The reporting of adverse clinical incidents – achieving high quality reporting:
the results of a short research study

James Coles
Dorothy Pryce
Dr Charles Shaw
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</table>
Executive Summary

1. In preparation for the new national reporting system for serious clinical incidents, this short study took place between August and October 2001. The three elements of the work were
   - Qualitative research based interviews of individuals and/or focus groups to find out how they believe they would react to reporting systems of different sorts
   - A survey of a sample of hospitals and practices to ascertain existing reporting systems
   - Gleaning experience from other countries by both formal (literature and internet reviews) and informal means.

The study aims were
   - To find out what different members of the clinical team would consider appropriate and effective in respect of reporting clinical incidents centrally. To elicit private and candid views on what would motivate clinicians under different circumstances to report or withhold information.
   - To review existing systems in the UK, so as to draw lessons about what works under what circumstances.
   - To glean evidence from abroad about the type of systems which have and have not succeeded in eliciting high response rates.

2. The evidence base for our conclusions is drawn from
   - An international literature and Internet review, together with informal discussions with a number of international experts in the area of patient safety
   - A survey of 171 risk managers in English acute trusts (121 replied) and a smaller survey of 25% of English PCG/Ts (36 replies)
   - Interviews with more than 60 clinicians across 23 specialties and departments
   - Discussions with researchers from ScHARR, who had recently completed a similar study in primary care.

3. Main areas for consideration are shown in the table below, divided into four aspects that are considered to have a major impact on the quality of reporting. The table lists features that are thought to drive reporting and contribute either positively or negatively. Of course, the converse of each feature might easily be placed in the other column but where they have been positioned has been determined by the strength of evidence we found in the study eg whether a factor was consider a greater barrier than an incentive to reporting.

4.

<table>
<thead>
<tr>
<th>Positive contribution</th>
<th>Negative contribution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acceptance of policy:</strong></td>
<td>- Lack of trust both at local level through to the very top of the NHS</td>
</tr>
<tr>
<td>- Clinicians’ desire to improve practice; benefits to patient care</td>
<td>- Having to address personal weaknesses in skills / knowledge</td>
</tr>
<tr>
<td>- Trust in an ‘aware’ management</td>
<td>- The need for an interested management</td>
</tr>
<tr>
<td>- Appreciation of a clinical learning opportunity</td>
<td></td>
</tr>
<tr>
<td>- Doctors could see a theoretical benefit</td>
<td></td>
</tr>
</tbody>
</table>
### Reporting of adverse clinical incidents

**- Positive blame-free culture needed**

- Need persuasion that potential benefits would be realised
- Concern about role in gaining control over clinicians
- ‘Over-selling’ the initiative – better to grow slowly but producing benefits at each step

**Identification of a reportable incident:**

- Acceptance of need for detailed guidance and definition
- Suggested provision of a helpline by NPSA

- Confused system and processes
- Doctors need to ‘own’ the reporting of incidents & take responsibility for it
- Need clarity about roles & responsibilities
- Need to recognise a ‘learning opportunity’
- Is it important / unusual enough (some incidents are considered routine)
- Role of reporting and educating juniors
- Identify the need to report all incidents, major or minor

**Concerns / enthusiasm about reporting:**

- Opportunity to air grievances about systems
- Opportunity to work with a ‘risk’ person to address issues
- Give existing reporting more weight
- Reporting equipment failures is thought beneficial
- Separation of reporting system from regulatory
- ‘Team’ attitude to reporting
- History of good local feedback
- Dissemination, sharing, benchmarking

- Reality of a blame-free culture
- Confidentiality; anonymity; protection from unjust censure
- Concern about audit trails - if the rules changed
- Lack of feedback from existing systems; is it all a waste of time?
- Lack of a follow-through to remedial action – need to address system failures
- alternative systems might produce same / greater benefits

**Practical issues:**

- Should interface & incorporate existing systems, eg ICD codes etc
- Reduce duplication of reporting
- Possible means to gain resources
- Provision of standard forms to produce consistency
- Realising the benefits
- Looking for support from the NPSA centrally; willingness to learn, if system is effective and supportive

- Available time
- Resource level need, available – to investigate each incident
- Resources need to be additional, rather than Trusts expected to absorb it through ‘efficiency’
- Gaining consistency of reporting to avoid biased interpretation
- Don’t over-depend on computing
1. Introduction

1.1 The NHS Plan introduced the proposal that there should be a mandatory system for reporting adverse events and near misses across the NHS. The Chief Medical Officer established an expert group which, reporting in ‘An Organisation with a Memory’\(^1\), recommended among other things that the NHS should develop

- unified mechanisms for reporting and analysis when things go wrong;
- a more open culture, in which errors or service failures can be reported and discussed;
- mechanisms for ensuring that, where lessons are identified, the necessary changes are put into practice;
- a much wider appreciation of the value of the system approach in preventing, analysing and learning from errors.

1.2 ‘Building A Safer NHS for Patients’\(^2\) set out the Government’s plans to implement these recommendations and to introduce the ‘new mandatory, national reporting scheme for adverse health care events and near misses within the NHS.’ Central to this was the creation of a new independent body, the National Patient Safety Agency (NPSA).

1.3 A draft document, ‘Doing Less Harm’\(^3\), produced by the Department of Health and the NPSA during the period of this short study, provides guidance as to how the new reporting system, which is due to go ‘live’ from April 2002, might operate. However, the document notes that this guidance is the subject of ongoing work and may change significantly before the system is finalised. It does though indicate current thinking and lists ten key local requirements for reporting by NHS health care providers.

1.4 The focus on patient safety within the NHS, which has been stimulated to some extent in the UK by a number of unfortunate episodes of poor clinical performance (including criminality), should be seen in the context of the high priority this topic is being given in health care systems throughout the world. The United States and Australia, in particular have made progress in this area, and have given the issues a great deal of thought while also gaining experience in pilot studies and other programmes.

1.5 CASPE Research was commissioned to undertake a short piece of research, between August and October 2001,

- To find out what different members of the clinical team would consider appropriate and effective in respect of reporting clinical incidents centrally. To elicit private and candid views on what would motivate clinicians under different circumstances to report or withhold information.
- To review existing systems in the UK, so as to draw lessons about what works under what circumstances.
• To glean evidence from abroad about the type of systems which have and have not succeeded in eliciting high response rates.

This was to be achieved by the research team undertaking three distinct pieces of work, bringing together findings from each to provide information about the features that are likely to result in a high quality, valued and valuable reporting system. The three elements to be addressed were

  • Qualitative research based interviews of individuals and/or focus groups to find out how they believe they would react to reporting systems of different sorts
  • A survey of a sample of hospitals and practices to ascertain existing reporting systems
  • Gleaning experience from other countries by both formal (literature and internet reviews) and informal means.

Results were to be presented in report form and discussed at a meeting of stakeholders.

1.6 This report, accompanied by the International Review annex, brings together the work undertaken, under the three strands identified above. Section 2 briefly describes the methods used to address each area, while section 3 provides the main findings of the study. Section 4 draws out common themes from across the three strands and identifies, from both positive and negative experiences, features of reporting systems that contribute to high quality reporting. Full details of the International Review are provided as an Annex, under separate cover, in order to keep this report reasonably short and concise.
2. Methods

2.1 As mentioned in the previous section, the research project that CASPE Research was commissioned to undertake involved three separate pieces of work, and three distinct groups of individuals and organisations – the international healthcare community, risk managers in acute trusts and those responsible for risk in PCG/Ts, and practising clinicians in acute trusts.

2.2 It was therefore possible to address each of the research areas:

- Gleaning experience from other countries by both formal (literature and internet reviews) and informal means
- A survey of a sample of hospitals and practices to ascertain existing reporting systems
- Qualitative research based interviews of individuals and/or focus groups to find out how they believe they would react to reporting systems of different sorts separately and in parallel, bringing together their findings towards the end of the study.

*International review*

2.3 The international review encompassed a standard approach to rapid literature reviews, interrogating Medline and other clinical databases, together with Internet searches using a number of search engines such as Google and Lycos. Searches initially focussed on the term ‘Patient Safety’ but this was later extended to incorporate terms such as ‘adverse clinical events’, ‘clinical incidents’ and ‘near misses’. In order to become more focussed on the specific nature of this particular piece of work, second level searches included the word ‘reporting’.

2.4 As well as the formal literature research, a number of organisations and individuals known to be experts in this area were contacted by phone, e-mail or in person at the International Society for Quality in Health Care’s Annual Conference held in Buenos Aires in October. The research team is very grateful to all those who have contributed their views and the benefit of their experience to this area of the work.

*Survey of current reporting systems – risk managers in acute trusts and PCG/Ts*

2.5 A questionnaire was derived from one developed by Dineen and Walshe that had been used to examine the progress of clinical risk management in the NHS. Questions on the identification and reporting of clinical incidents were drawn from this earlier survey instrument but were supplemented with a range of other questions of interest to this particular study. In particular, these included questions on progress made in monitoring incidents in areas targeted in ‘An Organisation with a Memory’ as well as asking for subjective views on the quality of current incident reporting, and perceived barriers and incentives to reporting.
2.6 This questionnaire was distributed to all 171 risk managers in acute trusts in England that could be identified from Binley’s database. The research team had hoped to be able to distribute the questionnaire electronically by e-mail, in order to facilitate a quick and easy response, as well as enabling a follow-up of non-responders but we were unable to get a comprehensive list of e-mail addresses from either the Department or proprietary sources.

2.7 Following receipt and initial analysis of the survey, a small number of risk managers were contacted to discuss particular findings in rather more detail. The results of these discussions both validated the survey findings and tended to reinforce information obtained from the clinician interviews.

2.8 A second questionnaire was developed for use by PCG/Ts and was circulated to a 25% sample of these organisations, again drawn randomly from existing databases. The survey was sent to chief executives, since it was not clear who was responsible for risk management within these organisations.

Clinician interviews and focus groups

2.9 A total of 69 people were interviewed between August and October 2001. Forty three one-to-one interviews were conducted with doctors, nurses, pharmacists, a radiographer, one risk manager and one non-clinical manager of cancer care. A further seven specialist registrars and 16 consultant clinicians were recruited to form two focus groups for triangulation of the interview findings, while a further three telephone interviews were conducted with risk managers.

2.10 A ‘long list’ of Trusts (approximately eight from each of the regions in England) was initially produced by considering published data on clinical performance in order to get a degree of variability. To obtain views from staff in variously sized hospitals, we purposefully selected ten University Teaching and District General hospitals (DGH) and prepared a list to achieve a cross section of health professions and specialties. The researchers wrote to the Medical Directors of the trusts asking them to propose clinical staff to approach for interview. Five trusts responded and from these 24 of their staff were interviewed. In a second pragmatic selection, we enlisted the help of known hospital contacts and colleagues to suggest other people we might approach. This yielded the other 19 individual interviews. Using this non-probabilistic, sampling method we conducted 43 qualitative interviews in two University Teaching Hospitals, six DGHs and one specialist Trust. Tables 1 and 2 below detail staff, specialties and regions represented.

Table 1: Professions of staff interviewed individually

<table>
<thead>
<tr>
<th>Profession</th>
<th>No interviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultants</td>
<td>16</td>
</tr>
<tr>
<td>Junior Doctors</td>
<td>7</td>
</tr>
<tr>
<td>Nursing staff</td>
<td>14</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>2</td>
</tr>
<tr>
<td>Radiographer</td>
<td>1</td>
</tr>
<tr>
<td>Theatre manager</td>
<td>1</td>
</tr>
</tbody>
</table>
Table 2(a): Specialties and departments represented

<table>
<thead>
<tr>
<th>Doctors</th>
<th>Nurses -Ward /Dept Manager and Staff-nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accident &amp; Emergency Dept</td>
<td>Accident &amp; Emergency Dept</td>
</tr>
<tr>
<td>Anaesthetics</td>
<td>Care of the Elderly</td>
</tr>
<tr>
<td>Care of the Elderly</td>
<td>Colo-rectal Surgery</td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>Coronary Care Unit</td>
</tr>
<tr>
<td>General Medicine</td>
<td>Endoscopy Unit</td>
</tr>
<tr>
<td>Neonatology</td>
<td>General Medicine</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>Neonatology</td>
</tr>
<tr>
<td>Nephrology (paediatric)</td>
<td>Paediatrics</td>
</tr>
<tr>
<td>Obstetrics and Gynaecology</td>
<td>Palliative Care</td>
</tr>
<tr>
<td>Pathology</td>
<td>General Surgery</td>
</tr>
<tr>
<td>Paediatrics</td>
<td>Theatre Manager</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>Others:</td>
</tr>
<tr>
<td>Radiology</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>General Surgery</td>
<td>Pathology</td>
</tr>
<tr>
<td>Thoracic medicine</td>
<td>Radiography</td>
</tr>
</tbody>
</table>

Table 2(b): NHS Regions represented in individual interview

<table>
<thead>
<tr>
<th>Region</th>
<th>Number of Trusts visited</th>
</tr>
</thead>
<tbody>
<tr>
<td>London</td>
<td>3</td>
</tr>
<tr>
<td>Northern &amp; Yorkshire</td>
<td>1</td>
</tr>
<tr>
<td>South East</td>
<td>2</td>
</tr>
<tr>
<td>South &amp; West</td>
<td>1</td>
</tr>
<tr>
<td>West Midlands</td>
<td>1</td>
</tr>
</tbody>
</table>

Other interviews were carried out via the telephone

2.11 Interviews took place in the hospital in which participants practised. The two focus groups were conducted at the King’s Fund, London where clinicians were attending training courses for Specialist Registrars (SpR) or Medical & Clinical Directors and were conducted by DP and JC.

2.12 The interview topics covered are shown in table 3. These topics were pursued iteratively. Most of the interviews were tape-recorded and transcribed verbatim, otherwise notes were taken during the interview. The NPSA is a new organisation and its work is currently being piloted. Asking questions about a hypothetical situation (NPSA reporting) can generate hypothetical answers. We therefore structured our first questions around current reporting, to elicit attitudes, experiences and difficulties.

Table 3: Interview topics covered

- Blame-free culture
- Confidentiality and transparency of reporting
- Definitions of reportable incidents – how do clinicians currently decide whether to report?
- Examples of adverse incidents; reporting and action therefrom
- Evidence (if any) of improvement in quality of patient care after local incident reporting
- Incentives and disincentives to reporting
- The balance between a training situation and reportable errors – where does it lie?
2.13 Analysis was conducted (by DP) using content analysis and coding emergent themes. The transcribed interviews were analysed inductively by reading and re-reading the transcripts. This process enabled the researcher to generate the main themes that were grounded in the data. We discussed some of the findings with participants of the focus groups and found their reactions compatible with our findings. Their comments were included in further analysis. The results of the interviews are described in more detail in section 3.4.

[Note: We have used the term ‘clinician’ in its widest sense to include doctors and nurses. Where opinions were different between the professions we refer to ‘doctors’ or ‘nurses’ and where they voiced similar feelings we have used the term ‘clinicians’.]

2.14 At the outset, it had been the intention that this research should include qualitative interviews with clinicians in the Primary Care sector. However, the School of Health and Allied & Related Research at Sheffield University (ScHARR) had recently undertaken a study into significant event reporting in Primary Care and a report by them was being prepared for the Department of Health.

2.15 With this in mind, it was decided not to replicate such a study. CASPE researchers spoke with those undertaking the research at ScHARR and brief details of their interim findings are presented in section 3.3. The underlying messages from this research were similar in nature to those identified by CASPE in their interviews with clinicians in the secondary care sector, and with risk managers and have been incorporated into the conclusions in section 4.
3. Findings of the Research

3.1 International Review

3.1.1 The international review (provided as a separate Annex to this report) describes recent and current activity in the development of patient safety reporting systems across a number of countries. These have been selected to include those countries that have established programmes or are in the process of so doing, having undertaken substantive reviews. A number of other countries are also undertaking work in the area of patient safety but programmes tend to be less developed.

3.1.2 The review firstly considers a number of organisations, mostly operating at the national level, and identifies the diagnoses they have made of the weaknesses of current reporting systems in the area of patient safety. This section also identifies principles and critical success factors for future reporting systems that have been derived from surveys, consensus meetings and ‘summits’. Table 4 below, briefly lists such factors and principles that are more fully described in section 1 of the Annex.

Table 4: Exemplar principles and critical success factors of reporting systems

<table>
<thead>
<tr>
<th>Principles</th>
<th>Some Critical Success Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create an environment of safety for reporting.</td>
<td>Accuracy of reporting; standardised definitions</td>
</tr>
<tr>
<td>Information reported should be comprehensively analysed to identify action.</td>
<td>Maintenance of confidentiality</td>
</tr>
<tr>
<td>Confidentiality for patients, professionals and organisations are essential.</td>
<td>Ability to obtain and evaluate preventive plans to reduce risk of recurrence</td>
</tr>
<tr>
<td>Reporting systems should facilitate the sharing of patient safety information.</td>
<td>Training on reporting</td>
</tr>
<tr>
<td>The legal status of reporting system information should be clarified and, if possible, become privileged.</td>
<td>Education of professionals</td>
</tr>
<tr>
<td></td>
<td>Restructuring peer review and credentialling processes to assure fairness</td>
</tr>
<tr>
<td></td>
<td>Reduce malpractice litigation</td>
</tr>
<tr>
<td></td>
<td>Media awareness of true nature of adverse outcomes and errors</td>
</tr>
<tr>
<td></td>
<td>Non-punitive corrective action plans</td>
</tr>
<tr>
<td></td>
<td>Demonstration of improved outcomes</td>
</tr>
<tr>
<td></td>
<td>On-site follow up</td>
</tr>
<tr>
<td></td>
<td>Better understanding of system v. practitioner issues</td>
</tr>
<tr>
<td></td>
<td>Feedback to improve patient safety</td>
</tr>
</tbody>
</table>

3.1.3 The review also describes, in section 2, established programmes in monitoring adverse events and near misses. Most of these are drawn from the health sector, although experience in other sectors is briefly examined. Most notable among these is the aviation sector which is known within popular culture for investigating ‘near misses’. The main features of the US system are the voluntary nature of the reporting and the decision taken in 1976 to separate the reporting system (now managed by NASA) from the regulatory body. Barach and Small reviewed non-medical reporting systems and identified barriers and incentives at the individual, organisational and societal
levels. Again, these are briefly listed in table 5 but are also reported in section 2 of the Annex.

Table 5: Barriers & incentives to reporting at individual, organisational and societal levels (Barach & Small)

<table>
<thead>
<tr>
<th>Individual</th>
<th>Organisational</th>
<th>Societal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Barriers:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) Fear of reprisals; lack of trust</td>
<td>Fear of litigation; costs; publicity</td>
<td>Legal impediments to peer review; confidentiality</td>
</tr>
<tr>
<td>2) Dependent on profession, scepticism, extra work</td>
<td>Dependent on organisation; cultural, bureaucratic</td>
<td>Public trend towards disclosure. Lack of trust; lack of education about system effects</td>
</tr>
<tr>
<td>3) Exposure to malpractice; licence suspension; increased premiums</td>
<td>It doesn’t apply to us; they can’t understand our problems anyway</td>
<td>Need more effective regulations; resource intense</td>
</tr>
<tr>
<td>4) Loss of reputation; loss of income or job</td>
<td>Wasted resources, potential loss of revenue; not cost effective</td>
<td>Cost more tax dollars to enforce; more bureaucracy</td>
</tr>
<tr>
<td><strong>Incentives:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) Provide confidentiality and immunity</td>
<td>Provide confidentiality and immunity</td>
<td>Ensure accountability, enforce reporting statutes</td>
</tr>
<tr>
<td>2) Professional values; integrity; educational</td>
<td>Become a leader in safety and quality; good for business</td>
<td>Enhanced community relations; build trust, improve health care</td>
</tr>
<tr>
<td>3) Prophylactic, follow the rules</td>
<td>Fear of censure</td>
<td>Enhances regulatory trust; more public accountability</td>
</tr>
<tr>
<td>4) Safety saves money</td>
<td>Public relations; improve reputation for quality</td>
<td>Improves confidence in healthcare system</td>
</tr>
</tbody>
</table>

3.1.4 The main emphasis of the review though has been on seeking evidence of good practice in the area of patient safety reporting. At this stage of development, ‘good’ has been defined quite broadly but might be encapsulated by practices which create an environment that is likely to encourage complete, consistent and reliable reporting of adverse events and near misses. The findings of this review are presented in the following paragraphs summarised under the headings of policy, organisation, methods of reporting and resources.

Policy

3.1.5 In introducing a system, the aims and processes depend largely on the ‘customer’. The balance across values (eg blame or transparency) and purpose (eg public accountability or safety improvement) must be explicit before an incident reporting system is designed. A lack of clarity, or subsequent changes to the stated aims, can introduce mistrust and lead the system into disrepute.

3.1.6 It is obvious that consistent terminology should be defined and adopted. Such terminology should be consistent with the stated aims and values of the
patient safety programme and, in this respect; careful consideration should be
given to the use of terms such as ‘error’, ‘mistake’ and ‘accident’ which
suggest causality and blame.

3.1.7 The scope and taxonomy of what is reportable should be defined sufficiently
closely to enable consistency and aggregation at national level (strategic) with
enough simplicity to be understood and used more locally (operational). This
has been one of the major challenges to programmes to date. Most imply
some level of resultant severity eg involving death or serious injury, or risk
thereof; prolonged hospital admission as well, as well as a differentiation
between an adverse outcome related to the natural course of the condition
and one related to its treatment, or lack thereof.

Organisation

3.1.8 The scope, authority and relationships of all reporting systems should be
clarified to identify how they relate to existing and future mandates, and to
make better use of existing sources of information on adverse incidents. It is
not only in the UK that there are a range of existing systems for reporting
subsets of incidents to different agencies. The effort associated with the
multiple reporting of the same incident eg to local management, professional
bodies, statutory agencies and central reporting should also be reduced, by
adopting common processes and data.

3.1.9 In a similar vein, the responsibilities of individuals and organisations, both
statutory and voluntary, with respect to the collection, analysis and
dissemination of information need to be further defined. This is particularly
important with regard to how the NPSA relates to CHI, NICE, the MDA, and
medical (and other) defence organisations. Additionally, other countries are
also considering appropriate mechanisms to enable the independent
evaluation of the effectiveness of incident reporting.

3.1.10 The reporting system should be designed to ensure that each identified stage
of the pathway is efficient and effective in producing information which leads
to increased patient safety. The main debate in this area lies in the relative
benefits of continuous, generic reporting (often relying on the ‘passive’
submission of a report of an event) and the more ‘active’ tracking of specified
events (for a limited time period). Concerns over the former approach centre
on whether the data collection will come to dominate analysis, feedback and
evaluation of change, which is seen to be essential to a successful system.

3.1.11 The design and presentation of the system should clearly provide the
incentives, assistance, protections, and confidentiality needed to encourage
spontaneous, timely and complete reporting. Education and training about the
system needs to reach local level (often knowledge is partial about similar
systems) and needs to be reinforced as junior staff change. Various design
factors that inhibit reporting across other systems are listed in table 6.
Table 6: Design factors that inhibit reporting (various studies)

| Lack of awareness of the need to report, and how to do so. |
| Lack of clarity about the responsibility for reporting a particular incident |
| Personal reputation |
| Threat of malpractice suits |
| High expectations of the patients’ family, or society |
| Possible disciplinary action by licensing bodies |
| Threat to job security |
| Expectation of other team members |
| Uncertain association between incident and adverse impact on patient |
| Too trivial, too well-known to report |
| Too bureaucratic; not enough time |

Methods of reporting

3.1.12 Several studies have shown there to be benefit in reportable incidents being identified through a variety of sources and methods. As well as the reporting of incidents envisaged for the NPSA, the use of existing sources of data such as clinical coding and coroners’ reports should be considered within an integrated process. Such use could result in a more efficient approach (see 3.1.10) but may also produce additional information and a means of triangulating and evaluating the original report.

3.1.13 Paragraph 3.1.5 previously identified the need for the values and aims of the system to be explicit from an early stage. One specific aspect of this issue is whether reporting is to be mandatory or voluntary. Mandatory systems are more usually related to public accountability and sanctions while most of those that focus on safety improvement are voluntary. Within a national system, there is probably a need for both but a mandatory system without the guarantee of confidentiality is likely to result in a less thorough reporting of incidents.

3.1.14 The burden of detailed reporting and the routing of such reports to different agencies e.g. MDU, Royal Colleges, local management should be minimised in order to encourage the participation of front-line staff. Electronic, technical and professional support should be available to assist in this.

3.1.15 The power of incident reporting to effect improvements across the NHS will depend on the capacity of the system to aggregate and recognise clusters of underlying features. This will depend on consistent recording, the availability and classification of appropriate information as well as the software, staff and processes needed. Effort should be focused on the early detection of trends from a variety of sources and settings.

3.1.16 The importance of feedback as a re-enforcement mechanism cannot be overstated. At local level, individual reporters should receive early acknowledgement of receipt of a report and assurance of resulting action; at national level, emerging lessons should be systematically disseminated. It is important that these lessons should be returned to those reporting particular incidents as well as being shared with public and independent bodies in the UK and overseas.
3.1.17 Although there is quite a lot of experience across a number of countries in setting up reporting systems on patient safety, there is limited evidence that such systems have been rigorously evaluated as to patient benefits. Difficulties in this respect relate to defining benefits eg does a reduction in the rate of reporting imply a reduction in the rate of the incident, and to the drivers and ability to change practice. However, the criteria, procedures, timescale and responsibility for evaluating and reporting on the cost and impact of incident reporting should be defined at an early stage. Ideally, these should focus on outcomes in terms of real reductions in the rate of adverse incidents.

Resources

3.1.18 The opportunity costs of staff time spent in collecting and reporting data should be quantified and recognised in the design and evaluation of the system. Front-line staff need to be persuaded that the system will be effective in bringing about beneficial change, at the expense of time spent on direct patient care. A second concern surrounds the ability of current staffing levels eg within risk management, to analyse and address in sufficient depth the number and importance of incidents that are likely to be reported.

3.1.19 All staff should be made fully aware of the aims, national definitions, procedures and pathways for reportable events. This appears to be an important issue with respect to junior staff who may only stay in a particular position, or with a particular healthcare organisation for a limited time and whose replacement then needs induction training. Risk management and adverse incident reporting should be a visible and permanent element in undergraduate, postgraduate and continuing development programmes. There should be special training provided to any co-ordinators responsible for the quality assurance of reporting systems at local and national level.

3.1.20 Information sources inside and outside the NHS need to be linked and standardised to help identify incidents and to support and enhance the main reporting system. Consistency of definition, threshold reporting and the use of other, existing databases will all contribute to increasing the value of the incident reporting system to the NHS.

3.1.21 The initial and recurring costs of computing, training, reporting, analysis and information exchange should be clearly defined and realistically budgeted. There is a major concern that the cost of the root cause analysis of serious reported incidents will be transferred to the risk management function within trusts without the resources to discharge this responsibility. This will inevitably lead to under-reporting or poor follow-through bringing the overall system into disrepute.

3.2 Survey of current systems - Risk managers

3.2.1 A questionnaire (provided at Appendix 1) was developed, incorporating certain questions from a survey tool used by Walshe and Dineen at the University of Birmingham was sent to the 171 Risk Managers in acute trusts in
England that could be identified from Binley’s database. Responses were received from 121 of them giving an overall response rate of 71%. Time constraints did not allow follow-up of non-responders, but a review of the questionnaires received suggest a broadly representative mix of trusts both geographically and by teaching/non-teaching split.

3.2.2 In this survey, the responses to most questions were heavily skewed in one direction or the other. A calculation of the standard error would suggest that in most cases the ‘true’ figure lies within 5 to 6% of the response estimated from the survey.

3.2.3 All those replying claimed to have a clinical incident reporting system, in marked contrast to the position in PCG/Ts (see section 3.3). Additionally 97.5% of acute trusts reported having a system that collected ‘near-miss’ situation. The quality of data collection in these systems is addressed later (at para. 3.2.15)

3.2.4 At present, less than 40% of those replying can use e-mail to report incidents, most (>90%) using paper forms to do so. Telephone or personal reporting is used by about 70% of trusts. It is also perhaps surprising that over 30% (31.4%) of trusts do not accept anonymous reporting of incidents. Both these results may have implications for the way that NPSA reporting is set up, at least in the early days.

3.2.5 Staff are currently expected to report incidents within 24 hours by 62% of trusts while a further 17% are expected to report within 48 hours. Most staff groups eg junior/consultant medical staff, nurses, pharmacists, pathologists have reported incidents in over 80% of trusts in the last 12 months, indicating both widespread occurrence of such incidents and a willingness to report, at least locally. However, over 10% of trusts do not provide any formal guidance about the type of clinical incident to report, while a further 50% only provide broad guidance.

3.2.6 Nearly 90% of trusts report that clinical risk management and clinical incident reporting are covered within induction programmes for clinical staff but beyond that less than 60% offer any additional guidance such as further training, written instructions or guidelines.

3.2.7 Table 7 below shows the rate at which particular types of incidents are reported across trusts and whether risk managers felt such reporting was mandatory or voluntary. No attempt was made at this stage to interpret what criteria was being used by risk managers in assessing this, nor whether there were any sanctions if clinicians did not report such incidents within a ‘mandatory’ system.
Table 7: Rate of reporting by type of incident (& its voluntary or mandatory nature)

<table>
<thead>
<tr>
<th>Type of incident</th>
<th>% Trusts reporting</th>
<th>% not reporting</th>
<th>Considered mandatory</th>
<th>Considered voluntary</th>
<th>Varies by incident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unexpected deaths</td>
<td>92.6</td>
<td>6.6</td>
<td>57.9</td>
<td>19.0</td>
<td>17.4</td>
</tr>
<tr>
<td>Attempted suicides</td>
<td>81.0</td>
<td>5.0</td>
<td>56.2</td>
<td>14.0</td>
<td>9.9</td>
</tr>
<tr>
<td>Unexpected poor outcomes</td>
<td>76.9</td>
<td>17.4</td>
<td>30.6</td>
<td>26.4</td>
<td>20.7</td>
</tr>
<tr>
<td>Unexpected returns to theatre</td>
<td>76.0</td>
<td>17.4</td>
<td>25.6</td>
<td>29.8</td>
<td>24.0</td>
</tr>
<tr>
<td>Unexpected operating complications</td>
<td>81.8</td>
<td>13.2</td>
<td>28.9</td>
<td>26.4</td>
<td>27.3</td>
</tr>
<tr>
<td>Drug errors</td>
<td>96.7</td>
<td>0.8</td>
<td>54.5</td>
<td>25.6</td>
<td>15.7</td>
</tr>
<tr>
<td>Patient falls</td>
<td>96.7</td>
<td>2.5</td>
<td>59.5</td>
<td>16.8</td>
<td>13.2</td>
</tr>
<tr>
<td>Near misses</td>
<td>97.5</td>
<td>1.7</td>
<td>32.2</td>
<td>35.5</td>
<td>28.1</td>
</tr>
</tbody>
</table>

3.2.8 It was reported that clinical incident reports almost always (>80%) contained patient details, date and time of the incident, the clinical service or directorate involved and the location of the incident. A factual account was always included by 74% of risk management systems, while a further 25% of managers reported this was ‘often’ included. Grades and names of staff involved in the incident were much less frequently recorded, as were the factors that contributed to the incident.

3.2.9 The rate of reporting of clinical incidents was very variable. In the last 12 months, between 9 and 9000 incidents had been reported (ignoring zero responses). The median across the 101 replies received was 800, the mean was 1529 and the inter-quartile range was 200 to 2000. Some of the variability in this figure may be due to the inconsistency with which near misses are recorded. Seventy-three per cent of replies said that near misses were included in the above figures, while 14 per cent said they were not. However, this latter group contained some of the highest frequency of reporting (max: 8000).

3.2.10 Of the four areas that ‘An Organisation with a Memory’ targeted for action, it is perhaps surprising that 22% of relevant Trusts do not yet have a system identifying information about spinal injection safety. Sixteen per cent do not have a system in respect of reducing suicide by mentally ill patients, 14% in respect of reducing drug errors and 11% in respect of Obstetrics safety. Where system exist, most also collect ‘near miss’ information.

3.2.11 Over 80% of reports were reviewed by the clinical team / ward manager where the incident occurred, the clinical directorate and the Trust risk manager or committee. Reports were reviewed by only about a quarter of Trust boards. Between 15 and 20% of reports do not remain confidential between the person reporting, the head of the clinical service involved and the risk manager, even if litigation is not an issue. However most reporting usually, or always, remains confidential within the Trust if litigation is not involved (approx. 89%).

3.2.12 Analysis of clinical incident data takes place either monthly or quarterly in over 80% of Trusts, but reporting tends to be somewhat limited. While the type of clinical incident is nearly always reported (97%), its frequency of occurrence is
reported less often (76% of Trusts), and contributory factors are reported much less frequently (38%).

3.2.13 Action resulting from incident reports is also somewhat infrequent. Publicising the underlying issues through memos etc., or re-training of specific staff ‘often’ or ‘always’ occurred in about two-thirds of Trusts. Extension to a fuller audit of practice, or to trust-wide staff training occurred much less frequently. Disciplining of staff as a result of clinical incident reports was said to never occur in 21.5% of Trusts, and seldom occur in 72.7%.

3.2.14 However, many risk managers did identify specific changes in clinical practice that had resulted from clinical incident reporting. Examples of these included:

- Risk assessment of elderly patients re: falls
- Review of purchasing volumetric & syringe pumps
- Formal count for the introduction of long lines and redesign of anaesthetic charts
- Potassium made a controlled drug

3.2.15 Risk managers were asked to mark on an analogue scale from 0 (incomplete) to 10 (complete) how complete clinical incident and near miss reporting was within their Trust. Results are shown on the graph below. Unsurprisingly, risk managers considered that reporting of actual events was more complete than the reporting of near misses. These responses were used to identify a number of Trusts at either end of the distribution whose risk managers were interviewed about their views on incident reporting. Additionally a number of...
qualitative questions within the survey were examined across these two
groups, to highlight differences that might inform the research about barriers
to, or opportunities for, the success of a national reporting system. The results
are described in the following paragraphs.

Qualitative Responses from risk managers with ‘complete’ and ‘incomplete’
reporting

3.2.16 In reply to a question about asking which factors encouraged clinical incident
and near miss reporting, risk managers who were in Trusts with ‘complete’
reporting provided a greater number of factors than those in the ‘incomplete’
group. Both sets of managers identified the need for a ‘blame free’ system to
become a reality, and identified that success was likely to depend on the
awareness, motivation and enthusiasm of staff. This in turn would depend on
the level of trust between staff and management. The ‘complete’ group (ie
those Trusts towards the right hand side of Figure 1 in paragraph 3.2.15)
additionally identified:–

- Training, and a willingness to understand the issues that cause
  incidents
- Feedback, and knowledge that action has been taken to reduce risk
  of recurrence
- Positive commitment to risk reduction, starting at the top.

The ‘incomplete’ group tended to cite reasons with a more negative focus,
such as:–

- Decrease in discipline; knowing disciplinary action will not usually
  occur
- Anonymity, confidentiality
- ‘Some staff see it as a way of off-loading the problem’; ‘covering
  your back’.

3.2.17 A second question asked for views about which factors discouraged reporting
of clinical incidents and near misses. Here, the two groups tended to be closer
in their views with fear of litigation, fear of blame and overcoming the existing
culture of senior clinical or managerial staff. Building on the previous
paragraph, responses also tended to cite the reverse of some of the positive
factors identified as reasons why progress in this area is difficult eg:

- Limited feedback; repetition of similar incidents without resolution; ‘nothing ever changes
- Pressure of work; complexity and size of form
- Uncertainty about whether and what to report.

Some worrying comments by a few risk managers from the ‘incomplete’ group
suggest rather more than lethargy on the part of senior staff may need to be
overcome, if the new reporting system is to be successful. These include
‘intimidation by senior medical staff’, ‘professional paranoia’, ‘heavy-handed
retribution for those involved’, ‘Big Brother’.
3.3 Survey of current systems - PCG/Ts

3.3.1 As mentioned in section 2, a study into significant event reporting in Primary Care had recently been undertaken by a research team from ScHARR at the University of Sheffield. The final report was in preparation, and an interim report was provided to the CASPE team and discussed with the ScHARR authors. Taking note of the core messages from this earlier study, the research team undertook a survey of PCTs and PCGs to provide comparable results to the survey being undertaken in secondary care and to augment some of ScHARR’s findings.

3.3.2 A 25% sample of Primary Care Trusts (PCTs) and Primary Care Groups (PCGs) was surveyed using a questionnaire adapted for general practice from the Risk Managers questionnaire. The response rate was a disappointing 36% (36 out of 100) but the short timescale of this study precluded any follow-up mailshot. Of these 36 responses, only six (17%) had an incident reporting system through which practices could report information about clinical incidents. Two of these were pilot studies. Two other PCTs were in the process of developing a system.

3.3.3 On a scale of 1-10, four of the six who had a system rated completeness of clinical incident reporting as low (2 or 3), one higher at 7 and one did not complete the question (see Figure 1 above for comparison with the assessment of risk managers in acute trusts). A similar question relating to near misses produced results that ranged between 1 and 7, (1,2,3,5,7) with three estimating it was less complete than incident reporting, one more complete and one the same.

3.3.4 More interesting though, in this very small sample, were the main factors that PCG/Ts reported encouraged adverse event and near miss reporting. These were cited as including:
- clinicians’ desire to improve practice and protect themselves and their patients
- anonymity
- time
- an ‘aware’ management
- appreciation of a clinical learning opportunity
- a chance to air grievances
- activity/reporting being linked to incentive payments and part of Clinical Governance local action plans

Having a ‘champion’ within the PCG/T and an opportunity for the individual practice to work with such a person who would further explain the aims and processes would also encourage reporting, it was thought.

3.3.5 Factors which discouraged reporting included:
- fear of recriminations, litigation and disciplinary measures
- having to address personal weaknesses in skills and/or knowledge
- lack of time
• the need for a learning culture, and interested management
• confused systems and processes

They also commented that in the interface with agencies outside health organisations, there was a need to establish and maintain trust.

3.3.6 The 30 PCG/Ts who responded to the questionnaire but did not yet have a system in place also responded to these two questions. The factors that they identified as either encouraging or discouraging reporting were similar to those identified by the six PCG/Ts that had experience of an operational system. The predominant discouraging factors were the fear of retribution, ‘shame’, criticism, litigation and disciplinary action. The lack of feedback or any obvious link between reporting and remedial action, as well as the time it took to complete forms and the bureaucracy of the procedure were also very important. The main encouraging factors identified were having an opportunity to learn from the adverse incidents and share the learning with other Trusts, anonymity, and the presence of a supportive team and managers.

3.4 Interviews with clinicians

3.4.1 A major aspect of the empirical research to support this report was a series of interviews with clinicians within the Health Service to elicit their views about a national reporting system on clinical incidents. The interviews were designed to identify their concerns, but also to gain a broader picture about the level of enthusiasm and support for such a system, practical issues about how it might work and other important considerations. In total, the views of 59 clinicians were obtained individually, or in focus groups across a broad range of specialties and professions. Details have already been provided in section 2 above.

3.4.2 Descriptive analysis of the interviews is provided below under four sub-headings:-
• Acceptance of policy of central reporting
• Identification of the need to report an incident
• Barriers to reporting – clinicians’ concerns
• Incentives to reporting – encouraging clinicians

Similar headings are used in section 4 where results from the other aspects are also brought together

Acceptance of policy for central reporting

3.4.3 Most staff had heard that there was to be a system of nationally collecting adverse clinical incident data, although few knew much detail and most comments were based on the outline provided by the interviewer at the start of the interview.
3.4.4 Most doctors could see a theoretical benefit to collecting national adverse clinical incident data - ‘I think it could be hugely important.’ Of these, some believed it was needed, was inevitable and could improve patient care

‘I think that people have gradually learnt that this is not an escapable area of the healthcare critical process and are much more willing, and realise the importance of doing it’ Anaesthetist

Consultants felt that doctors were willing to consider reporting centrally

‘it may be an instrument for change … so that if something happens we may be able to change that’

using root cause analysis as an instrument to prevent recurrences.

Their attitudes were quite positive, but among issues which could inhibit reporting and which was seen as reducing the value of current reporting were

‘insufficient resources to do more than analyse a few cases’

and the fact that it is often a

‘bolt on [task] to an already harassed managerial team’.

3.4.5 However, most would require more convincing on how a national agency could operate effectively. There were uncertainties about whether it would be provided with accurate information and whether it could produce positive changes. Some strongly doubted whether central reporting would produce any benefit to patients. In their view, data collected would be unreliable, both in completeness and accuracy of content. They believed Trusts and individuals had too much to lose from reporting errors candidly. Additionally, there was some dissatisfaction with Trusts’ protectionist attitude

‘What are the drivers?’

‘I’d like to see the safety of the patient comes first and not the position of the Trust’

while it was thought that the added administrative workload on clinicians could actively detract from patient care and not produce benefits for the patient.

3.4.6 Often doctors considered existing local and national audit methods and specialist generated action were more effective. More resources invested in local level reporting, analysis and response would, they felt, achieve greater improvements. While enhanced local level reporting is a requisite part of the NPSA proposals, there was concern that more staff and risk management resources would be needed locally to deliver this. Several considered that data should be collected, analysed and reported on all patient activities and outcomes, rather than focusing on one-off incidents, and that this would give a more balanced picture of the NHS. Clinicians pointed out that a great deal of more useful data could be collected if IT systems and coding personnel were used more efficiently.

3.4.7 Whether or not they accepted the policy, some senior doctors expressed cynicism about the reasons for the establishment of the NPSA and the use made of the information. They felt creating a national body was politically driven, that it was something that has to be seen to be done. They were also concerned that it might be an underhand way of gaining more control over the medical profession.
3.4.8 All clinicians would have to be assured of anonymity before reporting incidents to the NPSA.

3.4.9 Most nurses accepted the policy and thought there would be little difference in reporting nationally to what they were doing locally at present. A few thought that a national system might give greater weight to their reports, so concerns would be taken more seriously and action taken. They also saw the possibility of a ‘better picture’, of why incidents happen

‘whether you have pockets of this and that due to staff training’ Nurse CCU.

3.4.10 Nurses currently initiate the majority of forms reporting adverse clinical incidents. Doctors do so relatively infrequently, though this depends on the particular specialty. Junior doctors generally countersign the forms recording subsequent examination of the patient, but they do not necessarily have background knowledge of the whole process. The difference is that doctors mainly report adverse events to their own specialty, often verbally at department meetings and less often to external agents. They do not normally report the detailed background to an event, but do have the opportunity to discuss resultant complications in ward rounds, educational fora and surgeons’ periodic morbidity and mortality meetings. One SpR in Thoracic Medicine described

‘...a forum where we talk about interesting cases either that come in via the Emergency Department or via a Clinic. It is a non-confrontational educational meeting for all medical staff’.

When doctors do write a report of an incident it is usually in the patient’s notes, as part of an audit, or for a professional specialty enquiry e.g. NCEPOD.

3.4.11 Some doctors felt that many systems already existed locally to minimise mistakes and that the benefits from nationally reporting on these systems is limited. Whether or not the mistake actually occurs (or is avoided), local lessons will have already been learnt. It was not clear to some how other doctors would learn from an individual’s error that everyone knew should not have been made. If a situation currently has checks & guidelines (e.g. identifying the side of organ to be operated upon) and a mistake occurs

‘there isn’t something that needs reinforcing’ Consultant surgeon

3.4.12 Clinicians were interested in the follow-up to incident reports and some felt this an important role for an external body

‘In many ways the patient safety agency almost needs the ability to go in to a serious incident and sort it out in that Trust – I would far rather see that than collecting loads of nebulous data that are never going to harm anyone or will never happen’.

Consultant surgeon

‘Again the death of this chap – if that was reported nationally and people came down to inspect our HDU availability that might be useful if that meant we might get more money to have more beds’ Junior doctor

However, if the NPSA offered to visit the unit, it would have to be a ‘benign’ system or it would be seen as

‘Too much interference, too much big brother’.
There was some support for such a role being incorporated within external accreditation or evaluation, eg Healthcare Accreditation Programme, Health Quality Service.

3.4.13 There is already an acceptance for reporting equipment deficiencies to risk managers or nationally to the Medical Devices Agency. The NPSA is seen as a body that could provide rapid official information on unusual events that have happened across the NHS, identifying an underlying factor nationwide in ‘real-time’. For example, anaesthetists wanted a prompt and clear report on the recent situation with blocked airways. It was felt that there were a lot of reports (‘rumours’) but nothing official.

‘as we were all very anxious to know exactly what happened there. It just didn’t seem to be forthcoming, although a hazardous event report came out very quickly from the centre that said check all airway devices. It would have been much more helpful to know exactly what happened. What was this thing that fitted so critically into something else that stopped it working... I understand perhaps that once it was into the criminal investigation then things would go a bit quiet but there has to be a way of getting things [like this] out very quickly.’

3.4.14 Generally clinicians anticipated delays in feedback from the NPSA while action might be needed before the national body had time to interpret data. Clinicians also foresaw the possibility of unhelpful or impractical recommendations

‘How useful is it going to be in terms of protecting patients? And I suspect we are going to be flooded with lots of guidelines..... and written information which will be difficult to assimilate into practice.' Orthopaedic SpR

They also spoke of the ‘double-edged weapon’ of numerical analysis. If one person / Trust was open and completed forms and others concealed or omitted uncomfortable data, the reporter would be greatly disadvantage.

Many doctors assumed NPSA feedback would consist of league tables

‘If the national reporting system just counts numbers and says ‘this went down from 27,000 to 25,000 incidents’ – it will be useless.’ A&E

3.4.15 The NPSA methods are not currently expected by everyone to identify system failures

‘Those of us who have been and done investigations in other hospitals.... Often it is a system thing – and although the final result is that a person that has been harmed that may well have come out about by a number of circumstances, much of which will never be captured by this sort of process’ Consultant Surgeon

Repeatedly, clinicians cited existing circumstances where they believe patient safety was put at risk through NHS structural deficiencies. They feel that they cope with institutionalised poor practice and the dangers of unavailability or poorly recorded notes, absent investigation reports and lack of sufficient experienced staff, equipment and facilities were all mentioned repeatedly.

‘X-rays aren’t available in theatre for example, we can jump up and down and say we need the x-rays but if they are not there we don’t cancel the operation. We carry on doing the operation and hope that the report is enough or the – correct side has been marked. Consultant Surgeon

A failure to resolve these issues is seen by some as a reason for not making added effort to do uninteresting form filling (with possible negative outcome for themselves)
Reporting of adverse clinical incidents

3.4.16 Finally, people were also concerned that the reporting system could be used for a variety of reasons and that this would not necessarily be recognised centrally eg ‘settling personal scores’, or ‘malicious reporting’. In these cases, reporting nationally would not benefit the patient and could be misinterpreted. ‘Some anaesthetist will say that he filled in the form because he felt that the patient lost too much blood for that particular operation. They will say well – of course it is our job – we think this surgeon is not very good – but.. it needs feeding back locally - It is not appropriate for this system. The whistle-blowing element is not appropriate ..’

Consultant Surgeon

Identification of the need to report an incident

3.4.17 If the NPSA is to be successful in encouraging complete and accurate reporting of adverse clinical incidents, as well as addressing the concerns of clinicians and the practical difficulties of setting up a system, the Agency must first address the identification of the need to report an incident. There will be many reasons why incidents may go unreported, even among clinicians who are happy to co-operate with the new Agency. Some of these have been identified through clinician interviews and are described in the paragraphs in this section. Awareness raising, good communications and clear, concise definitions and guidance will be needed to assist in this area.

3.4.18 Irrespective of whether people were willing to report there was confusion about appropriate incidents for reporting. When asked about patient safety, doctors and nurses usually answered more generally about patient care. They did not see safety as a specific topic in its own right. However, nurses on the whole were clearer than doctors on what they are currently expected to report. They also do the majority of reporting. Individual nurses would ask a senior if they were unsure, and all senior nurses we interviewed said they promoted reporting. They felt there is a culture of reporting in the nursing profession, which is seen both as protection for the staff and an opportunity for improving the safety for patients. Sometimes it could be a struggle for nurses to find the time, e.g. staying after the end of a shift to complete a form, and an effort to own up to an error they felt ‘wretched’, about, but on the whole it was accepted practice.

3.4.19 Most doctors, particularly the juniors, considered it was the nurses' responsibility to complete incident forms. They also considered that the incidents nurses reported were minor. Patient falls, drug errors and delays in response to their request for patient care made up the majority of nurse reports and these were seldom seen by doctors as relevant to their work. When an incident was perceived to be within a doctor's domain, they wrote about actions taken in the patient notes. The preceding and immediate causes were rarely included.

3.4.20 One consultant formalised the concept of this doctor/nurse relationship by suggesting that reporting adverse incidents was the responsibility of the senior person in charge of the specific area where the incident occurred. Since there would usually be a nurse on duty in most departments it was seen
as being their responsibility. Most other clinicians considered the responsibility lay with the person most closely involved at the time but, although doctors were certain it was not their responsibility to report, it left the opportunity for ambiguity in interpretation.

3.4.21 Staff apply a personal selection criteria to decide whether to report. Criteria include severity of outcome or potential outcome. Doctors mainly judged that only if there was a negative outcome to an error was it worth reporting. They acknowledged that this often could not be determined until sometime after an event, and that it may exclude near misses.

3.4.22 Because of the perceived potential for harm, nurses usually ranked drug errors as serious (though also graded them by the potential outcome). However, doctors classed them as minor because they were so frequent. Several doctors said that it was the nurses who made the drug errors as they were the profession administering medication to the patient. When asked whether wrongly prescribed drugs could also be classed as drug errors several doctors looked surprised

'It’s part of the job of Pharmacy to pick up on those things and help correct those there – that is the system working it doesn’t need reporting. It is only if the system fails that [it needs reporting]…' Consultant Surgeon

(One person in the focus group highlighted the fallacy in these remarks, in that prescriptions written at night may not be seen by a pharmacist before administration.)

In the view of doctors, pharmacists and nursing staff would note a mistake and contact them if the prescription ‘needed altering’

‘We would be filling out a million forms if we did one every time we prescribed something incorrectly’. Junior surgeon

One DGH pharmacist who had more than 1,000 ‘pharmacist interventions’ a week confirmed the likelihood of this.

3.4.23 If an incident is perceived as a one-off mistake, clinicians often do not see a learning application for any one else, therefore they would not necessarily report the incident. For example, a young surgeon had obtained a patient’s written consent for an operation but named and placed an arrow on the diagram to the wrong finger. He also wrote the theatre list identifying the wrong finger. Fortunately, the correct finger looked obviously injured and no harm resulted. He had been responsible for admitting, consenting the patient for theatre and writing the theatre list

‘For all three things to be wrong must have probably meant that the one person did all three things …I was mortified when I realised, but how can you prevent an honest mistake?……I don’t see how you can rectify mistakes, so what’s the point of reporting?’

Interestingly he did not consider reporting this incident.

‘…it boils down to the nursing staff doing it or to starting it.’.

Doctors would, however, consider completing forms when prompted by a nurse.
Only one of the doctors interviewed said that they ever checked whether incident reports were completed and reached their destination. In this case, the doctor had legal experience.

3.4.24 The lack of a learning opportunity manifested itself in other ways. Some clinicians felt that where there were already proper rules and guidelines about a procedure and an error occurred because these were not followed, (eg removing a wrong kidney) there is

‘not anything that needs reinforcing’ Consultant Surgeon

In this view, the error is one of not abiding by a protocol; there is no other learning principle and therefore no point in reporting to an outside party.

3.4.25 The boundary between a junior learning their skills and a reportable near miss or adverse event is blurred. Many consultants would use such cases as a local teaching exercise. One consultant felt that if errors of judgement were reported seniors could learn lessons to incorporate into future teaching but others were less definite.

Nurses currently often did not complete a form if a doctor who is junior, or new to a department, made an error. They would rather guide and advise. If they had real concerns about a doctor’s practice they would discuss it with the next senior doctor or consultant and leave it to them to deal with the situation. Nurses did not expect the senior doctor would complete an adverse event form.

3.4.26 Some errors or near misses are recorded within a department and not forwarded to a central point within the Trust. Departments, including Pharmacy, Pathology and Accident and Emergency, often keep a list of incidents locally in a designated book. Errors such as those associated with labelling are recorded, possibly with minimal details and frequently were anonymous. This form of reporting would seem to have ‘become the normal thing to do’. Among the reasons for this may be the fact that departmental note book reports are often anonymous, people know what happens to the report, they can participate in meetings where the problem is discussed, see any changes made and can gain experience of the probable, personal cost and general outcome of reporting.

In one Trust, the risk manager had asked to see the Pathology department’s book. This was agreed to, providing it was viewed within the Pathology department. There were reservations about identifying staff and incidents if the information left the department in its raw state, ie not aggregated and anonymised.

3.4.27 Interviewees were asked where they had learnt about what constituted a reportable adverse incident and how to undertake reporting of such incidents. Replies varied. Information was sometimes given at induction, but the quality of induction itself varied. Some doctors did not have an induction on arriving at the Trust, and doctors who had changed departments during several years of practice in a Trust did not have an update. Doctors talked about the amount
of information they had to absorb at induction, and one said he didn’t know whether it was mentioned, because he slept through most of it as he had been on call all the previous night. Protected time and annual, mandatory updates were other issues raised within the training and education topic.

3.4.28 Equipment failures or its unavailability were seen as ‘easy and useful’ for doctors to report, possibly because this is impersonal.

3.4.29 Several participants mentioned deliberate use of the reporting system to target management for equipment, staff or facilities. Some campaigns produced the required result, with a piece of equipment or an extra staff member being provided. In other cases, staff did not know if any changes had been made or, if they were, whether or not their reporting had been a contributory factor.

### Barriers to reporting – clinicians’ concerns

3.4.30 Perhaps the most important barrier to reporting of adverse clinical incidents was identified by a Consultant Gastroenterologist who acknowledged that ‘Accept people don’t like to acknowledge their weaknesses or failings – in any walk of life’ Consultant Gastroenterologist

Again, one of the nurses interviewed said that a colleague had once begged her not to report an incident as he would be named as the person in charge of the ward, even though only indirectly involved in the incident. He was just frightened of being identified.

However, the impact of these views might be ameliorated if the reporting system operates in a supportive, positive and safe environment. The NPSA will need to work hard to allay the fears of clinicians such as those voiced in this section, which are fairly commonly held within the Service.

### Blame-free culture?

3.4.31 Perhaps the area where there is greatest concern lies in the notion that the system will not operate in a ‘blame free’ culture. While most think that avoiding blame is the correct course of action and accept the intention to protect confidentiality and anonymity (see next subsection), many clinicians remain to be persuaded that this can be made a reality. Political necessity, performance management, public accountability and consumer pressure are all thought to act against discussion of adverse incidents within such a culture. Concerns about the ‘blame-free culture’ include

‘... a very glib phrase to throw out, but is completely against the whole ethos of investigating the local flaw, [local] practice –………blame will ever be part of medical investigation.’ Consultant Gastroenterologist

‘I know everyone says that it is supposed to be supportive and it is a no blame situation but in the real world someone takes the rap.’ Thoracic Consultant

Amongst peers, it is recognised that the reality of ‘owning up’ to a serious adverse event is that it could damage a career. This depends on whether confidentiality is a realistic option at local level, or nationally when serious errors are reported.
Reporting of adverse clinical incidents

‘I think you have to address the fears and say why don’t people do these things. I am sure some people don’t do it for fear that they might lose their jobs, or being pilloried in the press. There could be a chief executive who says anyone in my Trust who instead of employee of the month is risk taker of the month and his or her names will be put around the Trust. They wouldn’t lose their jobs but they would lose the respect of their colleagues. I think you have to address those issues and give someone security – say we all make mistakes, no one is perfect.’ Thoracic SpR

3.4.32 A separate concern was raised in respect of consultant appraisal. Although recognising that this was not directly related to the work of the NPSA, one radiologist, in discussing the notion of ‘blame free’ working, said that the form proposed for use contains a section which was a disincentive to reporting. It requires consultants to record any critical incident reports, changes made and the outcome of any formal complaints made against them.

‘Consultants are expecting to be interrogated on this.’ Consultant Radiologist

Confidentiality

3.4.33 Staff generally accepted that incidents forms collected within their Trust identify place, staff and patient names. Everyone interviewed, however, wanted the information they provided to be anonymised before it left the Trust.

3.4.34 Clinicians were concerned about who would have access to the information.

‘…there is a question of who controls the information that arises, and who should have control of it’ Orthopaedic SpR

Nurses and doctors raised the issue of access by future employers, patients and patients’ relatives. In addition, doctors expressed fear of exposure to the media and indirectly to their peers. Even if names were not to be included on the national form or the hospital identified, some still considered there to be a potential for litigation, damage their reputation and their career. They would be unwilling to report if it could result in being penalised.

3.4.35 Concerns over confidentiality were partly linked to uncertainty (on the part of those interviewed) about the role and purpose of the NPSA. Is its purpose educational and informative – to provide information for clinicians and non-clinical managers to take appropriate action? Or is it to identify bad practice and bad clinicians, and discipline them – ‘naming and shaming’?

3.4.36 Clinicians assumed some level of confidentiality in the national reporting system, but would require precise clarification of NPSA’s approach. Issues such as the make-up of staff at the NPSA, who is to see the information about a professional individual, what are they going to do with it and how long will they keep it were raised. Further questions of who would routinely be included in the confidence, who would know the identity of the reporter, how is feedback to be organised, and in what circumstances will disclosure be permitted and to whom will be relevant. Reassurances are needed that all but gross or illegal actions would remain restricted to the reporters, risk managers and the NPSA before many clinicians will be prepared to report.

‘Depends what confidential means – confidential and not disclosable?… if it were not disclosed that might make a difference’ Consultant Radiologist
3.4.37 As the NPSA apparently will be able to identify and pinpoint a reporter (via the Risk Manager) should they choose, some doctors expressed concern (see also next section). This would mean an additional factor to take into consideration when deciding whether to report a particular incident, in case it might cause

‘someone up there to decide its worthy of investigation’ Consultant Radiologist

NPSA’s Audit trail

3.4.38 Unless clinicians have complete trust in the agency to which they report, the idea of having an audit trail back to them makes them feel vulnerable. Some of those interviewed referred to the established national confidential enquiries and the fact that they never identify an individual professional. These do not report to the General Medical Council nor to local Trusts. The implication from 'Doing Less Harm' was that Trusts were required to ‘co-operate’ with the DoH and ‘other stakeholders’ in analysing clinical incidents. Consultants pointed out that the agency or the government could unilaterally change definitions of identifiable, or potentially criminal, error at any time without the consent of the medical professional bodies. Some consultants believed that the truly criminally intent individual would not be identified by the NPSA’s methods, while they (the non-criminally intent consultant) might be identified and investigated, and even though theirs was an ‘honest mistake’ they could be professionally damaged. They told researchers that in the Bristol and Shipman cases people had reported concerns and it was not lack of reporting which allowed the situation to continue, it was the poverty of response.

3.4.39 Many clinicians are willing, or potentially willing, to report to their peers or to their local risk management, knowing that they can be identified. However, they are only willing for information to be forwarded to a national body if it is anonymised. The difference in outlook is due in part to the uncertainty about exactly how the NPSA intends to use the information. Doctors realise there is an audit trail back to them. Concern over the exact circumstances in which individuals can (or will) be identified is a barrier to reporting. The NPSA can clearly publicise its intentions and the safeguards it intends to use, but the level of trust in the NPSA’s operations will only come about with experience.

Disciplinary action

3.4.40 Local reaction to a reported incident is often not predictable. Because it is not necessarily related to the severity of outcome, staff cannot anticipate what the managerial response might be. It can seem inconsistent and unjust to many professionals. For example, an experienced nurse gave a patient the wrong pre-medication before theatre, with no ill effects, but the consultant surgeon had to fight to prevent her immediate suspension. Another trust, however, notes drug errors in the nurses’ files, counsels those involved and provided there is no further involvement in an adverse incident in the following six months, deletes the record from that individual’s file. This uncertainty about a just response is a further disincentive to reporting. Several senior nurses explained how they always made an effort to maintain consistency when
junior nurses reported an adverse incident. These, however, were nurses who felt supported by fair managers within a blame-free culture in their Trusts.

3.4.41 Errors by the different professions were also reported to be treated differently e.g. while suspension was threatened for the above nurse drug error, doctor’ prescribing errors are so frequent that they do not consider them errors and often go unreported.

‘That is part of the job of Pharmacy to pick up on those things and help correct those there – that is the system working it doesn’t need reporting’.

As mentioned earlier, one Trust had 1,000 ‘pharmacist interventions’ when drug errors of varying degrees of severity were noted. Differences between trusts are highlighted by the fact that in one Trust pharmacists recorded all causes of error, while in another those which were incorrectly prescribed were not reported because it would be ‘snitching’ on another person.

One pharmacist said that their profession expressed complete derision about the specific risk target for action in ‘An Organisation with a Memory’ which aimed to reduce by 40% the number of serious errors in the use of prescribed drugs by 2005. Pharmacists have clear evidence that the number of drug errors reported currently does not reflect the number of incidents. The actual number is thought to be much higher and therefore the denominator against which to measure progress is highly uncertain.

Litigation

3.4.42 Concern was frequently raised that any adverse clinical incident report could be the source of a litigation claim by patient or relative. A national system would have less incentive to avoid publicity than that within a local department, and doctors considered there to be even greater potential for litigation. There could be a tendency for patients and relatives to identify matters that had previously been raised internally (for the benefit of learning therefrom) and to claim damages. Unless there is a very clear indication that reporting incidents improves quality of health care, the fear of inviting litigation that had not previously been intended will discourage reporting to the NPSA.

3.4.43 Most clinical professions wanted to know what protection against litigation would be available if they reported to the NPSA. Claims for damages were one issue. However, another was the underlying fear that an ‘honest mistake’ could later be considered to be criminal e.g. the interviewer was told that doctors who had given intrathecal methotrexate in Ireland had been jailed, while manslaughter charges were pending for the surgeon who had recently removed the wrong kidney.

Media

3.4.44 Doctors of all grades expressed great concern that the media would get hold of and, in their eyes, misuse confidential information about adverse clinical events. Completing any adverse incident form was seen to be increasing the risk of this happening, while adding a national reporting system intensified this further.
There were many opportunities for exposure. They might occur locally, either from the NPSA reports or during the processes to which the form or subsequent analysis was subjected. NHS staff need the NPSA to pay great attention to their anxieties about protecting individual professionals’ rights from external agents.

**Mandatory**

3.4.45 ‘I thought it was already’ Nurse

Nurses routinely report drug errors, falls and some other incidents, with many seeing this as compulsory. It is part of the profession’s directives that already apply. On the other hand, interviewees wondered how it could be enforced if staff did not recognise an incident as reportable or, having recognised it, did not get around to reporting it, or actively decided not to report the incident.

‘...what worries me about any mandatory system and a lot of what we have to do know is mandatory but with little evidence base for it, so everything is being hurled at us and we are being told this is right, that is wrong, and the reaction to it will be the same old thing – that somebody will report it well and others won’t and might get into trouble for it.’ Consultant Surgeon

**Practical Barriers to reporting**

**Someone else’s responsibility**

3.4.46 Doctors, in general, do not take responsibility for reporting to risk managers about serious clinical incidents. They anticipate that nurses will initiate such reports and/or use audit, mortality and morbidity meetings as a means of discharging such responsibilities and meet verbally requested information requirements from seniors.

3.4.47 Some people feel that juniors are ‘not empowered to report’. Juniors often approach line managers with information about adverse clinical incidents and it is the line manager’s approach that affects whether the incident is reported or not. Sometimes, follow up activity stops there

‘...they may not. I think there are lots of little steps before a form is filled in, and one of the crucial steps is that someone has verbally said something about it, but feels they are not empowered to act, so they tell somebody else, and then I suspect often it stops there’

Most Trusts require or prefer seniors always to be informed prior to reporting. This can influence the level of reporting, either encouraging or discouraging it.

3.4.48 While doctors and nurses stressed they were giving the best care they could, they understood that overall care could be better. They felt that this was often linked to resources (over which they had little or no control), to staffing shortages and to structural obstacles (broken lifts were mentioned several times). Responsibility for incidents arising from such difficulties was ambiguous as was reporting in this area.

3.4.49 There was also uncertainty about changing from an effective, established pattern of reporting incidents which might discourage future reports. One A&E department had a book for instant reports, an A&E risk manager and regular reporting of incidents.
‘One has to be a little bit careful. …..its another agenda. [Our system] has been running quite some time. Quite smoothly and without much/any problems as far as I can see.’ A&E

**Feedback**

3.4.50 Relatively few people knew what happened in their Trust to the information provided on completed forms. Some saw responses and implemented changes in practice, but many only knew ‘a black hole’ into which reports vanished, never to be heard of again, except occasionally for an unqualified monthly or quarterly statistical report. Juniors received little feedback. Some of the nurses at ward level wondered what happened to the information

‘does anything come of it?…you would give up sending them in if nothing changes’

‘…..I think that is the reason that people are reluctant sometimes to fill in forms, because it goes off into a big black hole and they never get either feedback on an individual case, or even as a sort of quantified….total. this has happened x number of times.’ Senior Palliative Care nurse

Asked about any difference that the national collection of data might make, another Palliative Care nurse answered

‘I just think people would appreciate getting some form of feedback locally. Whether its national or not….. And, you know, I’ve filled out forms often and I’ve had no feedback as to what had gone on afterwards –and - you see just the same problem happening over and over again – so you see the forms being sent off and still nothing… you speak with the managers and still nothing’s being done.’

Asked whether they had ever seen any root cause analysis of an incident, a few had, but most had not. As a Consultant Neonatologist said

‘I don’t get the feeling that there is a constructive input from higher up. . Whether that is because people become so like a pyramid so that someone at the top is so inundated with rubbish that they can’t really attend to the serious things. But you don’t feel that it is particularly good from the top and you feel that you are putting it into a void. If we don’t do something at this level you have the feeling that it might not happen unless it is something tragic.’ Consultant Neonatologist

The current lack of feedback following reporting of an incident creates a negative effect and was one of the major elements raised by interviewees. Some changes had been implemented, and several were cited as possibly being associated with reporting (on specific targeted projects such as staffing), but the uncertainty meant the reporter’s contribution was uncertain and therefore there was a distinct possibility of no ‘reward’.

**The time factor**

3.4.51 Many interviewees groaned at the thought of increased paperwork. The prospect of duplication of form filling (if the NPSA requires a separate form to that of the local Trust, or the medical protection societies etc) is daunting.

When a specialty has its own large audit (e.g. the Swedish hip register or the RCP’s Stroke one) or adverse outcome data collection procedure (e.g. CEMAD, CESDI, NCEPOD) some specialists feel they already contribute to risk management and the improvement of patient care in a direct way. They therefore do not see how another less focused national body would benefit.
Reporting of adverse clinical incidents

patient care, and they would not appreciate any repetition of data reporting. There needs to be consideration given to extracting subsets of information for each of these bodies (including the NPSA) from a single form.

3.4.52 Junior and senior doctors expressed concern that increased documentation will reduce the amount of time spent on patient care

‘It is difficult to see how [the NPSA] will impact on our practice and the practice nation-wide and therefore people are unwilling to spend the extra time needed.’ Orthopaedic SpR

Clinicians feel they are already asked to organise a mountain of paperwork on top of their clinical duties

‘.. it happens and you think – I should fill in that form and then you come back, and your first three appointments arrive and by 1pm you are thinking I’ve got to do this etc and it doesn’t become a priority and never will be.’ Gastroenterologist

3.4.53 Practical difficulties around completing forms should also not be underestimated. Simple difficulties can often act as powerful disincentives not to bother reporting incidents

‘Incident forms ‘don’t have the right space really for all that you would want to write and I think we are trained a little bit more ….. - if there is something that you can see potentially that might have gone wrong or has gone wrong - then you write in the notes.’ Junior surgeon

Like missing items on a defined list of errors, the lack of inclusion can be taken to mean what is not there is not wanted.

Definitions

3.4.54 As mentioned earlier, there can be confusion over what is an adverse clinical incident. The broad definition of harm or potential harm to the patient covers an enormous area of NHS hospital care, especially in relation to near-misses. Improved guidance, or piloting of actual incidents to be collected can only improve the system.

‘If we try to make it too difficult you are going to get people not bothering to report or sliding round the edges, this wasn’t bad enough to report etc so you won’t get accurate figures at all.’ Obstetrics & Gynaecology

‘You really have to sort out the important elements, which could potentially lead to a major incident if they occurred.’ Anaesthetist

Additionally, the NPSA is demanding a level of decision making that has not previously been required,

‘difficult….you have got to make a judgement clearly as to whether the thing that you just witnessed was something that could have turned into something nasty.’ Anaesthetist

Frequency of reporting

3.4.55 Some clinicians queried the requirement to report all incidents. Firstly, it was thought that without a more targeted approach, any improvements in reporting levels (over time) could confound any attempt to monitor a reduction in the rate of errors. Apart from concerns about the potential of the need to make duplicate (or triplicate) reports – in the patient notes, to the NPSA and to medical defence organisations etc., clinicians also have views about the
learning potential to be derived from frequently / infrequently occurring incidents. It was thought that constantly reporting the same type of incident can be pointless, if no lesson can be learnt or change can not be effected. On the other hand, most clinicians felt that ‘one-off’ incidents were not relevant to anyone else.

“What is there to learn from an honest mistake?”

Incentives to reporting – Encouragement to clinicians

Trust attitude

3.4.56 Attitudes to reporting varied between the Trusts of those interviewed. Where there was a no-blame culture, reporting had apparently been advanced by committed managers who were prepared to educate and support their staff. Specific personalities - ward managers, current nursing directorate managers, and consultants often positively influenced the clinicians who accepted the principle and did report. Where trust existed, clinicians would be led by managers’ advice and example. In such cases, where junior doctors are encouraged or directed to complete forms they did. Otherwise they talked over problems with seniors and they were not recorded as incidents.

‘just raise continuously people’s awareness. Say it is not judgmental, not threatening, not going to lead to disciplinary action.’ Medical/Cardiac consultant

Variation in the culture of reporting showed in Trusts. For example a recent merger between hospitals showed one to be ahead with reporting and action, while the others lagged behind with discrepancies in the number of reports between directorates. In another case, a Trust had had no surgical director of risk management on its committee for over a year.

Team attitude

3.4.57 Where staff within a specialty considered that they worked together well as a team, it conveyed an atmosphere of considerable openness in reporting adverse events and near misses. The ‘younger’ specialties or departments e.g. A&E, Pharmacy, CCU and Pathology and those with a high use of high-tech machines e.g. neonatology, intensive care told the interviewer that they made an effort to report and confront problems as they arose, and supported their colleagues in the process. Because of this they saw the local solutions as important and useful. They were not always sure how much use a national reporting system would be to them, but their attitudes indicated a positive response to reporting, which needs to be nurtured in the national context.

‘We have a clinical incident group within A&E who looks at the form and we have a feedback cycle, so we audit constantly’ A&E

Local feedback

3.4.58 Feedback from local risk managers, general management and colleagues with suggestions and support for effective change is the most encouraging stimulus to local reporting.

Those clinicians who did have feedback were more enthusiastic about reporting and more knowledgeable about changes.
NPSA feedback

3.4.59 The clinical professions want the NPSA to produce feedback directly useful to them in their clinical practice. There was a demand, from clinicians, pharmacists etc for the NPSA to analyse mistakes and, more importantly, work out appropriate actions to avoid them in the future. One example from a surgeon was to provide

‘a map to streamline processes from the point at which a patient sees the surgeon in OPD to their actual operation and reduce potential error’.

where ‘each and every step has pitfalls’.

3.4.60 If the NPSA can disseminate other contributors’ ‘bright ideas’ on how to improve systems and practice, and provides information on how things were dealt with in other Trusts it would provide major incentives to clinical reporting. Clinicians also hoped for incidence statistics for cross-referencing and benchmarking with other Trusts.

‘The only problem about our reporting I suppose is that it stays within the unit it is not collated. It may be nice to collate within our area – Town X, Y and Z etc. To drive our protocol procedures – especially with long line incidents, we might want to combine and try to plan things a bit more cohesively and nationally as well.’ Consultant Neonatologist

‘I would like to see more national statistics coming out because we feel very isolated here’ Ward manager

‘…. if it is done nationally and it is recognised that this problem [epidural drug error] is not isolated to you and suddenly realise that it is a national problem, not just your hospital on a specific ward….. Then perhaps we can put many heads together to see what we can do to see if we can solve this problem’. Ward manager

3.4.61 There were illustrations of severe adverse incidents having ‘focussed’ the Trust's management to provide money for improvements. In one case, an obstetrician doubted whether the facilities would have been provided without such feedback. Whether or not this is an appropriate role for the NPSA ie to act as a pressure point for investment, may be questionable but if it provided such a stimulus it could be expected that incident reporting by clinicians would be enhanced. Another example was that surgeons who contributed to NCEPOD saw NCEPOD's reports as ‘positive ammunition’ and this definitely encouraged their willingness to report.

Form of feedback

3.4.62 We asked clinical staff about the form, in which they would prefer to receive feedback from the NPSA. Some clinicians preferred e-mail, some an internet site, others that it would have to be in paper form. Suggestions also included attaching notices to the BMJ, to the Trust’s newsletter, to the pay slip, or with the CMO’s reports. It appeared that having several means of delivering such information was needed avoiding an over-emphasis on the use of technology since some clinicians did not get to see their emails (which didn't always work), there were too few computers on the ward, as well as the more usual ‘we throw away the Trusts newsletter, no-one reads it’ or ‘we get too many flyers etc’.
3.4.63 But they were certain that the presentation style was critical. Information, which is ‘short and readable’ with ‘illustrations and recommendations’ would be best. A single, bullet-point paragraph was a popular format among doctors.

‘One of the things that alters our practice, although it doesn’t necessarily make sense, is if we’ve read or seen a case – a one-off case……. [it] influences us more than we would care to mention’ A&E Consultant

Nurses referred to the Medical Device Agency (MDA) and the way Adverse Reactions to Medicines is reported back. Doctors admired the short illustrative case histories of medical errors with brief recommendations that the Medical Defence Union (MDU) and the Medical Protection Society’ produce, and considered their style the best way of getting the information across

‘Rather than bland descriptions of what you must do - lists of things’.

Or

‘A big document which says “we have received 1,000 reports of this happening… which would be guaranteed to put people to sleep… or strict recommendations which we have to spend more time to implement rather than treating the patients’.

3.4.64 Many wanted the feedback of information from the NPSA to go to managers, the Clinical Director or perhaps the Risk Manager and for them to discuss reports with the Nursing Directorate and Speciality Managers, thereafter cascading the information down through the all the Trust’s clinical and PAM staff. Others thought the information might get lost through that route, as some managers are not so good as others are at communications.

3.4.65 Clinicians and doctors in particular felt they had ‘mountains’ of journals and administrative work to read. If the NPSA can assist Trusts by producing effective individual and Trust–wide feedback, supplemented by concise readable national recommendations distributed via several routes, staff would have repeated encouragement to report incidents in the future.

Caring and litigation

3.4.66 ‘I think a lot of people feel it is a fear of litigation but it is not, it is just a matter of caring what happens to a patient.’ Radiographer

Caring about patients is the biggest driver to reporting, providing that the incident can be seen to contribute to possible prevention of an adverse outcome for another patient. We have mentioned earlier that in some instances doctors, in particular, find it difficult to see how others can learn from a single incident, made as a result of someone else’s human error.

3.4.67 Clinicians pointed out that reporting was also seen to be a good defensive mechanism. It is a good way to record details while they are fresh in the mind in case of possible, future litigation or patient complaint. Also, if there was a serious adverse outcome and a clinician was found not to have reported the incident it could be more damaging to their career. However, many clinicians said (some rather reticently) that the main reason that makes people report is caring about what happens to the patient.
3.4.68 If a situation is serious, clinicians expected to report an incident even if it could result in possible litigation. However, it was not clear that this was always carried through to the completion of a form.

Confidentiality and Anonymity

3.4.69 Anonymity would encourage reporting, and essentially

‘If it was not anonymous people wouldn’t do it’

ie details reported would be incomplete, or ‘economical with the truth’.

3.4.70 Clinicians did ask for details of the NPSA’s policy on confidentiality. Some felt there was a place for totally anonymous reporting, even locally. It was thought that this encouraged reporting. Other initiatives in this area would also be productive - one pathologist suggested a coding system for staff names when reporting internally, so that names were not so easily available. Nurses though had ‘become de-sensitised to reporting’ and tended not to be ‘particularly worried about having their name on the form’ locally. They would continue reporting provided no personal identification was forwarded to the NPSA.

Practical incentives to reporting

Definitions

3.4.71 Consistent definitions and processes were seen as crucially important to the decision whether to report nationally. Without such consistency, it was considered the activity would be a waste of time. National guidelines about how and when to report were seen as vital. [Of course, ‘Doing Less Harm’ has made progress in this area but quite detailed information covering operational circumstances will also be needed]

3.4.72 There were differences of opinion about what incidents should be reported. Some Clinical Managers are irritated and give a ‘robust’ response when incident forms are used for reporting organisational incidents which can affect patient care. Others see it as a useful way of having such deficiencies rectified. For example

‘no porters available to transfer patients leading to blocked cubicles in A & E’

The NPSA could usefully provide guidance as to what is appropriate to adverse event reporting, in such circumstances.

Asked about the best way to establish definitions that are acceptable to clinicians. Interviewees thought the NPSA could valuably

‘Survey different groups, find critical pathways - what could go wrong and at what level [it was] worth reporting. There has to be the capability of a lesson learnt else [the NPSA] will be a witch-hunt or league table of adverse events.’

Education and Training

3.4.73 A good induction programme with subsequent training days was supported as a means of making staff aware of the point of reporting. Some of the doctors did not know whether it had been mentioned at their induction One at a London hospital did not have an induction even though he tried to. Another, at a different teaching hospital, slept through his because he had been on-call the night before. Others said there was so much to learn at that time that they
were overwhelmed and there was no other induction when they moved between posts within a Trust, even if they stayed for some years. Some nurses had further education courses, such as annual intravenous drug training and study days, where risk management and reporting was emphasised and they found this helpful.

3.4.74 One junior doctor gave the interviewer an example of an adverse event and said the consultant was told,

'I wouldn’t know who to report [it] to apart from the consultant in charge of the patient. Whether there is anyone else to report to….’

It would appear that the NPSA will need to focus fairly heavily on awareness raising, if reporting is to be successful:

‘An organisation has to accept that these things are necessary – part of the culture is part of the cost – you have to put time into training and one day pay back dividends – financially as well – you reduce risks, risk of litigation etc.’ (Radio 4)

Helpline

3.4.75 Several clinicians said it would be helpful to have a help-line for guidance on whether or not to report a particular incident. Doctors mentioned the useful MDU helpline in this respect. They felt an experienced NPSA individual could assist with making a decision over dilemmas such as near misses and the involvement of colleagues.

‘To speak to someone in an informal way – should I do this or that?’ Nurse

‘ – the difficulty is the grey area - if somebody didn’t do the job properly or didn’t do something very well.’

Administrative staffing

3.4.76 Consultants felt that if the Department was seen to provide sufficient risk management staff to investigate reports, analyse the root causes of incidents and feedback and audit the results, there would be a greater willingness to report.

With a few excellent exceptions, current feedback is mostly lacking. Senior staff were aware that risk managers had little time or resources to do very much with the amount of information they currently gather other than issue statistics, which were anyway felt sometimes to be a less than accurate representation of the overall Trust’s performance. Improving the staffing situation and providing people with high quality information and help, which clinicians were keen to receive could be expected to make a big difference to reporting – this was supported by those Trusts where feedback was good.

Several doctors emphasised the negative effects of poor record keeping and poor record availability in the NHS. Ensuring full and adequate records are available will both support evidence gathering and provide more protection for patients (and staff).
4. Conclusions

Acceptance of policy

4.1 Overall, there was a general acceptance that improvements in the monitoring of adverse clinical incidents should be beneficial to patient safety in the NHS. Many doctors also saw a theoretical benefit of national reporting, but were sceptical of how they would derive practical benefits from such reporting. A major aspect of discussion was the need to get more benefit from current reporting systems.

4.2 Figure 2 below gives a subjective, diagrammatic representation of the overall distribution of doctors’ views among those interviewed. On the left hand side, about 20% felt that national reporting could work in practice, with those towards the right of this section questioning the resources available to make it work. In the middle, are about two thirds of interviewees who felt it was fine in theory but, based on their current experiences, were rather more sceptical about how it would work in practice. Voicing this doubt, most suggested that delivery of the benefits of the system had to be proved. They were concerned that barriers such as confidentiality and quality of feedback would inhibit the system, or that findings might not benefit patients individually.

<table>
<thead>
<tr>
<th>Can work</th>
<th>Theoretically accepted</th>
<th>Not the right way to proceed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prove the benefits</td>
<td>Practical &amp; system difficulties</td>
<td>Realising benefits</td>
</tr>
<tr>
<td>?resources</td>
<td>eg anonymity, feedback</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>% of doctors interviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
</tbody>
</table>

On the right hand side, about 15% of doctors felt that it was not the right way to proceed and that there were better ways to achieve the same aims. Different data collection methods eg more targeting of specific areas and/or accreditation and peer reviews systems were among the alternatives.

4.3 The NPSA is a new organisation and while its aims have been set out in documents, clinicians are not yet fully happy that the identification of incidents (which can encompass errors, bad practice and impact of resource constraints) will not lead to the censure of clinicians. Clinicians cannot yet judge what the outcome of reporting nationally could mean to them in terms of personal disadvantage or patient benefit.
Creating a trusting environment

4.4 The above paragraphs indicate the size of the task facing the NPSA to establish itself within a ‘blame-free’ culture. There is no doubt that incident reporting systems do better when they have been set up within a trusting environment. Examples can be identified from the international review, while both the survey of risk managers and interviews with clinicians confirmed this, identifying great differences in the level of trust (and the success of reporting) at local level.

4.5 In the national context, it was the view of many that a no-blame culture had still to be established at the very top of NHS management. Many doctors interpreted recent outcomes of high-profile adverse event inquiries, in Bedford, Bristol and other NHS trusts, as punitive. Their view of the evidence was that however much it was the system that needed changing, clinicians and managers were dismissed or disciplined and unjustly made the scapegoats. Importantly, in these instances, it remained to be seen what action would be taken to address recommendations about system changes.

4.6 The unknown nature of the National Patient Safety Agency, together with society’s blaming attitude towards clinical staff provoked anxiety. Clinicians need to be reassured that issues such as the increasing number of compensation claims by patients and relatives, intrusive unfavourable media attention and the new revalidation scheme for doctors will not be exacerbated by reporting clinical incidents nationally. The key factor that would influence clinicians’ response to the NPSA was the balance between any increase in anxiety about the above issues and the compensatory potential benefit to patients.

4.7 However, the reporting system also envisages an increased level of activity at local level eg root cause analysis and reporting of serious incidents. In discussion with clinicians, it was equally clear that the level of trust between clinicians and management at a local level varied considerably. This had a direct and sizeable effect on the success (or otherwise) of incident reporting systems. Clinicians sometimes felt let down by senior managers who did little to support them, or who took precipitate action in order to get it off their hands. In some cases, it appeared that trust had broken down completely.

Realising Patient Benefits

4.8 It was mentioned above that some clinicians would be prepared to follow through particular incidents, even if this caused increased stress, if it was likely to benefit current or future patients. Clinicians were more positively inclined towards local and national reporting if they had witnessed changes resulting from analysed reported incidents, either within their own department or through good feedback from risk managers. This virtuous cycle of reporting – good feedback – action – maintained or enhanced quality of reporting was corroborated by the risk manager’s survey where the completeness of reporting and a higher level of practice changes appeared to be related.
4.9 Clinicians’ anxieties about reporting to the NPSA serve as a reminder that they feel they work under considerable stress and a variety of pressures. They make personal as well as professional decisions and the NPSA will need to prove that the additional practical and psychological effort involved in enhanced reporting, locally and nationally, will achieve improved patient safety. Evidence from similar clinical sources, perhaps including NPSA pilot sites, that demonstrate consequent system changes needs to be widely disseminated to support those who already embrace the concept of reporting and to encourage others. Re-enforcement of such messages will be needed over the medium term while the NPSA is ‘bedded in’. A lack of such benefits being realised by the new system, and any occasion where the sought-for trust between the NPSA, clinicians and healthcare organisations breaks down, will have a serious and deleterious impact on the work of the Agency and its future success.

4.10 An important aspect of realising patient benefits, needed before action to change practice can take place, is the provision of worthwhile feedback. It is clear that many trusts with incident reporting systems provide little or no feedback to those providing the reports. Some clinicians report receiving no feedback, saying that the information goes into a ‘black hole’, while others receive a purely statistical count. The risk managers’ survey also suggested that feedback contained little in the way of analysis of the contributory factors that led to an incident. However, there were areas of good practice where local risk managers worked with clinicians to identify the causes of a problem and to facilitate change. It must be recognising that such good practice is time-consuming, and there remains a question as to whether, at local level, the resources available within risk management will be sufficient to meet demands that might arise from enhanced reporting arising from the setting up of the NPSA.

4.11 Discussion raised a certain tension between local and central reporting with clinicians, by and large, being more interested in local feedback than a national response. This raised issues about whether any resources would be available locally in the risk management area in support of activities associated with the NPSA. In this context also, those doctors interviewed often asked about what others might learn from a single incident that took place elsewhere – the implication being that this was a chance error, and not related to system or practice based factors. Moving forward in this respect will require a significant investment in the level of training and awareness raising on the part of the NPSA.

4.12 Many of the comments made in this section have been attributed to doctors interviewed. While it is true that nurses and other professions have had more experience of reporting incidents, and therefore are more accepting of it, they do share some of the doctors’ concerns about a national system. These tend to focus on ensuring benefits realisation, whether the NPSA can, and will, operate in a blame free culture and whether sufficient resources will be available to ensure the system achieves its aims of improving patient care.
Identification of a reportable incident

4.13 Implicit in the aims and objectives of the NPSA, is the collection of data on reportable incidents on a consistent and high quality basis across the NHS. A pre-requisite to this is that such incidents are identified consistently and a report initiated. At present, there would appear to be a high level of inconsistency in the rate of reporting (as shown by the survey of risk managers) and a great deal of uncertainty about when to report an incident.

4.14 A good deal of this uncertainty arises from a ‘lack of ownership’ of reporting on the part of medical staff, and in particular senior medical staff. Initiating the reporting of an incident is seen to be a nursing task (partly because nurses are ‘ever-present’ but also, probably because it is well-known that they have systems for doing so) but it is not known how comprehensive is the range of incidents that they report. Drug errors, falls and some theatre incidents are commonly reported, but are medically-focussed incidents eg around diagnosis, tests results etc also reported through this route to the same extent? Once initiated, doctors do tend to complete their parts of the report form, but there is little in the way of an ‘audit trail’ to ensure that all initiated forms do reach completion or that they are forwarded to the appropriate recipient.

4.15 Involvement of doctors in incident reporting varied between specialties – those in team based specialties eg A&E, care of the elderly, psychiatry, and pathology, tending to be more involved.

4.16 Some doctors need to be educated as to the benefits of reporting incidents. Many could not see the learning potential of reporting a one-off mistake that was viewed as an idiosyncratic human error. Other similar reasons for not reporting incidents were:

- incidents (minor) being too frequent, an every day occurrence
- confusion between incidents and errors / near errors in training juniors
- whether incidents picked up through checking mechanisms should be reported
- perceived unimportance of some incidents that nurses report.

Some junior doctors tended not to feel empowered to report by form, only passing information verbally up the clinical management line.

4.17 Undoubtedly, the NPSA will be anticipating sending out guidance in this area, and this will clearly bring benefits. Systems with clear guidance will usually attract higher and more appropriate participation. A helpline, to discuss specific instances, was suggested. Attention should also be paid to awareness raising and ongoing training through a clinical career. Inclusion of patient safety topics in induction courses and periodic (annual) training is variable. Risk managers consider that such investment produces beneficial results.
4.18 It should be noted that ‘over-recording’ of incidents also needs to be avoided. Some interviewees cited evidence of deliberately using such systems to target management to improvement, staffing or facilities. Other perverse incentives may also exist, in this respect, eg being seen to be active, transferring responsibility, creating an expectation against which performance can improve.

Concerns about reporting

4.19 The major concern that clinicians have about reporting of incidents surrounds the identification of those involved and the possibility of unjust exposure, criticism, litigation and personal damage to their reputation and career. This concern is inextricably linked with the degree of trust (mentioned above) that individual clinicians have with their colleagues, trust management, the media and in higher echelons of management both in their profession and in the NHS. Clinicians are trained to look for evidence, and identify the cause of error, or incident. Most professionals are willing to accept a system that is aimed at getting to the root of a problem, providing any blame is minimised and appropriate.

4.20 This concern was voiced as the need for the reporting system to have clear rules about the anonymity and confidentiality of reporting. Anonymised systems have been shown to encourage greater participation, and most clinicians would support reporting within such a system. Those with experience of the national confidential enquiries felt that these could provide the NPSA with some guidance in this respect.

4.21 Some fears were expressed about possible audit trails back from the NPSA into the Trust, and to identifiable information being available locally. Also, it was considered that there needed to be very clear pre-defined criteria for disclosure. Experience abroad suggests that clinicians might be reassured if steps were taken to see whether reports could be subject to legal privilege. Outside of health, in the aviation industry, the separation of the incident reporting system from the industry regulation system has been important to establishing a no-blame culture. The designation of the NPSA (or other third party) as an arms length agency, with agreed rules re: storage and disclosure of information, and reports separate from both professional and managerial influence would be likely to allay some of the fears expressed.

4.21 A second concern of clinicians about the proposed national reporting system is that the additional reporting and activity that this will produce will result in action and changes to clinical, managerial and system practice that will benefit patient care. We have cited elsewhere the evidence that where systems have been introduced that actually produce change, these systems flourish. Conversely, it has been made clear to us that unless the proposed system can be shown to achieve benefits it will rapidly lose credibility with clinicians and is then likely to suffer from a reduced quality of reporting.
Practical Barriers

4.22 The need for the support of the professions was voiced in a number of contexts. Firstly, it was thought that a mandatory system would be unenforceable without their support. Secondly, professional involvement within the Agency was thought to be very important, in terms of evaluating incidents. Reporting within a professional framework was much more acceptable, and has been shown to be beneficial both within the reporting to the confidential enquiries in the UK, but also in systems abroad. Finally it was thought that multidisciplinary teams should be involved in identifying the incidents to be reported and in providing guidance.

4.23 These features, the provision of clear guidance and definition of an incident together with the development of a ‘team’ culture locally were voiced on many occasions as being important in achieving good reporting.

4.24 The main, practical barrier to reporting though was thought to be the availability of resources and the demands that were likely to be placed on available time. Resources would be needed in three areas

- clinician time to initiate additional incident reports, and provide input to root cause analysis
- time for risk management staff to liaise with and co-ordinate reporting to the NPSA; and to undertake root cause analysis of an anticipated much increased number of incidents
- resources required to rectify deficiencies identified by the analysis. These might include staff time to change systems and to retrain, but also may include new equipment, more staff or capital spend.

It was felt that leaving changes identified as required by the analysis unresourced would rapidly bring the system into disrepute, as had happened to medical audit in a large number of trusts.

4.25 Finally, there would be an early need to co-ordinate and rationalise current reporting of different types of incident. At present, reports about different incidents are made to a wide range of bodies, and the introduction of an additional reporting route was without enthusiasm. If the introduction of the NPSA can reduce the duplication of reporting, it would gain a good deal of support. While it was recognised that this might be more easily achieved through reporting by computer, it was pointed out that access and availability of computer screens and keyboards was still limited in many trusts. An over-dependence on reporting by computer, when not readily available, would be a mistake.
Appendix 1

Risk managers: clinical incident reporting

Clinical incident data collection

1. Does your Trust have an incident reporting system through which staff can report information about clinical incidents? □ Yes □ No - if No, please go to Q23.

2. Does your Trust’s incident reporting system collect ‘near-miss’ information? □ Yes □ No

3. Which methods can staff use to report clinical incidents or near misses in your Trust? Please tick all that apply.
   - Paper forms
   - Email
   - Telephone
   - In person
   - Other methods (informal & formal)
   Please describe ______________________________________

4. Is anonymous reporting accepted? □ Yes □ No

5. Within what time period are staff expected (or required) to report clinical incidents?
   - □ 24 hours or less
   - □ up to 48 hrs
   - □ Up to 1 week
   - □ Other – please describe ____________________________________

6. As far as you know, have any of the following professional staff groups reported clinical incidents in the past year?
   - Consultant Medical staff □ Yes □ No □ Don’t know
   - Junior Medical staff □ Yes □ No □ Don’t know
   - Consultant Pathologists/Radiologists □ Yes □ No □ Don’t know
   - Nursing staff □ Yes □ No □ Don’t know
   - Pharmacists □ Yes □ No □ Don’t know
   - Professions Allied to Medicine staff □ Yes □ No □ Don’t know
   - Others (please describe) □ Yes □ No □ Don’t know

7. What guidance is given to staff on the type of clinical incidents that they are expected to report through the clinical incident reporting system? Please tick one only.
   - □ No formal guidance is given - left to staff’s discretion what to report
   - □ Broad guidance offered on sort of incidents, perhaps with some examples
   - □ Detailed guidance offered with specific list of the types of incidents which should be reported.
8. What education and information does the Trust provide for clinical staff about clinical risk management and clinical incident reporting? Please tick all that apply.
- Covered in Trust induction programmes for clinical staff
- Written instructions/guidelines circulated to all staff
- Written instructions/guidelines displayed in each clinical directorate
- Written instructions/guidelines on Trust’s web site
- Specific risk management/Incident reporting training courses provided
- Other (please describe) ________________________________________________

9. Are the following incidents reported through your clinical incident reporting system? (If Yes please describe the system eg. Mandatory or voluntary)

<table>
<thead>
<tr>
<th>Incident</th>
<th>No, not reported</th>
<th>Yes, reporting mandatory</th>
<th>Voluntary</th>
<th>Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unexpected deaths</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attempted suicides</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unexpected poor outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unexpected returns to theatre</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unexpected operative complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug errors</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient falls</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Near misses</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others (please describe)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. How often is the following information reported in each clinical incident report?

- Details of patient or patients involved in incident
- Date and time of incident
- Directorate/ clinical service area where incident occurred
- Location and environment where incident occurred
- Factual account of incident
- Factors contributing to incident
- Grade(s) of staff involved in incident
- Name(s) of staff involved in incident

11. Approximately how many clinical incidents have been reported across the Trust during the last 12 months? ______

12. Are near-misses included in the above number?  
   - Yes  
   - No  
   If Yes, how many? ______
13. Specific risks were targeted for action in ‘An Organisation with a Memory’*. Do you yet have a reporting system to identify information about these specific areas?

<table>
<thead>
<tr>
<th>Clinical area</th>
<th>Yes</th>
<th>No</th>
<th>Present in this Trust</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spinal injection safety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obstetric &amp; Gynaecology safety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reducing drug errors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reducing suicides by mental patients</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

14. If you answered Yes, to any of Question 13, do you collect ‘near-miss’ information?

<table>
<thead>
<tr>
<th>Clinical area</th>
<th>Yes</th>
<th>No</th>
<th>Present in this Trust</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spinal injection safety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obstetric &amp; Gynaecology safety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reducing drug errors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reducing suicides by mental patients</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

15. Who reviews clinical incident reports once they have been completed? *Please tick all that apply.*

- Ward or clinical team manager for area where incident occurred
- Directorate or clinical service manager for area where incident occurred
- Person or committee responsible for clinical risk management across the Trust
- Trust board
- Other - please describe __________________________________________

16. Does the reported clinical incident remain confidential between the person / persons reporting it and.....

<table>
<thead>
<tr>
<th>Relation</th>
<th>Never</th>
<th>Usually</th>
<th>Unless litigation</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>the head of the clinical directorate or service?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>the person responsible for clinical risk management?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>the clinical service head and the risk manager?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>the Medical Director and the risk manager?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the report remain within the Trust?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

17. How often does the Trust produce analyses of its clinical incident data?

- Every month
- Every three months
- Every six months
- When requested
- Other (please describe) __________________________________________

18. Do the analyses you produce break down clinical incidents by any of the following characteristics?

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of clinical incident</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency with which incident has occurred</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factors contributing to incident</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please describe)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
19. How often have the following actions been implemented following clinical incident reports?

<table>
<thead>
<tr>
<th>Action</th>
<th>Never</th>
<th>Seldom</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wider-based collection of data</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Publicising underlying issues through memos/leaflets etc</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Re-training of specific staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trust-wide staff training</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disciplining of staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

20. Have any changes in clinical practice resulted from clinical incident reporting?

☐ Yes  ☐ No

If you answered Yes, please give an example below.

______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

21. In your opinion, how complete is the clinical incident and near miss reporting in your trust?

(Please put a cross on each line in the position which you feel best describes the completeness of reporting, where 0 = totally incomplete and 10 = totally complete)

<table>
<thead>
<tr>
<th>completeness</th>
<th>Incomplete</th>
<th>Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical incidents</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Near misses</td>
<td>0</td>
<td>10</td>
</tr>
</tbody>
</table>

22. What evidence (if any) do you have for your description of the above level of completeness?

______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

23. In your opinion, what are the main factors that encourage clinical incident and near miss reporting in your Trust?

1.________________________________________________________________________
2.________________________________________________________________________
3.________________________________________________________________________
4.________________________________________________________________________

24. In your opinion, what are the main factors that discourage clinical incident and near miss reporting in your Trust?

1.________________________________________________________________________
2.________________________________________________________________________
3.________________________________________________________________________
4.________________________________________________________________________
25. Are there any other significant issues or concerns to do with clinical incident and near miss reporting, which have not been addressed by this questionnaire but which you would like to raise? If so, please provide details below.

___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

Thank you for completing this questionnaire. Please return it either by e-mailing it to dpryce@kehf.org.uk or by post or fax to Dorothy Pryce, CASPE Research, 13 Cavendish Square, London W1G 0AN (Fax: 020 7307 2422)

Please return the questionnaire by 28th August 2001 if at all possible.

**Appendix 2**

**PCG & PCTs: Clinical incident reporting**

**Clinical incident data collection**

1. **Does your PCG/PCT have an incident reporting system through which GP practices can report information about clinical incidents?**
   - Yes
   - No - *if No*, please go to Q23.

2. **Does your PCT/PCG’s incident reporting system collect ‘near-miss’ information?**
   - Yes
   - No

3. **Which methods can GP practices use to report clinical incidents or near misses in your PCG or PCT?**
   - Please tick all that apply.
   - **Clinical incidents**
     - Paper forms
     - Email
     - Telephone
     - In person
     - Other methods (informal & formal)
   - **Near misses**
     - Paper forms
     - Email
     - Telephone
     - In person
     - Other methods (informal & formal)
   - **Please describe**

4. **Is anonymous reporting accepted?**
   - Yes
   - No

5. **Within what time period are practices expected (or required) to report clinical incidents?**
   - 24 hours or less
   - Up to 48 hours
   - Up to 1 week
   - Other – please describe

6. **As far as you know, have any of the following professional staff reported clinical incidents in the past year?**

   - **Medical staff**
   - **Trainee Medical staff**
   - **Nursing staff**
   - **Pharmacists**
   - **Administrative staff**
   - **Others (please describe)**

   - Yes
   - No
   - Don’t know
7. What guidance is given to practices on the type of clinical incidents that they are expected to report through the clinical incident reporting system? Please tick one only.

- [ ] No formal guidance is given - left to staff’s discretion what to report
- [ ] Broad guidance offered on sort of incidents, perhaps with some examples
- [ ] Detailed guidance offered with specific list of the types of incidents which should be reported.

8. What education and information does the PCT/PCG provide for clinical staff about clinical risk management and clinical incident reporting? Please tick all that apply.

- [ ] Covered in PCT/PCG induction programmes for all staff
- [ ] Written instructions/guidelines circulated to all staff
- [ ] Written instructions/guidelines displayed in each practice
- [ ] Written instructions/guidelines on PCT/PCG’s web site
- [ ] Specific risk management/incident reporting training courses provided
- [ ] Other (please describe) ______________________________________

9. Are the following incidents reported through your clinical incident reporting system? (If Yes please describe the system eg. Mandatory or voluntary)

<table>
<thead>
<tr>
<th>Incident</th>
<th>No. not-reported</th>
<th>Yes, reporting is</th>
<th>Mandatory</th>
<th>Voluntary</th>
<th>Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unexpected deaths</td>
<td>□</td>
<td>□ reporting is...</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Unexpected poor outcomes</td>
<td>□</td>
<td>□ reporting is...</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Misdiagnosis</td>
<td>□</td>
<td>□ reporting is...</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Drug errors</td>
<td>□</td>
<td>□ reporting is...</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Near misses</td>
<td>□</td>
<td>□ reporting is...</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Others (please describe)</td>
<td>□</td>
<td>□ reporting is...</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

10. How often is the following information reported in each clinical incident report?

<table>
<thead>
<tr>
<th>Information</th>
<th>Never</th>
<th>Seldom</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of patient or patients involved in incident</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Date and time of incident</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Clinical service area where incident occurred</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Location and environment where incident occurred</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Factual account of incident</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Factors contributing to incident</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Discipline(s) of staff involved in incident</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Name(s) of staff involved in incident</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

11. Approximately how many clinical incidents have been reported across the PCT/PCG during the last 12 months? ________

12. Are near-misses included in the above number?  [ ] Yes  [ ] No

   If Yes, how many? ________
Reporting of adverse clinical incidents

13. Specific risks were targeted for action in ‘An Organisation with a Memory’*. Do you yet have a reporting system to identify information about these specific areas?

<table>
<thead>
<tr>
<th>Area</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstetric &amp; Gynaecology safety</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reducing drug errors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reducing suicides by mentally ill patients</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

14. If you answered Yes, to any of Question 13, do you collect ‘near-miss’ information?

<table>
<thead>
<tr>
<th>Area</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstetric &amp; Gynaecology safety</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reducing drug errors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reducing suicides by mentally ill patients</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

15. Who reviews clinical incident reports once they have been completed? Please tick all that apply.

- Clinical service manager, in disciplines where staff are professionally managed
- Person or committee responsible for clinical risk management across the PCT/PCG
- PCT/PCG board
- Other - please describe

16. Does the reported clinical incident remain confidential between the person / persons reporting it and….

- the head of the clinical service?
- the person responsible for clinical risk management?
- the clinical service head and the risk manager?
- the Chairman or CEO of PCT/PCG and the risk manager?
- Does the report remain within the PCT/PCG?

<table>
<thead>
<tr>
<th>Confidentiality</th>
<th>Never</th>
<th>Unless</th>
<th>Usually</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Person</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical service</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chairman</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCT/PCG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

17. How often does the PCT/PCG produce analyses of its clinical incident data?

- Every month
- Every three months
- Every six months
- When requested
- Other (please describe)

18. Do the analyses you produce break down clinical incidents by any of the following characteristics?

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of clinical incident</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency with which incident has occurred</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factors contributing to incident</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please describe)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
19. How often have the following actions been implemented following clinical incident reports?

<table>
<thead>
<tr>
<th>Action</th>
<th>Never</th>
<th>Seldom</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiate further collection of data</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Publicising underlying issues through memos/leaflets etc</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Re-training of staff?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCT/PCG-wide staff training?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discipline of staff?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

20. Have any changes in clinical practice resulted from clinical incident reporting?

- Yes
- No

If you answered Yes, please give an example below.

_______________________________________________________
_______________________________________________________
_______________________________________________________
_______________________________________________________
_______________________________________________________
_______________________________________________________
Completeness of data and incentives to reporting

21. In your opinion, how complete is the clinical incident and near miss reporting in your trust? (Please put a cross on each line in the position which you feel best describes the completeness of reporting, where 0 = totally incomplete and 10 = totally complete)

<table>
<thead>
<tr>
<th></th>
<th>Incomplete</th>
<th>Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical incidents</td>
<td>0_________</td>
<td>10</td>
</tr>
<tr>
<td>Near misses</td>
<td>0_________</td>
<td>10</td>
</tr>
</tbody>
</table>

22. What evidence (if any) do you have for your description of the above level of completeness?

____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

23. In your opinion, what are the main factors that encourage clinical incident and near miss reporting in your PCT/PCG?

1______________________________________________________
2______________________________________________________
3______________________________________________________
4______________________________________________________

24. In your opinion, what are the main factors that discourage clinical incident and near miss reporting in your PCT/PCG?

1______________________________________________________
2______________________________________________________
3______________________________________________________
4______________________________________________________

25. Are there any other significant issues or concerns to do with clinical incident and near miss reporting, which have not been addressed by this questionnaire but which you would like to raise? If so, please provide details below.

____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

Thank you for completing this questionnaire. Please return it by post or fax to Dorothy Pryce, CASPE Research, 13 Cavendish Square, London W1G 0AN (Fax: 020 7307 2422)

Please return the questionnaire by 1st September 2001 if at all possible.

References


