr>
<td>Trewyn &amp; Sneider 2005: USA</td>
<td>Healing by design: New hospitals create places that improve patient outcomes</td>
<td>describes the design and building of three Wisconsin Hospitals focusing on patient safety</td>
<td>rep</td>
<td>two day forum which gathered physicians, nurses, staff members, patients and patient safety experts from around the country to have a say in hospital design consultation with patients their families and staff to improve quality and safety in new hospital design</td>
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<td>Source</td>
<td>Title</td>
<td>Description</td>
<td>Indication</td>
<td>Additional Information</td>
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<tr>
<td>Troller 1989: Australia</td>
<td>A drug information system: the patients' responses</td>
<td>describes the implementation and evaluation of drug information sheets given to patients by a GP</td>
<td>ind</td>
<td>drug information sheet detailing trade &amp; generic name, indication, contraindications, potential side effects, possible interactions, how taken, when &amp; how to consult HCP.</td>
</tr>
<tr>
<td>Trotto 2001: USA</td>
<td>They all fall: strategies for reducing falls among the elderly</td>
<td>describes steps that can be taken to minimise the risk of patient falls in a healthcare facility including educating patients</td>
<td>ind</td>
<td>falls prevention programme which includes education for patients about: safe transfer techniques the importance of moving slowly from sitting/lying to standing wearing any vision aids using handrails</td>
</tr>
<tr>
<td>Turcasso &amp; Weart 2000: USA</td>
<td>Managing polypharmacy issues</td>
<td>describes the problem of polypharmacy for elderly patients and suggests strategies for avoiding these problems including patent education and safety promoting aides</td>
<td>ind</td>
<td>patient education, with verbal and written information making sure patients know about their condition and medications safety aides such as dosette boxes, charts</td>
</tr>
<tr>
<td>University of California at Berkeley, 2005: USA</td>
<td>Why the pharmacist matters</td>
<td>describes pharmacists as an under-used resource and urges patients to adopt a regular pharmacist and use his/her skills. Moves on to list behaviours which will reduce the risk of medication error</td>
<td>ind</td>
<td>use of a regular pharmacist list of recommendations for safe medication use</td>
</tr>
<tr>
<td>VA National Centre for Patient Safety 2006: USA</td>
<td>Understanding Your Surgery: Ensuring Correct Surgery</td>
<td>pamphlet which aims to 'help you understand what will happen before your surgery and how your doctors and nurses are taking steps to make sure everything goes as planned'</td>
<td>ind</td>
<td>pamphlet containing information about what to expect in the days and hours leading up to a surgical procedure including suggested questions to ask to become better informed</td>
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<tr>
<td>van Ganse et al., 2005: France</td>
<td>A large simple clinical trial prototype for assessment of OTC drug effects using patient-reported data</td>
<td>a study to assess the usefulness of patient generated data about adverse drug events</td>
<td>rep</td>
<td>8633 patients were randomised to one of 3 analgesics available over the counter for mild to moderate pain for 7 days. They recorded any adverse events in a diary</td>
</tr>
<tr>
<td>van Grootheest 2005: Netherlands</td>
<td>Pharmacovigilance in the Netherlands - Involvement of Health Professionals and Patients</td>
<td>describes the initiation and progress of an adverse drug event reporting system in the Netherlands open to both HCPs and patients</td>
<td>ind</td>
<td>patients and HCPs report adverse drug events on an online system</td>
</tr>
<tr>
<td>van Grootheest et al 2005: Netherlands</td>
<td>Direct reporting of side effects by patients: positive experiences of the first year</td>
<td>describes an evaluation of patient and HCP reporting of medication adverse effects between April 2003 and March 2004. Concluded that information obtained from patients is reliable and they would continue to collect this information</td>
<td>ind</td>
<td>web based reporting system open to patients and health care professionals</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Summary</td>
<td>Methodology</td>
<td>Conclusion</td>
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<tr>
<td>Van Grootheest &amp; de Jong-van den Berg 2004: Netherlands</td>
<td>Patients' role in reporting adverse drug reactions</td>
<td>reviews the literature about patients' reporting of adverse drug events, decides that there is not enough evidence to evaluate the effectiveness of this but concludes that from the Dutch experience patient reports should be accepted as a serious source of information both contributing to existing information about drug adverse effects and raising patient awareness.</td>
<td></td>
<td>ind direct patient reporting of adverse drug effects</td>
</tr>
<tr>
<td>Van haecht et al 1990: Belgium</td>
<td>Package inserts for antihypertensive drugs: use by the patients and impact on adverse drug reactions</td>
<td>describes a study that compared patient and physician orientated drug package inserts, their use by patients and their impact on adverse drug event reporting. Found that reading package inserts did not increase the number of side effects reported by patients but made them more likely to attribute side effects to medication especially those patients with a lower level of education.</td>
<td>ind patient package insert in all packets of medication questionnaire administered by GP about adverse drug effects</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Title and Location</td>
<td>Summary</td>
<td>Ind</td>
<td>Notes</td>
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<tr>
<td>Van Hecht 1991: Belgium</td>
<td>Impact of patient package inserts on patients satisfaction, adverse drug reactions and risk perception: The case of NSAIDS for posttraumatic pain relief</td>
<td>RCT comparing traditional and simplified patient package insert for NSAIDs</td>
<td>ind</td>
<td>traditional drug package insert replaced by insert which used lay terminology, explicit headings and simple syntax</td>
</tr>
<tr>
<td>van Kanegan and Boyette (2003)</td>
<td>How to survive your hospital stay: the complete guide to getting the care you need - and avoiding the problems you don't</td>
<td>describes the problem of medical errors, why they occur and how to avoid them</td>
<td>ind</td>
<td>patient advisory (book)</td>
</tr>
<tr>
<td>Vincent &amp; Coulter 2002: UK</td>
<td>Patient Safety: what about the patient?</td>
<td>describes the roles patients can play in improving safety in medical care</td>
<td>ind</td>
<td>patients could be involved in: helping to reach an accurate diagnosis, deciding on an appropriate treatment or management strategy, choosing a suitably experienced and safe provider, ensuring that treatment is going to plan, identifying side effects or adverse events quickly and taking action</td>
</tr>
<tr>
<td>Virginians Improving Patient Care and Safety 2001: USA</td>
<td>Be Involved in Your Health Care: Tips to Help Prevent Medical Errors</td>
<td>lists action patients can take to help reduce the risk of patient safety events</td>
<td>ind</td>
<td>tip sheet with advice about: medicines, hospital stays, surgery, home health equipment, other steps you can take</td>
</tr>
<tr>
<td>Vitense 2005: USA</td>
<td>Promoting patient safety within implantable medical devices: patient alert</td>
<td>describes a study to evaluate patients' roles in internal defibrillator system checks</td>
<td>ind</td>
<td>audible alarm after routine system checks which are designed to alert patients to a problem and encourage them to attend clinic for the problem to be resolved</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Overview</td>
<td>Method</td>
<td>Implications</td>
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<tr>
<td>Volans 1987: Australia</td>
<td>Monitoring the safety of over the counter drugs</td>
<td>describes the inadequate safety monitoring of over the counter medication and argues that this could be improved in a number of ways including education of the public through package inserts, pharmacists and prescribers</td>
<td>Ind</td>
<td>education through package inserts and advice from pharmacists and prescribers</td>
</tr>
<tr>
<td>Wald et al 2001: USA</td>
<td>Requirements Development for a Patient Computing System</td>
<td>describes the approach adopted towards developing a web-based system that connects patients electronically with their physicians’ offices. This involved use of a patient focus group to test the system and discuss issues such as confidentiality, technology and ageing and the use of e-mail to contact physicians</td>
<td>Rep</td>
<td>patient focus group reviewed mock-up of system and discussed potential problems/issues</td>
</tr>
<tr>
<td>Wald et al 2001: USA</td>
<td>Requirements Development for a Patient Computing System</td>
<td>describes the proposed elements of a web-based system which connects patients directly with their physicians’ offices</td>
<td>Ind</td>
<td>patient computing system which enables patients to: communicate with HCPs have access to health &amp; disease information see certain aspects of their medical records</td>
</tr>
<tr>
<td>Author</td>
<td>Title</td>
<td>Study Details</td>
<td>Findings</td>
<td>Notes</td>
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<tr>
<td>Wale, J.B., 2005: USA</td>
<td>Engaging Patients and Family Members in Patient Safety - the experience of the New York City Health and Hospitals Association</td>
<td>describes initiatives undertaken by the corporation to increase the involvement of patients and family members in the delivery of mental health services</td>
<td>provision of information brochures about inpatient services, personalised treatment plans developed with input from patient and family with individualised de-escalation techniques, use of peer counsellors as part of clinical team, provision of parent advocates for parents of children &amp; adolescents with mental health problems</td>
<td>informing the plan, informing systems improvements</td>
</tr>
<tr>
<td>Watzke 2000: Austria</td>
<td>A Prospective Controlled trial comparing weekly self testing and self-dosing with the standard management of patients on stable oral anticoagulation</td>
<td>compares self management of anticoagulation therapy by patients with standard management in an anticoagulation clinic</td>
<td>102 patients were allocated to either an intervention or control group. Intervention group were taught how to self-test and self dose at home, they were instructed to test weekly rather than the usual monthly/bi-monthly</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Weingart 2001-7 ongoing: USA</td>
<td>Partnering with Patients to Find Adverse Events</td>
<td>describes a proposal to evaluate patient reporting of adverse events within the inpatient and outpatient settings</td>
<td>inpatient reporting of medical errors, outpatient reporting of medication errors through internet based system</td>
<td>informing systems improvements</td>
</tr>
<tr>
<td>Weingart et al 2004: USA</td>
<td>Lessons from a patient partnership intervention to prevent adverse drug events</td>
<td>Partnering with hospitalized patients to monitor medication use is a feasible strategy for reducing drug errors</td>
<td>intervention patients given drug safety information and their medication list controls just given drug safety information</td>
<td>monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>AHRQ, 2005</td>
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<tr>
<td>Reference</td>
<td>Title</td>
<td>Description</td>
<td>Target Group</td>
<td>Outcomes</td>
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<tr>
<td>Weingart et al 2005: USA</td>
<td>What Can Hospitalized Patients Tell Us About Adverse Events? Learning From Patient-Reported Incidents</td>
<td>describes a study that elicited incident reports from patients to identify and characterise adverse events and near misses. It found that patients are capable of identifying adverse events affecting their care. Many of these were not captured by the hospital incident reporting system or the patient's individual medical record.</td>
<td>ind</td>
<td>patients reported adverse events to a reporting system</td>
</tr>
<tr>
<td>Weiss 2003: USA</td>
<td>Enlist patients in error prevention</td>
<td>describes AHRQ's efforts to encourage HCPs to involve patients by encouraging questions and giving information in the form of a fact sheet (20 tips to help prevent medical errors’) and others. Also directs patients and HCPs to further sources of similar information.</td>
<td>ind</td>
<td>list of recommendations for patients to follow</td>
</tr>
<tr>
<td>Wera 1980: France</td>
<td>Educational role and responsibilities of the pharmacist</td>
<td>describes the patient role in safe medication use including sharing information about themselves with prescribers and using non-prescription drugs wisely.</td>
<td>ind</td>
<td>patients sharing information about their medication and allergy history with prescribers and using OTC medication sensibly</td>
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<thead>
<tr>
<th>Source</th>
<th>Title</th>
<th>Description</th>
<th>Type</th>
<th>Implementation</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wertenberger 2005: USA</td>
<td>The Development of a Patient Safety Programme Across the Continuum of Care</td>
<td>describes a primary care based intervention to prevent falls and medication errors for at risk patients after discharge from secondary care</td>
<td>ind</td>
<td>patient assessment and education evaluation of home environment follow-up via camera phone</td>
<td>informing the plan monitoring and safe delivery of treatment informing systems improvements</td>
</tr>
<tr>
<td>Wetherell, R. &amp; Wetherell, A, 2004: UK</td>
<td>Special report: mental health. Service-user involvement in risk management within mental health care</td>
<td>describes the use of personal safety plans with service users and their participation in risk management</td>
<td>ind</td>
<td>personal safety plan used by service users to document their needs and views</td>
<td>informing the plan informing systems improvements</td>
</tr>
<tr>
<td>WHO 2005: International</td>
<td>World Alliance for Patient Safety Forward Programme 2005</td>
<td>describes the World Alliance for Patient Safety action areas including involving patients and consumers</td>
<td>rep</td>
<td>Patients for Patient Safety which will establish an inventory of current patient and consumer involvement initiatives being implemented create routes of access for participation for patients and consumers facilitate a baseline survey of consumers and providers support initiatives to design and evaluate programmes for consumer &amp; patient involvement develop model policies &amp; guidelines for patient and consumer involvement create a network of advisors from the healthcare consumer network that want to apply the philosophy within patient safety initiatives</td>
<td>informing systems improvements</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>WHO 2006: International</th>
<th>London Declaration: Patients for Patient Safety</th>
<th>declaration made by Patients for Patient Safety in November 2005 to be the voice of all patients in the movement to create a world in which healthcare harms fewer patients</th>
<th>rep declaration of intent including: collaboration in devising &amp; promoting programmes for patient safety &amp; empowerment developing &amp; driving a constructive dialogue with all partners concerned establishing systems for reporting and dealing with healthcare harm on a world wide basis defining best practices that deal with healthcare harm of all kinds and promote these practices world wide</th>
<th>informing systems improvements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wiegman and Cohen 1999: USA</td>
<td>The Patient's Role in Preventing Medication Errors</td>
<td>describes what patients can do to decrease the possibility that they will experience a medical error. Includes a list of questions patients should ask when they receive a medication in hospital or pharmacy and how they can make sure they don't receive medication meant for someone else. Also highlights groups of patients who are at higher risk of experiencing a medication error such as children or the elderly.</td>
<td>ind a number of interventions including: twelve basic questions about the name and nature of the medication, how it should be taken and what to expect from it patient maintained, up to date record of current medication checking that HCP is giving right medication to right patient taking an advocate to hospital if too unwell to speak up use of medication schedule for older patients sharing relevant information about previous allergies/adverse reactions with all HCPs</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Author</td>
<td>Title</td>
<td>Description</td>
<td>Methodology</td>
<td>Results</td>
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<tr>
<td>Willeumier 2004: USA</td>
<td>Advocate Health Care: a system wide approach to quality and safety</td>
<td>describes the implementation and evaluation of the safety strategy at one healthcare institution includes involvement of patient representatives</td>
<td>ind/re rep</td>
<td>patient input sought through inpatient interviews; quarterly focus groups and mailed surveys; families invited to participate in ethics conferences to examine patient safety events; patient safety hotline for reporting potential safety issues</td>
</tr>
<tr>
<td>Williams 2004: UK</td>
<td>Learning from mistakes</td>
<td>describes the scale and nature of medical mistakes in the NHS, reports the findings from six discussion groups about how patient care could be made safer, provides a list of tips for patients and comments that involving patients in safety promotion will require a considerable culture shift and a clearer role definition</td>
<td>rep</td>
<td>six discussion groups, four made up of people who had regular contact with NHS and two of people who had used the NHS within the last six months but not regularly</td>
</tr>
</tbody>
</table>

informing systems improvements
<table>
<thead>
<tr>
<th>Author(s) (Year)</th>
<th>Title</th>
<th>Description</th>
<th>Ind</th>
<th>Tips for Patients</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Williams 2004</td>
<td>Learning from Mistakes describes the scale and nature of medical mistakes in the NHS, reports the findings from six discussion groups about how patient care could be made safer, provides a list of tips for patients and comments that involving patients in safety promotion will require a considerable culture shift and a clearer role definition.</td>
<td></td>
<td>List of tips for patients: take a list of questions to consultations, take notes or ask a friend to accompany you, tell your doctor about any meds you are taking, including OTC &amp; herbal, share information about your medical history and any allergies, previous adverse reactions, ask for clarification if you don't understand, tell the pharmacist if the medication you are given is not what you expected, let your doctor know if medication is causing side effects or not working, chase up test or scan results, ask to review GP &amp; hospital notes, referral letters and results to make sure they are accurate.</td>
<td>Informing the plan, monitoring and safe delivery of treatment.</td>
<td></td>
</tr>
<tr>
<td>Winokur &amp; Beauregard 2005</td>
<td>Patient Safety: mindful, meaningful and fulfilling</td>
<td>Description of the pursuit of a culture of patient safety at William Beaumont Hospital including examples of the roles patients play in this.</td>
<td>Patient and their families are given the 'Partners in Safety' Brochure which outlines patient responsibilities such as: ask questions, raise concerns, know medication, take part in decisions, educate yourself.</td>
<td>Informing the plan, monitoring and safe delivery of treatment.</td>
<td></td>
</tr>
<tr>
<td>Winokur &amp; Beauregard 2005</td>
<td>Patient Safety: mindful, meaningful and fulfilling</td>
<td>Description of the pursuit of a culture of patient safety at William Beaumont Hospital including examples of the roles patients play in this.</td>
<td>Patients and their families are involved in the design of key processes such as: patient ID process, handover/transfer process, prevention of infant abduction, medication administration process, infection control.</td>
<td>Informing systems improvements.</td>
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<tr>
<td>Reference</td>
<td>Title</td>
<td>Description</td>
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<td>Goals</td>
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<tr>
<td>Wise 1997: USA</td>
<td>Reducing patient falls: three strategies, one goal</td>
<td>describes different strategies to prevent falls in three different areas of one healthcare facility. One strategy involves educating patients at risk of falls and their families. Patients taught how to get up after a fall, how to summon help as well as how to avoid falls.</td>
<td>ind</td>
<td>informing system improvements</td>
<td></td>
</tr>
<tr>
<td>Wolverton 1992: USA</td>
<td>Monitoring for adverse effects from systemic drugs used in dermatology</td>
<td>describes the safety monitoring process for 8 major drugs/drug groups used in dermatology. This involves significant patient involvement in reporting key signs or symptoms that facilitates early diagnosis of often potentially serious adverse effects.</td>
<td>ind</td>
<td>monitoring and safe delivery of treatment</td>
<td></td>
</tr>
<tr>
<td>Wood et al 1999: Australia</td>
<td>Falls: a coordinated strategy</td>
<td>describes a response to the issue of falls at one healthcare institution which included staff and patient education and interventions.</td>
<td>ind</td>
<td>informing the plan</td>
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<tr>
<td>Woods 2003: USA</td>
<td>How to use your medicine safely</td>
<td>a patient education guide written at 5th grade level advising patients about medication safety</td>
<td>ind</td>
<td>patient education guide to safe medication-taking advises to: share information ask about new meds tell the prescriber if you think you will have trouble taking a medication check the label take as instructed store as instructed keep in original container when in hospital: ask what you are being given make sure your identity is checked ask for a pre-discharge review for a child: know your child's weight ask about dosing devices ask about side effects and when to seek help (includes a blank medication wallet card)</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Wooten 2005: USA</td>
<td>Polypharmacy. Keeping the elderly safe</td>
<td>describes how pharmacists can help to reduce the risk of adverse reaction to medication in older patients including 'brown bagging' and patient education</td>
<td>ind</td>
<td>brown bag' approach - patients encouraged to bring all their medication to each HCP encounter (including OTC &amp; herbal meds) teaching patients about medication and expected side effects encouraging patients to use the same pharmacists</td>
<td>informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Author</td>
<td>Year</td>
<td>Country</td>
<td>Study Description</td>
<td>Methodology</td>
<td>Recommendations/Initiatives</td>
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<tr>
<td>Wootton</td>
<td>1975</td>
<td>UK</td>
<td>Prescription for Error describes a study that explored patient's medication taking and their interpretation of instructions for medication taking. Found wide variation, misinterpretation and unsafe practice. Recommends personalised drug cards for all patients.</td>
<td>ind</td>
<td>Informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Yates</td>
<td>2004</td>
<td>USA</td>
<td>Sentara Norfolk General Hospital Accelerating Improvement by Focusing on Building a Culture of Safety describes the patient safety initiatives at one health care institution includes a number of patient involvement initiatives</td>
<td>ind/re p</td>
<td>Brochure and video encouraging patients to ask questions using focus groups to gain patient input into design of facilities provision of a patient advocacy programme so patients and their families can report concerns about care or safety</td>
</tr>
<tr>
<td>Yeager</td>
<td>2005</td>
<td>USA</td>
<td>Measured response to identified suicide risk and violence: what you need to know about psychiatric patient safety describes a number of ways that risk of harm can be reduced on psychiatric inpatient wards including involving recovering patients as consumer volunteers use of peer interaction between inpatients and volunteer consumers who may be perceived by patients as less threatening and more understanding to their needs</td>
<td>rep</td>
<td>Informing the plan monitoring and safe delivery of treatment informing systems improvements</td>
</tr>
<tr>
<td>Yunker</td>
<td>1990</td>
<td>USA</td>
<td>Patient self-medication on a rehabilitation unit describes a self-medication programme on a rehabilitation unit self-medication programme for inpatients on a rehabilitation unit, part supervised, part unsupervised. Training and support delivered by pharmacist and nursing staff</td>
<td>ind</td>
<td>Informing the plan monitoring and safe delivery of treatment</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Description</td>
<td>Methodology</td>
<td>Findings</td>
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<tr>
<td>Zipperer 2003: USA</td>
<td>Consumer Health Librarians and Patient safety: An Awareness Role?</td>
<td>describes strategies consumer health librarians might adopt to involve patients in safety promotions. Includes patient safety education materials from various organisations</td>
<td>ind</td>
<td>various patient involvement in patient safety resources such as online materials from AHRQ and NPSF resources for patient advisory councils promotion of resources in the community prior to patient contact with hospitals informing the plan monitoring and safe delivery of treatment informing systems improvements</td>
<td></td>
</tr>
<tr>
<td>Zurita and Nohr, 2004</td>
<td>Patient Opinion – HER assessment from the users perspective</td>
<td>describes a project which evaluated electronic health records from a patient perspective</td>
<td>rep</td>
<td>patient feedback via interviews and focus groups informing systems improvements</td>
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### Appendix 1.4: Comments and opinion pieces

<table>
<thead>
<tr>
<th>author</th>
<th>title</th>
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<tbody>
<tr>
<td>ACP 2004</td>
<td>Patient safety: the other side of the quality equation</td>
<td>Describes seven learning modules focusing on important aspects of safety in ambulatory care: includes 'The role of the patient'</td>
<td>USA</td>
</tr>
<tr>
<td>Adams &amp; Boscarino 2004</td>
<td>A Community Survey of Medical Errors in New York</td>
<td>Describes a survey to assess the characteristics of patients who report medical errors. Found that 20% of New York households had experience of a medical error and that an individual's greater knowledge about health increased the likelihood of them reporting a medical error. Respondents who were divorced/separated/widowed/African-American and those from high-income households were less likely to report. Young, frequent users of health services and the better informed were more likely to report.</td>
<td>USA</td>
</tr>
<tr>
<td>Adams et al 2000</td>
<td>Reducing Medical Errors and Improving Patient Safety</td>
<td>Lists institutions and organisations that have 'made a difference' Describes a number of initiatives to reduce the risk of patient safety events including educating patients to manage their anticoagulant therapy, formation of a Patient and Family Advisory Council and encouraging patients to speak up if something disturbs them</td>
<td>USA</td>
</tr>
<tr>
<td>Agee 1996</td>
<td>How to write clear instructions</td>
<td>Describes format for writing instructions for patients to follow at home. Emphasises the importance of knowing the intended readers and writing in a way that will be appropriate for them. Other important features are: giving a preview being clear providing some what if? examples checklists who to contact with problems</td>
<td>USA</td>
</tr>
<tr>
<td>AHA 2004</td>
<td>Nurses identify barriers to teaching patients about their medications</td>
<td>Describes a survey which found that lack of adequate information and time constraints may hinder nurses' efforts to educate patients about their medication on discharge from hospital</td>
<td>USA</td>
</tr>
<tr>
<td>AHRQ 2001</td>
<td>Making Healthcare Safer: a critical analysis of patient safety practices (summary)</td>
<td>Describes a review of patient safety practices concentrating mainly on secondary care &amp; attempts to identify a set of proven patient safety practices (by the National Quality Forum) that should be used by hospitals with the aim that this will enable patients to identify the steps taken by healthcare institutions to improve safety. Identifies areas for research on patient involvement Picked out patient self management of anticoagulation as one of the most highly rated research areas</td>
<td>USA</td>
</tr>
<tr>
<td>Researcher</td>
<td>Title</td>
<td>Description</td>
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<tr>
<td>AHRQ 2006</td>
<td>Patient Safety Research Highlights</td>
<td>Describes completed patient safety research projects including those involving patients such as: an intensive care error reporting system available to the public, drug information sources available at the point of care reduces risk of adverse drug event, most people have difficulty understanding pharmaceutical label instructions regardless of cultural background and level of education, patients are increasingly satisfied with electronic healthcare records and web based communication, visual aids may improve the accuracy of medication assessment especially for patients with communication barriers. AHRQ PSNet one stop portal of resources continues to grow, improving patient safety through web-based education for physicians, nurses &amp; patients.</td>
<td>USA</td>
</tr>
<tr>
<td>Alaszewski 2000</td>
<td>Balancing Act</td>
<td>Describes the trend of associating risk with danger and hazards. Cautions that this view of risk-seeking out hazards and writing risk assessments may decrease natural cautiousness and make accidents and untoward events more likely to happen. Points out that it may be better to balance threats and opportunities involving all in the decision making process.</td>
<td>UK</td>
</tr>
<tr>
<td>Alvarez &amp; Sciamanna 2006</td>
<td>Empowering Patients to Improve Safety</td>
<td>Describes the programmes that have specifically aimed to include patients in promoting their own safety since 1999 'To Err is Human' lists strategies such as: JCAHO's 'Speak Up' campaign, patients increased use of the internet and websites such as <a href="http://www.myexpertdoctor.com">www.myexpertdoctor.com</a> Partners in your care which aims to involve patients, the public and HCPs in good hand hygiene. It calls for an expansion of the tools of patient empowerment so they can be increasingly involved in promoting their own safety.</td>
<td>US</td>
</tr>
<tr>
<td>Anderson P 2002</td>
<td>The NPSA's plans to improve safety and involve patients</td>
<td>Description of progress of NPSA and their plans to involve patients including: consulting public/patients about patient safety priorities, developing a public and patient reporting system, user involvement in looking at a range of solutions how to move the focus away from individual to system failure, how to ensure that patients don't need to go to the media or courts to get the 'full story' after a patient safety event.</td>
<td>UK</td>
</tr>
<tr>
<td>Author</td>
<td>Title</td>
<td>Description</td>
<td>Country</td>
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<tr>
<td>Annear</td>
<td>Show and Tell: Patient involvement helps prevent medical error</td>
<td>Describes 2 cases where medical error led to patient death - maintains that greater patient involvement may have prevented this. Describes the formation of several groups, which are working to increase patient involvement in promoting their own safety. Consumers Advancing Patient Safety (CAPE); National Patient Safety Foundation (NPSF); Persons United Limiting Substandards and Errors in Healthcare (PULSE). All groups advocate patients becoming partners and active participants in their own healthcare.</td>
<td>US</td>
</tr>
<tr>
<td>Anonymous</td>
<td>AHA Issues: quality and patient safety</td>
<td>Describes how the mission of the AHA 'fits' with the IOM Reports 'To Err is Human' and 'Crossing the Quality Chasm'. Through the six quality aims: patient safety; patient centredness (including pt &amp; family involvement); efficiency; effectiveness; equity; timeliness; system re-design.</td>
<td>USA</td>
</tr>
<tr>
<td>Anonymous</td>
<td>Medication Safety Issue Brief: focusing on the human factor</td>
<td>Describes how healthcare providers have enlisted the help of human factors experts to improve patient HCP communication and care processes and to design healthcare facilities. Human factors engineering is the study of the relationships among people, the tools they use and the environments in which they live and work.</td>
<td>USA</td>
</tr>
<tr>
<td>Anonymous</td>
<td>Patient Reporting Scheme Delayed</td>
<td>Describes the piloting of a scheme for patients to report suspected medication side effects via NHS Direct. Response to the scheme has been poor and planned national roll out has been delayed. Calls for a national system which takes reports directly from patients.</td>
<td>UK</td>
</tr>
<tr>
<td>Anonymous</td>
<td>Best of the rest: Patients not receiving adequate information about NSAIDs risks?</td>
<td>Describes a study that examined the knowledge of patients taking long-term analgesics for musculo-skeletal pain about the risks and benefits of long-term use. Between 50 &amp; 80% of those asked had no knowledge of potential adverse effects from NSAIDs and COX-2 inhibitors. After the introduction of an educational intervention all patients expressed a preference for a safer, although less effective, option to their current medication.</td>
<td>USA</td>
</tr>
<tr>
<td>Anonymous</td>
<td>Patient, protect thyself?</td>
<td>Comments on the reports that suggest that while patients are generally able to recognise medical errors, many do not report them due to their expectations of the patient and HCP role. Suggests that safety tips recommended to patients are problematic because of lack of evaluation of their effectiveness and no patient participation in their development. Concludes that open communication between HCPs and patients could stop some errors but this would involve a shift in the power balance.</td>
<td>USA</td>
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<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Description</td>
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<tr>
<td>Aspden et al 2004</td>
<td>Patient safety achieving a new standard for care</td>
<td>Describes the ways in which patients and their families might be involved in developing patient safety initiatives and the roles they might play in promoting their own safety. Summarises the available information about patient involvement and makes recommendations for further exploration.</td>
<td>USA</td>
</tr>
<tr>
<td>Baker 2003</td>
<td>Safety in Practice</td>
<td>Describes the launch of the NPSA’s National Reporting and Learning System, its impact on primary care and how it will relate to the current system of Significant Event Audit (SEA). Goes on to recommend that practices should involve patients in ensuring safer care both on an individual level, reporting incidents, and as representatives, reviewing reports and designing solutions</td>
<td>UK</td>
</tr>
<tr>
<td>Bakris 1988</td>
<td>It may seem obvious to you….giving medication instructions to patients</td>
<td>Letter to journal editor from doctor detailing case report of incorrect drug administration by a patient. Male patient took nitro-glycerine transdermal patch orally. Author states that despite clear package insert physicians should reinforce instructions on how to take/apply certain medications.</td>
<td>USA</td>
</tr>
<tr>
<td>Ballard KA 2003</td>
<td>Patient safety: A shared responsibility</td>
<td>Describes what stakeholders have done and what remains to be done in order to promote patient safety. In relation to patient involvement, it highlights their right to education about their condition/treatment, accessing information (e.g. through federal/state groups, patient advocacy groups and the internet), checking credentials/competencies of HCPs and the ‘institutional report card’.</td>
<td>USA</td>
</tr>
<tr>
<td>Ballinger C, Payne S 2002</td>
<td>The construction of the risk of falling among and by older people</td>
<td>Describes ways in which providers and users constructed and managed ‘risk’ in a day hospital for older people. Authors argue that rigid definitions defined in purely physical or functional terms produce services which do not address older peoples’ concerns and in which they will be reluctant to participate.</td>
<td>UK</td>
</tr>
<tr>
<td>Banning M 2004</td>
<td>Enhancing concordance with prescribed medication in older people</td>
<td>Describes ways in which nurses can work with patients/professionals to improve medication concordance. Discusses merits and problems of education initiatives, information sharing and alternative interventions.</td>
<td>UK</td>
</tr>
<tr>
<td>Name et al.</td>
<td>Title</td>
<td>Abstract</td>
<td>Location</td>
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<tr>
<td>Barnes et al 1998</td>
<td>Reporting of adverse reactions to herbal remedies: consumers’ attitudes</td>
<td>Describes a study that sought to determine the attitudes of users of herbal medicines to reporting adverse drug reactions to their GP compared with conventional over the counter medicines. Found that they were more likely to consult their GP about serious ADRs to conventional medicines than to herbal remedies</td>
<td>UK</td>
</tr>
<tr>
<td>Basch et al 2005</td>
<td>Safety assurances for dietary supplements: policy issues and new research paradigms</td>
<td>Describes and comments on issues relating to herbal therapies and potential risk to patients who take them from adverse events and interactions. In relation to patient involvement specifically the authors comment that in determining the most effective and efficient means to inform/educate consumers of potential risks, standardisation of labelling with specific information requirements (interactions, reported adverse events) should be considered.</td>
<td>USA</td>
</tr>
<tr>
<td>Batalden et al 2006</td>
<td>From one to many</td>
<td>Describes the development of the microsystems approach that includes patients in the healthcare team. Microsystems contain members who may have different roles over time, information and technology and a common purpose.</td>
<td>USA</td>
</tr>
<tr>
<td>Bates et al 2005</td>
<td>American College of Endocrinology and American Association of Clinical Endocrinologists position statement on patient safety and medical system errors in diabetes and endocrinology</td>
<td>Position statement on patient safety by ACE and AACE. Describe specific areas of concern related to endocrinology, highlight systematic problems and provide recommendations for achieving safer medical care. Authors recommend ‘improving patient self-care through education and communication’. State that more effective strategies to improve communication are essential, raises issue of medical literacy and ethnic minorities in relation to barriers to care. Also advocate more individualised, ongoing evidence based educational strategies and maintaining personal health records which will allow diabetes patients to document their health status and may allow them to interact with electronic health records.</td>
<td>USA</td>
</tr>
<tr>
<td>Bernsten et al 2004</td>
<td>A qualitative study of attitudes toward error in patients facing brain tumour surgery</td>
<td>Describes qualitative study of attitudes towards error in patients due to have brain tumour surgery. Themes that emerged included trust, feelings about error and discussing error.</td>
<td>Canada</td>
</tr>
<tr>
<td>Bernsten 2006</td>
<td>Implementation of patient centeredness to enhance patient safety</td>
<td>Describes aims and recommendations in the IOM ‘Crossing the Quality chasm, a new health system for the 21st century’ with focus on patient-centredness and comments on the lack of implementation. Uses case study to show where IOM rules could be applied.</td>
<td>USA</td>
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<tr>
<td>Author</td>
<td>Title</td>
<td>Abstract</td>
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<tr>
<td>Berwick</td>
<td>Enhancing patient safety and reducing errors in health care</td>
<td>Documents keynote address to NPSF conference about taking steps to improve safety of medication system. This includes involving patients as active partners in checks e.g. identifying themselves, assessing drug choices and doses and reviewing allergy information.</td>
<td>USA</td>
</tr>
<tr>
<td>Blaska</td>
<td>The myriad medication mistakes in psychiatry: a consumer’s view</td>
<td>A consumer of mental health services describes common medication mistakes in the field. Concludes that patients are responsible for correcting errors (along with professionals) by raising questions, speaking up, keeping informed and listening to his/her body.</td>
<td>USA</td>
</tr>
<tr>
<td>Bonapace</td>
<td>User-centred approach in designing furniture for healthcare facilities</td>
<td>Describes the main components of the user-centred approach in product development process of furniture for healthcare facilities. This involves real users and representative groups of end-users in gathering information to help guide design decisions.</td>
<td>Italy</td>
</tr>
<tr>
<td>Boyle et al</td>
<td>Medication misadventure in cancer care</td>
<td>Describes the nature and scope of medication errors especially in cancer care. Also recommends guidelines (compiled from medication error literature) to minimize errors in chemotherapy. Points in the guidelines relating to patient involvement are: optimize patient partnership with drug delivery process verification, create process for ensuring all patients are given information about their meds, have an established template for writing down instructions and reminders to reiterate medication teaching, establish a normative climate of enquiry in the setting of care i.e. want to hear patient questions etc and finally, to advise patients to discard all discontinued or unused drugs.</td>
<td>USA</td>
</tr>
<tr>
<td>Brass et al</td>
<td>Label development and the label comprehension study for over-the-counter drugs</td>
<td>Describes a suggested framework for future over the counter medication label development. Suggests three main stages: what are the messages? how can the messages best be communicated? does the proposed label meet its objectives. Recommend this be followed by an actual use study.</td>
<td>USA</td>
</tr>
<tr>
<td>Brennan &amp; Safran</td>
<td>Patient Safety: remember who it’s really for</td>
<td>Comments that initiatives to involve patients in patient safety either as representatives or individuals needs to incorporate patient preferences and needs, requires an informed and motivated populace and mechanisms which integrate safe practices and investment in safety enhancing devices and care strategies</td>
<td>USA</td>
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<tr>
<td>Author</td>
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<tr>
<td>Brennan</td>
<td>2004</td>
<td>Patient safety. Remember who it’s really for.</td>
<td>Describes how patient safety programs largely address provider-interests and overlook patient preferences and needs. Argues that active engagement of the patient in the patient safety agenda is necessary for its success.</td>
</tr>
<tr>
<td>Brodell</td>
<td>1997</td>
<td>Prescription errors. Legibility and drug name confusion</td>
<td>Describes a review of certain aspects of medication errors including case studies. Authors recommend various actions to reduce errors. Those involving patients are: encouraging patients to bring prescription medications with them i.e. ‘brown bag’ approach, careful verbal education of patients about the name and purpose of all drugs being prescribed.</td>
</tr>
<tr>
<td>Broostad &amp; Martin</td>
<td>1981</td>
<td>Clinical pharmacy services: Part II - the issues</td>
<td>Describes clinical pharmacy services at one medical centre and the ‘required activities’ of the role. Pharmacists are required to ‘actively participate in (and document) patient medication education programs (discharge counselling of all patients on warfarin, those with compliance problems or extensive drug regimens, allergy verification etc).</td>
</tr>
<tr>
<td>Brown et al</td>
<td>2006</td>
<td>Diagramming patients’ views of root causes of adverse drug events in ambulatory care. An online tool for planning education and research</td>
<td>Describes a study that sought patients’ views of the causes of adverse events in primary care. Found that exploration of causes and potential solutions to minimise the risk of adverse events failed to take into account (due to lack of evidence) several practical and motivational antecedents for patients</td>
</tr>
<tr>
<td>Brushwood</td>
<td>1986</td>
<td>Drug information for patients</td>
<td>Describes the importance of patient education in drug prescription (pre PPIs). Goes on to explain the duties of the manufacturer, pharmacist, physician and hospital from a medico-legal perspective.</td>
</tr>
<tr>
<td>Buckle et al</td>
<td>2003</td>
<td>System design and Patient Safety</td>
<td>Describes the formation of the Design for Patient Safety Network that advocates a user-central, systems-based approach to design in healthcare. It will adopt a multi-disciplinary approach with input from patients and patients representative organisations such as the NPSA</td>
</tr>
<tr>
<td>Cahill</td>
<td>1998</td>
<td>Patients' perceptions of bedside handovers</td>
<td>Describes a study which explored patients’ perceptions of the bedside handover and identified 3 main categories of perceptions: maintaining a professional distance, establishing professional sharing &amp; maintaining patient safety</td>
</tr>
<tr>
<td>Author</td>
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<td>Summary</td>
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<tr>
<td>Choonara 2004</td>
<td>Direct reporting of suspected adverse drug reactions by patients</td>
<td>Describes the extension of adverse drug event reporting via the yellow card system to patients. Notes that the value of this has not yet been assessed but early indications are that patients report adverse drug events earlier than HCPs. Also comment on the tension between MHRA as body to monitor pharmacovigilance as well as licensing meds.</td>
<td>UK</td>
</tr>
<tr>
<td>Christenson 1979</td>
<td>Information about medicines: self-administration and medicine control in hospital departments</td>
<td>Describes a system for safe medication administration in hospital which involves making sure that patients are fully informed about their medication, how and when to take it.</td>
<td>Denmark</td>
</tr>
<tr>
<td>Cohen &amp; Davis 1992</td>
<td>How to prevent eye medication errors</td>
<td>Describes potential mix up of containers that hold ophthalmic medication and a solution for identifying occult blood in faeces. Recommends that patients are advised not to store them together and calls for clearer labelling for solutions that are not to be used in the eye.</td>
<td>USA</td>
</tr>
<tr>
<td>Cohen &amp; Smetzer 2005</td>
<td>Patient-controlled analgesia safety issues</td>
<td>Describes problems that can occur with patient controlled analgesia and ways to reduce the risk of this including educating patients and families about correct use of PCA prior to the operative procedure when alert and receptive</td>
<td>USA</td>
</tr>
<tr>
<td>Cohen 1999</td>
<td>Errors associated with medication administration</td>
<td>Comments that the responsibility for medication error rarely lies with the person administering it but can usually be attributed to system error. Makes a number of recommendations to reduce the risk of error including educating patients about their medication</td>
<td>USA</td>
</tr>
<tr>
<td>Cohen 2004</td>
<td>Medication errors. Patient education. Put it in writing.</td>
<td>Describes results of a survey of nurses that indicated that half have no written information to give patients on safe medication use when they leave the health care setting. Recommends asking your facility staff development department to help get appropriate teaching materials or seek help from reliable outside sources. Gives some examples - AHRQ and Medline Plus.</td>
<td>USA</td>
</tr>
<tr>
<td>Colias 2004</td>
<td>Partners in prevention. Patient safety awareness week aims to help consumers head off medical errors.</td>
<td>Describes a ‘Patient Safety Awareness Week’ organised by the NPSF, to encourage partnership between patients/families and providers. Article highlights a range of activities that participating hospitals have planned such as: a one-week hotline for patients and staff to report safety concerns, roundtable discussions, distributing wallet cards for patients to record all meds/phone numbers and submitting pieces to local newspapers.</td>
<td>USA</td>
</tr>
<tr>
<td>Combes et al 2001</td>
<td>Status of Quality Initiatives Pt 2</td>
<td>Describes a review of patient safety activity on a national level and asks how patients can be involved</td>
<td>US</td>
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<tr>
<td>Author</td>
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<tr>
<td>Coulter 2006</td>
<td>Patient safety: what role can patients play?</td>
<td>Describes progress of the patient safety movement in the UK and calls for exploration of facilitator/barriers to being involved in promoting their own safety.</td>
<td>UK</td>
</tr>
<tr>
<td>Cowan 2004</td>
<td>Clinical Risk Management: Medication safety in 2004: the NHS agenda</td>
<td>Describes the publication of the DoH report ‘Building a Safer NHS for Patients - Improving Medication Safety’. It outlines the recommendations made by the report including: patients taking on responsibility for their own medication management, good communication, agreed and prioritised goals, set and maintained using patient groups. It also emphasises that the NPSA has a role to play in providing this report and acting on the recommendations.</td>
<td>UK</td>
</tr>
<tr>
<td>Cox 2002</td>
<td>Overview of the Partnership Symposium 2001: Patient Safety - Stories of Success</td>
<td>Describes the conference partnership symposium 2001 to disseminate research information and to assist in the development of a safer health care system including discussion of the creation of partnership models for HCPs patients and families to work together.</td>
<td>USA</td>
</tr>
<tr>
<td>Croonen 2005</td>
<td>EMEA wants safer drugs</td>
<td>Describes various methods adopted to improve medication safety and the differences between the European and American approach. Highlights the use of a patient reminder card in addition to usual medication insert to inform patients about possible side effects.</td>
<td>NL</td>
</tr>
<tr>
<td>Danish Ministry of Internal Affairs and Health 2003</td>
<td>Note concerning the establishment of an adverse events reporting system</td>
<td>Describes the plans for the establishment of a national adverse event reporting system initially open only to HCPs but, after further study, access will be extended to patients and their relatives.</td>
<td>Denmark</td>
</tr>
<tr>
<td>David 2005</td>
<td>A system based approach to drug use in hospital</td>
<td>Describes how improvements can be made in a hospital setting to reduce the risk of medication errors: understanding how systems function, greater computerisation, encouraging HCPs to feel responsible for the system as a whole rather than just their personal work and involving patients in decision making and treatment implementation.</td>
<td>France</td>
</tr>
<tr>
<td>Davis 1990</td>
<td>Detection and Prevention of Ambulatory Care Pharmacy Dispensing Errors</td>
<td>Describes how the risk of medication errors can be decreased by having good systems in place in an ambulatory care pharmacy, including patient counselling when they collect their medication.</td>
<td>USA</td>
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<td>Year</td>
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<tr>
<td>1994</td>
<td>Davis</td>
<td>A well-informed patient is a valuable asset. Describes two incidents where patients or carers spoke up to prevent a potentially serious medication adverse event. Points out that knowledge of patient/carer, their willingness to speak out and receptiveness of staff were three key factors in preventing serious consequences.</td>
<td>USA</td>
</tr>
<tr>
<td>1999</td>
<td>Day et al.</td>
<td>Towards the safer use of non-steroidal anti-inflammatory drugs. Describes the strategies adopted in Australia to reduce adverse events attributable to the use of non-steroidal anti-inflammatory drugs (NSAID). Recommends that consumers, pharmacists and prescribers should all be targeted to focus on better management of painful musculo-skeletal conditions and to further reduce the adverse drug events associated with NSAID use.</td>
<td>Australia</td>
</tr>
<tr>
<td>2001</td>
<td>Delbarco</td>
<td>Leaping into Patient Safety. Describes how the Leapfrog Group members are recognising and rewarding patient safety initiatives by providers and ensuring consumers have access to quality measures information so they can make informed provider choices.</td>
<td>USA</td>
</tr>
<tr>
<td>2003</td>
<td>Denham</td>
<td>Patient Centeredness in the Frontline Emergency Department. Record of the proceedings of a conference which explored patient centredness in rural emergency departments and how patients and their families might be involved in promoting safety with HCPs.</td>
<td>USA</td>
</tr>
<tr>
<td>2005</td>
<td>Dennison</td>
<td>Creating an organizational culture for medication safety. Describes how changing organizational culture can reduce the risk of medication errors. This includes involving patients by taking opportunities to teach them about their medication and encouraging them to share information about themselves with HCPs.</td>
<td>USA</td>
</tr>
<tr>
<td>2004</td>
<td>Dept of Health</td>
<td>NPSA Guide sets up work on patient safety. Describes the implementation, in Wales, of the NPSA's guide ‘Seven steps to patient safety’ which ‘sets out tangible steps to build a culture of learning from patient safety incidents’. Step 5 encourages staff to ‘involve and communicate with patients and the public by developing ways to communicate with them’.</td>
<td>UK</td>
</tr>
<tr>
<td>1999</td>
<td>Dewitt &amp; Sorofman</td>
<td>A model for understanding patient attribution of adverse drug reaction symptoms. Describes a study to explore if patients have a common framework through which they identify symptoms as an adverse drug reaction. 338 adults were given a self-administered questionnaire. Study found that patients do have knowledge about adverse drug reaction symptoms that is substantially accurate and concludes that patients have a role in reporting adverse drug reactions especially as part of medication post marketing surveillance.</td>
<td>USA</td>
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<tr>
<td>Author(s)</td>
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<td>Dickey</td>
<td>Are your patients using OTCs wisely?</td>
<td>Describes the explosion in the use of OTC medicines and complimentary therapies and concerns that patients may be using them inappropriately. Outlines problems that may occur then recommends how HCPs can work with patients to reduce the risk of problems with OTC meds including advising patients to follow dosing guidelines, not taking them for prolonged periods and consulting a physician before taking them if they have a chronic condition.</td>
<td>USA</td>
</tr>
<tr>
<td>Dodds</td>
<td>Patient Detection of a Drug Dispensing Error by Use of Physician-Provided Drug Samples</td>
<td>Describes a drug dispensing error discovered by a patient who had been given sample tablets of an anti-inflammatory medication and a follow-up prescription for when the sample tablets ran out. The medication dispensed looked different to the sample tablets, patient returned them to the pharmacy where it was discovered that the wrong tablets had been dispensed. Authors highlight this as an example of a positive benefit form the otherwise questionable use of free drug samples.</td>
<td>USA</td>
</tr>
<tr>
<td>Dolovich</td>
<td>Ensuring that Patients' Drug Information Needs are Met</td>
<td>Comment on the need to ensure that patients' needs for information are met. Patient’s and HCP’s views on the information needed by patient have often been found to be mismatched. Emphasises importance of using different ways of conveying information to suit patients’ needs that vary between patients and change over time.</td>
<td>USA</td>
</tr>
<tr>
<td>Doucet &amp; Queneau</td>
<td>Adverse Drug Reactions in the Elderly</td>
<td>Comments that adverse drug reactions are more frequent and serious in elderly patients and cautions that HCPs need to be pro-active in the prevention of adverse drug reactions in this group. This will involve better info for both HCPs and patients and greater care and monitoring by healthcare professionals of medication taking in this group.</td>
<td>France</td>
</tr>
<tr>
<td>Dowell et al</td>
<td>Urban Outpatient Views on Quality and Safety in Primary Care</td>
<td>Patients were asked how workplace conditions affect the quality of care and medical errors. Patients discussed 3 general categories of error, errors of inattention, medication errors and technical errors. Patients showed understanding of complex systems failures that can lead to adverse events. Errors were more often attributed to inattention than incompetence.</td>
<td>USA</td>
</tr>
<tr>
<td>Duffy et al</td>
<td>Risk Assessment and management in acute mental health care</td>
<td>Describes the difficulties of achieving balance between the risk of violence and homicide by mental health service users on the one side and of self-harm and suicide on the other. The authors suggest how patients and their carers/family can be involved in assessing risk, building on management plans. Note that it is important to appreciate that user and carer defined risk may be different to that of HCP. Aim is to avoid patient becoming an object of care rather than a collaborator/partner.</td>
<td>UK</td>
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<tr>
<td>Author</td>
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<td>Dupuits 2002</td>
<td>The Effect of the Internet on Pharmaceutical Consumers and Providers</td>
<td>Describes the effect of the internet on medication prescribing and consumption. It is a source of information for consumers and increases their potential for self-care through the direct purchase of medication. It also provides the means for HCP and patient interaction by e-mail and a tool for registering adverse drug events. Patients can also talk to each other via talk boards and community networks.</td>
<td>USA</td>
</tr>
<tr>
<td>Durbin 2006</td>
<td>Patient safety perceptions: A survey of Iowa physicians, pharmacists, and nurses</td>
<td>Describes a study that assessed the perceptions of HCPs (physicians, nurses &amp; pharmacists) regarding the impact of parts of the healthcare system on patient safety and strategies for improving patients’ safety. The only strategies which received majority support from all staff groups was improving patient education regarding their role in healthcare &amp; sharing info between providers &amp; settings. In addition all groups rated individual characteristics of patient and family and staff norms, values and education as having a major impact on patient safety. The authors call for involvement of patients in promoting patient provider partnerships and designing interventions, educational materials and methods of sharing information across settings.</td>
<td>USA</td>
</tr>
<tr>
<td>Elder et al 2005</td>
<td>How experiencing preventable medical problems changed patients' interactions with primary health care</td>
<td>Explored how patients’ experiences with self-perceived preventable problems have changed their behavioural interactions with the healthcare system. Found that anger, mistrust and resignation were the most common feelings reported which resulted in behaviours such as stopping going to the doctor, acquiring knowledge or getting a second opinion.</td>
<td>USA</td>
</tr>
<tr>
<td>Entwistle 2004</td>
<td>Nursing shortages and patient safety problems in hospital care: is clinical monitoring by families part of the solution?</td>
<td>Editorial describing potential use of families in ‘clinical monitoring’ of patients where there are low levels of nurses. Discusses a number of issues in relation to this; lack of evidence of effectiveness the expectations and attitudes of families and HCPs towards this role families’ capacity to contribute accommodating families e.g. overnight education and support for family participation responsibility for patient wellbeing.</td>
<td>USA and UK</td>
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<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Description</td>
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<tr>
<td>Entwistle, Mello and Brennan 2005</td>
<td>Advising patients about patient safety: current initiatives risk shifting responsibility</td>
<td>Describes an analysis and critique of five leading US based safety advisories, based on literature reviews and interviews. Found: lack of attention to patient perspectives they say little about what HCPs should do patients given little practical support to carry out recommended actions HCPs responses may render actions ineffective some messages suggest inappropriate shifting of responsibility onto patients behaviours conflict with expectations many people have, and think HCPs have, of patients' roles.</td>
<td>USA and UK</td>
</tr>
<tr>
<td>Farver et al 1993</td>
<td>Patient Counselling: there is a need</td>
<td>Describes the case study of a patient who transferred tablets received via mail order into wrongly labelled bottles and had been taking warfarin instead of paediatric aspirin. The authors emphasise that patient education is an important part of a pharmacist's role and outlines the key characteristics of this. Comment that this is problematic if patients obtain medication via mail order.</td>
<td>USA</td>
</tr>
<tr>
<td>Favaretti &amp; Pieri 2006</td>
<td>Patient Safety in Italy</td>
<td>Describes the emergence of the patient safety movement in Italy and ongoing projects including a national association for patients' rights that has promoted two initiatives. The first uses working groups of citizens, HCPs and hospital managers to carry out safety and quality checks on participant hospitals. The second involves a number of hospitals monitoring major medical errors and analysing citizens claims - from this has come a joint patient professional charter which aims to reduce the occurrence of medical errors.</td>
<td>Italy</td>
</tr>
<tr>
<td>Fernandopulle 2003</td>
<td>What can consumer adverse drug reaction reporting add to existing health professional-based systems? Focus on the developing world</td>
<td>Presents an overview of possible reasons for under-reporting of adverse drug events by HCPs especially in the developing world where it is particularly poor. The author explores the potential for and the problems posed by a consumer reporting system while highlighting the current low priority given by pharmaceutical companies to the provision of new safety information to developing countries. He points out that there are aspects of health care systems in the developing world which make consumer involvement desirable such as low consumer protection, the use of drugs which have been withdrawn in developed countries, a less litigious environment, 'doctor shopping', and the availability of many medications over the counter.</td>
<td>Sri Lanka</td>
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<tr>
<td>Author</td>
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<td>Summary</td>
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<tr>
<td>Fetter 2001</td>
<td>The Role of Patients and Families in Reducing Medical Errors</td>
<td>Proposes that patients and their families have a responsibility to act as a partner in their health care, making sure, to the best of their ability, that they are well informed, that they keep HCPs informed, are vigilant in monitoring care, report concerns promptly and follow the plan of care. The author sees informing and empowering patients and families to do this as a nursing responsibility</td>
<td>USA</td>
</tr>
<tr>
<td>Firth-Cozens 2003</td>
<td>The role of the National Patient Safety Agency</td>
<td>Describes the setting up and organisation of the National Patient Safety Agency and its collaborators including patient and consumer groups and its intention to set up a reporting system accessible to patients and the public</td>
<td>UK</td>
</tr>
<tr>
<td>Foust 2005</td>
<td>Opportunities for Improving Post-Hospital Home Medication management Among Older Adults</td>
<td>Describes the factors contributing to problems of post-hospital home medication management among older adults. Sees hospital and community pharmacists as important for educating and counselling patients through this transitional period</td>
<td>USA</td>
</tr>
<tr>
<td>Gallus 1999</td>
<td>Towards the Safer Use of Warfarin I: an overview</td>
<td>Describes how safe warfarin therapy involves careful patient selection, patient education, patient/physician communication, rapid response to overdose/bleeding and patients assuming responsibility for dose control. In summary it involves a therapeutic partnership between patient and physician</td>
<td>Aust</td>
</tr>
<tr>
<td>Gardini</td>
<td>Safety and Quality of Healthcare</td>
<td>Opening speech for quality and safety conference which sets the context and stresses the importance, for safety, of patient involvement in planning health care systems form the outset</td>
<td>Italy</td>
</tr>
<tr>
<td>Gerbert 1995</td>
<td>Risk perception and risk communication: benefits of dentist-patient discussions</td>
<td>Describes a survey of 4061 dental patients that explored their concerns and the frequency of dentist initiated risk related discussions. Found that the successful communication of risk is complicated and that standardised communication of risk based on the conviction that &quot;communication must be good&quot; fails to appreciate the complexity of the task.</td>
<td>USA</td>
</tr>
<tr>
<td>Gladfelter 2006</td>
<td>Managing Patient Expectations</td>
<td>Comments that it is not enough to give patients information so they can be active participants in their care, their understanding of this information must be evaluated. Describes a web-based tool that allows patients to view information about their procedure in their own time and send questions prompted by the viewing to their physician. Encourages HCPs to ensure that patients understand the information provided.</td>
<td>USA</td>
</tr>
<tr>
<td>Goeltz &amp; Hatlie 2002</td>
<td>Trial and Error in my quest to be a partner in my health care: a patient's story</td>
<td>Describes a patient's efforts to become a partner in her healthcare and the barriers and aids experienced by her. Ongoing commentary by Martin Hatlie, Patient Safety Expert</td>
<td>USA</td>
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<td>Author</td>
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<tr>
<td>Goeltz 2003</td>
<td>Be a partner in your healthcare</td>
<td>Comments that it is possible to be a partner in your health care by checking with rather than checking up on health care professionals. Uses her own experience to describe how this can be done.</td>
<td>USA</td>
</tr>
<tr>
<td>Goodman 2004</td>
<td>How can nurses help patients work more effectively with nurses to improve the safety of patient care?</td>
<td>Comments that nurses are in a unique position to assess the information needs of patients to enable them to become partners in their care and play a role in ensuring their care is safe. Emphasises the need to assess understanding. Points out the importance of, for example, informing parents of the correct dose of medication for their child's weight so they can check each time it is given.</td>
<td>USA</td>
</tr>
<tr>
<td>Goodwin 1997</td>
<td>Independence, Risk and Compulsion: Conflicts in Mental Health Policy</td>
<td>Comments on the tensions between the goal of independence for patients with mental health problems and the perceived risk to both patients and other members of the community. Calls for the development of a patient voice in service implementation.</td>
<td>UK</td>
</tr>
<tr>
<td>Grantmakers in Health 2001</td>
<td>Advancing Quality through Patient Safety</td>
<td>Describes a scoping review of medical error, public and private sector initiatives to promote patient safety and potential future opportunities for funding including empowering consumers to become positive mechanisms for improving patient safety by making quality measures publicly available, by educating them about the sort of questions to ask HCPs and by asking them to share their experiences of healthcare and suggest how it could be made safer.</td>
<td>USA</td>
</tr>
<tr>
<td>Grissenger &amp; Rich 2002</td>
<td>JCAHO: Meeting the standards for patient safety</td>
<td>Describes the tools available to pharmacists to make the medication use process safer including making sure that patients know about their condition, medication and the role they can play in the safe delivery of care including making sure their ID is accurate in hospital, raising concerns and sharing information about all the medication they are taking.</td>
<td>USA</td>
</tr>
<tr>
<td>Grissinger 2001</td>
<td>Pressured to give an answer instantly</td>
<td>Comments that HCPs often feel they have to give an answer to questions from patients rather than admit they are not sure or don't know. Adds that patients should be encouraged to ask and keep asking if they are not satisfied with the answers they receive.</td>
<td>USA</td>
</tr>
<tr>
<td>Gurwitz 2002</td>
<td>Risk management in therapeutics: when the patient becomes the last line of defence</td>
<td>Describes the efforts to contact patients taking a particular medication after it had been withdrawn. Argues for a personalised health web-page for all patients where patients can receive up to date information and alerts about a drug regimen.</td>
<td>USA</td>
</tr>
<tr>
<td>Gurwitz 2003</td>
<td>Incidence and preventability of adverse drug events among older persons in the ambulatory setting</td>
<td>Describes a study which used multiple sources to ascertain the incidence of adverse drug events among older people (30 397 person years of observation) and concluded that, among other interventions, patient &amp; family involvement in their pharmaceutical care through targeted education and with access to appropriate information has the</td>
<td>USA</td>
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<tr>
<td>Haack et al 2005</td>
<td>The other side of the needle: a patient's perspective</td>
<td>Describes a survey to evaluate the safety of and patient satisfaction with the procedure of fine needle aspiration of breast lumps by a cytology team with the aim of increasing patient satisfaction, safety and reducing medical error. Found that communication, especially of risks was an area for improvement but satisfaction was high</td>
<td>USA</td>
</tr>
<tr>
<td>Haefeli 2006</td>
<td>Drug administration errors - what information is required to enable patients to safely take their drugs?</td>
<td>Comments that it is important for physicians and pharmacists to make sure that patients and their caregivers not only understand how and when to take their medication but also that they are physically able to, for example, negotiate blister packs, split tablets if needed and use an inhaler effectively</td>
<td>Switz</td>
</tr>
<tr>
<td>Hainsworth 2004</td>
<td>Improving medication safety</td>
<td>Describes a number of recommendations for nurses to improve medication safety including: a booklet for patients receiving oral anticoagulants, a patient held alert card for patients undergoing a course of treatment with cytotoxic drugs to alert staff to the possibility of immuno-suppression, low blood count or septicaemia, patient held records for those taking methotrexate</td>
<td>UK</td>
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<tr>
<td>Halinski 2006</td>
<td>The Patient Safety Challenge</td>
<td>Describes the formation of a Patient Safety Committee within a nephrology network that aims to improve patient safety by improving systems, processes and communication. Involves a number of initiatives including informing patients what they can do to ensure patient safety</td>
<td>USA</td>
</tr>
<tr>
<td>Hamelin et al 2005</td>
<td>The Role of Patient education in the Safe Management of Autologous HSCT Patients in an Outpatient Setting</td>
<td>Describes the importance of education of patients undergoing a course of chemotherapy to ensure that they seek help appropriately and in a timely fashion</td>
<td>Canada</td>
</tr>
<tr>
<td>Hamilton 2000</td>
<td>The Quality of Australian Health Care Study: Implications for Education of Failure in Quality and Safety of Healthcare</td>
<td>Describes a study of adverse outcomes in healthcare resulting from error. Argues that lessons learned from this study should inform the curriculum for education of health care practitioners and that the system of care should enable patients to have a role in the provision of safe care</td>
<td>Australia</td>
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<tr>
<td>Hardwick &amp; Batiuk 2002</td>
<td>Severe prolonged Tacrolimus overdose with minimal consequences</td>
<td>Describes a case study in which, due to a prescribing error, a man received a 10-fold increase in the daily dose of one of his oral medications. Concludes that education about the importance of accurate dosing, potential interactions and questioning a change in tablet appearance could help to prevent such errors.</td>
<td>USA</td>
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<tr>
<td>Hatfield &amp; Smith 1988</td>
<td>The Role of the Consumer in Quality Assurance</td>
<td>Describes how the provision of mental health services is dominated by provider rather than consumer agendas with little opportunity for the consumer voice to be heard. Although there is increasingly consumer representation there can be resistance to their participation by service providers who may feel that users are not assertive or knowledgeable enough. The authors argue that consumer groups are becoming more powerful and that there should be meaningful representation of service users on appropriate boards and management groups.</td>
<td>USA</td>
</tr>
<tr>
<td>Hatlie &amp; Wagner 1999</td>
<td>The National Patient Safety Foundation: Creating a Culture of Safety</td>
<td>Describes the NPSF’s function as a forum for discussion, exploration and learning about patient safety and medical error issues. NPSF is a partnership of practitioners, providers, manufacturers, researchers, patient and consumer advocates, regulators and policy makers. It is committed to leading the transition from a culture of blame to a culture of safety.</td>
<td>USA</td>
</tr>
<tr>
<td>Hatlie &amp; Wagner 1999</td>
<td>The National Patients Safety Foundation: Creating a culture of safety</td>
<td>Describes the achievements of the NPSF, a partnership of healthcare providers, health product manufacturers, researchers, patients and consumer advocates, regulators and policy makers and its aim to ensure that all are involved in and are responsible for patient safety.</td>
<td>US</td>
</tr>
<tr>
<td>HCPro 2004</td>
<td>Measuring the effectiveness of patient safety information</td>
<td>Asks if patient safety information provided for patients is read and understood by its intended audience.</td>
<td>US</td>
</tr>
<tr>
<td>Health Foundation 2006</td>
<td>Making healthcare safer for patients</td>
<td>Describes the initiatives adopted by hospitals recruited for the Safer Patients Initiative. Highlights emerging lessons about improving safety and leading change including patients being involved in safety efforts but adds that there is, as yet, little evidence for the effectiveness of this.</td>
<td>UK</td>
</tr>
<tr>
<td>Heffner et al 2006</td>
<td>Hospital Internet Site Content on Patient Safety and Medical Errors</td>
<td>Describes a review of the information available to patients via the internet about what hospitals are doing to improve patient safety and service quality. The review found that although many hospitals provide information about service quality while only about a quarter specifically described programmes to improve patient safety.</td>
<td>USA</td>
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<td>Helmlinger</td>
<td>Rally educates both consumers and nurses</td>
<td>Describes a nurse demonstration at a democratic convention which aimed to increase support and awareness of the Patient Safety Act 1996 which would require the publication by healthcare providers of staffing levels, skill mix and patient outcomes as well as providing whistle blowing protection for HCPs speaking out.</td>
<td>USA</td>
</tr>
<tr>
<td>Hendrickson &amp; Burgess</td>
<td>Creating enforceable negotiated risk agreements</td>
<td>Describes a case where a negotiated risk agreement was drawn up to enable a couple with very different dependencies to remain together in assisted living accommodation. Outlines the legal and ethical background to these agreements and some of the difficulties associated with them.</td>
<td>USA</td>
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<tr>
<td>Hernandez</td>
<td>Dentistry and self-medication: a current challenge</td>
<td>Reviews the concept of self-medication within the context of dentistry. Argues that self-medication is desirable because it can complement the work of HCPs and represents an independent attitude in patients. However, incorrect use of medication can lead to unwanted side effects &amp; the authors argue that there is a role for HCPs educating and guiding patients in their use of over-the-counter medication.</td>
<td>Spain</td>
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<tr>
<td>Herxheimer</td>
<td>The role of consumers</td>
<td>Describes the different types of adverse effects of medication and how HCPs can work with patients to reduce the risk of adverse effects occurring through education and example.</td>
<td>France</td>
</tr>
<tr>
<td>Herxheimer</td>
<td>Communicating with patients about harms and risks</td>
<td>Describes the difficulties of communicating harms and risks to patients, some strategies for doing this and ways patients may be involved in, for example, treatment monitoring.</td>
<td>UK</td>
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<tr>
<td>Hesselgrave</td>
<td>Polypharmacy: the relationship between information and decision making</td>
<td>Describes the tension between the need for free flow of information to ensure patients stay safe and the restrictions posed by the need for protection of personal data. Concluded that HCPs needed to improve their knowledge of patients' medication, patients and the public need to get more involved at both a personal and a community level and effective communication between all HCPs and patients is the best way to avoid medical error.</td>
<td>USA</td>
</tr>
<tr>
<td>Hibbard et al.</td>
<td>Can Patients Be Part of the Solution? Views on Their Role in Preventing Medical Errors</td>
<td>Describes a study to assess patients' perceptions of the effectiveness of a number of recommended actions for preventing medical errors. Found that most actions are viewed as effective. However, respondents indicated that they were unlikely to engage in many of the recommended actions.</td>
<td>USA</td>
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<tr>
<td>Hoffman &amp; Proulx</td>
<td>Medication errors caused by confusion of drug names</td>
<td>Describes the problem of look alike sound alike drug names, exacerbating factors and interventions to reduce the risk of confusion including educating patients about the potential for confusion and the importance of understanding their drug therapy.</td>
<td>USA</td>
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<td>Hofler 2005</td>
<td>Public Reporting, Patient Safety and Quality Improvement</td>
<td>Argues that reports of adverse events &amp; near misses should be afforded legal protection so they cannot then be used to support a case of purported medical malpractice. Instead reports should be used to improve the system and provide quality data to aid decision making by consumers</td>
<td>USA</td>
</tr>
<tr>
<td>Horvath 2004</td>
<td>Thomas M Smith on Virginia Commonwealth University's Patient Safety Fellowship</td>
<td>Describes the VCU Patient Safety Fellowship and contributor T M Smith stresses the need to increase patient and family involvement in patient safety with initial efforts rooted in medicine safety. Argues that cultural change is needed for many patients to feel comfortable about getting involved</td>
<td>USA</td>
</tr>
<tr>
<td>Howe 2006</td>
<td>Can the patient be on our team? An operational approach to patient involvement in interprofessional approaches to safe care</td>
<td>Exploration of putting patients at the heart of a team based approach to the prevention and management of potential and actual clinical errors in their own care. Extrapolates from patient-centred approach &amp; shared decision making literature to discuss the possible challenges and barriers to patient involvement in safety promotion. Describes a number of potential approaches and concrete ways in which individual patients might be included in a team approach</td>
<td>UK</td>
</tr>
<tr>
<td>Hughes et al 2001</td>
<td>Benefits and Risks of self-medication</td>
<td>Describes the benefits of self-medication, some of the risks and how these can be minimised through education of patients both about the nature of non-prescription medication and the importance of informing prescribers about all medication use (prescription and non-prescription)</td>
<td>UK</td>
</tr>
<tr>
<td>Hughes et al 2002</td>
<td>Symptom or adverse drug reaction? An investigation into how symptoms are recognised as side effects of medication</td>
<td>Describes a study that attempted, through focus group interviews with 22 patients and 15 pharmacists, to investigate the process of identification of adverse drug reactions (ADR) from the perspective of patients and pharmacists. It found that patients tended only to report serious ADRs to a pharmacist or doctor dealing with less serious ones themselves. In addition there was a high level of agreement between patients and pharmacists as to the key factors used to identify ADRs</td>
<td>UK</td>
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<tr>
<td>Hurst 2001</td>
<td>Vigilant watching over: Mother's actions to safeguard their premature babies in the newborn intensive care unit</td>
<td>Describes a study of the safety promoting behaviours of 12 mothers of newborn babies in a NICU; their negotiation with, ‘management’ of and attempts to work in partnership with HCPs and the factors that help and hinder these practices.</td>
<td>USA</td>
</tr>
<tr>
<td>Infante 2006</td>
<td>Bridging the ‘systems’ gap between interprofessional care and patient safety: sociological insights</td>
<td>Comments that a systems approach to patient safety tends to exclude the patient and argues that a patient safety system model would include all the actors including the patient and would take into account the different perspectives, knowledge and expertise of all those involved</td>
<td>Mexico</td>
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<td>Author</td>
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<td>Inlander</td>
<td>1993</td>
<td>Read this. Now!</td>
<td>Describes the experience of the author who challenged the result of a screening blood test because one of the results (cholesterol level) was so different from his norm. By questioning this and demanding a retest he avoided commencement of treatment for prostate cancer. The samples of blood taken by his physician on the morning he visited had been muddled and his 'results' where, in fact, those of another patient. He cautions that patients should be assertive, informed and not intimidated by 'those in white coats'</td>
</tr>
<tr>
<td>Itoh et al</td>
<td>2006</td>
<td>Patient views of adverse events: comparison of self-reported healthcare staff attitudes with disclosure of accident information</td>
<td>Describes a study that compared the views of Danish and Japanese patients about the actions of healthcare staff after an adverse event. Found that Japanese patients were highly suspicious about healthcare staff attitudes to disclosure of accident information and this distrust is amplified if respondents are asked in general terms rather than as a response to a concrete case study. Calls for the inclusion of patients' points of view into healthcare risk management.</td>
</tr>
<tr>
<td>JCAHO</td>
<td>2000</td>
<td>Highly publicised report focuses national attention on medical errors</td>
<td>Describes the release of the report 'To Err is Human' and the recommendations made by the committee which wrote the report which included increasing the role of consumers in healthcare safety</td>
</tr>
<tr>
<td>JCAHO</td>
<td>2002</td>
<td>Closing the gap in patient safety</td>
<td>Describes a number of different ways in which patients and their families can be encouraged by HCPs to become involved in reducing the risk of medical error including the 'speak up' campaign and other ways of giving patients and their families 'permission' to raise concerns</td>
</tr>
<tr>
<td>JCAHO</td>
<td>2002</td>
<td>Mobilizing evidence, experience and tools to meet the 2003 National Patient Safety Goals</td>
<td>Describes some of the problems encountered when attempts are made to implement recommended patient safety actions such as surgical site marking and reading back medication orders given orally. Finds that interventions need to incorporate the role of the patient as well as HCPs.</td>
</tr>
<tr>
<td>JCAHO</td>
<td>2005</td>
<td>Patient-Inclusive Care Encouraging Patients to Be Active Participants in Their Care</td>
<td>Describes the National Patient Safety Goal 13 - Encourage the Active Involvement of Patients and their Families in the Patient's Care as a Patient Safety Strategy. Provides advice for HCPs about how to do this focusing on inviting patients to ask, medication safety &amp; patient identification, patient vigilance and raising public awareness.</td>
</tr>
<tr>
<td>James</td>
<td>2005</td>
<td>Insulin-treated inpatients and prescribing errors</td>
<td>Describes the incidence of and reasons for prescribing errors in insulin treated patients and how they can be prevented including encouraging patients to report error and encourage the promotion of a culture where all can learn from mistakes</td>
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<td>Author</td>
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<tr>
<td>Jarernsiripornkul et al</td>
<td>Patient reporting of adverse drug reactions: useful information for pain management?</td>
<td>Describes a study to compare reports of adverse drug reactions obtained directly from patients via postal questionnaire compared with more standard methods. Found that the 10 most frequently reported symptoms had all been previously reported via other methods but that patients did not report symptoms they perceived to be adverse effects to their doctor and post marketing surveillance (e.g.: Yellow card system) did not reflect the frequency of symptoms revealed through direct patient reporting</td>
<td>UK</td>
</tr>
<tr>
<td>Jencks</td>
<td>Public reporting of serious medical error</td>
<td>Describes the debate, which followed the publication of 'To Err is Human', about public reporting of medical errors. Called for research into the way reporting systems work, how this information could be made useful for the public and what the legal implications of such reporting would be</td>
<td>USA</td>
</tr>
<tr>
<td>Joglekar et al</td>
<td>Medication for the elderly: what do patients know?</td>
<td>Describes a study to assess elderly patient's recall of their drug regimens on admission to hospital. Found that a significant number of patients recalled little useful knowledge or understanding of their medication. The authors called for improved drug counselling, clear labels on medication and emphasised the importance of patients bringing their current medication with them when admitted</td>
<td>UK</td>
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<tr>
<td>Kaiser Family Foundation</td>
<td>National Survey on Consumers' Experiences With Patient Safety and Quality Information</td>
<td>Update of annual report charting patients' views of healthcare quality and safety (previous survey 2000). Over half of the public said they were dissatisfied with the quality of health in the US. One in three say they or a member of their family have experienced a healthcare error. There was some mismatch between what patients thought would be effective ways to reduce the risk of medical error and the strategies recommended by experts. Many say they are already adopting the recommended 'five steps to safer healthcare'</td>
<td>USA</td>
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<tr>
<td>Kaiser Family Foundation</td>
<td>Update on Consumers' Views of Patient Safety and Quality Information</td>
<td>Update of annual report charting patients' views of healthcare quality and safety. Some indication from this update that patients are becoming more proactive in safety promoting behaviour such as telling HCPs about allergies and adverse reactions in the past without being asked, creating their own set of med records to ensure that HCPs have all info &amp; chasing up results of tests they have had</td>
<td>USA</td>
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<tr>
<td>Kaiser Permanente Institute for Health Policy</td>
<td>Roundtable Discussion: Reporting as a means to improve patient safety</td>
<td>Describes a roundtable discussion at Claremont University where patient and aviation safety experts and health policy leaders from around the US met to discuss designing and implementing patient safety reporting systems</td>
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<td>Kapp 1990</td>
<td>Liability Issues and the Assessment of Decision-Making Capability in Nursing Home Patients</td>
<td>Describes the tension between patient autonomy and the minimisation of risk among residents of nursing homes. Argues that although there are undoubtedly some people in nursing home care who lack the functional ability to be involved in decisions about their care this does not apply to all and methodologies could and should be developed to distinguish between these two groups.</td>
<td>USA</td>
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<tr>
<td>Karch 1999</td>
<td>Like taking a vitamin: why patients don't mention their daily medications</td>
<td>Describes the difficulties of obtaining an accurate drug history from newly admitted patients who may not think of their routine, over the counter or herbal medication is worth mentioning.</td>
<td>USA</td>
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<tr>
<td>Karch 2006</td>
<td>The Gray Areas of Black Box Warnings: Who is responsible for heeding them?</td>
<td>Describes the use of 'black box warnings' which are placed on drug labels by the FDA to highlight serious possible side effects, provide cautions regarding administration and detail monitoring guidelines but no-one is ultimately responsible for ensuring that this information is seen and understood by patients and there is evidence that they are ignored by HCP. Author highlights the importance of encouraging patients to ask questions about meds &amp; side effects.</td>
<td>USA</td>
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<tr>
<td>Kasaven 2004</td>
<td>Open plan dispensaries can improve care and reduce errors</td>
<td>Describes how open plan dispensaries can improve care and reduce errors because the patient has the opportunity, through observation, to become involved in the dispensing process and may raise concerns if the medication does not have the same appearance as before. This may be because the supplier has changes but may also be because the pharmacist is dispensing the wrong medication.</td>
<td>UK</td>
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<tr>
<td>Kato 2002</td>
<td>How safety management should be practiced in the surgical sphere</td>
<td>Describes how safety management involving patient should be complimentary to the overall quality of the medical service in order to identify errors and adverse events.</td>
<td>Japan</td>
</tr>
<tr>
<td>Kenny et al 2001</td>
<td>Guideline for the prevention of falls in older persons</td>
<td>Describes evidence based guidelines for fall prevention including patient education</td>
<td>USA</td>
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<tr>
<td>Kershaw 2003</td>
<td>Patient use of the internet to obtain health information</td>
<td>Describes a review which explored patient use of the internet as a source of health information and how this might affect patient practitioner relationships as well as the potential for harm related to poor quality or inaccurate information, medical consulting over the internet and availability of prescription only medication.</td>
<td>UK</td>
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<tr>
<td>Kester &amp; Stoller 2003</td>
<td>Prevalence and Causes of Medication Errors: A Review</td>
<td>Describes a review of the prevalence and causes of medication error and concludes that better education of patients about their medication would enable them to 'provide another level of oversight' to reduce the risk of medication error.</td>
<td>USA</td>
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<td>Author(s)</td>
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<td>Kirby 1991</td>
<td>Patient access to medical records</td>
<td>Describes some of the issues which are raised by patient access to medical notes so they can check for errors as well as becoming more informed about their condition and treatment.</td>
<td>UK</td>
</tr>
<tr>
<td>Kissinger 2003</td>
<td>The medication connection: how nurse and patients can prevent error</td>
<td>Describes ways in which nurses can avoid medication errors including encouraging patients to know their medication and speak up if they are concerned.</td>
<td>USA</td>
</tr>
<tr>
<td>Kizer &amp; Blum 2005</td>
<td>Safe Practices for Better Health Care</td>
<td>Describes the 30 National Quality Forum endorsed safe practices and 27 promising practices which are identified as a high priority for further research including encouragement of the use of advocates &amp; the development of strategies to involve consumers in the implementation of safe practices.</td>
<td>USA</td>
</tr>
<tr>
<td>Knapp 2006</td>
<td>Bronson Methodist Hospital: Journey to Excellence in Quality and Safety</td>
<td>Describes the key strategies for improving patients safety at Bronson Methodist Hospital including 'It's OK to ask' campaign and patient feedback tools.</td>
<td>USA</td>
</tr>
<tr>
<td>Kogan et al 2001</td>
<td>Problems and Challenges in Patient Information Retrieval: A Descriptive Study</td>
<td>Describes a study that identified and classified the problems encountered by patients while performing information retrieval tasks on the web. It revealed that patient information retrieval often failed to provide useful results due to: use of inappropriate query terms poorly indexed website content medical jargon misunderstanding and misinterpretation A lack of hits often led to patients feeling that HCPs were not telling them the 'whole' truth and led to unnecessary anxiety.</td>
<td>USA</td>
</tr>
<tr>
<td>Kohn et al 2000</td>
<td>To Err is Human: Building a Safer Healthcare System</td>
<td>Describes the extent of the patient safety problem in USA. Includes half a page which stresses the importance of giving patients information and paying attention to their values and preferences.</td>
<td>USA</td>
</tr>
<tr>
<td>Konishi 2003</td>
<td>Risk management through clinical pathways</td>
<td>Describes how to improve the medical system through involving nurses, doctors, other service providers and patients in developing clinical pathway tools. Advise that if patient and/or their family is involved in the pathway they can identify the stage they are in and can confirm the process etc.</td>
<td>Japan</td>
</tr>
<tr>
<td>Koutantji et al 2005</td>
<td>The patient's role in patient safety; engaging patients, their representatives and health professionals</td>
<td>Points out the lack of attention paid to involving patients in promoting their own safety while using health care services. Describes how patients might be involved, drawing on literature on patients' involvement in engaging with and managing their own health and health care. Calls for the development of interventions and further research to explore the attitudes of patients and their representatives to being involved in these ways.</td>
<td>UK</td>
</tr>
<tr>
<td>Kranich 2004</td>
<td>Risk management from the perspective of the patient</td>
<td>Describes ways in which patients could be involved in promoting their own safety while using health services. Includes patient education to become more actively involved in treatment decision making and taking responsibility with HCPs for own care</td>
<td>Germany</td>
</tr>
<tr>
<td>Kulkarni &amp; Cornely 2002</td>
<td>Do physical therapists teach their older patients how to get up after a fall?</td>
<td>Describes a study to ascertain how many physical therapists routinely teach older patients how to get up after a fall. Found that just over a third said they sometimes did, although two thirds said falls were a problem in older patients. Authors recommend that this practice is more widely adopted</td>
<td>USA</td>
</tr>
<tr>
<td>Kurtzweil 1995</td>
<td>Liquid medication dosing devices and syringes</td>
<td>Advises nurses about available measuring devices for liquid medication and the risks and benefits of each method. Includes examples of instructions which could be given to parents/patients with liquid medication and Describes the FDA attempts to standardise dosing devices and provide public education</td>
<td>USA</td>
</tr>
<tr>
<td>Kuzel et al 2004</td>
<td>Patient reports of preventable problems and harms in primary health care</td>
<td>Describes a study that aimed to develop patient focused typologies of medical errors and harms in a primary care setting. Found that patient perception of error included, as well as technical errors in diagnosis and treatment, psychological and emotional harm, often related to the breakdown of a relationship with a HCP.</td>
<td>USA</td>
</tr>
<tr>
<td>Landro 2006</td>
<td>What drugs do you take? Hospitals seek to collect better data and prevent errors</td>
<td>Wall Street Journal comment about hospitals’ attempts to improve medication reconciliation procedures as inadequate reconciliation is thought to be responsible for as many as half of all medical errors and one fifth of adverse events. It Describes a number of strategies adopted including medication lists for each patient contained in an empty tablet bottle and labelled the ‘vial of life’, linking local medical records to hospital records as well as standardising the medication reconciliation system</td>
<td>USA</td>
</tr>
<tr>
<td>Lang 2002</td>
<td>An interview with Joanne E Turnbull PhD, Executive Director, National Patient Safety Foundation</td>
<td>Describes an interview with the executive director of the NPSF where she talks about the role of technology in patient safety and how patient involvement should be patient led</td>
<td>USA</td>
</tr>
<tr>
<td>Larson 2002</td>
<td>Measuring, monitoring and reducing medical harm from a systems perspective: a medical director’s personal reflections</td>
<td>Describes 5 critical elements for reducing and preventing harm to patients from a systems perspective. Also looks at the opportunities offered by involving patients and the public as partners with HCPs in improving safety</td>
<td>USA</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Abstract</td>
<td>Country</td>
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<tr>
<td>Leape 1998</td>
<td>Promoting Patient safety by Preventing Medical Error</td>
<td>Describes various organisations formed to promote the reduction of medical error such as the NPSF and outlines their work including involvement of patients and their families by enabling them to become well informed partners in the delivery of care</td>
<td>US</td>
</tr>
<tr>
<td>Lesar et al 2003</td>
<td>Using the ISMP Medication Safety Self-Assessment to Improve Medication Use Process</td>
<td>Describes the implementation of The ISMP Medication Safety Self-Assessment for hospitals. Assessment criteria include patients included as active partners in their care from education about their medication to suggestions for ways to avert errors</td>
<td>USA</td>
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<tr>
<td>Lester 2004</td>
<td>How online patient networks can enhance quality and reduce errors</td>
<td>Describes how the internet has increased the accessibility of community based patient care networks which are often consulted before or instead of HCPs. Argues that the speed by which information is conveyed to members about, for example, side effects of medication could reduce medical errors if providers were integrated into the networks</td>
<td>USA</td>
</tr>
<tr>
<td>Levings 1999</td>
<td>Towards the safer use of dosettes</td>
<td>Describes a study that examined incidents in which problems involving dosettes had been identified. They concluded that patients must be thoroughly assessed to ensure that a dosette box is suitable for them and these assessments should be continued regularly. In addition filling errors caused half of the incidences and the authors recommend a standard filling and checking procedure.</td>
<td>Australia</td>
</tr>
<tr>
<td>Ley 1998</td>
<td>The National Patient Safety Foundation Regional Forums</td>
<td>Describes the regional forum programme of the NPSF that brings together, in regions or communities, the groups that need to work together to make change. This includes consumer groups</td>
<td>USA</td>
</tr>
<tr>
<td>Ley 2001</td>
<td>Patient Safety: a personal and professional perspective</td>
<td>Describes a physician’s experience when accompanying her daughter who was a hospital inpatient and experienced respiratory depression due to medical error. She calls for HCPs to welcome the involvement of patients in safety promotion and emphasises the importance of education and communication</td>
<td>USA</td>
</tr>
<tr>
<td>Liang 2002</td>
<td>A system of medical error disclosure</td>
<td>Describes a system of medical error disclosure that provides education about the systems nature of error, promotes mutual respect and involves the patient and family as a partner in error reduction. Argues that the ‘health care partnership agreement’ is a way of achieving the latter aim (see A182)</td>
<td>USA</td>
</tr>
<tr>
<td>Lin 1997</td>
<td>The Role of the Pharmacy Department in the Prevention of Adverse Drug Events: A Survey of Current Practices</td>
<td>Describes a survey that attempted to map the adherence to recommendations on the prevention of adverse drug events in hospitals among 50 Louisiana Hospitals. Found that patient discharge counselling was underutilised and recommended that this be expanded</td>
<td>USA</td>
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<tr>
<td>Authors</td>
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<td>Description</td>
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<td>Litovitz</td>
<td>Implication of Dispensing Cups in Dosing Errors and Paediatric Poisonings: A Report from the American Association of Poison Control Centres</td>
<td>Describes dosing errors that occur due to misunderstandings about correct doses of liquid medication using dispensing cups. Suggests that dispensing cup markings use a single measure, that a uniform labelling system should be adopted and teaspoon, tablespoon abbreviations should not be used and that consumers are educated regarding the proper use of dispensing cups</td>
<td>USA</td>
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<tr>
<td>Loeb</td>
<td>Patient Safety is NOT an oxymoron</td>
<td>Describes the beginnings of the patient safety movement at a conference at Annenberg in 1996. This led to the development of patient safety organisations who gathered for another conference in 1998 which considered many topics including how to incorporate patients into the dialogue about safety and error reduction</td>
<td>USA</td>
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<tr>
<td>Logue</td>
<td>Self-medication and the elderly: How technology can help</td>
<td>Describes assistive devices available to help those with memory or dexterity problems self medicate safely. Emphasises the importance of evaluating patient need carefully before selecting devices</td>
<td>USA</td>
</tr>
<tr>
<td>Lowe et al</td>
<td>Routine Use of Ultrasound During Pregnancy</td>
<td>Describes the debate about the routine use of ultrasound scan during pregnancy - although one scan per pregnancy is virtually risk free there is less evidence about the safety of multiple scans especially when performed by inexperienced operators. Argues that mothers need to be fully informed about the risks of multiple scans to facilitate informed decision making</td>
<td>USA</td>
</tr>
<tr>
<td>Ludwig</td>
<td>Duty of information, patient's leaflet and physician's data sheet from the judicial point of view</td>
<td>Describes the responsibilities of medication manufacturers to provide information for patients and physicians through package inserts and data sheets respectively. Cautions that relying on package inserts to inform patients about their medication is not enough and physicians should back this up with verbal information, taking into account the patient's intellectual level</td>
<td>Germany</td>
</tr>
<tr>
<td>MacLeod</td>
<td>The Optimal Drug Therapy Symposium 2001: A call for action</td>
<td>Describes the consensus achieved and the recommendations produced at the Optimul Drug Therapy Symposium 2001. Includes recommendations for enhanced patient education through traditional means and via the internet and public involvement in post marketing surveillance and developing improved drug therapy</td>
<td>Canada</td>
</tr>
<tr>
<td>Malling</td>
<td>Minimising the risks of allergen-specific injection immunotherapy</td>
<td>Describes the risks involved in allergen specific immunotherapy and how these might be minimised including involving patients through education and as part of the checking procedure. Involvement of patients as active partners may also be useful when patients need therapy outside the specialist allergy clinic setting</td>
<td>Denmark</td>
</tr>
<tr>
<td>MAPS 2005</td>
<td>Strategies for Safety</td>
<td>Describes the proceedings of a conference looking at developments in patient safety since 'To Err is Human' including patient and family involvement through patient and family committees</td>
<td>USA</td>
</tr>
<tr>
<td>Markham &amp; Smith 2006</td>
<td>Limits to patient choice: example from anaesthesia</td>
<td>Describes a review of pre-operative information about the rationale for fasting given to patients and how this reflects the latest research evidence that prolonged fasts are unnecessary in healthy patients. Finds that despite the latest research information patient choice would be problematic in this area because patients are given little information about the nature of the fasting, that some information is delivered in a punitive or declarative tone that does not foster a partnership approach. In addition operations, anaesthetists and patients vary and it may not be always possible or safe for patients to have a choice</td>
<td>UK</td>
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<tr>
<td>Martin and Mann., 1981</td>
<td>Clinical Pharmacy Services: Part II – the issues</td>
<td>Describes a programme to develop a clinical pharmacy including patient counselling and a Pharmacy Services Brochure which helps to educate inpatients and increase public awareness of the pharmacy service</td>
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<tr>
<td>Marwick 1998</td>
<td>FDA gets advice on Modernization Act compliance</td>
<td>Describes the FDA’s preparation of a response to the Modernization Act 1998. This has involved consultation with a variety of groups including consumer organisations who have stressed the importance of a national medication safety and education programme with messages relevant for all</td>
<td>USA</td>
</tr>
<tr>
<td>McCarthy &amp; Blumenthal 2006</td>
<td>Stories from the sharp end: case studies in safety improvement</td>
<td>Describes a number of programmes implemented by health care organisations to improve patient safety which share common elements including involving consumers both by encouraging them to protect themselves from errors and using them as a resource to design and evaluate safe systems and procedures</td>
<td>USA</td>
</tr>
<tr>
<td>McErlane 2005</td>
<td>Keeping track of the patch: transdermal delivery in obese patients</td>
<td>Describes the problems that can occur when transdermal patches delivering controlled release of medication are not removed. Emphasises the importance of documenting both application and removal of patches and educating patients to do the same</td>
<td>USA</td>
</tr>
<tr>
<td>McKinnon 2005</td>
<td>A painless introduction to pharmacology. Part 3: adverse drug events</td>
<td>Describes different types of adverse drug reactions and what can be done to reduce the risk of these including good history taking, patient education and public involvement in health initiatives</td>
<td>UK</td>
</tr>
<tr>
<td>McMaster 2005</td>
<td>Update on the National Patient safety Goals - Changes for 2006</td>
<td>Describes updated patient safety goals as they apply to trauma nursing</td>
<td>US</td>
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<tr>
<td>Author(s)</td>
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<td>Medawar 2002</td>
<td>Paroxetine, Panorama and user reporting of ADRs: Consumer intelligence matters in clinical practice and post-marketing drug surveillance</td>
<td>Describes a study that compared the data obtained from 1,374 emails relating to patient's problems with paroxetine sent as a response to a TV documentary with that from a discussion forum (862 messages) on similar themes gathered over a period of 3 years. Suggest that immersion in a large body of data such as the former may be more valuable than exposure to a steady trickle of reports</td>
<td>UK</td>
</tr>
<tr>
<td>Meyer et al 2003</td>
<td>The US Agency for Healthcare Research and Quality's activities in patient safety research</td>
<td>Describes AHRQ's recent and current initiatives to improve patient safety. Includes public outreach to educate the public about patient safety concerns - one of these initiative is ‘Five Steps to safer Healthcare’</td>
<td>USA</td>
</tr>
<tr>
<td>Meyer et al 2003</td>
<td>The US Agency for Healthcare Research and Quality's current and recent activities in patient safety research</td>
<td>Describes an update of the Agency for Healthcare Research and Quality’s current and recent activities in patient safety research including ‘Five Steps to safer Healthcare’</td>
<td>USA</td>
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<tr>
<td>Minnesota Alliance for Patient Safety 2006</td>
<td>Strategies for Safety (conference highlights)</td>
<td>Describes a Patient Safety conference which described safety interventions, some including patients and their representatives</td>
<td>USA</td>
</tr>
<tr>
<td>Mitchell et al 1998</td>
<td>Patients as a direct source of information on adverse drug reactions</td>
<td>Describes a study set up to evaluate the reliability and validity of patient reporting of adverse drug reactions. Found that patients were less likely than HCPs to attribute symptoms to drug treatment but that patient reporting of all clinical events after commencing a new medication may be a method for post-marketing surveillance</td>
<td>Australia</td>
</tr>
<tr>
<td>Moody 2002</td>
<td>The Safety of Medicines - A Patient's View</td>
<td>Conference paper commenting on the inadequacy of pharmaceutical advertising as a source of information for patients and advocating the provision of evidence-based comprehensible information to enable patients to make safe choices especially in developing countries</td>
<td>NL</td>
</tr>
<tr>
<td>Moody 2002</td>
<td>The safety of medicines: a patient's view</td>
<td>Describes the safety issues for patients in developing countries that lack the regulatory bodies of developed countries. This means that patients are at risk from counterfeit products and lack access to effective medication and reliable sources of information. This compromises their ability to be involved in their care and responsible for their own safety</td>
<td>NL</td>
</tr>
<tr>
<td>Moore 2004</td>
<td>Health care literacy and patient safety: the new paradox</td>
<td>Describes the problem of health illiteracy and how this affects patients’ ability to be involved in their care and promote their own safety. Calls for a change in the way HCPs communicate with patients taking into account their ability to understand and simplifying information given to make it more accessible for all</td>
<td>USA</td>
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<tr>
<td>Author</td>
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<td>Summary</td>
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<td>Morath 2003</td>
<td>Changing the healthcare culture: the consumer as part of the system of care</td>
<td>Describes how consumer demands are driving up the quality of healthcare and documents a number of initiatives where HCPs, patients and their families have worked together to improve the safety of care</td>
<td>USA</td>
</tr>
<tr>
<td>Moskowitz 1992</td>
<td>Cutting malpractice costs with contracts?</td>
<td>Describes how malpractice cases in the USA may be reduced by patients and physicians being explicit with each other, via written contracts, about what sort of relationship they would like - one with shared decision-making and clear responsibilities or one where the patient is happy to leave decision-making to the physician. This, the author argues would lead to less defensive practice, less unnecessary procedures and, potentially, safer care</td>
<td>USA</td>
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<tr>
<td>Mullner 2003</td>
<td>Patient Safety and Medication Errors</td>
<td>Describes the problem of medical error and outlines several strategies to improve patient safety including improving availability of patient information and patients’ knowledge about their treatment</td>
<td>USA</td>
</tr>
<tr>
<td>Murie 2003</td>
<td>Amiodarone monitoring: involving patients in risk management</td>
<td>Describes an audit of monitoring of amiodarone therapy in primary care. Found this was suboptimal and identified a role for patients and carers through patient held-record cards, direct patient adverse event reporting, follow-up information based on patient experiences and better links between HCPs, patients, the pharmaceutical industry and Committee on Safety of Medicines</td>
<td>UK</td>
</tr>
<tr>
<td>Murray 2002</td>
<td>Better to be safe than sorry</td>
<td>Describes the potential for injury from medical devices and highlights the importance of education and training of patients and carers in the correct use of these devices</td>
<td>UK</td>
</tr>
<tr>
<td>Nahimy 2005</td>
<td>Keeping the youngest patients safe</td>
<td>Describes the phenomenon of infant abduction from hospitals and strategies that can be adopted to reduce the risk including patient education.</td>
<td>USA</td>
</tr>
<tr>
<td>Nau &amp; Erickson 2005</td>
<td>Medication safety: patients’ experiences, beliefs and behaviours</td>
<td>Describes a study to measure patients’ experiences of medication error and how, if at all, this affects their own medication safety behaviour and beliefs about pharmacy safety. Found that those who had experienced a medication error have lower perceptions of pharmacy safety and engage in more medication safety behaviours than those who have no such experience</td>
<td>USA</td>
</tr>
<tr>
<td>Naylor 2006</td>
<td>Georgia Hospital Association: Patient Safety Improvement Corps</td>
<td>Describes the proposed evaluation and monitoring of a patient safety programme involving health care establishments in Georgia</td>
<td>USA</td>
</tr>
<tr>
<td>NHS Confederati on 2001</td>
<td>Building a safer NHS for patients</td>
<td>Describes the response to An Organisation with a Memory including the setting up of the NPSA and exploration of a reporting and complaints system for patients and carers</td>
<td>UK</td>
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<tr>
<td>Author(s)</td>
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<tr>
<td>Nicholas &amp; Agius 2005</td>
<td>Towards safer IV medication administration</td>
<td>Describes the problem of IV medication error and strategies that may be employed to reduce the risk of this including provision of accessible information for patients and families. Authors call for patients and their families to be involved in developing this information.</td>
<td>USA</td>
</tr>
<tr>
<td>Norman 1994</td>
<td>Pills can kill</td>
<td>Describes the problem of adverse medication events due to patients not using their medication correctly. Writes that nurses are in a unique position to educate patients and the public about correct medication use and so reduce the risk of harm due to adverse medication events.</td>
<td>Australia</td>
</tr>
<tr>
<td>NPSA 2004</td>
<td>Seven steps to patient safety: A guide for NHS staff</td>
<td>Describes how patients and their families can be involved in the analysis of patient safety issues as well as playing a role in reducing the chance of harm.</td>
<td>UK</td>
</tr>
<tr>
<td>NPSA 2004</td>
<td>Framework for action: Right patient - right care</td>
<td>Describes how patients can erroneously receive care that is not intended for them or be matched with specimens other than their own. Sets out the findings of two studies and proposes a way forward. Patient groups were involved in this process, providing the patient's view.</td>
<td>UK</td>
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<tr>
<td>Oermann 2004</td>
<td>Interview with Suzanne Delbanco, Executive Director of the Leapfrog Group</td>
<td>Describes the goals and current activity of the Leapfrog Group and their view that consumers have a part to play in improving their safety both by asking questions or raising concerns and by exercising choices.</td>
<td>USA</td>
</tr>
<tr>
<td>Olson 1978</td>
<td>Drug misuse among the elderly</td>
<td>Describes the problem of drug misuse among the elderly, the causes for it and how they can be avoided. Maintains that one strategy is patient education as well as talking to patients to find out what works for them.</td>
<td>USA</td>
</tr>
<tr>
<td>O'Mahony 1999</td>
<td>Safety and supply issues from consumers’ point of view</td>
<td>Describes patient perception of the safety of blood and blood product transfusion and how this has changed over time. Also discusses the difficulties sometimes experienced with supply of blood and blood products. Calls for patient involvement in developing a consensus about regulation, safety and supply and the involvement of consumers in the work of the National Blood Transfusion service.</td>
<td>UK</td>
</tr>
<tr>
<td>Orr et al., 2001</td>
<td>A select few</td>
<td>Describes a reader panel's responses to the Bristol Inquiry Report call for public involvement in the selection of HCPs, with nationally agreed criteria. Panel member's views were varied and they expressed concerns about HCP privacy, and further depletion of nurse numbers.</td>
<td>UK</td>
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<tr>
<td>Oulton 2003</td>
<td>Inside view: patient safety concerns us all</td>
<td>Describes the international and interdisciplinary nature of medical error and maintains that all are responsible for it. Calls for all HCPs to work with patients making them equal partners in care with two way information sharing.</td>
<td>USA</td>
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<td>Reference</td>
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<td>Abstract</td>
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<td>Pankaskie 2002</td>
<td>patient safety resources on the internet</td>
<td>Describes a number of patient safety websites available to patients and HCPs. Argues that patients who are better informed can play a role in reducing the incidence of medical error</td>
<td>USA</td>
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<tr>
<td>Parfieniuk et al 2006</td>
<td>The understanding of the term 'iatrogeny'</td>
<td>Describes the term iatrogeny and the major causes that led to its emergence. Authors state that in general terms to avoid medical mishaps doctors should encourage patient involvement by acting emphatically and carefully conveying information. The need for better healthcare education that would 'create conditions for cooperation between medical staff and patients' and 'increase public trust in the health care system' is stressed. In analysing the relationship between iatrogeny and medical testing, the authors reiterate international law provisions that stipulate that tests can only be conducted with the patient's consent and his/her full access to related information.</td>
<td>Poland</td>
</tr>
<tr>
<td>Patient Safety Advisory 2005</td>
<td>When Patients Speak: collaboration in patient safety</td>
<td>Describes how patients can collaborate in their healthcare to improve their own safety. Illustrates this with a number of case studies where patients/families speaking up may have influenced the final outcome. Includes some ways in which HCPs can facilitate patient involvement</td>
<td>US</td>
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<tr>
<td>Pedreira &amp; Marin 2004</td>
<td>Patient safety initiatives in Brazil: a nursing perspective</td>
<td>Identifies the nursing workforce in Brazil as the key to patient safety promotion. Lists a number of patient safety promotion initiatives including patient and family involvement in decision making and monitoring adverse events</td>
<td>Brazil</td>
</tr>
<tr>
<td>Pennsylvan ia Patient Safety Summit 2000</td>
<td>Summary Proceedings</td>
<td>Describes the proceedings of a patient safety summit with audience comprised of representatives and professionals from the political and private sector. Patient Involvement highlights include AHRQ's 20 tips and women receiving a copy of their mammography report in lay language and the potential for this to be extended to other radiological investigations to increase patient involvement and possibly reduce errors</td>
<td>USA</td>
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<tr>
<td>Peota 2004</td>
<td>Health Literacy and Patient</td>
<td>Examines the link between health literacy and patient outcomes, safety and satisfaction. Calls for the involvement of patients and their families in the development of healthcare processes and systems</td>
<td>USA</td>
</tr>
<tr>
<td>Peters et al 2006</td>
<td>Why worry? Risk perceptions and willingness to act to reduce medical errors</td>
<td>Describes a study that examined the role of worry and perceived risk in patient’s precautionary actions to improve safety. Found that worry about medical errors was a better predictor of such behaviours than risk perceptions</td>
<td>USA</td>
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<tr>
<td>Author(s)</td>
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<td>Petti 2001</td>
<td>Perceptions of seclusion and restraint by patients and staff in an intermediate-care facility</td>
<td>Describes the use of patient and staff feedback after restraint incidents, mainly to maintain safety, as learning tools for patients and staff.</td>
<td>USA</td>
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<tr>
<td>Pincock 2003</td>
<td>New plan launched to tackle Britain's high rate of hospital infection</td>
<td>Describes the problem of MRSA in the UK and new plans launched to tackle the high rates of hospital-acquired infection. Calls for a debate with patient advocates to come up with solutions.</td>
<td>UK</td>
</tr>
<tr>
<td>Pizzi et al 2001</td>
<td>Other Practices Related to Patient Participation</td>
<td>Describes practices related to patient participation in protecting their own safety including advice sheets, disease/procedure specific advice, practices to improve non-compliance and access to medical records. Notes that there is little evidence for the efficacy of these interventions or patients' ability &amp; willingness to use them and calls for further research.</td>
<td>USA</td>
</tr>
<tr>
<td>Queneau &amp; Grandmotte t 1998</td>
<td>Prevention of avoidable iatrogenic effects: the obligation for vigilance</td>
<td>Describes the problem of medical error, unrealistic expectations of 'zero risk' interventions/treatments by the general public and preventative strategies including patients following the advice of HCPs.</td>
<td>France</td>
</tr>
<tr>
<td>Queneau et al 1992</td>
<td>Analysis of the causes of and proposed new preventative measures for iatrogenic illness</td>
<td>Describes a study that analysed the causes of iatrogenic illnesses over a 24hr period in one French hospital. They concluded that the main causes were poor patient understanding of how to take prescribed medication. Recommendations were for better communication training for HCPs, improved history taking, making sure that information about patients is shared between HCPs and kept up to date, ensuring that patients take on responsibility for sharing relevant information with HCPs, better printed information supplied with medication by pharmaceutical companies, using the media to promote the idea of the 'medic-patient' relationship and the importance of taking treatments correctly.</td>
<td>France</td>
</tr>
<tr>
<td>Raef 2004</td>
<td>Five years after 'To Err is Human': a look at the patient safety landscape</td>
<td>Provides an overview of patient safety initiatives in the USA between 1999 and 2004. Describes a case study of how a sentinel event launched one hospital's Patient Safety Quest</td>
<td>USA</td>
</tr>
<tr>
<td>Raschetti 1999</td>
<td>Suspected adverse drug events requiring emergency department visits or hospital admissions</td>
<td>Describes a study that prospectively collected data on visits to an emergency department due to adverse drug events over 1 year. Half of the total ADE related admissions were assessed as preventable. Authors call for improvement in patient awareness about the proper use of drugs through education and improvement of the physician/patient relationship.</td>
<td>Italy</td>
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<tr>
<td>Author(s)</td>
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<tr>
<td>Reese 2001</td>
<td>An ounce of prevention</td>
<td>Describes a survey of the rate of adverse drug events in nursing homes, why they happen and what can be done to reduce the risk of them happening including patient and family education about their medication, potential side effects and when to seek help.</td>
<td>USA</td>
</tr>
<tr>
<td>Roper 2002</td>
<td>Consumer perspective employment in the psychiatric service system: a Victorian view on safety issues.</td>
<td>Describes the issues and dilemmas raised from a consumer point of view by employment to present a consumer perspective on safety within the mental health system. These were: difficulties knowing where their roles 'fitted' into the system being asked to view the service through a medical model while they were employed to provide a unique consumer perspective being fitted into the system rather than the system changing to accommodate their needs the difficulties of being a lone provider of a minority perspective when teaching students The author calls for a 'fully resourced 'place of our own’</td>
<td>Australia</td>
</tr>
<tr>
<td>Rosovsky 1997</td>
<td>The Safe Medical Devices Act and Home Health Care: Risk management issues and solutions</td>
<td>Describes the implications for home healthcare agencies of the Safe Medical Devices Act including assumption of responsibility for safety. Recommends that agencies and patients take on this role and families are given verbal and written instruction about how to use devices safely.</td>
<td>USA</td>
</tr>
<tr>
<td>Royston &amp; Cox 2003</td>
<td>Anaesthesia: the patient's point of view</td>
<td>Describes the safety concerns of patients prior to undergoing anaesthetic and how modern developments in anaesthesiology might provide solutions to these. Also comments that persuading more patients to voice these concerns to anaesthetists and providing information about therapeutic options available remains a challenge.</td>
<td>UK</td>
</tr>
<tr>
<td>Rozovsky 1997</td>
<td>The Safe Medical Devices Act and Home Health Care: Risk Management Issues and Solutions</td>
<td>Describes the difficulties experienced applying legislation for safe use of medical appliances in the home including assigning responsibility for training, reporting and risk assessment. Highlights the need for patients and their families to be trained in the use of equipment with backup from clear written instructions.</td>
<td>USA</td>
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<tr>
<td>Author</td>
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<tr>
<td>Rucker</td>
<td>Risk, respect, responsibility: educational strategies to promote safe medicine use</td>
<td>Describes the wide range of educational material produced to increase patient knowledge about taking medication safely. Points out that there is an assumption among providers of educational material will lead to better informed patients who will self-medicate more safely. There is, however, a shortage of evaluation of educational campaigns. The paper argues for a study to define 'success' in a campaign; evaluation surveys after campaigns and to this end, the development of an evaluation tool.</td>
<td>USA</td>
</tr>
<tr>
<td>Rucker</td>
<td>Risk, respect, responsibility: educational strategies to promote safe medicine use</td>
<td>Describes a number of different educational programmes by the pharmaceutical industry, non-profit making organisations &amp; government agencies to promote the safe use of medication and comments that there is little evaluation of these programmes and their effect on behaviour.</td>
<td>USA</td>
</tr>
<tr>
<td>Ruland</td>
<td>Improving patient safety through informatics tools for shared decision making and risk communication</td>
<td>Describes the tools available to patients and HCPs to facilitate shared decision-making and risk communication. Argues that failure to engage patients in decision making and risk assessment, that is not eliciting patient preferences, lacking or misinterpreting relevant data &amp; ineffective communication can lead to intended outcomes not being achieved, compromising patient safety. Highlights the role of IT in shared decision making to 'process, structure, integrate and individualise information'.</td>
<td>Norway</td>
</tr>
<tr>
<td>Rundall et al</td>
<td>Prescribing Safely in Ambulatory Care</td>
<td>Describes a survey of physicians’ views on how they ensured their prescribing was safe. They described a number of strategies including using reference material, consulting pharmacists and medication educational materials. They also suggested new safety approaches which included electronic medical records based systems that flag potential errors and making sure that patients are educated to improve their knowledge of their own medication.</td>
<td>USA</td>
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<tr>
<td>Author(s)</td>
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<tr>
<td>Runkle &amp; Scheffler 1998</td>
<td>Enhancing patient safety and reducing errors in healthcare: responses form multiple perspectives</td>
<td>Describes the comments from the plenary session at the end of the conference. When panellists were asked to reflect on various aspects of patient safety including who is responsible for patient safety, who should be included in patient safety efforts, how and to what degree should patients and consumers be involved, what part the legal system plays, what kind of error reporting system would be most useful &amp; how should HCPs and the public be educated about patient safety. The panellists expressed a wide range of opinions but concluded that patients, the public and their representatives are critical stakeholders in the patient safety movement even if their opinions and perceptions are not always strictly 'rational' or 'scientific'. Their participation can provide many opportunities for patient safety improvement.</td>
<td>USA</td>
</tr>
<tr>
<td>Sage 2002</td>
<td>Putting the patient in patient safety</td>
<td>Argues that health care providers need to involve patients in patient safety by incorporating their perspectives into organisational quality improvement, improving safety after error and improving customer satisfaction</td>
<td>USA</td>
</tr>
<tr>
<td>Sage 2002</td>
<td>Putting the Patient in Patient Safety</td>
<td>Argues that to fully involve patient in patient safety HCPs need to move from their own to patients’ definition and that time should be spent on finding out what doctors are doing right and sharing this good practice rather than the opposite.</td>
<td>USA</td>
</tr>
<tr>
<td>Sandars &amp; Esmail 2001</td>
<td>Threats to Patient Safety in Primary Care: a review of the research into the frequency and nature of error in primary care</td>
<td>Describes a review of the relevant literature. Reveals that threats to patient safety in a primary care setting range from between 5 to 80 per 100,000 consultations. Most do not result in actual patient harm. The importance of human (patient and practice staff) and system factors is highlighted</td>
<td>UK</td>
</tr>
<tr>
<td>Santell 2004</td>
<td>Better communication may reduce medical errors in the home</td>
<td>Describes how patients who are given drug samples from doctor’s offices often do not know how to take them as they are often issued without instructions. Urges HCPs to encourage patients to ask questions about their medication and how to take it.</td>
<td>USA</td>
</tr>
<tr>
<td>Santell and Camp 2004</td>
<td>Better Communication may Reduce Medical Errors in the Home</td>
<td>Describes reports submitted to the US Pharmacopeia that reveal that communication problems and lack of knowledge about medication are reported by patients as major causes of medication error. Author calls for better communication and patient counselling processes by HCP</td>
<td>USA</td>
</tr>
<tr>
<td>Savitz 2005 (ongoing)</td>
<td>Improving the quality of early cancer care</td>
<td>Describes an ongoing project about care in early cancer which focuses on how it can be designed/redesigned to improve quality through six IOM goals of safety, effectiveness, patient centredness, timeliness, efficiency and equity</td>
<td>USA</td>
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<tr>
<td>Author(s)</td>
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<tr>
<td>Schiff 1995</td>
<td>Red Man syndrome and the red button system</td>
<td>Describes the limitations of most current adverse drug event reporting systems and the types of systems which could replace them including relying on computerised systems to identify actual and potential adverse drug events using lab data, prescribing information and patient history, or involving combining a reporting system with a more general helpline from which patients, HCPs and carers can seek advice as well as reporting any adverse effects</td>
<td>USA</td>
</tr>
<tr>
<td>Schiff et al 2005</td>
<td>Diagnosing diagnosis errors: Lessons from a multi-institutional collaborative project</td>
<td>Describes a study that examined the literature about diagnosing error and developed a taxonomy delineating where in the process errors most commonly occur. Ideas for improvement include engaging patients on multiple levels to become co-producers of safer medical diagnosis practices</td>
<td>USA</td>
</tr>
<tr>
<td>Schmitt 2006</td>
<td>Interprofessional approaches to creating safe, high quality health care</td>
<td>Editor's introduction to themed patient safety issue. Introduces paper by A Howe which focuses on a patient centred approach and an array of initiatives which would productively engage patients as team members in the effort to improve patient safety</td>
<td>UK</td>
</tr>
<tr>
<td>Schrappe 2005</td>
<td>Patient Safety and Risk Management</td>
<td>Describes the efforts to improve patient safety within the German healthcare system and highlights what needs to change for progress to be made including strengthening patient participation</td>
<td>Germany</td>
</tr>
<tr>
<td>Schulmeister 2001</td>
<td>Oops! He did it again</td>
<td>Describes the problem of medical errors and how nurses can play a key role in ensuring that healthcare consumers are encouraged to be informed and ask questions about their healthcare</td>
<td>USA</td>
</tr>
<tr>
<td>Sharpe 2003</td>
<td>Promoting Patient Safety: an ethical basis for policy deliberation</td>
<td>Describes the approach to patient safety from a policy level and discusses the responsibility for safety and whether patients are responsible for keeping themselves safe. Concludes that patient involvement should be facilitated but that their capacity to be involved varies on many levels and many patients will be in situations where they are unable to take responsibility for the quality of safety of their care at that time.</td>
<td>USA</td>
</tr>
<tr>
<td>Shaw et al 1999</td>
<td>Adverse effects of herbal remedies and OTC medicines</td>
<td>Comments on a study which looked at adverse reactions to herbal/complimentary therapies suggests that consumers should be educated to report adverse reactions to over-the-counter drugs and to inform HCPs that they are taking them.</td>
<td>UK</td>
</tr>
<tr>
<td>Sheridan &amp; Hatlie 2005</td>
<td>Including Consumers as Reporters to Learning Systems</td>
<td>Notes the enactment of the Patient Safety and Quality Improvement Act 2005 that provides a 'safe' medical error reporting system for HCPs in the USA. Author notes that patients and the public will not be invited to report and regrets the lack of patient input citing successful systems in the UK and Australia. Argues that while US public policy is driven by fear of</td>
<td>USA</td>
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</table>
litigation and where patients and the public are perceived as adversaries rather than partners it will not be a system than learns from all it's mistakes

<table>
<thead>
<tr>
<th>Reference</th>
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<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Sheridan et al 2006</td>
<td>Building a global network of consumer partners</td>
<td>Describes the launch and development of the WHO World Alliance for Patient Safety and the establishment of Patients for Patient Safety to ensure that the patient perspective is included in the work of the world alliance. This has now started with the recruitment and coaching of consumer champions</td>
<td>USA</td>
</tr>
<tr>
<td>Siegel &amp; Bennett 2006</td>
<td>Creating partnerships through patient safety awareness week</td>
<td>Describes the activities at one hospital during National Patient Safety Awareness week which included patient safety stations distributed around the hospital from which staff distributed safety kits and discussed medication safety with patients and families, new patient orientation sessions during which patients are encouraged to be active participants in ensuring their environment stays safe and patient safety videos available to view 24hrs a day.</td>
<td>USA</td>
</tr>
<tr>
<td>Sleigh 2005</td>
<td>Labor Union Role in Patient Safety</td>
<td>Describes how labour unions have influenced the patient safety agenda by insisting that patient safety and quality are embedded as purchasing principles in agreements with employers</td>
<td>USA</td>
</tr>
<tr>
<td>Smallwood 2003</td>
<td>Safety and Quality in Healthcare: what can England and Australia learn from each other?</td>
<td>Describes &amp; contrasts the healthcare systems in the UK &amp; Australia and the inroads that have been made in both systems to improve patient safety. Comments in both countries the move towards consumers and HCPs sharing decision making and responsibility is to be welcomed</td>
<td>Australia</td>
</tr>
<tr>
<td>Smetzer 2001</td>
<td>Safer Medication Management</td>
<td>Describes how a systems approach can help to reduce medication errors. In addition it is important for HCPs to keep patients informed about medication, encourage them to ask questions and speak up if they have concerns</td>
<td>USA</td>
</tr>
<tr>
<td>Smith 2003</td>
<td>Reducing ophthalmic drug related injuries in older patients</td>
<td>Describes drug related injuries to patients that may or may not have been the result of a drug error. Draws attention to the potentially toxic effects of ophthalmic medication and stresses the importance of patient education and regular medication review to reduce the risk of adverse drug event</td>
<td>USA</td>
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<tr>
<td>Author</td>
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<tr>
<td>Smith 2003</td>
<td>Patient Information: risk and choice</td>
<td>Describes the tensions in the production of patient information about anaesthesia and the need to balance the information about risk with the reassurance that this risk is minimal because of the skills and training of the anaesthetist. Argues that patients have the right to make choices but that these may be limited in anaesthesia. In addition with choices come responsibility and an anaesthetist may choose not to anaesthetise a patient who has chosen not to fast as instructed.</td>
<td>UK</td>
</tr>
<tr>
<td>Smythe 2001</td>
<td>The meaning of 'being responsible' for safe care in childbirth</td>
<td>Describes the development of midwifery services and with it the shift of responsibility for safety during childbirth from the woman and family to health professionals and hospitals. With the move towards autonomous midwifery the responsibility appears to be moving to a shared position with women. Concludes that the notion of responsibility needs to be brought to question rather than assumed.</td>
<td>New Zealand</td>
</tr>
<tr>
<td>Soutoul 1981</td>
<td>The medico-legal risk in gynaecology: the circumstances of the risk, its prevention and treatment</td>
<td>Describes circumstances which lead to a risk of complaint by the patient in common practice and gynaecological surgery and draws up rules to avoid this risk including making sure that all procedures are explained to patients, thereby minimising the risk of adverse events.</td>
<td>France</td>
</tr>
<tr>
<td>Spath 2003</td>
<td>Can you hear me now? Providers must give patients a voice in efforts to reduce medical errors</td>
<td>Describes a number of hospitals and healthcare systems that have undertaken strategies to involve patients in the safety process and emphasises that patients cannot take on the role of healthcare partner if providers are not willing to partner alongside them.</td>
<td>USA</td>
</tr>
<tr>
<td>Spath 2006</td>
<td>Involving patients in safety</td>
<td>Comments on the effort by organisations to involve patients and their families in safety initiatives and the lack of evaluation of information and educational material that aims to achieve this. Cites the Entwistle et al 2005 study that found that there was little involvement of patients in the production or evaluation of patient safety educational resources and this may mean that they fail to engage patients. There were also concerns that there was an attempt to shift responsibility for safety onto patients. Argues that future consumer directed educational materials should have public input to ensure they reflect the patient's perspective. In addition health care organisational culture needs to change into one which accepts patients as part of the healthcare team.</td>
<td>USA</td>
</tr>
<tr>
<td>Stead 2003</td>
<td>Significant Event Audit: a building block to developing a safety culture</td>
<td>Describes the role of significant event audit in patient safety and how patients might be involved.</td>
<td>UK</td>
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<tr>
<td>Author(s)</td>
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<tr>
<td>Stewart 2000</td>
<td>Focus on Error Prevention</td>
<td>Comments on problem of medication error and contributing factors. Makes a number of recommendations for pharmacy practice including making sure patients are counselled about the reason for the medication and how it should be taken. If this is not possible face to face the author recommends a phone call.</td>
<td>USA</td>
</tr>
<tr>
<td>Strachan 2004</td>
<td>Nursing Information</td>
<td>Describes the link between poor communication of information in healthcare and adverse events and recommends that patient participation in and ownership of their information is crucial, alongside better communication between HCPs, to reducing the risk of medical error.</td>
<td>UK</td>
</tr>
<tr>
<td>Stull et al 2006</td>
<td>Board-certified oncology pharmacists: partners in the multidisciplinary care of cancer patients</td>
<td>Describes how an oncology pharmacy clinical specialist on the clinical team improves outcomes for patients and reduces the risk of adverse event and medical error. They can involve patients in this through education of individual patients and the wider public.</td>
<td>USA</td>
</tr>
<tr>
<td>Sukkari 2001</td>
<td>Cisapride and patient information leaflets</td>
<td>Describes a study that compared information leaflets for patients in Canada issued with Cisapride with the leaflet approved by the US FDA. They found that the Canadian leaflets omitted important information which was thus potentially dangerous and recommend that all drug information leaflets should be regulated by the federal government and meet regulated standards.</td>
<td>Canada</td>
</tr>
<tr>
<td>Sulser 2006</td>
<td>A patient's perspective on haemophilia</td>
<td>Describes the need for patients with haemophilia to be informed about their condition to enable them to make informed choices. Comments that many lost trust in 'official' organisations during the AIDS epidemic and this gave rise to consumer advocacy organisations which now play a key role in disseminating information and representing those with haemophilia.</td>
<td>USA</td>
</tr>
<tr>
<td>Swift 2001</td>
<td>Preventing medical errors: communicating a role for medicare beneficiaries</td>
<td>Describes a study that used focus groups to explore patients' attitudes to specific kinds of safety promoting behaviour advocated by patient safety organisations (such as 'Five Steps to Safer Healthcare'. Found that patients preferred those actions which took a collaborative approach and that public health campaigns to reduce errors need not undermine trust in providers.</td>
<td>USA</td>
</tr>
<tr>
<td>Teague 2005</td>
<td>Harness the public to improve cleanliness</td>
<td>Describes the progress of the NPSA 'Clean hands' campaign - encouraging patients to ask HCPs to wash their hands. Comments that engaging both patients and staff is key to success.</td>
<td>UK</td>
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<tr>
<td>Author</td>
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<tr>
<td>Thompson</td>
<td>Getting practical about patient safety</td>
<td>Describes presentations at the NPSF 2002 conference about how facilities are being made safer. Specifically, Describes patient/family involvement through interdisciplinary team meetings where patients are encouraged to attend.</td>
<td>USA</td>
</tr>
<tr>
<td>Tingle</td>
<td>Patient and Public Involvement: implications for risk managers</td>
<td>Describes the reforms to risk management outlined in the NHS plan to facilitate public and patient involvement in risk management processes through patient forums in every trust, PALS, overview and scrutiny committees and the Commission for Patient and Public Involvement</td>
<td>UK</td>
</tr>
<tr>
<td>Tingle</td>
<td>Nurses must know the steps to ensure safety of patients</td>
<td>Describes the NPSA launched and sponsored seven steps booklet and ‘ask about medicines’ card. The step 5 booklet details patient and public involvement and provides guidance for this. The card features five questions and five tips to help patients learn more about their medication.</td>
<td>UK</td>
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<tr>
<td>Tingle</td>
<td>Nurses must be more aware of patient safety initiatives</td>
<td>Describes the package of guidance and support launched by the NPSA for NHS staff to help improve patient safety. Includes guidance about involving and communicating with patients and the public</td>
<td>UK</td>
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<tr>
<td>Tom</td>
<td>Medication Error Reports from the USP-ISMP Medication Errors Reporting Programme</td>
<td>Describes a number of medication error reports and near misses. For several of them patient education did or could have prevented or lessened the likelihood of the error</td>
<td>USA</td>
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<tr>
<td>Trueland</td>
<td>Clicks can be dangerous</td>
<td>Describes the difficulties of evaluating the quality of online health information and the importance of conveying to patients that some of it is misleading or inaccurate. Describes an initiative which provides a guide to specialist search engines which only offer access to accredited information and others such as BMJ.com which is peer reviewed</td>
<td>UK</td>
</tr>
<tr>
<td>Turnbull</td>
<td>All Components of the System must be Aligned</td>
<td>Describes a number of initiatives designed to involve patients in improving healthcare safety. Emphasises that all ‘parts’ of the healthcare system, including patients, need to appreciate that each action has a reaction and change in one part of the system will have an effect elsewhere in the system</td>
<td>USA</td>
</tr>
<tr>
<td>Uhl et al</td>
<td>Information on medication use in pregnancy</td>
<td>Describes how the FDA is working towards providing quality data for both patients and HCPs about medication use in pregnancy to enable them to make informed decisions about risks and benefits</td>
<td>USA</td>
</tr>
<tr>
<td>Underdahl</td>
<td>James Bagain on patient safety initiatives</td>
<td>Details of a message which appeared on the NPSF discussion group page detailing the points raised by James P Bagian, one of which was that patients should be encouraged to be active partners in their own care ‘an educated patient is a very good thing’</td>
<td>USA</td>
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<tr>
<td>Author(s)</td>
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<tr>
<td>Unruh &amp; Lugo 2005</td>
<td>Healthcare safety: what does managed care have to do with it?</td>
<td>Describes the effect on healthcare quality and safety of managed care organisations and health plans. These organisations promote healthcare safety through consumer education about emergency management, safe medication practice and effective communication with physicians.</td>
<td>USA</td>
</tr>
<tr>
<td>Unruh et al 2005</td>
<td>Managed care and patient safety: risks and opportunities</td>
<td>Describes a review of the literature about the relationship of managed care to patient safety. Finds that both risks and opportunities exist for patient safety promotion including consumer education to increase awareness and facilitate safer safe-care practices.</td>
<td>USA</td>
</tr>
<tr>
<td>Valbones 2005</td>
<td>The Design of Artefacts in support of drugs prescribing: An analysis of the discharge process of patients based on activity theory</td>
<td>Describes problems encountered by pharmacists and patients interpreting discharge documents which detail prescribed drugs and instructions for taking them. Advocates that attention is paid to how the document is used by all those involved (physician, pharmacist and patient) when designing discharge documentation.</td>
<td>Italy</td>
</tr>
<tr>
<td>van Grootheest et al 2003</td>
<td>Consumer Adverse Drug Reaction Reporting: a new step in pharmacovigilance?</td>
<td>Describes an overview of various countries’ experience of consumer reporting of adverse drug reactions. Concludes that there is insufficient data available to establish that this will be an effective tool for pharmacovigilance.</td>
<td>NL</td>
</tr>
<tr>
<td>van Grootheest et al 2004</td>
<td>Do pharmacists’ reports of adverse drug reactions reflect patients’ concerns?</td>
<td>Describes a study that compared two data sets, questions to a drug information line and pharmacist’s reports to a pharmacovigilance centre regarding drugs and ADRs over the same 14-month period. Concluded that generally pharmacist’s reports reflected patient concerns except with regard to ADRs in the psychiatric spectrum.</td>
<td>NL</td>
</tr>
<tr>
<td>van Grootheest et al 2005</td>
<td>The patient should be able to report and research side effects on the internet</td>
<td>Describes the reactions of three patient safety experts to web based reporting of medication side effects by patients. Currently this is not anonymous to facilitate feedback - the pros and cons of this are debated. Concerns were raised about the security of web-based reporting. One expert felt that primary responsibility for reporting should be with HCPs but all felt that patients were capable of reliable reporting.</td>
<td>NL</td>
</tr>
<tr>
<td>van Gruting &amp; de Gier 1992</td>
<td>Medication assistance: the development of drug surveillance and drug information in the Netherlands</td>
<td>Describes the development of drug surveillance and drug information in the Netherlands. Predicts that patients will increasingly involved in drug surveillance through the use of patient held smart cards to ensure that information exchange between HCPs is timely.</td>
<td>NL</td>
</tr>
<tr>
<td>Author(s) and Year</td>
<td>Title and Description</td>
<td>Summary</td>
<td>Country</td>
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<tr>
<td>van Haecht et al 1990</td>
<td>Package inserts for anti-hypertensive drugs: use by the patients and impact on adverse drug reactions</td>
<td>Describes a study that compared patient and physician orientated drug package inserts, their use by patients and their impact on adverse drug event reporting. Found that reading package inserts did not increase the number of reports of side effects but made patients more likely to attribute side effects to medication especially those patients with a lower level of education.</td>
<td>Belgium</td>
</tr>
<tr>
<td>van Norman et al 2004</td>
<td>Informed consent: ethical implications in clinical practice</td>
<td>Describes the tensions between safety culture and production pressures within healthcare services and anaesthetists part in this.</td>
<td>USA</td>
</tr>
<tr>
<td>Vincent 2006</td>
<td>Why it's safer to involve the patient</td>
<td>Describes ways in which patients might and should, if possible, be involved in promoting their own safety when using healthcare services. Notes a number of examples such as sharing information, speaking up if things are out of the ordinary and comments that little is known about how these interventions will be received by the public.</td>
<td>UK</td>
</tr>
<tr>
<td>Vogt 2002</td>
<td>Effective communication of drug safety information to patients and the public</td>
<td>Describes new insights and new resources drawn from recent developments in both medicine and the social sciences that have led to leaders taking a 'new look' at medicine safety and how patients and the public must be involved through new ways of communicating drug safety information.</td>
<td>USA</td>
</tr>
<tr>
<td>Wachter &amp; Shojania 2004</td>
<td>The Faces of Errors: A Case-Based Approach to Educating Providers, Policymakers and the Public about Patient Safety</td>
<td>Describes the success of an approach to educating patients and providers about safety by presenting anonymised cases of medical mistakes.</td>
<td>USA</td>
</tr>
<tr>
<td>Wachter and Shojania, 2004</td>
<td>Internal bleeding, the truth behind America’s terrifying epidemic of medical mistakes</td>
<td>Describes a number of cases where patients have been harmed while using healthcare services. Outlines a number of solutions including some suggestions of what patients can do to promote their safety.</td>
<td>USA</td>
</tr>
<tr>
<td>Wallenius 1995</td>
<td>3rd European Workshop on Drug Information</td>
<td>Report emphasising the importance of medication information which is tailored patient need both in terms of their capacity to understand and the stage they are at in their patient journey</td>
<td>Finland</td>
</tr>
<tr>
<td>Waller 2006</td>
<td>Making the most of spontaneous adverse drug reaction reporting</td>
<td>Describes the future possibilities for adverse drug event reporting systems including direct patient reporting, its potential advantages and disadvantages, and the need for further investigation of this method.</td>
<td>UK</td>
</tr>
<tr>
<td>Waterman et al 2004</td>
<td>Hospitalised patients’ comfort with and participation in medical error prevention</td>
<td>Describes a phone survey in which patients were asked how comfortable they were taking 8 error prevention actions and whether they took these actions during their last hospitalisation. Most patients agreed they could help prevent errors and most said they were comfortable asking. Asking HCPs if they had washed their hands was not something most felt comfortable with. Half of those who reported that an error occurred reported it to staff. Only 4% asked if HCPs had washed their hands. Patients who were non-caucasian or had been in hospital longer than 11 days were more likely to ask docs if they had washed their hands.</td>
<td>USA</td>
</tr>
<tr>
<td>Waterman et al 2006</td>
<td>Hospitalised patients’ attitudes about and participation in error prevention</td>
<td>Explored patient views about error prevention and how ‘comfort’ with a suggested action translated into action while an outpatient. Patients were more comfortable with collaborative rather than confrontational safety behaviours. Comfort with a particular behaviour was not the only factor which affected actual adoption of the behaviour.</td>
<td>USA</td>
</tr>
<tr>
<td>Weber 2004</td>
<td>Health care must be transformed: codified data, patient involvement are keys</td>
<td>Argues that to improve safety data should be recorded in a codified form so it could be analysed to learn lessons and patients should be allowed to contribute to their own care and documentation by, for example, completing a questionnaire online before seeing a physician.</td>
<td>USA</td>
</tr>
<tr>
<td>Weingart 2005</td>
<td>Patient Reported Medication Symptoms in Primary care</td>
<td>Describes a study of patient reported medication related symptoms in primary care. Found that 69% of these were discussed with GPs the remainder resulted in 19 ameliorable &amp; 2 preventable ADEs. Physicians failure to change medication as a response to symptoms resulted in 31 ameliorable ADES.</td>
<td>USA</td>
</tr>
<tr>
<td>Weisbaum 2005</td>
<td>Is consent required for publication of medical errors?</td>
<td>Describes the tension between respecting patient confidentiality rights and the need to share and learn from medical errors that may involve publication of patient information. Calls for a specific policy stance on publication of medical errors as this is of overriding importance for public health.</td>
<td>Canada</td>
</tr>
<tr>
<td>White 2002</td>
<td>Patient Safety: an ethical imperative</td>
<td>Discusses the tension between responsibility for safety and patient autonomy and concludes that health care professionals are ultimately responsibility for patient safety.</td>
<td>USA</td>
</tr>
<tr>
<td>White 2005</td>
<td>Conference Brief Report: National Patient Safety Foundation’s 7th Annual Patient Safety Congress ‘Let’s get on with it - Round 2’</td>
<td>Summary of proceedings at NPSF conference including the involvement of patients and their families.</td>
<td>USA</td>
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<tr>
<td>Author(s)</td>
<td>Title</td>
<td>Description</td>
<td>Location</td>
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<tr>
<td>Williams 2002</td>
<td>Speaking Up Saves Lives: the National Patient Safety Agency</td>
<td>Describes the first year of the NPSA and achievements including the involvement of patients and carers in developing policies and procedures</td>
<td>UK</td>
</tr>
<tr>
<td>Wilkinson and Wilkinson, 2001</td>
<td>Administration of blood transfusions to adults in general hospital settings: a review of the literature</td>
<td>Describes efforts to improve safety of blood transfusion. Reviews information designed to help patients make informed decisions about the need for and alternatives to transfusion</td>
<td>UK</td>
</tr>
<tr>
<td>Wolosin et al 2005</td>
<td>Am I safe here? Improving patients’ perceptions of safety in hospitals</td>
<td>Describes the results of a survey of over 600,000 patients about their perceptions of safety in US Acute Care Hospitals and proposes a number of recommendations for health care institutions to improve patient perceptions of safety</td>
<td>USA</td>
</tr>
<tr>
<td>Woodward 2004</td>
<td>Achieving a safer health service part 2: reporting requirements</td>
<td>Describes the development of the National Reporting and Learning System by the NPSA including the definition of patient safety, patient safety incidents, level of severity and data capture pathways. As with all the NPSA’s work patients and the public are involved in developing solutions and setting priorities</td>
<td>UK</td>
</tr>
<tr>
<td>Wooten 2003</td>
<td>Medicine cabinet staples are not without risk</td>
<td>Describes a survey that revealed that patients often exceed the recommended dose of OTC medication. Recommends that HCPs warn patients that no medication is without risk &amp; that they should follow instructions</td>
<td>USA</td>
</tr>
<tr>
<td>Young 2003</td>
<td>Patient safety is primary job for Missouri pharmacist</td>
<td>Describes role of patient safety specialist in US hospital. Highlights individual pharmacist and her role that includes mainly medication safety issues and wrong-site surgeries and wrong diagnoses based on poor pathology. The job involves talking to staff about issues and involving patients. Patients are invited to participate in committees and patient-orientated medication safety education program. The program describes how to manage medication regimens and has a tear-off wallet sized card called 'Mind Your Meds' where patients can document medication information and have it easily available.</td>
<td>USA</td>
</tr>
<tr>
<td>Zhang &amp; Wen Jin 2006</td>
<td>Participating in Patients for Patient Safety and Advocating for Care Without Harm</td>
<td>Describes the WHO Patients for Patient Safety Initiative and agrees that any initiative in China should involve patients, their families and the public</td>
<td>China</td>
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</tbody>
</table>
### Appendix 1.5: patients’ willingness and ability to adopt safety behaviours

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Title</th>
<th>Summary</th>
<th>Factors Which Affect</th>
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</thead>
<tbody>
<tr>
<td>AHRQ, Kaiser Family Foundation 2004</td>
<td>National Survey on Consumers’ Experiences With Patient Safety and Quality Information</td>
<td>Update of annual report charting patients’ views of healthcare quality and safety (previous survey 2000). Over half of the public said they were dissatisfied with the quality of health in the US. One in three say they or a member of their family have experienced a healthcare error. There was some mismatch between what patients thought would be effective ways to reduce the risk of medical error and the strategies recommended by experts. Many say they are already adopting the recommended ‘five steps to safer healthcare’</td>
<td>People with experience of the healthcare system as users are more likely to take safety action than those without. Nearly half of all people surveyed believe that mistakes made by individual HCPs is a more important cause of error than mistakes made by healthcare organisations.</td>
</tr>
<tr>
<td>AHRQ, Kaiser Family Foundation 2006</td>
<td>Update on Consumers’ Views of Patient Safety and Quality Information</td>
<td>Update of annual report charting patients’ views of healthcare quality and safety. Some indication from this update that patients are becoming more proactive in safety promoting behaviour such as telling HCPs about allergies and past adverse reactions to medication without being asked, creating their own set of medical records to ensure that HCPs have all information they need &amp; chasing up results of tests they have had.</td>
<td>Nearly half of all people surveyed still believed that mistakes made by individual HCPs is a more important cause of error than mistakes made by healthcare organisations although just over one third believe institutions are a more important cause. Participants increasingly taking actions which help to co-ordinate care (informing the management plan) - like telling a HCP about a drug allergy when not asked</td>
</tr>
<tr>
<td>Anon 2006</td>
<td>Patient, protect thyself?</td>
<td>comments on the reports which suggest that patients are generally able to recognise medical errors but many do not report them due to their expectations of the patient and HCP role. Suggests that safety tips recommended to patients are problematic because of lack of evaluation of their effectiveness and no patient participation in their development. Concludes that open communication between HCPs and patients could stop some errors but this would involve a shift in the power balance between these relationships</td>
<td>beliefs about patient and HCP role power imbalance between HCPs and patients</td>
</tr>
<tr>
<td>Ballinger C, Payne S 2002</td>
<td>The construction of the risk of falling among and by older people</td>
<td>Describes ways in which providers and users constructed and managed 'risk' in a day hospital for older people. Authors argue that rigid definitions defined in purely physical or functional terms produce services which do not address older peoples' concerns and in which they will be reluctant to participate.</td>
<td>risk of falling - staff focused on physical risk, patients more concerned about risk to personal and social identities. some patients saw the interventions as infantilising and stereotyping</td>
</tr>
<tr>
<td>Bernstein et al 2004</td>
<td>A qualitative study of attitudes toward error in patients facing brain tumour surgery</td>
<td>Describes qualitative study of attitudes towards error in patients due to have brain tumour surgery. Themes that emerged included trust, feelings about error and discussing error.</td>
<td>patients feelings about medical error varied between fear and no concern 'I don't worry about things I can't control' discussion of errors could help dispel feelings of anxiety 'I like to know that you are this concerned about errors occurring'</td>
</tr>
<tr>
<td>Brennan &amp; Safran 2004</td>
<td>Patient Safety: remember who it's really for</td>
<td>comments that initiatives to involve patients in patient safety either as representatives or individuals needs to incorporate patient preferences and needs, requires an informed and motivated populace and mechanisms which integrate safe practices and investment in safety enhancing devices and care strategies</td>
<td>lack of patient involvement in development</td>
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<tr>
<td>Brown et al 2006</td>
<td>Diagramming patients' views of root causes of adverse drug events in ambulatory care. An online tool for planning education and research</td>
<td>describes a study which sought patients' views of the causes of adverse events in primary care. Found that exploration of causes and potential solutions to minimise the risk of adverse events failed to take into account (due to lack of evidence) several practical and motivational antecedents for patients</td>
<td>did not ask for/give information from/to because of cognitive impairment, lack of language/education to explain the problem forgot, distracted, cognitive impairment, embarrassed, worried about effect on medical record (implications for employment/driving), fear of being rude/inappropriate. does not want to make lifestyle changes, drug abuse, lacks money for treatment, care in more than one location patient believes behaviour contributes to condition, condition carries social stigma, believes could lose job, insurance coverage does not report side effects and consequent non-adherence as fears consequences, violation of privacy, visits to house, benefits system, expectation that doctor will tell them what to do does not disclose/ask for info because of poor relationship with doctor, caregivers at home do not exchange information, patient has more than one set of records worry, fear, embarrassment, time constraints all impact on patient/HCP interface, patient goes to more than one pharmacy</td>
</tr>
<tr>
<td>Cahill 1998</td>
<td>Patients' perceptions of bedside handovers</td>
<td>describes a study which explored patients' perceptions of the bedside handover and identified three main categories of perceptions ' maintaining a professional distance, establishing professional sharing &amp; maintaining patient safety'</td>
<td>more likely to take part when information exchange is about him/herself rather than about treatment contribution affected by assertiveness, confidence, previous experience and cultural background contribution a problem for patients if not well or not well informed taking part does not sit well with passive recipient patient role nursing/medical jargon used ? to exclude but some found reassuring warmth, humanity, caring incompetent handover led to loss of trust one study found patient contribution 9% constrained by time lack of clarity for patient and nurse role reassuring as patient hears information being passed on but raises anxiety if information wrong some see as an opportunity to correct false info &amp; misconceptions</td>
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<tr>
<td>Duncanson &amp; Pearson 2005</td>
<td>A study of the factors affecting the likelihood of patients participating in a campaign to improve staff hand hygiene</td>
<td>describes a study which aimed to seek patient opinion on being asked to participate in a campaign to improve staff compliance with hand washing and to identify factors that may influence the likelihood of patients asking staff to wash their hands</td>
<td>older people less likely to ask about hand washing extrovert more likely to ask easier to ask if jovial atmosphere with no retributions for patients when they ask findings support patient centred approach and importance of positive relationships between patients and HCPs suggestions from patients of factors which might make it easier for patients to ask signs, more sinks, patients given formal instructions, induction on admission, making it fun, slogans, guidelines for patients, being able to see HCPs washing their hands, bring back matron, discipline staff</td>
</tr>
<tr>
<td>Elder et al 2005</td>
<td>How experiencing preventable medical problems changed patients' interactions with primary health care</td>
<td>explored how patients' experiences with self-perceived preventable problems have changed their behavioural interactions with the healthcare system. Found that anger, mistrust and resignation were the most common feelings reported which resulted in behaviours such as stopping going to the doctor acquiring knowledge or getting a second opinion</td>
<td>loss of trust associated with avoidance (of health-service use) or advocacy (actively seeking better care)</td>
</tr>
<tr>
<td>Entwistle 2004</td>
<td>Nursing shortages and patient safety problems in hospital care: is clinical monitoring by families part of the solution?</td>
<td>Editorial describing potential use of families in 'clinical monitoring' of patients where there are low levels of nurses. Discusses a number of issues in relation to this; lack of evidence of effectiveness the expectations and attitudes of families and HCPs towards this role families' capacity to contribute accommodating families e.g. overnight education and support for family participation responsibility for patient wellbeing</td>
<td>some patients may not have family support there is a danger that patients and their families will be expected to work around system deficiencies</td>
</tr>
<tr>
<td>Author</td>
<td>Title</td>
<td>Description</td>
<td>Findings</td>
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<tr>
<td>Entwistle, Mello and Brennan 2005</td>
<td>Advising patients about patient safety: current initiatives risk shifting responsibility</td>
<td>Describes an analysis and critique of five leading US based safety advisories, based on literature reviews and interviews. Found: lack of attention to patient perspectives they say little about role of HCPs patients given little practical support to carry out recommended actions HCPs responses may render actions ineffective some messages suggest inappropriate shifting of responsibility onto patients behaviours conflict with expectations many people have, and think HCPs 'have, of patients' roles.</td>
<td>HCPs may be hostile to safety behaviours recommended systems not set up for patient involvement advisories do not state what system improvements have already been made or that some adverse events are not preventable, are often not accompanied by strategies to get staff on board not speaking up/bad patient conflicts with notion of passive recipient 'good' patient patients not involved in developing potential negative effects of increased patient involvement, and transfer of responsibility, loss of trust, slow down in system improvement campaign messages shaped by what HCPs thought patients could &amp; should do</td>
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<tr>
<td>Goeltz 2003</td>
<td>Be a partner in your healthcare</td>
<td>comments that it is possible to be a partner in your health care by checking with rather than checking up on health care professionals. Uses her own experience to describe how this can be done</td>
<td>speaking up will get you labelled as difficult patient and family have a part to play in safety 'remember this is not about catching someone in an error. It is about being a partner in your care and sharing the responsibility'</td>
</tr>
<tr>
<td>Goeltz 2003</td>
<td>Trial and error in my quest to become a partner in my health care: a patient's story</td>
<td>describes a patient's journey from minimal involvement to partnership in her healthcare treatment alongside a commentary by Martin Hatlie, President for Partnership for Patient Safety. Notes the difficulties she encountered with her role as 'patient', her relationship with healthcare professionals and how their perceptions of her and their roles affected her aim to be involved in decisions about her care</td>
<td>well educated, previous experience of error, good communication skills, experience of safety systems loss of trust led to self-advocacy (Elder) 'I let the system intimidate me into being quiet' 'I was tired of bucking the system at that moment and emotionally overwhelmed' I had to be an effective partner with the people treating me didn't initially reveal breathlessness as thought it was due to weight gain and was embarrassed 'the nurses were happy to co-operate with my 24/7 team because we acted as part of the team not the family police checking on them’ 'partnering only happened because he [the doctor] allowed it to’ good communication time got different messages from different HCPs trust based on belief in surgeon's expertise and competence</td>
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<tr>
<td>Goodman 2004</td>
<td>How can nurses help patients work more effectively with nurses to improve the safety of patient care?</td>
<td>comments that nurses are in a unique position to assess the information needs of patients to enable them to become partners in their care and play a role in ensuring their care is safe. Emphasises the need to assess understanding. Points out the importance of, for example, informing parents of the correct dose of medication for their child's weight so they can check each time it is given</td>
<td>time for staff to teach knowledge of the 'system' vital for participation of patient and family e.g.: do they know when consultant rounds are - taken for granted information often not passed on lack of formal assessment of patients' prior knowledge HCP &amp; organisations reluctance to acknowledge safety issues</td>
</tr>
<tr>
<td>Authors</td>
<td>Title</td>
<td>Summary</td>
<td>Findings</td>
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<tr>
<td>Hibbard et al 2005</td>
<td>Can Patients Be Part of the Solution? Views on Their Role in Preventing Medical Errors</td>
<td>describes a study to assess patients’ perceptions of the effectiveness of a number of recommended actions for preventing medical errors. Found that most actions are viewed as effective. However, respondents indicated that they were unlikely to engage in many of the recommended actions.</td>
<td>patients are less likely to take safety action which involves questioning HCPs greater sense of self-efficacy is linked to engaging in preventative action knowledge about medical error increased self-efficacy</td>
</tr>
<tr>
<td>Hoffman et al 2003</td>
<td>Bedsafe: a bed safety project for frail older adults</td>
<td>describes a project to assess, provide interventions for and evaluate effects of these for patients at risk of falling. Pays particular attention to the reduction of the use of bedrails which can cause injury though entrapment. This required a multi-disciplinary team of HCPs, technicians, patients and their families to work together to reduce the psychological dependence on the use of bedrails</td>
<td>bedrails associated with safety for patients and their families for many years changing what was thought to be a safe system called for a re-establishment of trust and a graduated approach used family advocate who had good communication skills and understood reason for change</td>
</tr>
<tr>
<td>Howe 2006</td>
<td>Can the patient be on our team? An operational approach to patient involvement in interprofessional approaches to safe care</td>
<td>exploration of putting patients at the heart of a team based approach to the prevention and management of potential and actual clinical errors in their own care. Extrapolates from patient-centred approach &amp; shared decision making literature to discuss the possible challenges and barriers to patient involvement in safety promotion. Describes a number of potential approaches and concrete ways in which individual patients might be included in a team approach</td>
<td>capacity ability motivation to act argues for staff education and initiatives to change culture also the importance of incentives</td>
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<tr>
<td>Source</td>
<td>Title</td>
<td>Description</td>
<td>Findings/Key Points</td>
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<tr>
<td>Hurst 2001</td>
<td>Vigilant watching over: Mother’s actions to safeguard their premature babies in the newborn intensive care unit</td>
<td>describes a study of the safety promoting behaviours of 12 mothers of newborn babies in a NICU; their negotiation with, 'management' of and attempts to work in partnership with HCPs and the factors which help and hinder these practices.</td>
<td>negotiating skills mothers' worried about the ramifications of their own actions for their babies' care mothers' attempts at collaboration were unrecognised</td>
</tr>
<tr>
<td>Johnson &amp; Bament 2002</td>
<td>Improving the quality of hospital services: how diverse groups of consumers prefer to be involved</td>
<td>describes a study which asked over 2000 consumers about their preferences for participating to improve safety and quality in hospitals</td>
<td>older adults less keen to take part in system improvement consumer group members more willing willingness to be involved varied by age and education but not among regular hospital goers need to believe it's worthwhile to take part</td>
</tr>
<tr>
<td>Koutantji et al., 2005</td>
<td>The patient's role in patient safety: engaging patients, their representatives and health professionals</td>
<td>provides an overview of the roles patients might play in promoting their own safety while using healthcare services</td>
<td>patient 'privileged witness of events' staff attitudes and willingness to partner with patients to improve safety is key factor challenging behaviours 'a considerable extension of the patient's role' draws on wider patient involvement literature to conclude that demographic and contextual factors will affect patients' willingness and ability to be involved as well as attitude and response of HCPs suggests taxonomy further developed in Vincent and Coulter, 2002</td>
</tr>
<tr>
<td>Lozowski et al 1993</td>
<td>Parental intervention in the medical care of children with cancer</td>
<td>describes ways in which parents of children with cancer intervened to prevent or correct a medical mistake in their child's treatment</td>
<td>parents intervened more often if they had high level of income and education and were involved in a self-help group those who were married intervened more often parents who are least satisfied with emotional support from HCPs intervene more often 'you have to trust each other but you don't know whether they maybe treat you any different. You are not sure' 'I always feel I want to be on the positive side of the doctor. I don't want to ever have him upset with us for any reason’ parents are concerned about being perceived as overassertive or aggressive overprotective or critical. They are concerned about irritating the staff and</td>
</tr>
<tr>
<td>Nau and Erikson, 2005</td>
<td>Medication Safety: Patients' Experiences, Beliefs and Behaviours</td>
<td>describes the results of a postal survey of 920 university employees about their medication safety experiences, beliefs and behaviours</td>
<td>most respondents did not worry about medication safety and believed that their local pharmacy drug dispensing process was safe. Most adopted 'basic safety related behaviours' such as checking the medication label and reading the package insert but only around a quarter discussed their meds with a pharmacist. Those patients who had past personal experience, or knew someone who had experience, of medication error were more likely to engage in multiple safety related behaviours.</td>
</tr>
</tbody>
</table>
| Peters et al, 2006 | Why worry? Worry, risk perceptions and willingness to act to reduce medical errors | describes the results of a study to explore the role of worry and risk perceptions about medical error in patients' actions to prevent error. | the more a patient worried about medical error the more likely he or she was to take preventative action. Personal experience of medical error was not related to a perception of greater risk of or more worry about medical error. If participants perceived that errors were preventable they were more likely to indicate that they would take preventative actions. Preventative actions - actions from patient safety tip sheets such as 'if you have a test in the hospital how likely are you to ask about the results if you are not told?'
<table>
<thead>
<tr>
<th>Quirk et al 2005: USA</th>
<th>Risk management by patients on psychiatric wards in London: an ethnographic study</th>
<th>describes a study which explored how patients on an acute psychiatric ward use various strategies to maintain a safe environment for themselves when faced with the threat of assault or sexual harassment from interactions with other patients on the ward</th>
<th>patients don't feel safe from risk of violence so adopt strategies to avoid, diffuse potential incidents and warn others about potential risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robinson and Nash, 2000</td>
<td>Consumers' Role in Patient Safety</td>
<td>describes the 'disconnect' between professional and consumer notions of how consumers might play an active role in promoting patient safety</td>
<td>Of Pennsylvanian consumers surveyed in 1992, only 12% were aware of outcomes data for cardiac surgery made publically available and only 1% used it to inform their decision. A survey conducted for NPSF (1513 respondents) revealed that most perceived that individual error was the most likely cause of medical error and the most effective way of preventing error was to stop 'bad' healthcare workers practising. Most consumers obtained information about medical mistakes from friends or relatives or television. Healthcare was perceived as moderately safe and less than a third of patients would take action to actively promote their safety after being affected by a medical mistake.</td>
</tr>
<tr>
<td>Roper 2003: Australia</td>
<td>Consumer perspective employment in the psychiatric service system: a Victorian view on safety issues.</td>
<td>describes the issues and dilemmas faced by consumers of mental health services being employed to provide their perspective on safety within the service and in research departments</td>
<td>Staff had problems knowing how to respond to her, found her presence difficult. There was no mechanism for her to feed up from or back down to the consumers. She was supposed to represent. She was encouraged to 'learn the ways' of the organisation and fit into existing structures, adopting the 'right' language, viewing issues through the medical model rather than their unique contribution and viewpoint being valued, she felt constrained by the system.</td>
</tr>
<tr>
<td><strong>Swift 2001</strong></td>
<td>Preventing medical errors: communicating a role for Medicare beneficiaries</td>
<td>describes a study which used focus groups to explore patients’ attitudes to specific kinds of safety promoting behaviour advocated by patient safety organisations (such as ‘Five Steps to Safer Healthcare’). Found that patients preferred those actions which took a collaborative approach and that public health campaigns to reduce errors need not undermine trust in providers.</td>
<td>limited by ability to evaluate medical information information makes you worry some messages such as checking with a pharmacist that the medicines dispensed were the ones prescribed were perceived as unnecessary as systems already in place to make sure of this i.e.: pharmacist rings the surgery to verify scripts patients like to feel listened to and respected preferred messages where their role was clear prefer patient doctor collaboration to confrontational role i.e.: prefer ‘share information about allergies and adverse reactions’ to ‘make sure you can read your prescription’</td>
</tr>
<tr>
<td><strong>Vincent &amp; Coulter 2002</strong></td>
<td>Patient Safety: what about the patient?</td>
<td>describes the roles patients can play in improving safety in medical care</td>
<td>well informed patients are more likely to adhere to treatment - better health outcomes patients don’t feel they have enough time in a consultation to get over necessary info to their community practitioner</td>
</tr>
<tr>
<td>Waterman et al 2004</td>
<td>Hospitalised patients’ comfort with and participation in medical error prevention</td>
<td>describes a phone survey in which patients were asked how comfortable they were taking eight error prevention actions and whether they took these actions during their last hospitalisation. Most patients agreed they could help prevent errors and most said they were comfortable asking. Asking HCPs if they had washed their hands was not something most felt comfortable with. Half of those who reported that an error occurred reported it to staff. Only 4% asked if HCPs had washed their hands. Patients who were non-caucasian or had been in hospital longer than eleven days were more likely to ask docs if they had washed their hands</td>
<td>older Caucasians less likely to ask 45% of sample said they would ask HCPs if they had washed their hands - only 4.6% of those who had the opportunity did 84% said they would confirm their identity with a nurse 37% who had the opportunity did</td>
</tr>
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</table>
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Appendix 2.1

1. Quality criteria for assessment of included experimental/quasi-experimental studies

(a) Was the assignment to the treatment groups really random?
Adequate approaches to sequence generation
- Computer-generated random numbers
- Random number tables
Inadequate approaches to sequence generation
- Use of alternation, case record numbers, birth dates or week days

(b) Was the treatment allocation concealed?
Adequate approaches to concealment of randomisation
- Centralised or pharmacy-controlled randomisation
- Serially-numbered identical containers
- On-site computer based system with a randomisation sequence that is not readable until allocation
- Other approaches with robust methods to prevent foreknowledge of the allocation sequence to clinicians and patients
Inadequate approaches to concealment of randomisation
- Use of alternation, case record numbers, birth dates or week days
- Open random number lists
- Serially numbered envelopes

(c) Were the groups similar at baseline in terms of prognostic factors?
(d) Were the eligibility criteria specified?
(e) Were the care provider, patient and outcome assessors blinded to the treatment allocation?
(f) Were the point estimates and measure of variability presented for the primary outcome measure?
(g) Did the analyses include an intention to treat analysis?
## Characteristics of excluded studies

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study characteristics</td>
<td>- Characteristics of the RCTs excluded (e.g., recruitment strategies, sample sizes, and study outcomes)</td>
</tr>
<tr>
<td>Data analysis</td>
<td>- The methods used to analyze the data (e.g., statistical tests, software used)</td>
</tr>
<tr>
<td>Results</td>
<td>- The main findings of the trial (e.g., statistical significance, effect sizes, and confidence intervals)</td>
</tr>
<tr>
<td>Discussion</td>
<td>- The authors' conclusions and implications of the trial results</td>
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### Appendix 2.2 Characteristics of excluded studies
<table>
<thead>
<tr>
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<th>Design Description</th>
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<td>Anonymous 2000</td>
<td>Not an experimental/quasi experimental design (uncontrolled study).</td>
</tr>
<tr>
<td>Anonymous 2003</td>
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</tr>
<tr>
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<td>Not an experimental/quasi experimental design (survey).</td>
</tr>
<tr>
<td>Anonymous 2006a</td>
<td>Not an experimental/quasi experimental design (case study).</td>
</tr>
<tr>
<td>Anonymous 2006b</td>
<td>Not an experimental/quasi experimental design (case study).</td>
</tr>
<tr>
<td>Aikens 2005</td>
<td>Not patient involvement in patient safety (about patient beliefs and their medication).</td>
</tr>
<tr>
<td>Al-Agilly 2007</td>
<td>Not an experimental/quasi experimental design (uncontrolled study).</td>
</tr>
<tr>
<td>Alemagno 2004</td>
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<td>Anderson 1983</td>
<td>Aim of the study is not ‘to enhance patient safety’ (to promote the independence of women on postpartum unit).</td>
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<td>Ansell 2005</td>
<td>Not an experimental/quasi experimental design (guidelines).</td>
</tr>
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<td>Anthony 2005</td>
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<td>Barat 2001</td>
<td>Not an experimental/quasi experimental design (cross-sectional study).</td>
</tr>
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<td>Basch 2007</td>
<td>Not an experimental/quasi experimental design (uncontrolled study).</td>
</tr>
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<td>Beger 1999</td>
<td>Not an experimental/quasi experimental design (uncontrolled study).</td>
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<tr>
<td>Bernstein 2004</td>
<td>Not an experimental/quasi experimental design (qualitative study).</td>
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<tr>
<td>Beyth 2000</td>
<td>Individual study of self-management of anticoagulation, systematic review available.</td>
</tr>
<tr>
<td>Brown 2003</td>
<td>Not patient involvement in patient safety (study about informed consent).</td>
</tr>
<tr>
<td>Cohen 2007</td>
<td>Not an experimental/quasi experimental design (opinion piece).</td>
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<td>Coulter 2006</td>
<td>Review of patient-focused interventions but not a systematic review.</td>
</tr>
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<td>Davidson 2007</td>
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<td>Davis 2006</td>
<td>Not an experimental/quasi experimental design (cohort study).</td>
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<td>de Thurah 2004</td>
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<td>Heneghan 2006</td>
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<td>Jenson 2003</td>
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<td>Koertke 2005</td>
<td>Not an experimental/quasi experimental design (uncontrolled study).</td>
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<td>Logue 2002</td>
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## Appendix 2.3 Methodological quality of included studies

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<td>Not stated</td>
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<td>Not stated</td>
<td>N</td>
<td>N</td>
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<tr>
<td>Were the groups similar at baseline in terms of prognostic factors?</td>
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<td>N</td>
<td>Y</td>
<td>Y</td>
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<td>Y</td>
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<td>N</td>
<td>N</td>
<td>Y</td>
</tr>
</tbody>
</table>
Appendix 2.4 References for Excluded Studies


inputEmailclassification


**Appendix 3.1 Assessment form for patient safety reporting systems**

Organisation:
Web address:
Country of Origin?
Type or types of report?
Anonymous? Y/N (N but confidentiality guaranteed)
Mandatory or voluntary reports?
Public/private system?
Who can report?
Type of report accepted?
What information is asked for?
What happens to the information?
Who has access to the information?
Are recommendations produced?
Who is involved in this process?
Any statutory obligation for healthcare organisation to implement recommendations?
Any other relevant information?

Appendix 3.2 Questionnaire to establish details of patient involvement in reporting systems

Patient Involvement in Patient Safety

Patient Safety Reporting Systems which accept reports from patients/the public.
We would be grateful if you would complete the questions below and return it to us by either e-mail, post or fax (numbers below):

1. Did you consult patients/the public when constructing this system?
   Y/N

   If yes, how?

   If not why not?

2. Has the system been evaluated since it was set up?
   Y/N.

   Were patients/the public involved in this?
   Y/N.

   If yes, how?

   If not why not?

3. Were changes made as a result of this evaluation?
   Y/N

4. How do you publicise the site/system?

5. What percentage of your reports are from patients/the public?
6. Would you be happy for us to contact you by telephone if we would like more detail?
   Y/N

If yes, please insert number, name and preferred time for us to ring:

Many thanks for your time….  

Contact details:

Jill Hall, tel +44 (0)1904 321329 jh545@york.ac.uk
Maggie Peat, tel +44 (0)1904 321726 mp152@york.ac.uk
fax +44 (0)1904 321382

Address:
Patient Involvement in Patient Safety Project
Department of Health Sciences
Seebohm Rowntree Building
University of York
York
YO10 5DD
Appendix 4.1: GROUND RULES FOR FOCUS GROUP PARTICIPANTS

Thank you for coming everyone – your contribution is much appreciated

This project is about how patients might be involved in keeping themselves safe while using healthcare services and things that might make this easier or more difficult.

The aim of this afternoon is to build on and develop as a group the topics which came up in individual interviews conducted earlier. It is your views that we are interested in so we’d like you to do the talking.

Ground rules for the focus group

- We would like to find out about the range of views and experiences that exist, so if you hear something which is different from your own view, we would really like to hear from you. There are no right or wrong answers.

- Having said that, as we will be audio recording the discussion please take turns speaking so we can make out what you have said.

- What is said in the room goes no further.

- You have the right to withdraw from the discussion (and the project) at any time without giving a reason.
Appendix 4.2: GROUND RULES FOR CONDUCTING THE FOCUS GROUPS

Role of the facilitator:
Introducing the group
Welcome participants/ introductions
Overview of the topic and purpose of the study
Role of the facilitator(s) – the facilitator is there to stimulate/ enable, but not direct/control the discussion
Consent (verbal)
Read through ground rules for participants
Audio-recording: confidentiality and anonymity/ taking turns to speak

Conducting the group
Remember: the moderator is not a participant
Emphasise that there are no right or wrong answers - we want to hear about the full range of views – where people agree or disagree
Introduce and explain roles exercise and use of vignettes
Manage the group: draw in quiet participants/ seek to avoid over domination of group by particular individual members; make sure group does not break down into different simultaneous conversations
Use non-verbal strategies to ensure everyone has an opportunity to be involved
Don’t rush in where there is a silence – a five second pause may elicit an additional point of view
Avoid judgemental responses

Closing the group
Ask co-facilitator for any additional questions/ comment – co-facilitator gives short summary of main points
Thank participants for taking part in group
Talk about how discussion will be used
Reassure re confidentiality and anonymity
Feedback to participants re study

Mention of Phase 3 of project – we would like to contact re anyone who might be interested in participating
Expenses sheets and comments sheets to take away/ ask if we may contact them by phone if clarification of any points raised is needed

Focus Groups: role of the co-facilitator
Welcome participants
Deal with latecomers/ interruptions/ distractions
Set up/ check recording equipment
Observe group interaction - take notes on group dynamics
Keep an eye on time
Deal with any unforeseen issues/ distress that might arise
Towards end: Give a short summary of the key points of the discussion
Ask if any additional questions and consider if any comments to follow up
Appendix 4.3

PATIENT INVOLVEMENT IN PATIENT SAFETY: PRESENTATION OF FINDINGS FOR PARTICIPANTS AND COLLABORATORS

Venue: New Lecture Theatre, Bradford Royal Infirmary, Education Centre
Date: Monday 23rd March 2009  Time: 6-8pm

Programme:

18:00-18:30 Welcome drink and nibbles

18:30-19:30 Welcome – Miles Scott, Chief Executive, Bradford Hospitals Trust

Presentation of study findings:

- Context and background
- Overview of literature
- Presentation of qualitative findings
- Presentation of pilot study
- Summary and implications for future dissemination

19:30-20:00 Q&A session and comments to the panel (research team)
Chaired by Professor John Wright, Bradford Institute for Health Research at Bradford Infirmary

20:00 Thank you and closing comments from study Principal Investigator, Professor Ian Watt
Appendix 4.4: Details of study participants included in the analysis of interviews

Group 1: Patients with diabetes

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Gender</th>
<th>Age</th>
<th>Ethnicity</th>
<th>Occupation</th>
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<tbody>
<tr>
<td>101</td>
<td>Female</td>
<td>64</td>
<td>White British</td>
<td>Housewife</td>
</tr>
<tr>
<td>102</td>
<td>Male</td>
<td>66</td>
<td>Asian Indian</td>
<td>Teacher</td>
</tr>
<tr>
<td>104</td>
<td>Female</td>
<td>71</td>
<td>Asian Pakistani</td>
<td>Housewife</td>
</tr>
<tr>
<td>106</td>
<td>Female</td>
<td>64</td>
<td>White British</td>
<td>Machinist and carer</td>
</tr>
<tr>
<td>109</td>
<td>Male</td>
<td>71</td>
<td>White British</td>
<td>Security guard (retired)</td>
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Group 2: Patients who have undergone treatment for breast cancer

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<tr>
<th>Patient ID</th>
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<th>Age</th>
<th>Ethnicity</th>
<th>Occupation</th>
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<td>203</td>
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<tr>
<td>209</td>
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<td>66</td>
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Group 3: Parents of children with asthma

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<tbody>
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<td>303</td>
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<td>36</td>
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<td>304</td>
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<td>School administrator</td>
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<tr>
<td>308</td>
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<td>40</td>
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<td>309</td>
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<td>48</td>
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Group 4: Patients who had undergone joint surgery

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<tr>
<td>402</td>
<td>Female</td>
<td>59</td>
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</tr>
<tr>
<td>406</td>
<td>Male</td>
<td>72</td>
<td>White British</td>
<td>British Telecom engineer (retired)</td>
</tr>
<tr>
<td>407</td>
<td>Female</td>
<td>77</td>
<td>White British</td>
<td>Dressmaker</td>
</tr>
<tr>
<td>408</td>
<td>Female</td>
<td>78</td>
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<td>Past experience of nursing</td>
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Group 5: Patients (family members or representatives) who had made a complaint about their care

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<tbody>
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<td>Specialist nurse</td>
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<td>509</td>
<td>Male</td>
<td>71</td>
<td>White British</td>
<td>Printing trade</td>
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Group 6: Patients with mental health problems

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<tr>
<td>603</td>
<td>Female</td>
<td>44</td>
<td>Asian Indian</td>
<td>Nurse in care home</td>
</tr>
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<td>605</td>
<td>Female</td>
<td>53</td>
<td>White British</td>
<td>Managerial role in office</td>
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<tr>
<td>607</td>
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<td>50</td>
<td>White British</td>
<td>Doctor (part-time)</td>
</tr>
<tr>
<td>609</td>
<td>Male</td>
<td>60</td>
<td>White British</td>
<td>Retired head teacher</td>
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Appendix 4.5: Details of Focus Group Participants

**Patient Focus Group 1**

<table>
<thead>
<tr>
<th>Identifier</th>
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<td>Retired Head Teacher</td>
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<td>2</td>
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<td>Retired engine driver</td>
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<td>65</td>
<td>White British</td>
<td>Builder/ coalman</td>
</tr>
<tr>
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<td>64</td>
<td>White British</td>
<td>Machinist and carer</td>
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<tr>
<td>5 (107)</td>
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<td>73</td>
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<td>Retired weaver</td>
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**Consumer Focus Group 1**

<table>
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<th>Occupation</th>
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<td>White British</td>
<td>Pharmacist (retired)</td>
</tr>
<tr>
<td>2</td>
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<td>White British</td>
<td>Housewife</td>
</tr>
<tr>
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<td>Female</td>
<td>69</td>
<td>White British</td>
<td>Caterer (retired)</td>
</tr>
<tr>
<td>4</td>
<td>Female</td>
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<td>Housewife</td>
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</tr>
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<td>White British</td>
<td>Engineer (retired)</td>
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**Patient Focus Group 2**

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<tbody>
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<td>Administrator</td>
</tr>
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<td>Senior Care Assistant</td>
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<td>51</td>
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**Consumer Focus Group 2**

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<td>Housewife</td>
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<td>Female</td>
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### Patient Focus Group 3

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<td>Homemaker</td>
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</tr>
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### Consumer Focus Group 3

<table>
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### Patient Focus Group 4

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<td>HGV driver (retired)</td>
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<tr>
<td>4 (408)</td>
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<td>78</td>
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<td>Dressmaker</td>
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### Consumer Focus Group 4

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<td>Office manager (retired)</td>
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<td>2 (508)</td>
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<td>Specialist Nurse</td>
</tr>
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### Consumer Focus Group 5

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<td>Female</td>
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<td>White British</td>
<td>Retired teacher</td>
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<tr>
<td>4</td>
<td>Female</td>
<td>57</td>
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<td>Housewife</td>
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### Patient Group 6

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<td>52</td>
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<td>White British</td>
<td>Housewife</td>
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<td>3 (606)'s</td>
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<td>44</td>
<td>White British</td>
<td>Counsellor</td>
</tr>
<tr>
<td>partner</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>59</td>
<td>White British</td>
<td>Retired Head Teacher</td>
</tr>
<tr>
<td>5 (610)</td>
<td>Female</td>
<td>67</td>
<td>White British</td>
<td>Retired Laboratory Assistant</td>
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### Consumer Focus Group 6

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<tbody>
<tr>
<td>1</td>
<td>Female</td>
<td>52</td>
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<td>Unemployed (ex-mental health nurse)</td>
</tr>
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<td>Male</td>
<td>60</td>
<td>White British</td>
<td>Retired shopkeeper/journalist</td>
</tr>
<tr>
<td>3</td>
<td>Female</td>
<td>61</td>
<td>White British</td>
<td>Not given</td>
</tr>
<tr>
<td>4</td>
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<td>50</td>
<td>White British</td>
<td>Volunteer</td>
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Appendix 4.6: Individual Interview Topic Guide

PIPS Topic Guide: Individual Interview

(Place and date of birth & current or last profession)

GENERAL AWARENESS OF HEALTHCARE SAFETY ISSUES

Are you concerned about your own safety when you use health services?

What sort of things might go wrong?

Can you think of any examples of stories that you have heard about? Prompt if necessary eg infection, wrong tablets.

Where have you learnt these from? Prompt if necessary: eg media (papers, TV and radio)

What about from family, friends or colleagues?

SPECIFIC PERSONAL EXPERIENCES OF ERRORS, HARM OR THREATS TO SAFETY

Have you ever had any personal experience of errors or harms as a result of using healthcare?

Probe:
What was the error/harm?
What caused it?
Could it have been prevented?
Could something have been done to reduce the consequences?

Have you ever been in or witnessed a situation where something could have gone wrong? (could be to themselves or a close other) Prompt if necessary: eg X-rays going missing; wrong tablets; wrong records

Probe:
Please describe the situation
What was the cause of the incident?
Could it have been prevented?
Could something have been done to reduce the consequences?

VIEWS ABOUT PATIENT ROLES IN HEALTHCARE SAFETY

Are there ways in which patients can try to make sure they are safe?

What kinds of things might they do?
Do you think patients should be expected to take measures to keep themselves safe?
What kinds of things do nurses and doctors do to keep patients safe?
Do you think that nurses and doctors expect patients to keep themselves safe?

If you were in a situation that might result in harm to yourself (or thinking back to the situation you described) what might you/did you do in that situation?

Probe:
What would make that easier?
(eg being informed; staff inviting comment; badges
What would make that more difficult?
(eg, feeling unwell; fear of consequences)

How would you feel about doing any of the following:

- Finding out more about your condition from the internet and/or specialist groups
  Probe: what would make it easier/ more difficult?
  Probe: if don’t want info – can you think of a situation where you might?

- Asking for clarification if you haven’t understood something you have been told by the nurse/doctor/pharmacist
  Probe: what would make it easier/ more difficult?

- Ringing to find out about a test result (X-ray, blood test, CT scan)
  Probe: what would make it easier/ more difficult?

- Questioning a nurse/doctor/ pharmacist when your tablets look different
  Probe: what would make it easier/ more difficult?

- Asking nurses and doctors if they have washed their hands
  Probe: what would make it easier/more difficult?

PERCEPTIONS OF RISK

What do you think the chances are that something might go wrong if you are using health services?
Probe: differences in hospital/GP/community

For every hundred people who go into hospital how many, do you think, are affected by a medical error?
Prompt with chart(?)

(The estimate is about 10 in every 100 hospital patients, and about half of the errors are preventable)

Do you think these figures affect how people view or use of health care services in any way?
In your opinion, which are the most serious kinds of errors that could occur? Why do you think they occur?

How do you think staff would react when things go wrong?

**THOUGHTS ABOUT CONTRIBUTING TO REPORTING SYSTEMS**

How do you think the NHS tries to learn from its mistakes?

If you were harmed in any way, would you let anyone know? How would you go about that?

It has been suggested that accidents and near misses that have, or might have harmed patients, should be reported, so that everyone can learn from them. What do you think about this idea?

Have you heard of any reporting systems? Which ones?

*If Yes,*
How did you find out about them?
Have you ever reported anything?
Would you do it again?

*If NO, prompt:*
Have you heard of the Yellow Card System (MHRA)?
Have you heard of the National Patient Safety Agency?

At the moment, some systems only accept reports from NHS staff, but it has been suggested that patients could also contribute.

What do you think of this idea?

What sort of things might you report to these systems?

What would make it more/less likely that you would report something? *Prompt if necessary: eg anonymity of system, fear of consequences, feedback.*

Some hospitals recruit patients to take part in discussions and decision making that might affect patients within the hospital. This is to provide a patient’s perspective which may not be obvious to HCPs & managers. Do you think this is a good idea? Is it something that you would consider doing? *If not explore why*

Have you got anything to add on the topic of patient safety that I have not asked you about?

**Thank patient for participating in interview**
**Give general reassurance/information re focus group**
Appendix 4.7: PIPS Topic Guide: *(Parent Interview)*

(Place and date of birth & current or last profession)

**GENERAL AWARENESS OF HEALTHCARE SAFETY ISSUES**

Are you concerned about your child's safety when they use health services?

What sort of things might go wrong?

Can you think of any examples of stories that you have heard about? *Prompt if necessary eg infection, wrong tablets.*

Where have you learnt these from? *Prompt if necessary: eg media (papers, TV and radio)*

What about from family, friends or colleagues?

**SPECIFIC PERSONAL EXPERIENCES OF ERRORS, HARMS OR THREATS TO SAFETY**

Have you ever had any personal experience of errors or harms as a result of your child using healthcare?

Probe:
What was the error/harm?
What caused it?
Could it have been prevented?
Could something have been done to reduce the consequences?

Have you ever been in or witnessed a situation where something could have gone wrong? *(could be to themselves or a close other)* *Prompt if necessary: eg X-rays going missing; wrong tablets; wrong records*

Probe:
Please describe the situation
What was the cause of the incident?
Could it have been prevented?
Could something have been done to reduce the consequences?

**VIEWS ABOUT PATIENT ROLES IN HEALTHCARE SAFETY**

Are there ways in which parents can try to make sure their children are safe?

What kinds of things might they do?
Do you think parents *should* be expected to take measures to keep their children safe?

What kinds of things do nurses and doctors do to keep patients safe?

Do you think that nurses and doctors *expect* parents to keep their children safe?

If you were in a situation that might result in harm to your child (or thinking back to the situation you described) what might you/did you do in that situation?

Probe:
What would make that easier?
(eg being informed; staff inviting comment; badges)
What would make that more difficult?
(eg, fear of consequences)

How would you feel about doing any of the following:

- Finding out more about your child’s condition from the internet and/or specialist groups
  *Probe: what would make it easier/ more difficult?*
- Asking for clarification if you haven’t understood something you have been told by the nurse/doctor/pharmacist
  *Probe: what would make it easier/ more difficult?*
- Ringing to find out about a test result (X-ray, blood test, CT scan)
  *Probe: what would make it easier/ more difficult?*
- Questioning a nurse/doctor/pharmacist when your child’s tablets or medication look different
  *Probe: what would make it easier/ more difficult?*
- Asking nurses and doctors if they have washed their hands
  *Probe: what would make it easier/more difficult?*

**PERCEPTIONS OF RISK**

What do you think the chances are that something might go wrong if your child is using health services?
*Probe: differences in hospital/GP/community*

For every hundred people who go into hospital how many, do you think, are affected by a medical error?
*Prompt with chart(?)*

*(The estimate is about 10 in every 100 hospital patients, and about half of the errors are preventable)*
Do you think these figures affect how people view or use health care services in any way?

In your opinion, which are the most serious kinds of errors that could occur?

Why do you think they occur?

How do you think staff would react when things go wrong?

THOUGHTS ABOUT CONTRIBUTING TO REPORTING SYSTEMS

How do you think the NHS tries to learn from its mistakes?

If your child was harmed in any way, would you let anyone know? How would you go about that?

It has been suggested that accidents and near misses that have, or might have harmed patients, should be reported, so that everyone can learn from them. What do you think about this idea?

Have you heard of any reporting systems? Which ones?

If Yes,
How did you find out about them?
Have you ever reported anything?
Would you do it again?

If NO, prompt:
Have you heard of the Yellow Card System (MHRA)
Have you heard of the National Patient Safety Agency?

At the moment, some systems only accept reports from NHS staff, but it has been suggested that patients could also contribute.

What do you think of this idea?

What sort of things might you report to these systems?

What would make it more/less likely that you would report something? Prompt if necessary: eg anonymity of system, fear of consequences

Have you got anything to add on the topic of patient safety that I have not asked you about?

Thank patient for participating in interview
Give general reassurance/information re focus group

**General Awareness of Healthcare Safety Issues**

After being in hospital are you now less or more concerned about your own safety when using healthcare services?

Did you experience anything that made you concerned about your own or other's safety?

What was that?

What about things that nearly happened/near misses?

What did you do?

Would you like to have done anything else?

What would have made that easier?

How did the hospital staff react?

Will your experience affect the way you use health services in the future?

Have you thought about reporting this?

**Views about patient roles**

Are there ways in which patients can try and make sure they stay safe?

What kinds of things might they do?

Do you think patients should be expected to keep themselves safe?

What kind of things do nurses and doctors do to keep patients safe?

Do you think nurse and doctors expect patients to keep themselves safe?

Do you think taking part in this study has made you more aware of things that might go wrong?

Has it made you think differently about what you can do to keep yourself safe?
Appendix 4.9: VIGNETTES FOR USE IN THE FOCUS GROUPS

- Vignettes for use with patients with diabetes

**Moira’s story**

Moira has got Type II diabetes. She doesn’t have to use insulin injections but takes tablets every day to control it. She also takes a number of other tablets for high blood pressure, high cholesterol and arthritis. These tablets sometimes upset her stomach. Her GP has prescribed another tablet to help with this stomach upset. She takes 15mg each day. Moira’s stomach gets worse and she rings her GP practice to make an appointment. There are no appointments available with her usual GP but she is able to see a different GP. This GP decides to increase the dose of the tablet to 30 mg. When Moira goes to the pharmacist to collect the new prescription it says to take 30 mg twice a day. This is not what Moira recalls the doctor telling her and she is not sure if she should take the new dose.

- What should Moira do?
- What do you think Moira would actually do? Why is that?
- Do you think something like this could happen to you?

**Jasmine’s story**

Jasmine was born in Pakistan in 1941 and came to live in Bradford in 1966. She is now sixty six years old and two years ago she was diagnosed by the doctor as having diabetes. She says she does not really speak or read English, but she has a little understanding of the language. Her daughter usually goes with her to her appointments if she can. Jasmine was told by the doctor that she would not need to have insulin injections, but that she would have to take tablets every day, and attend the diabetic clinic regularly for check ups and advice. She is very happy with the service that she gets from her doctor, and she feels really well looked after.

- What do you think are the things that might make Jasmine feel she is ‘in safe hands’ when she attends this surgery?
- What could happen to undermine her feeling of being ‘in safe hands’?
MARY’S STORY

Mary is 72 and she went into hospital a month ago to have her knee joint replaced. She was a bit nervous about the admission because it is the first time that she has not had her husband by her side—he died last year and Mary misses him so much because she used to depend on him to help her in all kinds of ways. Mary feels that she is quite a shy person, and she doesn’t like to cause any upset or bother, so she was a bit worried about having to ‘look out’ for herself in hospital. She was surprised at how busy the ward was. The nurses seemed to be rushed off their feet, and the doctors didn’t have a lot of time to talk to you. Mary tried to ‘keep her head down’ while she was on the ward—for example, she only rang the buzzer when it felt absolutely necessary because she didn’t want to be a nuisance, but sometimes she wished that a nurse would come and ask her if she needed anything, or just talk to her.

- Why do you think people feel the need to have someone else there to ‘look out’ for them when they are in hospital?
- What could be done to reduce the need for someone?
- Why do you think Mary was worried about ringing the buzzer while she was in hospital?
- Do you think doctors and nurses like people asking questions about their treatment and care, and why is that?

JANE’S STORY

Jane is in hospital after surgery. She is stiff and uncomfortable. Her sheets are crumpled up underneath her and she is finding it hard to change her position because of the pain. A nurse came in about 2 hours ago with clean linen and said she would be ‘back in a tick’ but she hasn’t returned. Jane is worried about getting sore but feels a bit nervous about ringing the bell.

- Why might Jane be nervous about ringing the bell?
- Should she be anxious?
- What might make her less worried?
- Can speaking up make you less safe?
Jean’s story

Jean has arthritis and has just started a new treatment which is working really well. It is given by injection at home but she also has frequent admissions to hospital. The medication can interact badly with many other medications so she has to keep an eye on that. When she is admitted to hospital she likes to know what the nurses are giving her. Often they tell her what it is, or check it with her, but sometimes they just give it to her. If they do, she will ask, but she feels a bit nervous about this.

- Do you think she should be checking?
- How might staff react to that?
- Why do you think some staff react negatively to being questioned?
- Are there ways she can check without causing problems?
- How would you feel about checking on staff?

Jack’s story

Jack has got arthritis in his hip and is in hospital to have a joint replacement. He has the operation and is back on the ward. A doctor comes to see Jack and says that she has come to give him his insulin injection. Jack is not a diabetic but he knows that there is another patient on the ward with the same name. Jack thinks the doctor may have got the wrong person but is worried about speaking up.

- Why do you think he is worried?
- What should Jack do?
- What do you think most people would do in reality?
- If Jack was feeling drowsy after the anaesthetic how do you think this would affect him in this situation?
- How could the situation have been avoided in the first place?
Penny’s story

Penny’s son, Jake, has a serious liver condition. He spent more time in hospital than out of it during his first year, and now he is 7 years old. Jake is under the specialist at the city hospital for his liver condition, but the specialist unit is 20 miles away. As children from all over England are treated there, Jake sometimes has to be admitted to his local hospital when he becomes ill. Although the staff there are lovely, Penny doesn’t feel as confident in them as she does in the staff on the specialist unit, who seem to know everything there is to know about Jake’s condition.

Penny feels as if she needs to be with Jake all the time at the local hospital in order to keep an eye on the staff. She has been concerned about a number of things recently. For example, one of the staff nurses had given Jake his medication by injection instead of by mouth. Luckily, the nurse gave him the right dose, and it didn’t do him any harm, but still, it was a mistake.

Basically, Penny feels she just can’t relax while Jake is in the local hospital. On the specialist unit she just feels like she can hand over all the responsibility for his care to the staff, and get on with the important job of being Jake’s mum. However, at the local hospital she always has the feeling that something might go wrong.

- Should Penny feel anxious?
- Should parents have to ‘keep an eye’ on staff?
- Why might parents feel more confidence in some staff than others?
- What makes you feel you are in safe hands?
- Have you ever been in a similar situation? If so, how did you feel about it?

Jenny’s story

Jenny was taking her daughter to clinic for review. She was expecting to be told that Amy would need a grommet in one of her ears to try and prevent any more infections. Amy had a lot of time off school in the previous year and Jenny was keen to get this sorted out.

They waited ages in clinic and when they finally went in to see the doctor she seemed rushed and harassed. The doctor had some notes open in front of her but she asked Jenny why Amy was being seen today. Jenny was a bit concerned as she wondered why the doctor needed to ask, but she told the story of Amy’s ear infections. The doctor had a quick look in Amy’s ear, first asking Jenny which ear it was that was affected. Jenny was now really worried. She asked the doctor if the letter from her GP was in the notes. The doctor looked puzzled and said that it was. She then gave them the
Jenny couldn’t understand why the doctor didn’t seem to know what was going on. She left feeling uncomfortable and very worried about her daughter’s approaching surgery.

- Do you think Jenny is right to be worried?
- Have you had this experience?
- Why do you think the doctor ‘checked’ with Jenny?
- Are there ways to do this without making people feel worried that staff don’t know what they are doing?

Maria’s story

Maria has two daughters, Gemma who is 13 and Julie who is 11 years. Julie was diagnosed with asthma when she was 2, and she is in and out of hospital due to frequent attacks. The last time Julie had a severe attack was late on a Saturday night. Maria recognised all the signs and symptoms, and she thought she should phone for an ambulance, but it didn’t arrive as quickly as she hoped.

When the ambulance got there, the paramedic said that Julie’s ‘sats’ were not too bad and that he didn’t think she needed to go to the hospital. Maria was not happy with this and she wanted to insist that they should go to A&E, but the paramedic was a bit unpleasant with her. She wished her husband was there, but he was away for work.

When they got to A&E, the receptionist said that they couldn’t find Julie’s notes, and that the doctor would need them before he could see her. They had been at a clinic the week before, and Maria thought the notes were probably still there.

A&E was full of people wandering around, and Maria couldn’t see many staff around. All the time, Julie’s breathing seemed to be getting worse and Maria was getting more and more worried.

- Should Maria feel worried?
- How do you think Maria felt when she tried to insist on going to A&E?
- Have you ever been in a situation like this? If so, how did you feel about it?
- Have you ever experienced a problem with medical notes?
Vignettes for use with patients who raised a concern or made a complaint about their care

Diane’s story

Diane is a sixty-five year old woman who went into hospital for major surgery. She was quite poorly for much of the time she was in hospital and she was glad that her husband, George, was able to come in every day during visiting hours. George was unhappy with a number of things that he saw on the ward. For instance, on one occasion, a nurse gave Diane some intravenous antibiotics and soon afterwards Diane appeared flushed and sweating. George went to the desk and reported this to a doctor who just told him that they would keep an eye on her and not to worry. But he didn’t even go to look at Diane. A couple of days later, George noticed that a nurse was about to give Diane four tablets, instead of her usual two and it turned out that the nurse was not clear about the dose. Another thing that worried George was that the nurse who came to remove Diane’s drain from her wound said that she’d never done this procedure before and George felt that she should have been supervised but she wasn’t. When he got home, George wondered whether he should report these incidents to someone or whether he was overreacting.

- Should George report what had happened, and if so, who should he report to?
- Is it better to report things face to face or in writing?
- What might be the hospital staff reaction to George making a report?
- Have you ever been in a situation where you have thought about reporting something or made a report?

Eric’s story

Eric presented a very detailed complaint to a hospital trust regarding care he had received from the Ear Nose and Throat, or ENT, and Cardiology Departments. His complaint concerned the Trust’s Patient Advice and Liaison Service and their handling of delays in his appointments, missing notes and his being removed from the Trust under the Violent Incident Policy, as well as the length of time he waited to get a hearing aid. Eric’s letters were quite hard to follow but the Trust worked extremely hard to address all his concerns. It was clear from the Trust’s letters to Eric that they took the complaints seriously and that the departments had worked together to produce a co-ordinated response. Eric wasn’t happy with the first letter he had received from the Trust but this was followed by a second letter, which laid everything out in detail. Statements had been taken from the appropriate staff and incorporated into the Trust’s investigation letter, with all the medical terms explained. The Trust showed great patience in dealing with Eric, who could sometimes be aggressive and confrontational on the phone. The Trust was willing to provide detailed accounts of his care and treatment over a long period of time and everything was explained clearly. In the end, Eric felt the complaint had been dealt with to his satisfaction.
What do you think about the way that Eric’s complaint was handled?
Do you think that Eric’s experience is typical or not typical of people who have made a complaint?

Vera’s story

Vera, an 82 year old patient, was admitted to hospital with pneumonia. She is the primary carer for her husband, who has arthritis and is blind. After a week, she was discharged at short notice, without the family being informed. Her family was concerned that she was made to leave her bed and sit around for hours waiting to be discharged, and that her mobility was still limited. Vera also had difficulties with the drugs she needed when she left hospital. Her family cared for her, but after four days she had to be re-admitted to hospital following an emergency call from her GP.

The family made a complaint to the trust who suggested a meeting. At the meeting, the trust admitted that it had failed to follow correct procedures when discharging Vera. The consultant still maintained that the patient was fit to be discharged, but admitted that there had been no consideration of recuperative care or Vera’s social circumstances.

The complaint was referred to the Healthcare Commission for review. They upheld the complaint and found that the assessment of Vera was inadequate. Her discharge from hospital had not been discussed in advance with her family, even though the trust’s procedures stated that 24 hours’ notice should be given, and there was no consideration of her circumstances as a carer.

As a result, the consultant met Vera’s family and offered a verbal apology. The Chief Executive of the trust wrote a letter to apologise for the distress caused, acknowledging that the arrangements for her discharge did not take account of her social needs. He also said that the hospital discharge policy would be reviewed.

Do you think complaints like this occur often, and why is that?
What do you think about the way the complaint was handled?
How could discharge policies be improved?
How does this compare with your own experiences?
Appendix 4.10

THEMATIC FRAMEWORK USED IN ANALYSIS OF THE QUALITATIVE DATA

<table>
<thead>
<tr>
<th>ID</th>
<th>Clinical Group</th>
<th>Location</th>
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</thead>
<tbody>
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<td>Age</td>
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</tr>
<tr>
<td>E</td>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>R</td>
<td>Ethnicity</td>
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</tr>
<tr>
<td>E</td>
<td>Occupation</td>
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</tr>
<tr>
<td>R</td>
<td>Characterisation</td>
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<tr>
<td>A</td>
<td>Roles</td>
<td></td>
</tr>
<tr>
<td>L</td>
<td>Barriers and Facilitators</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>Expectations/ reflections</td>
<td></td>
</tr>
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<td>W</td>
<td>General safety awareness</td>
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</tr>
<tr>
<td>A</td>
<td>General attribution</td>
<td></td>
</tr>
<tr>
<td>R</td>
<td>Staff reaction</td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>Reporting self</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>Reporting NHS</td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>NHS Learning</td>
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</tr>
<tr>
<td>S</td>
<td>Knowledge and Information</td>
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### Appendix 4.11: Participants’ estimates of probability of error, perceptions of serious errors and attribution of errors

#### Group 1  Patients with diabetes

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Gender</th>
<th>Age</th>
<th>Ethnicity</th>
<th>Occupation</th>
<th>Estimated probability of error</th>
<th>Perceptions of ‘serious errors’</th>
<th>Attribution</th>
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<tbody>
<tr>
<td>101</td>
<td>Female</td>
<td>64</td>
<td>WB</td>
<td>Housewife</td>
<td>10%</td>
<td>No concerns</td>
<td>Staff don’t listen; busyness of wards</td>
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<tr>
<td>102</td>
<td>Male</td>
<td>66</td>
<td>AI</td>
<td>Teacher</td>
<td>10%</td>
<td>A&amp;E waiting times</td>
<td>Human fallibility</td>
</tr>
<tr>
<td>104</td>
<td>Female</td>
<td>71</td>
<td>AP</td>
<td>Housewife</td>
<td>10-20%</td>
<td>None cited</td>
<td>Staff don’t spend time with patients; are less caring than previously; patients discharged too soon</td>
</tr>
<tr>
<td>106</td>
<td>Female</td>
<td>64</td>
<td>WB</td>
<td>Machinist and carer</td>
<td>10%</td>
<td>Risk of MRSA would deter from hospital; misdiagnosis</td>
<td>Staff shortages; HCP workload; nurses spend too long on paperwork, not enough time on patient care</td>
</tr>
<tr>
<td>109</td>
<td>Male</td>
<td>71</td>
<td>WB</td>
<td>Security guard (ret)</td>
<td>15%</td>
<td>MRSA/ wrong site operation</td>
<td>HCP workload</td>
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## Group 2 Patients treated for breast cancer

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<th>Patient ID</th>
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<th>Age</th>
<th>Ethnicity</th>
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<tbody>
<tr>
<td>202</td>
<td>Female</td>
<td>51</td>
<td>WB</td>
<td>Clinical psychologist</td>
<td>10%</td>
<td>Infection; wrong site surgery; drug errors</td>
<td>Staff shortages; pressure of work</td>
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<tr>
<td>203</td>
<td>Female</td>
<td>57</td>
<td>WB</td>
<td>Building custodian</td>
<td>10%</td>
<td>Infection/ MRSA; any error resulting in death</td>
<td>Human fallibility</td>
</tr>
<tr>
<td>205</td>
<td>Female</td>
<td>46</td>
<td>WB</td>
<td>Social worker</td>
<td>Not given</td>
<td>Not cited</td>
<td>Hospitals large organisations with potential for error; human fallibility</td>
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<tr>
<td>208</td>
<td>Female</td>
<td>32</td>
<td>WB</td>
<td>Administrator</td>
<td>20%</td>
<td>Infection/ MRSA; peri-operative errors</td>
<td>Human fallibility; pressure of work</td>
</tr>
<tr>
<td>209</td>
<td>Female</td>
<td>66</td>
<td>WE</td>
<td>Care officer</td>
<td>&gt;10%</td>
<td>Infections; peri-operative errors</td>
<td>Negligence of staff</td>
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## Group 3 Parents of children with asthma

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<th>Patient ID</th>
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<th>Age</th>
<th>Ethnicity</th>
<th>Occupation</th>
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<th>Perceptions of 'serious errors'</th>
<th>Attribution</th>
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<tr>
<td>302</td>
<td>Female</td>
<td>41</td>
<td>ABP</td>
<td>Nursery worker</td>
<td>‘don’t know’</td>
<td>Wrong operation; medication</td>
<td>Staff shortages; pressure of work</td>
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<tr>
<td>303</td>
<td>Female</td>
<td>36</td>
<td>WB</td>
<td>Homemaker</td>
<td>2-3%</td>
<td>Neglect; death</td>
<td>‘Sometimes down to patients themselves’</td>
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<tr>
<td>304</td>
<td>Female</td>
<td>33</td>
<td>WB</td>
<td>Administrator</td>
<td>50%</td>
<td>Wrong operation</td>
<td>Not given</td>
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<tr>
<td>308</td>
<td>Female</td>
<td>40</td>
<td>WB</td>
<td>Lunch supervisor</td>
<td>2-3%</td>
<td>Misdiagnosis; wrong drugs; item unretrieved</td>
<td>Surgeons have heavy workload, work long hours; junior doctors work long hours – leads to ‘human error’</td>
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<tr>
<td>309</td>
<td>Female</td>
<td>48</td>
<td>ABP</td>
<td>Housewife</td>
<td>5%</td>
<td>Wrong meds</td>
<td>Human error</td>
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Group 4 Patients undergoing joint surgery

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<th>Patient ID</th>
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<th>Age</th>
<th>Ethnicity</th>
<th>Occupation</th>
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<th>Perceptions of ‘serious errors’</th>
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<td>401</td>
<td>Male</td>
<td>72</td>
<td>WB</td>
<td>Sales manager</td>
<td>2-3%</td>
<td>Wrong operation</td>
<td>Pressure on staff; lack of time</td>
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<tr>
<td>402</td>
<td>Female</td>
<td>59</td>
<td>WB</td>
<td>Special needs assistant</td>
<td>‘no idea’</td>
<td>Permanent injury; death</td>
<td>Not given</td>
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<tr>
<td>406</td>
<td>Male</td>
<td>72</td>
<td>WB</td>
<td>Engineer (BT)</td>
<td>‘won’t guess’</td>
<td>Wrong drug dose; lack of hygiene</td>
<td>Staff lack training; some are not up to the job</td>
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<td>77</td>
<td>WB</td>
<td>Dressmaker</td>
<td>1%</td>
<td>Wrong operation</td>
<td>Not given</td>
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<td>Female</td>
<td>78</td>
<td>WB</td>
<td>Past experience of nursing</td>
<td>‘fingers crossed’</td>
<td>Wrong operation</td>
<td>Lack of communication</td>
</tr>
</tbody>
</table>

Group 5 Patients who have raised a safety issue or made a complaint

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Gender</th>
<th>Age</th>
<th>Ethnicity</th>
<th>Occupation</th>
<th>Estimated probability of error</th>
<th>Perception of ‘serious errors’</th>
<th>Attribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>507</td>
<td>Female</td>
<td>54</td>
<td>WB</td>
<td>Inland revenue officer</td>
<td>5%</td>
<td>Peri-operative; lack of hygiene</td>
<td>Not given</td>
</tr>
<tr>
<td>508</td>
<td>Female</td>
<td>42</td>
<td>WB</td>
<td>Specialist nurse</td>
<td>10-15%</td>
<td>Medication errors; wrong operations; (dis) information</td>
<td>Swiss cheese model; chain of events; workload pressures; inexperienced staff</td>
</tr>
<tr>
<td>509</td>
<td>Male</td>
<td>71</td>
<td>WB</td>
<td>Printing trade</td>
<td>‘don’t know’</td>
<td>Medication errors; wrong procedures</td>
<td>Workload pressures; staff have too much on their minds; are tired; lack information</td>
</tr>
<tr>
<td>511</td>
<td>Female</td>
<td>50</td>
<td>BC</td>
<td>Carer</td>
<td>10%</td>
<td>Item not retrieved post-operatively; MRSA</td>
<td>Lack of communication; ‘cutbacks’; overwork and tiredness</td>
</tr>
<tr>
<td>512</td>
<td>Female</td>
<td>61</td>
<td>WB</td>
<td>Foster carer</td>
<td>‘no idea’</td>
<td>Not given</td>
<td>Not given</td>
</tr>
<tr>
<td>Patient ID</td>
<td>Gender</td>
<td>Age</td>
<td>Ethnicity</td>
<td>Occupation</td>
<td>Estimated probability of error</td>
<td>Perceptions of ‘serious errors’</td>
<td>Attribution</td>
</tr>
<tr>
<td>------------</td>
<td>--------</td>
<td>-----</td>
<td>-----------</td>
<td>------------------------</td>
<td>-------------------------------</td>
<td>--------------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>602</td>
<td>Female</td>
<td></td>
<td>WB</td>
<td>Catering assistant</td>
<td>1-2%</td>
<td>Infection</td>
<td>‘Cutbacks’</td>
</tr>
<tr>
<td>603</td>
<td>Female</td>
<td>40</td>
<td>Al</td>
<td>Nurse in care home</td>
<td>1-2% for cross infection</td>
<td></td>
<td>Not given</td>
</tr>
<tr>
<td>605</td>
<td>Female</td>
<td>53</td>
<td>WB</td>
<td>Manager (business)</td>
<td>20-30%</td>
<td>Medication errors; neglect of nutrition</td>
<td>Staff shortages; nurses do too much paperwork</td>
</tr>
<tr>
<td>607</td>
<td>Female</td>
<td>50</td>
<td>WB</td>
<td>Doctor</td>
<td>5%</td>
<td>Wrong operation</td>
<td>Not given</td>
</tr>
<tr>
<td>609</td>
<td>Male</td>
<td>60</td>
<td>WB</td>
<td>Retired head teacher</td>
<td>&gt;50%</td>
<td>‘surgeons killing patients’</td>
<td>Surgeons not accountable to anyone</td>
</tr>
</tbody>
</table>
Appendix 4.12: Number of undesirable events identified by respondents from each clinical group and the location where they occurred

<table>
<thead>
<tr>
<th>Clinical Group</th>
<th>Hospital</th>
<th>Primary Care</th>
<th>Interface</th>
<th>A&amp;E/ambulance</th>
<th>OPD</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with diabetes</td>
<td>4</td>
<td>5</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>Patients treated for breast cancer</td>
<td>11</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>18</td>
</tr>
<tr>
<td>Parents of children hospitalised with asthma</td>
<td>11</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>15</td>
</tr>
<tr>
<td>Patients undergoing joint surgery</td>
<td>24</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>31</td>
</tr>
<tr>
<td>Patients who have raised a safety issue or made a complaint</td>
<td>27</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>32</td>
</tr>
<tr>
<td>Patients with severe and enduring mental health problems</td>
<td>14</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>91</td>
<td>18</td>
<td>5</td>
<td>4</td>
<td>10</td>
<td>128</td>
</tr>
</tbody>
</table>

Abbreviations: Accident and Emergency (A&E)  
Out Patient Department (OPD)
Appendix 4.13: Specific numbers of undesirable events recounted by individuals from each clinical group

**Patients with diabetes**

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>101</th>
<th>102</th>
<th>104</th>
<th>106</th>
<th>109</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of events</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

**Patients who have had treatment for breast cancer**

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>202</th>
<th>203</th>
<th>205</th>
<th>208</th>
<th>209</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of events</td>
<td>8</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

**Parents of children hospitalised with asthma**

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>302</th>
<th>303</th>
<th>304</th>
<th>308</th>
<th>309</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of events</td>
<td>3</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

**Patients scheduled for joint replacement surgery (prior to operation)**

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>401</th>
<th>402</th>
<th>406</th>
<th>407</th>
<th>408</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of events</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

**Patients scheduled for joint replacement surgery (after operation)**

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>401</th>
<th>402</th>
<th>406</th>
<th>407</th>
<th>408</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of events</td>
<td>12</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

**People who have raised a (safety related) issue with PALS or made a complaint about their health care**

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>507</th>
<th>508</th>
<th>509</th>
<th>511</th>
<th>512</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of events</td>
<td>3</td>
<td>6</td>
<td>10</td>
<td>10</td>
<td>3</td>
</tr>
</tbody>
</table>

**People with severe and enduring mental health problems**

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>602</th>
<th>603</th>
<th>605</th>
<th>607</th>
<th>609</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of events</td>
<td>2</td>
<td>2</td>
<td>10</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>
Appendix 5.1

Patient Stories
Story 1
Hello, My name is XXXXX. I have had both hips replaced left one 21 years ago
and the right last year.
I am here to describe what happened when the drain was removed from my leg
following my hip replacement last year.
About 10 minutes after the Staff Nurse removed the drain I noticed a lot of blood
beside my leg on the bed. The Staff Nurse and a Doctor who were in the ward at
the time hurried to help stop the bleeding. They worked very hard to control the
bleeding which was quite difficult for a while and the doctor refused to take any
phone calls or messages until he had stopped the bleeding. They told me an
artery had been snagged when the drain was pulled out. They were reassuring
and calm which helped me remain calm too.
Later that evening when the Staff Nurse came into the ward she apologized to
me. She seemed to think I thought she was responsible for what had happened –
I didn't. All I thought was I had been unlucky – it was just one of those things.
The following day my consultant came to see me. He seemed surprised when I
told him what had happened. He left the ward without a word. I was puzzled. I
thought he would come back. That he had gone to check with the nursing staff.
However, I didn't see him again until I went for my out patients appointment 6
weeks after my discharge, which had been delayed because I had lost so much
blood. I wondered if he blamed himself. If he thought I blamed him. I didn't. I
thought I had just been unlucky.
Story 2

I am here today to tell XXXXX’s story and his experience while in hospital. I am telling XXXXX’s story in the hope that we can all reflect on his experience and hopefully make any future admissions a more positive experience.

XXXXX is a young man with a learning disability. He has Down’s syndrome and autism. He is unable to give informed consent. XXXXX had significant weight loss over a period of time and weighed only five stone. An admission was planned for investigative procedures to take place under general anaesthetic.

Planning

It was agreed that an oral sedative (liquid) would need to be ordered for XXXXX to take on the ward prior to going to theatre. Mum, XXXXX and I would meet on the ward but stay in the day room as XXXXX does not like the ward environment and would be more likely to try and leave the ward.

I would discuss with the anaesthetist when he met how to ‘manage’ XXXXX once in the anaesthetic area and would stay with XXXXX until he was anaesthetised. While I was in theatre with XXXXX Mum would go for a walk as she gets very anxious when XXXXX goes to theatre. It was hoped that the oral sedative would work well enough for XXXXX to be compliant enough for the mask to be used to sedate him enough so he could then have the cannula inserted into his hand.

I would have already have spoken to the anaesthetist to explain that XXXXX would try and get off the bed and not to be fooled by his small stature. Because XXXXX is unable to understand what is happening his anxiety levels increase and he immediately wants to disappear. Despite weighing only five stone XXXXX is extremely agile and physically very flexible. He is known affectionately as ‘Jack Flash’!

What actually happened

No oral sedative had been ordered and could not be located in time to give to XXXXX.

I spoke with Mum who decided that she still wanted the procedure to go ahead as she was fearful for XXXXX’s health and concerned that he would continue to deteriorate. She was upset that XXXXX could not have the sedative to relax him as this also meant she would have to go down to theatre with him (otherwise XXXXX would not have gone). She then had to make a quick exit to avoid XXXXX seeing how upset she was.
Once in theatre XXXXX jumped off the bed before staff could hold him still enough to hold the mask on long enough to make him ‘drowsy’. XXXXX was on the floor in the corner extremely frightened. The second attempt was a success and XXXXX was successfully anaesthetised.

XXXXX came round from the anaesthetic very quickly and tried to climb off the trolley. Because we could anticipate this happening, myself and extra staff were by his trolley to prevent him injuring himself.
Story 3

In 2005 I had 12 sessions of chemotherapy treatment, following a lumpectomy. Prior to my treatment, I had an introductory visit to the Chemo Suite, which was very informative, helpful and reassuring. It was emphasised how important it would be for me to contact the Unit, should I feel at all unwell, e.g. high temperature, during this period of treatment.

When treatment started, my initial impression of the Chemo Suite was one of being extremely impersonal, e.g. open-plan room, no privacy/confidentiality. The door to the Suite was permanently left open, thereby some patients would be on full view to people coming/going onto Ward 15. It seemed a very open, busy, and public place with quite often a never-ending stream of people coming in and out. A small area of the room was used for admin purposes, including answering the telephone. There did not seem to be one appointed person to greet patients, and this would often result in people hovering at the door trying to announce him or herself to anyone whose attention they could get, whilst trying not to disturb staff, who were clearly busy administering the chemo.

Although I was told at the beginning of my treatment that I should contact the unit if I was feeling unwell, it became clear from my experience as a patient having chemotherapy administered that the disturbance from patients ringing with problems caused by the chemotherapy was problematic for the staff and distracted from the day to day running of the unit.

When contacting the chemo suite to check out any symptoms/feeling of unwell, the ‘busyness’ of the suite usually came across in how and what was said by staff. On one occasion, I was concerned about possible swelling to my arm, and I was told, although I felt As a patient I could understand this and when contacting the unit to check out any symptoms the ‘busyness’ of the suite usually came across in how and what was said by staff. Inevitably when I developed swelling in my arm I was initially reluctant to contact the unit because knew that me being given attention would be disruptive and potentially make the unit even busier. However, I was persuaded to ring by my husband and was told, although I felt... somewhat reluctantly, that I should come in and wait and see a doctor. I duly did this, to find the chemo suite incredibly busy, with no room even in the waiting area. After being initially assessed, I then sat in the corridor and waited to see a doctor. An hour and a half went by and as I was out of sight of the Suite, I was concerned that I might be forgotten. However, I felt unable to check this out with anyone, and I began to consider going home and returning another day. Fortunately I was able to get the attention of a passing nurse coming onto the ward, and consequently I was then seen by a Doctor, after which it seemed to be ‘all systems go’. It was explained to me the possibility of a clot, and the importance of a scan/procedure being done that day in order to check this. The
results of the scan showed no clot thankfully, but as there was some difficulty with my veins, a PIC line was put in my arm to avoid any future problems whilst administering the chemo.

Although my needs as a patient were eventually addressed, I feel that should I have followed my instinct and left the hospital, there was always the possibility that things could have perhaps turned out differently. The messages staff give us through their behaviour and comments can be as powerful as official instructions. Rightly or wrongly as a patient I was all too aware of the pressures that NHS staff are working under and the effect that this can have on how a service is delivered. However, the type of service a patient receives should not be dependent on whether a person is able to assert him or herself and be persistent, especially at a time when they already have to cope with what is usually a difficult time due to their health.
Story 4

Three and a half years ago my Mum was admitted to hospital in extreme pain. She was 81 years old at the time and had previously been fit, healthy and alert. Pain relief was given by various drugs, including morphine which, along with the pain, affected her mental processes.


The hospital was unable to completely pinpoint the cause of Mum’s pain. Pain relief was given by various drugs, including morphine. Her mental processes were affected by the pain and the medication.

The hospital was unable to pinpoint the cause of her pain and after nearly four weeks Mum was discharged from hospital. She was sent home by ambulance and Dad and I had been told to be at home to receive her.


Mum to be sent home by ambulance. She was discharged alone as Dad was told he couldn’t accompany her in the ambulance, he must be at home to receive her. I came out of work to be there on the day. At this point my parents were trying to cope on their own.

Mum arrived with a plastic bag filled with medication, including morphine. The only details supplied with the drugs were the number of doses and tablets per day to take. There was no other discharge information. Mum wasn’t able to tell us if she had been given any details at the hospital.

Mum arrived with a plastic bag filled with medication, including morphine. The only details supplied with these drugs were the number of doses per day, and the number of tablets for each dose. There was no other discharge information. If any was given at the hospital to Mum, she wasn’t in any condition to absorb or retain the information.

Mum had been discharged to the care of her GP. Information was sent from the hospital to the GP surgery, but not in time to reach the GP on Discharge day. So on the day of discharge:
The GP didn’t know Mum had been sent home
The GP didn’t have any details of Mum’s stay in hospital
And of course, the GP wasn’t there on her return (and isn’t likely to be)
The GP didn’t have plans to visit Mum – as he had no knowledge of the situation.
Immediate care and support to both elderly parents (Dad has emphysema, glaucoma, diabetes, no sight in one eye, severe deafness) had to be given by us, the family. We had no information from the hospital, and no previous experience of caring for an elderly parent who was now frail, confused, had poor mobility, and in poor health. Immediate responsibility was ours — with no information or support. We had responsibility for morphine, which required the signature of two staff nurses in the hospital; this responsibility was frightening in itself.

We had no discussion prior to discharge on how Mum would cope at home, and no equipment was in place for her return home. We had no information to help us keep both of my parents safe. It left my parents and the family very uncertain and anxious.

We didn’t know the purpose of most of the drugs (on other occasions, this had led to some not being taken).
We didn’t now the best times of day for each drug.
We didn’t know the best combination of drugs, to be taken at each time.
We had no information on side effects.
We had no copy of the OT assessment (we were told Mum would have to request it), so we didn’t know what we should safely encourage her to do, or how to do it.
We had no information on future care, any treatment, physiotherapy, or OT equipment.
We had no contact numbers.
We had no information about caring for an elderly frail person — so we didn’t know that mental confusion was a side effect of constipation, and also water infections.

We had no information on the “Norm” that we should expect, so no knowledge that Mum was veering from the Norm — only through a visit from the Community Health Team sent at a weekend to deal with an emergency, did we discover Mum was taking sedatives during the day. We thought the morphine was making her dopey!

Simple basic communication on discharge, would have avoided lots of anxiety, and weeks of trying to find out information, and who we could supply the information. It could also have helped us avoid crises, and save NHS resources. Most of all it would have been much easier to ensure my parents safety.

TWO & A HALF YEARS LATER – Sept 2007

Mum was discharged for the fourth time. Yet again we were given no information. Upon discharge she had Cellulites, and was sent home with 2 weeks of antibiotics.

No information was given on what to expect with the Cellulites, how it would be checked, or what to do at the end of the two weeks of anti-biotics.
I had to ring the hospital to find out that the GP surgery had been sent a fax on the day of discharge saying that the Cellulites should be monitored. It took a further week of phone calls & finally a letter to find out that the GP arrangement for monitoring was to SELF Monitor. 48 hours later Mum was an emergency admission. How do you keep someone safe without information?

I collected Mum from hospital on the Monday evening, no information given. On Thursday, when she was in great pain, I made a discovery accidentally – the hospital had taken Mum off the morphine and painkillers for nerve pain that she had been on for two & a half years, resulting in yet another request for an emergency doctor to call.

Elderly people frequently don’t ask: WHAT DO THEY DO - if they have no one to speak up for them, no one to keep asking questions, no one who is “bold” enough to call out a doctor, to question medication or lack of it.

Lack of communication and rebuffs from staff drives carers to other sources of information, e.g. the Internet – not always a reliable source, and not always the best way to ensure a patient’s safety. As carers we need information to keep patients safe, we can also give information to help keep a patient safe.
Story 5

In 2006, after being prescribed antidepressants periodically and becoming a control freak for 30 years which enabled me to survive as a lot of the time I was living in a mixed state, I was sectioned under the MHA. I was suffering hypomania due to bi-polar disorder.

Even though deep down I knew this to be the best option for me at the time – finally having the correct diagnosis and medication was in one way a relief – but having all your control taken away in one foul swoop is extremely hard.

This led me to become extremely aggressive especially when not believed on several occasions by certain members of staff. Whilst my mood generally became much calmer - yet again on several occasions I was not believed, leading myself back to aggression which usually led to being dragged off, pinned down and injected.

A lot of mood swings, calm, high, low in a short space of time, not to mention the upset for the other patients.

The day my section was lifted I was given so many hours per day where I could leave the hospital. I kept my side of the bargain sticking to the rules which is not easy being a control freak.

My psychiatrist told me he would be visiting me on the ward on a certain day. On that day I asked staff what time he was coming to see me and I again I was not believed. They told me I was mistaken and he wasn’t coming. I went out for my set hours thinking there must have been a mistake.

The following day I was told my hours had been cut and I wasn’t allowed to leave the hospital as I wasn’t there the previous day when my psychiatrist called to see me. I refused to stay in the hospital after that. I agreed to go daily for my medication. The first time I went back I remember being frightened that they were going to lock me up again when I entered the building. My trust had totally gone.

I know I needed to be hospitalised as I was mad at the time but that didn’t mean I was a liar.
Ethical Approval Documentation