Summary

There are many opportunities for clinical information systems, defined as “A paper or computer-based tool which manages patient data, medical knowledge or other information to improve clinical decisions and actions”, to ameliorate clinical errors and improve patient safety. There are also many questions about such systems, ranging from how to match the system to the user requirements and barriers to change to the cost-effectiveness of paper and computer based systems. Extensive work on preventable adverse patient events in the USA suggests certain clinical sites, specialties and kinds of error on which any future patient safety programme should focus. However, it is possible to identify both paper and clinical information systems which are likely to ameliorate most kinds of error. We conducted a survey to identify willing sites for such research in the UK but the overall results were disappointing. However, a number of hospital sites and the co-ordinating office for 130 Co Op pharmacies indicated their willingness to collaborate. Turning to methodological issues that will arise during such a research programme, we have identified several topics which probably need fuller discussion with potential bidders in a workshop before proposals are finalised. Finally, we suggest that it will be easier to identify potential bidders and sites once the scope of the R&D programme, areas of focus and specific questions to be studied are clarified. This report attempts to bring together material to support this clarification process, and draft material for the commissioning brief.

Table of contents

1. Introduction and background ................................................................. 3
   Patient safety and the epidemiology of clinical errors .................................. 3
   Clinical information systems ....................................................................... 4
   Review of information systems for reducing drug related errors .................... 5
2. Study aim and objectives ........................................................................... 7
3. Study survey methods ................................................................................. 8
   Sample size, type and location .................................................................... 8
   Method for eliciting names and addresses of sites for survey ......................... 8
   Incentives and follow up of non-responders .................................................. 9
   Data analysis .............................................................................................. 9
4. Study results ............................................................................................... 10
   Points on the patient trajectory where safety may be compromised ................ 10
   Risk factors for clinical errors amenable to clinical information systems .......... 10
   Taxonomy of clinical information systems .................................................... 15
   Opportunities for clinical information systems to intervene in patient safety .... 15
   Possible priority areas: ............................................................................. 15
   Key questions to be answered about information systems and patient safety ... 16
     Barriers to change and system requirements: ............................................. 16
   Type of system user: .................................................................................. 17
1. Introduction and background

The Department of Health plans to launch an R & D programme soon to explore the contribution of clinical information systems to patient safety [Anon 2001]. The aim of the current project is to support and carry out necessary groundwork for that programme.

Patient safety and the epidemiology of clinical errors

Patient safety can be threatened in many ways, ranging from poor maintenance causing patients to fall to clinical errors. The focus of the proposed programme is on improving the management of information to improve patient safety, so clinical decisions and errors – of omission and commission – are most relevant.

A number of points in the patient trajectory are known to be error prone, including:

- Drug prescribing, including dosage and route errors, interactions, allergy, polypharmacy and repeat prescribing
- Drug dispensing and administration
- Carrying out surgical and other procedures
- Monitoring patients with acute or chronic illness or on hazardous therapies and responding to abnormal test results
- Communication, eg. communicating changes in policy, implementing such changes, transcribing orders or test results and communicating with patients
- Triage and diagnosis in primary, community and emergency care settings
- Referral of patients
- Preventive care

A priority is to identify those clinical scenarios or settings in which preventable errors occur most frequently and for which clinical information systems are an appropriate remedy. Such scenarios can then be targeted by the R&D programme.

We know from other settings that information handling problems are a major cause of human error—see table 1. Thus, information systems have great potential to ameliorate human errors.

Table 1: Information handling problems and risk factors for error
(adapted from Reason, 1998)

<table>
<thead>
<tr>
<th>Information handling problem</th>
<th>Risk ratio for human error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor signal to noise ratio</td>
<td>10</td>
</tr>
<tr>
<td>Designer-user mismatch</td>
<td>8</td>
</tr>
<tr>
<td>Error cannot be reversed</td>
<td>8</td>
</tr>
<tr>
<td>Information overload</td>
<td>6</td>
</tr>
<tr>
<td>Risk not accurately perceived</td>
<td>4</td>
</tr>
<tr>
<td>Poor feedback from the system</td>
<td>4</td>
</tr>
<tr>
<td>Poor instructions or procedures</td>
<td>3</td>
</tr>
<tr>
<td>Inadequate checking</td>
<td>3</td>
</tr>
</tbody>
</table>
There are many ways to reduce errors and improve patient safety, including education, changes in staff relationships or team organisation, improving the design of buildings, equipment and disposables, or clinical process redesign. However, this report focuses on the role of clinical information systems in reducing medical errors.

**Clinical information systems**

A clinical information system can be defined as:

“A paper or computer-based tool which manages patient data, medical knowledge or other information to improve clinical decisions and actions.”

(adapted from Wyatt Lancet 1991, 1994)

It is important to include paper and other “low tech” approaches to managing clinical information and to distinguish them from high tech computer systems because of their different implications for cost, flexibility and the reluctance of clinicians to use computers, especially in secondary care. Some examples of paper based and computerised clinical information systems are listed in Table 2.

**Table 2: Examples of paper and computer based clinical information systems**

<table>
<thead>
<tr>
<th>Paper, low tech systems</th>
<th>Computer, high tech systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition-specific paper checklist</td>
<td>On-screen condition-specific form</td>
</tr>
<tr>
<td>Coloured sticker on case notes of diabetics to prompt annual retinal screening</td>
<td>Automated reminder about annual retinal screening for diabetics</td>
</tr>
<tr>
<td>Printed care pathway for total hip replacement</td>
<td>Computer forms and reminders derived from care pathway for total hip replacement</td>
</tr>
<tr>
<td>Printed formulary in clinic rooms</td>
<td>eBNF on health centre or hospital intranet</td>
</tr>
</tbody>
</table>

Clinical information systems are increasingly being used at many safety critical points in the health service to capture, process or communicate patient data or clinical knowledge. Such information systems can influence patient safety in two ways:

1. The systems provide an opportunity to prevent clinical errors and omissions before they occur, or to identify those which are occurring through a variety of mechanisms. These include functions of proven clinical effectiveness such as drug interaction checking [Vadher 1997], calculation of drug dosage [Walton 2001], reminders [Davis 1995] and other decision support functions [Hunt 1998]. Good design is clearly important, especially with increasingly complex systems [Nolan 2000].

2. However, even simple information systems can threaten patient safety through malfunction or poor design. An example is failure to communicate abnormal test results to A&E staff when a new order communications system was implemented [Kilpatrick 2001]. This resulted from insufficient analysis of the manual information processing methods the system replaced, imperfect though they may have been. The systems can themselves threaten patient safety. Other examples include systems with poor “information design” [Cartmill 1992, Wyatt 1998], calculation errors [Wilkinson 2000], bad logic [Fox 1993] or which simply take too long to use [Tierney 1993]
Thus, implementing well designed, effective systems and eliminating poorly designed systems provides a significant opportunity for the NHS to improve the safety of clinical practice and self care.

Since drug prescribing and administration are a common form of preventable error, it is appropriate to examine the potential of clinical information systems in this area in a little more detail.

**Review of information systems for reducing drug related errors and improve patient safety**

In the USA, preventable errors in drug prescribing and administration are amongst the commonest category of medical error, and much attention has focused on the use of information systems to reduce them. Using conventional medical records and paper formularies, one in three prescriptions for drugs to which the patient had a known allergy were still given [Bates 1995]. Reasons for this included that:

1. The record of drug allergy was not retained from one encounter to the next
2. There was no fixed place in the record to place it
3. When present, the record only mentions allergy to a specific drug, instead of generalising it to the drug family
4. No-one systematically checked prescriptions against the drug allergy data in the patient record

Bates [Bates 2000] has reviewed this area and suggests the framework in Table 3 for classifying information systems relevant to the medication process.

**Table 3: Stages in the medication process, and computer systems relevant to these**

(Adapted from Bates 2000)

<table>
<thead>
<tr>
<th>Stage in the medication process</th>
<th>Relevant computer systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribing</td>
<td>Computer based prescribing</td>
</tr>
<tr>
<td></td>
<td>Decision support systems</td>
</tr>
<tr>
<td>Transcription of drug order</td>
<td>Electronic communications</td>
</tr>
<tr>
<td>Drug dispensing</td>
<td>Robots for filling prescriptions</td>
</tr>
<tr>
<td></td>
<td>Bar coding</td>
</tr>
<tr>
<td></td>
<td>Automated dispensing devices</td>
</tr>
<tr>
<td>Drug administration</td>
<td>Bar coding</td>
</tr>
<tr>
<td></td>
<td>Automated dispensing devices</td>
</tr>
<tr>
<td>Maintaining the patient's drug record</td>
<td>Computerised drug records</td>
</tr>
<tr>
<td>Monitoring of ADR rate and severity</td>
<td>Computerised monitoring of adverse events</td>
</tr>
</tbody>
</table>

According to Bates, computer based prescribing, with or without decision support, is the most effective method to reduce errors. It works by enforcing identifiable, structured, legible orders, which then allow the prescription to be checked automatically for allergy, interactions, dose, compatibility with renal / liver function and for appropriate feedback given to the prescriber. In studies such systems have reduced overall prescribing errors by 83% and serious errors by 55% [Bates 1998]. Even a simple order entry system with no decision support reduced errors by 64% [Bates 1999]. In another study, the pilot DSS led to 84% drop in near misses and 17%
drop in drug related injury; later, once more support was added, the injury rate dropped 60% from 2.9 to 1.1 per 1000 patient days [Bates 1999].

Turning to systems used in dispensing and drug administration, up to 2000 there were no published studies of robots for filling prescriptions. However, in one unpublished study, the dispensing error rate dropped from 2.9% to 0.6% [Weaver PE, presented at American Soc of Health System Pharmacists 1998]. There was also no published data on the effectiveness of bar coding. However, outside medicine the use of bar codes leads to a 16% fall in keyboard data entry errors, as well as being less stressful to workers [Bates 2000]. In one hospital the use of bar codes was associated with an 80% drop in drug administration errors [Bates 2000]. However, the lack of a common approach to bar code structure and format is a significant obstacle, which requires action by drug manufacturers.

Automated dispensing devices store supplies of commonly used drugs and dispense them for each patient on receipt of coded messages from a prescribing system. However, they require bar coded drug supplies and a link to hospital information system. Without such links, they can even increase error rates, for example by people refilling the supply hopper with the wrong drug. Computerised drug records and electronic communications are clearly necessary information infrastructure to support these and other functions.

To help evaluate adverse drug events (ADRs) and when implementing improvements in prescribing and drug administration it is important to be able to monitor these events reliably and cheaply. Self reporting by clinicians only detects about 1 in 20 adverse events, but appropriately configured computers can detect suspicious phenomena associated with an ADR such as high drug concentrations, abnormal test results or use of an antidote for detailed review by a pharmacist [Classen 1991]. In head-to-head comparisons, voluntary reporting detected 4% of ADRs, a computerised monitor detected 45% and routine pharmacist chart review detected 64%. While less sensitive, the costs of computer monitoring were 1/5 the costs of human chart review, making it practical as a routine technique.

All of these studies were based in the USA, which has a number of significant differences to the UK, including:

- Different training for doctors and salary / reimbursement system
- Extensive use of routine chart reviews
- Different relationships between doctors, nurses and other clinical team members (eg. nurses fill out request forms in response to medical orders)
- More extensive current use of IT systems, including for capturing the use of drugs and disposable for charging purposes
- More informed and demanding public, with greater tendencies to seek second opinions and litigation

The applicability of these insights to the UK therefore needs to be modelled or empirically tested.
2. Study aim and objectives

The aim of this study is to assist those writing the commissioning brief for the R&D programme on clinical information systems and patient safety. The ultimate aim of the programme is assumed to include the identification of one or more clinical information systems proven to reduce the incidence or severity of errors occurring at key decision points.

Specific objectives of the current project include:

- To identify common or serious threats to patient safety which are potentially amenable to intervention from clinical information systems
- Identify relevant categories of information systems and develop a one or 2-dimensional taxonomy of these systems
- To catalogue existing and emerging clinical information systems which could be relevant to patient safety, and identify sites at which they are or will be installed for future projects
- To suggest a list of questions that funded projects should address, and a list candidate paper and computer based information systems for further evaluation
- To identify key issues relevant to the logistics, ethics and scientific rigour of projects to be funded under the programme
- To assemble some draft project selection criteria
3. Study survey methods

Sample size, type and location

To be suitable for one of the planned NHS R&D projects, the system needs to be robust and transferable, used by clinicians (in the broadest sense, including doctors, NHSDirect nurses, pharmacists etc.) making decisions which affect patient safety on sizeable patient populations. In view of the recent Concordat, systems used by independent contractors such as High Street pharmacists, optometrists and the private health sector should probably be included. The organisations and clinicians concerned need to be willing, at least in principle, to collaborate on such research. The majority of systems included will be commercially developed and supported, as research results on one-off or locally developed systems will be of little interest to other sites around the UK.

Examples of eligible systems include:
- Prescribing systems used by doctors and nurses
- Case finding and recall systems for cervical cytology, flu vaccination and other health prevention activities
- The NHS Clinical Advice System used by nurses in walk-in centres and NHSDirect call centres
- Drug interaction systems used by pharmacists

Method for eliciting names and addresses of sites for survey

1. The vendors or developers of eligible robust, supported systems already in use by or soon to be released to the NHS, High Street pharmacists, private health organisations etc. in the UK were identified. Techniques included informal contact with representatives of user groups, email enquiries, consulting business / trade associations (eg. Computer Services and Suppliers Association), etc. Professional bodies including the RCGP, National Pharmaceutical Association and the Royal Pharmaceutical Society were also contacted to discover which software packages their members used. Only the NPA replied.

2. A search was made of the Internet using Google for the contact details of clinical information system suppliers. In addition, a very useful list of such suppliers was found at http://www.cs.man.ac.uk/mig/resources/uknhsit.html.

3. Using the addresses recovered in steps 1 and 2, letters were sent to software suppliers, enclosing a form and information about which categories of software and sites were eligible for the study (Appendix 1). The form asked questions about the software package itself and also for the names and addresses of 5 eligible sites where the software was in use. All contact with vendors made it clear that we were merely seeking information about their system and possible study sites, their participation was optional, and that co-operation carried no commercial benefits other than possible positive study results at some future stage.

4. Using the site addresses elicited in step 3, as well as some other addresses found on the NHSIA’s website on the ERDIP programme etc., letters were sent to system guardians at sites suggested to be suitable for R&D. The letters explained the project and enclosed a form requesting details of the software used and of the organisation (Appendix 2). The form also asked if the organisation would be willing in principle to take part in R&D.
5. A database was built up of the contact details of all organisations and individuals 
contacted during the study, for future reference. This will be provided electronically 
to the R&D programme.

**Incentives and follow up of non-responders**
We tried to encourage responses by emphasising potential benefits for suppliers and 
study sites in our letter. Non-responders were sent 2 mailed reminders each enclosing 
a further copy of the questionnaire and mailing label. Where requested or otherwise 
appropriate, a phone call was used to follow up.

**Data analysis**
Conventional descriptive methods were used to analyse the survey data.
4. Study results

Points on the patient trajectory where safety may be compromised

During a patient’s path through the health system, patient safety may be compromised at any one of a large number of points – see Figure 1.

Figure 1: Points on the patient pathway where safety may be compromised

However, a key question is, exactly where in this complex trajectory do preventable errors likely to be amenable to clinical information systems occur? To answer this, we need to examine empirical data on the location and type of clinical errors and their preventability.

Risk factors for clinical errors amenable to clinical information systems

The best source of data about preventable errors remains the Harvard medical practice study and Leape’s 1994 re-analysis [Leape 1994]. The methods employed are as follows. A random sample of case notes was obtained from all patients hospitalised in New York in 1984, with oversampling of high-risk specialities which was compensated for in the final results. Trained nurse-abstractors searched each record for any of 18 markers of an injury. Suspicious records were reviewed by two doctors to decide if there was an adverse event, whether it was reasonably avoidable (“caused by a mistake in performance or thought”), the extent of the disability caused and where the event happened.

Overall 30,195 records reviewed by nurses of which 7,743 were referred to doctors and 1,133 showed adverse events – 3.7% of all hospital discharges. Half of the
adverse caused disability for less than a month, 7% for longer, and 14% of those suffering an event died as a result. 70% of the events were preventable (see definition below) and 28% of the events were caused by negligence – i.e. were due to unambiguous errors. Half of all events were related to a surgical operation and one in five to drug administration. Events were twice as common in patients over 65 years, and were commoner in those undergoing cardiac, vascular and neurosurgical operations. Event rates varied by factor of 10 between hospitals but were not correlated with hospital size or location. However, adverse events were more frequent in teaching hospitals.

A preventable event was defined as one that resulted from an error or failure to follow accepted practice. An event was unpreventable if it resulted from a complication that could not be prevented with the current state of knowledge; it could then be predictable or unpredictable. An event was potentially preventable if no actual error could be identified, but the event usually reflected low standards of care or technique.

The results showed that 70% of all events were found to be preventable, 6% potentially preventable, and 24% unpreventable. This ratio did not vary with patient age, or whether the event occurred inside or outside hospital.

### Table 4: Adverse event rate and number preventable by site where event occurred
(data from Leape 1994)

<table>
<thead>
<tr>
<th>Site</th>
<th>Details of site</th>
<th>Percent of all events</th>
<th>No. of events</th>
<th>Percent preventable</th>
<th>Number preventable</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Within hospital</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>81%</td>
<td>80000</td>
<td>71%</td>
<td>56500</td>
</tr>
<tr>
<td>Operating room</td>
<td></td>
<td>41%</td>
<td>40400</td>
<td>71%</td>
<td>29000</td>
</tr>
<tr>
<td>Ward</td>
<td></td>
<td>27%</td>
<td>26000</td>
<td>68%</td>
<td>17700</td>
</tr>
<tr>
<td>Emergency room</td>
<td></td>
<td>3%</td>
<td>2900</td>
<td>93%</td>
<td>2700</td>
</tr>
<tr>
<td>Labour ward</td>
<td></td>
<td>3%</td>
<td>2800</td>
<td>79%</td>
<td>2200</td>
</tr>
<tr>
<td>ICU</td>
<td></td>
<td>3%</td>
<td>2600</td>
<td>70%</td>
<td>1800</td>
</tr>
<tr>
<td>Radiology</td>
<td></td>
<td>2%</td>
<td>2000</td>
<td>61%</td>
<td>1200</td>
</tr>
<tr>
<td>Other hospital</td>
<td></td>
<td>3.4%</td>
<td>3200</td>
<td>63%</td>
<td>2000</td>
</tr>
<tr>
<td><strong>Outside hospital</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>14%</td>
<td>13600</td>
<td>66%</td>
<td>9000</td>
</tr>
<tr>
<td>Doctor’s office</td>
<td></td>
<td>8%</td>
<td>7600</td>
<td>63%</td>
<td>4700</td>
</tr>
<tr>
<td>Home</td>
<td></td>
<td>3%</td>
<td>2700</td>
<td>60%</td>
<td>1600</td>
</tr>
<tr>
<td>Ambulatory surgical unit</td>
<td></td>
<td>1.4%</td>
<td>1340</td>
<td>95%</td>
<td>1300</td>
</tr>
<tr>
<td>Other non hospital</td>
<td></td>
<td>2%</td>
<td>2000</td>
<td>65%</td>
<td>1300</td>
</tr>
<tr>
<td><strong>Not clear</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>5%</td>
<td>5000</td>
<td>65%</td>
<td>3300</td>
</tr>
</tbody>
</table>
In Leape’s data, the operating room, ward and doctor’s office (UK equivalent: outpatient dept / GP surgery) were the commonest sites, accounting between them for three quarters of all preventable errors.

### Table 5: Preventable adverse event rates by clinical specialty
(data from Leape 1994)

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Adverse event rate per patient</th>
<th>No. of events</th>
<th>Percent preventable</th>
<th>No. preventable (rank)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular surgery</td>
<td>16%</td>
<td>3200</td>
<td>61%</td>
<td>1950 (8)</td>
</tr>
<tr>
<td>Thoracic surgery</td>
<td>11%</td>
<td>3600</td>
<td>63%</td>
<td>2300 (6)</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>10%</td>
<td>3000</td>
<td>74%</td>
<td>2200 (7)</td>
</tr>
<tr>
<td>General surgery</td>
<td>7%</td>
<td>22,300</td>
<td>73%</td>
<td>16300 (2)</td>
</tr>
<tr>
<td>Urology</td>
<td>5%</td>
<td>4800</td>
<td>72%</td>
<td>3500 (5)</td>
</tr>
<tr>
<td>Orthopaedics</td>
<td>4%</td>
<td>6700</td>
<td>78%</td>
<td>5200 (3)</td>
</tr>
<tr>
<td>General medicine</td>
<td>3.6%</td>
<td>37000</td>
<td>64%</td>
<td>23700 (1)</td>
</tr>
<tr>
<td>Obstetrics</td>
<td>1.5%</td>
<td>5000</td>
<td>76%</td>
<td>3800 (4)</td>
</tr>
<tr>
<td>Neonatal</td>
<td>0.6%</td>
<td>1700</td>
<td>unknown</td>
<td>&lt; 1700 (9)</td>
</tr>
<tr>
<td>Other</td>
<td>3%</td>
<td>11000</td>
<td>75%</td>
<td>8300</td>
</tr>
<tr>
<td>All</td>
<td>4%</td>
<td>98600</td>
<td>70%</td>
<td>69000</td>
</tr>
</tbody>
</table>
While the surgical specialities had the highest rates of adverse and preventable events per patient, in fact general medicine accounted for the largest actual number of preventable events – in part because it is a large grouping. General surgery, obstetrics and the surgical specialities came next. Overall, the first three specialities accounted for two thirds of all preventable errors.

**Table 6: Preventable adverse event rates by type** (data from Leape 1994)

<table>
<thead>
<tr>
<th>Type of event</th>
<th>% of preventable events</th>
<th>No. of negligent</th>
<th>% negligent</th>
<th>No. negligent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical error in operation, procedure</td>
<td>44%</td>
<td>30400</td>
<td>20%</td>
<td>6000</td>
</tr>
<tr>
<td>Diagnostic error or delay</td>
<td>17%</td>
<td>11700</td>
<td>71%</td>
<td>8300</td>
</tr>
<tr>
<td>Failure to provide necessary prophylactic therapy</td>
<td>12%</td>
<td>8000</td>
<td>50%</td>
<td>4000</td>
</tr>
<tr>
<td>Error in dose of method of using drug</td>
<td>10%</td>
<td>7000</td>
<td>37%</td>
<td>2600</td>
</tr>
<tr>
<td>Inadequate monitoring or follow up of treatment</td>
<td>5%</td>
<td>3200</td>
<td>37%</td>
<td>1200</td>
</tr>
<tr>
<td>Delay in treatment or responding to abnormal test</td>
<td>4.6%</td>
<td>3150</td>
<td>70%</td>
<td>2200</td>
</tr>
<tr>
<td>Failure to act on the results of tests</td>
<td>2.3%</td>
<td>1600</td>
<td>55%</td>
<td>880</td>
</tr>
<tr>
<td>Use of outmoded tests or therapy</td>
<td>1.4%</td>
<td>950</td>
<td>56%</td>
<td>530</td>
</tr>
<tr>
<td>Failure to use indicated tests</td>
<td>1.1%</td>
<td>780</td>
<td>91%</td>
<td>710</td>
</tr>
<tr>
<td>Error in preparing patient for / administering treatment</td>
<td>1.1%</td>
<td>780</td>
<td>9%</td>
<td>70</td>
</tr>
<tr>
<td>Other</td>
<td>2%</td>
<td>1203</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>All</td>
<td>100%</td>
<td>69000</td>
<td>40%</td>
<td>28000</td>
</tr>
</tbody>
</table>
Turning to preventable errors caused by negligence, classified using Leape’s 14 point system [Leape 1994 p. 16], the commonest were technical errors in operations or procedures, accounting for nearly half. However, such technical errors in performing operations and procedures are unlikely to be amenable to clinical information systems. The next most common preventable errors were diagnostic errors or delays, failure to give necessary prophylactic treatment, error in dose or method of using a drug, inadequate monitoring or follow up of treatment, and failure to act on the results of tests. These together account for half of the preventable errors, and all are amenable to information systems. It is also interesting to explore the number of preventable errors which were due to negligent actions – unambiguous errors. These are shown in Figure 4.

**Figure 4: Negligent (unambiguous) clinical errors by type, most common first**
(data from Leape 1994)

While not a multivariate analysis, this does suggest that any programme to reduce avoidable or negligent clinical errors should focus on the areas listed in Table 7.
Table 7: Areas where preventable errors amenable to information systems most frequently occur (using analysis above, original data from Leape 1994)

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Areas where preventable errors amenable to information systems most frequently occur</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical sites</td>
<td>Operating theatres&lt;br&gt;Clinical wards&lt;br&gt;Outpatient dept / GP surgeries&lt;br&gt;</td>
</tr>
<tr>
<td>Clinical specialities</td>
<td>General medicine&lt;br&gt;General surgery&lt;br&gt;Obstetrics&lt;br&gt;Surgical specialities</td>
</tr>
<tr>
<td>Types of error</td>
<td>Diagnostic errors or delays&lt;br&gt;Failure to give necessary prophylactic treatment&lt;br&gt;Error in dose or method of using a drug&lt;br&gt;Inadequate monitoring or follow up of treatment&lt;br&gt;Failure to act on the results of tests</td>
</tr>
</tbody>
</table>

**Taxonomy of clinical information systems**

There are many different kinds of clinical information system relevant to patient safety. To help classify an individual system and understand its potential to reduce errors, it is suggested that detailed information about the following significant dimensions & potential effect modifiers are captured using the form in Appendix 3.

- Broad category of system: paper, computer, other
- Targeted users: doctors, nurses, pharmacists, patients, etc.
- Scenario of use: active care, preventive care, reflective practice, policy analysis (Information systems designed purely for educational or research use are outside the scope of this programme)
- Type of decision or action targeted prescribing, drug administration, carrying out procedures, monitoring patients, communication, triage, etc.
- Type of interaction: passive browsing of data, active alerts or reminders, case simulation

A two dimensional taxonomy of such systems was developed (Appendix 4), and was used successfully by respondents to classify systems during the survey of potential research sites.

**Opportunities for clinical information systems to intervene in patient safety**

The table in Appendix 5 explores the many kinds of clinical error and maps them to low tech paper systems or high tech computer systems which might prevent them. It suggests opportunities to develop systems, or systems which may already have been developed, perhaps on a small scale, which should be identified and evaluated for their impact on this type of error.

**Possible priority areas:**

Criteria for a priority area could include that preventable errors are relatively common, majority of errors are likely to be amenable to clinical information systems, and there is a fit with government health priorities.
Potential priority areas are:
- Drug prescribing in primary and secondary care, particularly for coronary artery disease and mental health
- Repeat prescribing and polypharmacy, especially in the elderly eg. those in nursing homes
- Drug administration in secondary care?
- Response of doctors and other clinicians to abnormal lab tests or imaging results, perhaps in coronary artery disease
- Triage in primary care out-of-hours services and A&E – especially for CAD, mental health
- Referral from primary to secondary care for investigation of suspected cancer

Key questions to be answered about clinical information systems and patient safety

The review of literature and other factors prompted a list of key questions about CIS and patient safety, focusing on barriers to change and system requirements, type of system user and cost effectiveness of the systems. These are listed in the subsections below. Some may be appropriate to include in a future R&D programme commissioning brief.

Barriers to change and system requirements:
- What clinician, patient, drug, organisational or other factors currently prompt clinicians to seek information from paper, electronic or peer sources during prescribing and repeat prescribing? To which sources do they most frequently turn, and why?
- Why, and how frequently, do clinicians ignore the advice from decision support or alarm systems, or turn off advanced functions such as drug interaction alerts? How often does this threaten patient safety?
- How can such systems be redesigned to improve their perceived value, actual usage rates and impact on patient safety? For example,
  - Is there a benefit in presenting safety-related information to clinicians in alternative ways from reminders / alerts? Possible alternatives include: indicating abnormal results with colour coded text, symbols or graphical icons; giving an ongoing text critique or commentary on user actions; pre-emptively altering screen contents to reflect safety constraints (eg. in a prescribing system, greying out or deleting drug names to which the patient is allergic)
  - What is the role of personal data assistants, pagers, mobile phones and other portable wireless devices in delivering information about and helping clinicians respond to critical incidents, compared to conventional PC applications?
  - Dispensing robots, bar coded drug supplies and patient wrist bands and other automated drug dispensing and administration devices are under-evaluated; what is their potential in the UK?
- What information infrastructure (eg. common patient identifiers, electronic primary – secondary care links, standard bar code labels for drugs) needs to be in place for information systems to contribute to patient safety?
- Do patient records in retail pharmacies, general practice, hospital, out-of-hours or walk-in centres and other clinical settings contain sufficient accurate coded clinical data to allow prescribing and other decision support systems to deliver reliable, useful safety-related information?
• Do reminders and alerts scale, ie. do users respond to the second and third reminder per case (or tenth and twentieth per clinic session) as much as to they do to the first?
• How can we encourage clinicians to record the reason they overrode an alert or ignored a reminder?
• How can reminder / alert systems or more advanced systems be upgraded swiftly and reliably, to keep them in line with clinical and health service developments?

**Type of system user:**
• Can the information systems used by retail pharmacists be used to quantify and reduce drug related errors in primary and community care?
• Can a practice nurse or other primary care team member with a suitable system make fewer repeat prescribing errors than the current method with a receptionist and GP review?

**Cost-effectiveness:**
• What is the added value of simple on-screen reminder / alert computer systems over well designed low tech paper reminders?
• What is the added value of complex disease management, care pathway or protocol-directed care systems over simple on-screen reminder / alert systems?
• Is the impact of an information system on patient safety transient; for how long do any effects last?
• What are the development, training and maintenance costs of effective systems per adverse event / serious risk prevented?
• How much extra time does it take a clinician to use computer based prescribing and / or respond to decision support, compared to paper prescribing and use of the paper BNF?
• Given the significant differences in health systems, consumer attitudes etc. between the USA and UK, which of the many US studies on information systems for reducing errors or identifying adverse events can be applied to the UK?

**Logistics and quality: methods to improve the value of research on clinical information systems and patient safety**

A number of methodological and other issues are relevant to obtaining high quality, useful results from research of this type. These are listed in the sections which follow.

**The need for generalisable research results**

A fundamental principle of research – in fact, the key distinction between research and audit – is that the results must be applicable in settings different from those studied. However, some of the clinical information systems used in the NHS were developed in-house, depend strongly on local data definitions and ways of working or a local advocate, and were never intended to be used elsewhere. It would be a mistake to study such systems except when other reasons predominate. Other systems started life as a generic commercial package but have been so carefully tailored over the years to the specific general practice or hospital department that investigators would hesitate to generalise from results in that setting to other settings with the “same” system.
Thus, it would be unwise to concentrate R&D efforts only on clinical information systems that were locally developed or significantly enhanced, or on those used only in a handful of NHS settings, since the results will not generalise beyond the setting or system studied. This scoping study therefore attempted first to identify research sites which are likely to produce generalisable results because the information system concerned is transferable. This was interpreted as professionally developed systems, as these are designed to be used in a variety of settings, are well documented, and both training and support are available.

Key issues about study methods

Key methodological issues of which investigators should be aware include:

Category of research needed: Primary research (original studies) or secondary research (systematic reviews, economic modelling or other analyses of published data) may be required.

Choice of study techniques. The techniques used should match the study question, not the technology being studied. Thus, qualitative or survey techniques may be most useful for exploring user perceptions and requirements, while rigorous experimental methods will be required to assess system impact.

Selection criteria: Investigators should aim for generality across NHS staff, procedures and clinical settings where feasible. However, be aware of the rarity of errors and near misses: it may be more appropriate to select sites or procedures with higher than average rates. Fully describe and adhere to all selection criteria for patients, clinicians, organisations, critical incidents etc.

Gold standards for appropriateness studies: aim to choose unambiguous clinical errors and validate this by showing high levels of agreement between independent judges. Otherwise, use established methods such as the Delphi or nominal group process to develop a peer review standard.

Measures for surveys: either find and use a published instrument that has already been validated or apply established psychometric techniques to develop a new reliable, valid instrument before using it in a demonstration study. Many tables and directories of validated instruments have been published, especially in the psychology literature.

Measures for impact studies: study actual clinical practices, errors, patient outcomes, complaints, satisfaction, or near misses. Use validated instruments and reliable methods to assess appropriateness. Use of high quality routine data (eg. from an incident reporting system) may reduce Hawthorne effects, allows more frequent assessment (so that the onset and duration of impact can be studied) and reduces study costs. Measure the cost of system development, implementation, training and support. Include measures to determine why the intervention failed, if it did; this will often require qualitative methods.

Interventions: Study systems that can be readily reproduced, to ensure generality. Aim to compare simple against complex systems in the same study to explore the added value of the latter. Complex interventions: be honest in describing all components of the intervention. Give a full description of the interventions to allow others to replicate the work.
**Experimental study design:** be aware of contamination (carry over) but only use a cluster randomised design if the carry over rate is likely to exceed 30% [Torgerson 2000]. If a cluster approach is used, apply the correct methods for sample size calculation and to analyse study results [see draft MRC guidelines on cluster trials 2001]. Consider a balanced incomplete block design if Hawthorne effects are anticipated to be a major factor [Friedman & Wyatt 1998]. Aim for pragmatic rather than explanatory studies; factorial designs will rarely be needed. Consider external and internally controlled before-after or interrupted time series study designs if an RCT proves unfeasible [Wyatt 2001]

**Ethical aspects of the studies**

Investigators should:
- Seek the advice of, and clearance from, local or regional ethics committee
- Seek advice from experts in study design, analysis, health economics, qualitative methods, and patient or consumer input where appropriate.
- Adhere to the Data Protection Act and other relevant regulations concerning the protection of confidential information – both patient and clinician performance data
- Remember that powerful interventions often have side effects, making the overall balance of risks and benefits in actual clinical use hard to predict. Thus, it is often ethical to carry out a randomised trial of a potentially powerful system, since it may also take longer to use, divert attention or health care resources away from other areas, or malfunction causing harm

**Definitions, programme scope and possible project selection criteria**

**Definition of clinical information systems and scope of the programme**

The proposed definition of a clinical information system is:

“A paper or computer-based tool which manages patient data, medical knowledge or other information to improve clinical decisions and actions.”

The possible scope of the programme is:

“Evaluating the costs, usability or impact of clinical information systems to improve patient safety and reduce clinical errors in priority areas in UK primary, community and secondary care. Information systems designed purely for educational or research use are outside the scope of this programme.”

**Draft project selection criteria**

Research team selection criteria:
1. Knowledge and experience in the patient safety / clinical errors area
2. Includes a clinician, statistician, psychologist, ethnographer, health economist, medical informatics expert etc., as appropriate
3. Experience of multi-disciplinary working and project management
4. Able to provide adequate supervision, deliver final report on time and to NHS R&D quality standards
5. Will focus on answering one or more of the listed study questions using appropriate rigorous techniques to generate results likely to interest the NHS

Site selection criteria:
1. Patient care activity on-site, or patients as clients (e.g. NHS Direct call centre)
2. One or more eligible information systems
3. Part of the NHS, or a contractor to the NHS (e.g. retail pharmacy, private hospital…)
4. Sizeable caseload in which the system is used. The actual numbers required will depend on frequency of adverse events in your population – the rarer the adverse event, the more clinical contacts needed in any study. As a rough guide, a minimum of 50 clinical contacts per week is needed
5. IT literate workforce who are willing to use clinical systems

System selection criteria:
1. The system is a clinical information system, as defined by the programme
2. The system is likely to improve patient safety in one of the priority areas
3. The system could, at least in principle, be rolled out to other UK sites, ie.
   - it is sufficiently well engineered for routine clinical use
   - it uses an open systems architecture
   - it adheres to relevant NHS standards, eg. for confidentiality, data backup, clinical coding or message structure
   - user training, documentation and support are all available
   - the system source code has been deposited in escrow as a precaution against the commercial failure of the software provider

Potential material relevant to the commissioning brief
Several of the sections included in this report could be concatenated and edited to form a draft commissioning brief for the programme, including:

- Draft definition of CIS, suggested programme scope
- List of possible priority areas
- Selection form the critical questions to be answered
- Advice on methods to be used
- Ethical issues
- Selection criteria for investigators, sites, projects

Results of the survey of CIS suppliers and sites
Response rates to the surveys of system suppliers and potential study sites were very disappointing, at 30% and 42% respectively. However, we were able to identify 7 organisations who agreed in principle to collaborate with an R&D programme – see Appendix 6. These included large NHS Trusts such as Wirral with their own EPR system, a health community developing an electronic health record as part of the NHS IA’s ERDIP programme, and several small pharmacies. Most interesting of all, however, was the response from the central software installation / training function of Co Op pharmacies, who support 130 retail pharmacies. They are willing to collaborate, have a sufficient number of sites to enable an RCT (randomising pharmacies) to be conducted, and even have data on the impact of the commercial system they support on the detection rate of ADRs.

Reasons for the low survey response rates may have included:
• The fact that the R&D programme does not currently exist
• The letters came from academia rather than part of the NHS
• There was no tangible incentive for suppliers or sites to respond or participate

A further survey could build on these techniques and materials to identify other relevant systems and sites interested in participating, if necessary.
5. Conclusions and recommendations

There are many opportunities for clinical information systems, defined as “A paper or computer-based tool which manages patient data, medical knowledge or other information to improve clinical decisions and actions”, to ameliorate clinical errors and improve patient safety. There are also many questions about such systems, ranging from how to match the system to the user requirements and barriers to change to the cost-effectiveness of paper and computer based systems. Extensive work on preventable adverse patient events in the USA suggests certain clinical sites, specialities and kinds of error on which any future patient safety programme should focus. However, it is possible to identify both paper and clinical information systems which are likely to ameliorate most kinds of error.

We conducted a survey to identify willing sites for such research in the UK but the overall results were disappointing. However, a number of hospital sites and the co-ordinating office for 130 Co Op pharmacies indicated their willingness to collaborate. Turning to methodological issues that will arise during such a research programme, we have identified several topics which probably need fuller discussion with potential bidders in a workshop before proposals are finalised. Finally, we suggest that it will be easier to identify potential bidders and sites once the scope of the R&D programme, areas of focus and specific questions to be studied are clarified. This report attempts to bring together material to support this clarification process, and draft material for the commissioning brief.

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Appendix 1 Sample letter and survey forms to suppliers

Knowledge Management Centre, University College London
29-30 Tavistock Square, London WC1H 9EZ
Email: wyatts@compuserve.com

The Managing Director
iSOFT
Bridgewater House
58-60 Whitworth Street
Manchester M1 6LT

Wednesday, 21 July 2004

Dear Sir or Madam,

Clinical information system study sites

We are currently working on behalf of Prof. Richard Lilford, NHS R&D, and the Chief Medical Officer on how to improve patient safety through the use of information systems. The aim is to identify sites willing to participate in future R&D where information systems are used which are suitable for study. In order to construct this list of sites, we are approaching you as a supplier of clinical information systems to enquire about your products and request details of suitable sites where your systems are used. As you will appreciate, any system demonstrated in this R&D programme to increase patient safety will be in great demand. Therefore, products included in our report may gain favourable publicity and market share – although we cannot guarantee this!

To help us, please read the attached list A of software categories on the yellow sheet, and determine which of your products are suitable for this R&D programme. We need to know about each eligible information system, highlighting features which could increase (or decrease) patient safety. Please fill out a separate copy of the attached white form for each eligible software product, and enclose any relevant brochures with your reply.

Finally, we need to identify sites where there is (or soon will be) an information system which can impact patient safety, e.g. by drawing attention to adverse drug interactions or recalling patients due for revaccination. Please examine the attached eligibility criteria, list B on the yellow sheet, decide which five of your current or prospective clients would be most suitable for this project, and record their contact details on the form. This will enable us to contact them to assess their eligibility and willingness to co-operate with R&D.

We would be very grateful for your reply, by 15th of August if at all possible.

Thank you very much for your help.

Yours sincerely,

David Wyatt
Knowledge Management Centre
NHS Patient Safety and Software R&D Project: Software Information Form

Your name and name of software supplier:

Website URL: ________________________________

Name of software package: ____________________________

Category number: (see list A on yellow sheet)

If there is a separate website for the software package, please state its URL here:

__________________________

Target users and setting for software package: (please tick all that apply)

<table>
<thead>
<tr>
<th>Users</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>GP</td>
<td>GP surgery</td>
</tr>
<tr>
<td>Nurse</td>
<td>Outpatient department</td>
</tr>
<tr>
<td>Hospital specialist – speciality:</td>
<td>Inpatient ward</td>
</tr>
<tr>
<td>Junior hospital doctor</td>
<td>Community pharmacy</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>Other:</td>
</tr>
<tr>
<td>Patient</td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
</tr>
</tbody>
</table>

Ways in which software might reduce risk of adverse patient events:

1.
2.
3.
Comments:

Reported incidents in which the software increased risk to patients e.g. when used or installed incorrectly:

1.
2.
3.
Comments:

Names and addresses of five most suitable sites with system guardian for us to contact: (see eligibility criteria, list B on yellow sheet)

1.
2.
3.
4.
5.

Please return this by 15/8/01 to: David Wyatt, Knowledge Management Centre, University College London, 29-30 Tavistock Square, London WC1H 9EZ
List B: Criteria for Eligible Sites

**Necessary criteria – each site must pass all of these**

6. Located in the UK
7. Patient care activity on site or patients as clients (e.g. call centre)
8. One or more eligible information systems (see list A)
9. Part of the NHS, or a contractor to the NHS (e.g. High Street pharmacy, private hospital…)
10. “Sizeable” caseload in which software used – actual numbers required will depend on frequency of adverse events in that population (the rarer the adverse event, the more clinical contacts needed per month). As a rough guide, a minimum of 50 clinical contacts per month is needed
11. If a study is planned within a single large health organisation, there needs to be a sufficient number of units (doctors, wards etc.) to randomise
12. IT literate workforce who are willing to use clinical systems
13. Good IT training and support on site, or within an hour
14. Good information infrastructure – local area network, point of care workstations, patient master index

**Preferred – as many as possible of these**

15. System owner / guardian willing or even keen to collaborate with an R & D project
16. Accessible to researchers – geography / transport
17. Single patient identifier, use of clinical coding system; internet connectivity
18. Clinical audit capacity
19. Experience in R & D – e.g. previous R&D project holder / collaborator
20. Good departmental information systems to capture clinical practice & near miss events in e.g. laboratory, pharmacy
21. Incident reporting system which is used
22. Clinical staff turnover 20-30%+ per year, to allow staggered / alternating study designs
23. Medium to high adverse or near miss event rates
24. Typical NHS organisation in terms of case mix, staff ratios etc. – to ensure that study findings are generalisable to other settings
25. Workload not excessive, to ensure that study protocol can be followed
Appendix 2 Sample site letter and survey forms for clinical sites

Knowledge Management Centre, University College London
29-30 Tavistock Square, London WC1H 9EZ
Email: wyatts@compuserve.com

Mr Paul Charney Head of Informatics
Wirral Hospitals NHS Trust

Wednesday, 21 July 2004

Dear Mr Charney,

Sites for studying clinical information systems and patient safety

We are currently working on behalf of Prof. Richard Lilford, NHS R&D, and the Chief Medical Officer to identify sites using information systems that may impact patient safety and who may be willing to participate in future R&D. Following a recommendation from the Information Authority we are approaching you as the guardian of a clinical information system to enquire whether you may be willing in principle to collaborate with a future R&D-funded project. The incentive is that you may be eligible for support for the R&D taking place in your organisation, and you are likely to be able to use study results in promoting your system and organisation.

To help us, please examine the site eligibility criteria below, checking that you are indeed suitable for a potential R&D project, and record your details on the site information form. This will enable us to communicate your eligibility and willingness in principle to collaborate with NHS R&D.

1. Patient care activity on-site, or patients as clients (e.g. NHS Direct call centre)
2. One or more eligible information systems (see list on yellow sheet)
3. Part of the NHS, or a contractor to the NHS (e.g. High Street pharmacy, private hospital…)
4. Sizeable caseload in which the system is used. The actual numbers required will depend on frequency of adverse events in your population – the rarer the adverse event, the more clinical contacts needed in any study. As a rough guide, a minimum of 50 clinical contacts per week is needed
5. IT literate workforce who are willing to use clinical systems

Second, please read the list of system categories on the attached yellow sheet, and determine whether your system is suitable for this R&D programme. We would like to hear about each eligible information system, highlighting features which increase (or decrease) patient safety. Please fill out a separate copy of the system information form for each eligible system that you are responsible for.

We would be very grateful for your reply by 14th September if at all possible. I attach an address label for the return envelope.

Thank you very much for your help.

Yours sincerely,

David Wyatt, Research Assistant
UCL Knowledge Management Centre
NHS Patient Safety and Software R&D Project: Site Information Form

Please fill out this form and a separate copy of the system information form for each eligible system that you are responsible for, and staple all pages together. Thank you.

Your name and role: ____________________________
Organisation: __________________________________
Address: ______________________________________

Phone number: ________________________________
Email address: ________________________________

Would you be willing in principle to take part in an NHS R&D project next year?
Yes † Maybe † No

If you answer Yes, you will not be committed to taking part in R&D at a later date.
What concerns might you have about participation? (e.g. privacy, disruption to work)
_____________________________________________________________________________________

If you are unwilling to take part in R&D, you need not fill in the remainder of the questionnaire, but please return it all the same.

What is your approximate clinical staff turnover per year? ________% of total

Briefly describe the IT training and support you have on site:
_____________________________________________________________________________________

What information infrastructure do you have on site?
• Patient master index: covering inpatients covering outpatients
• Single patient identifier across: labs radiology theatres other:_____
• Clinical coding systems: _______________________________________
• Point of care workstations – number: _____________________________
• Networks: Local area network Intranet Internet connection NHSnet connection
• Other: ________________________________________________________

What departmental information systems are there?
• Laboratory: ______________________________________________________
• Pharmacy: _____________________________________________________
• Radiology: ____________________________________________________
• Theatre: _______________________________________________________ 
• Clinical audit: _________________________________________________
• Other: ________________________________________________________

Is there an adverse clinical incident reporting system? Yes No
If yes, how many incidents were reported last month? ____________

Has your organisation been involved in any externally funded R&D projects in the last 2 years?
Yes † No † Don’t know
If yes, please tick the funding source(s):
NHS R&D Regional Responsive Funding NHS R&D National Programme
NHS IA Funding MRC Wellcome Other: __________________________
NHS Patient Safety and Software R&D Project: System Information Form

Please copy this form as necessary, fill out a separate copy for each eligible system that you are responsible for, and afterwards staple all pages together with the Site Information Form. Thank you.

Your name and organisation: __________________________________________________________

Name of system: ________________________________________________________________

Category code(s): (see list on yellow sheet) ____________________________________________

Other category, if not mentioned in list: ____________________________________________

What is the approximate number of local users of the system? (please write numbers against all that apply)

- GPs: ____________________
- Nurses: ____________________
- Hospital specialists: _______________ speciality: ____________________
- Junior hospital doctors: ________
- Pharmacists: ________________
- Patients: _________________
- Other: _______________ please state: ____________________________________________

In what setting is the system used? (please tick all that apply)

- GP surgery
- Outpatient department
- Inpatient ward
- Community pharmacy
- Other – please state: __________________________________________________________

In how many cases (approximately) is the system used per week? ______________

Approximately how many units with an IT literate workforce who are prepared to use this system could be included in a future R&D project?

- Clinical teams: ________________
- Wards: ________________
- Doctors: ________________
- Nurses: ________________
- Other: _______________ please state: ____________________________________________

Which adverse patient events do you believe the system avoids, and approximately how often? (please continue on a separate sheet if necessary)

<table>
<thead>
<tr>
<th>Type of adverse event or near miss</th>
<th>Rate (% of patients) without the system</th>
<th>Rate (% of patients) with the system</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Are you aware of any incidents in which the system increased risk to patients, e.g. when used or installed incorrectly? Please describe:

________________________________________________________________________________________

Thank you very much for completing this questionnaire. Please staple all pages together and return it by 14/9/01 to: David Wyatt, Knowledge Management Centre, University College London, 29-30 Tavistock Square, London WC1H 9EZ
Appendix 3: Form to record significant system dimensions

Broad category of system
- Paper based: checklist / sticker / rubber stamp / label / other:
- Computer based: patient record / reminder / alert (inc. message to pager / email / SMS etc.) / complex decision support / other:
- Other: verbal / 2\textsuperscript{nd} person checks work of 1\textsuperscript{st} / other:

Targeted users:
- Doctors: primary / secondary / tertiary / other:
- Nurses: practice nurse / A&E / ward / ICU / outpatient / NHSDirect call centre / district nurse / midwife / other:
- Pharmacists: hospital / retail / drug information pharmacist / other:
- Laboratory staff
- Other clinical professions: physiotherapists / radiographers / occupational therapists / dieticians / speech therapists / other:
- Member of the public: patient / carer / other:
- Other – specify:

Scenario of use
- Active patient care: disease / condition:
- Preventive care: condition / procedure:
- Reflective practice: clinical audit / quality improvement / other:
- Policy making: policy analysis / formulation / communication
- Other – specify:

NB. Information systems designed purely for educational or research use are outside the scope of this programme

Type of decision or action targeted
- Drug prescribing: dosage and route errors / interactions / allergy / polypharmacy / repeat prescribing / other:
- Drug dispensing and administration: bar coded labels on syringes / blood for transfusion / other:
- Carrying out surgical and other procedures: which?
- Monitoring and investigation: patients with acute conditions / chronic illness / those on hazardous therapies / responding to abnormal test results / other:
- Communication: communicating changes in policy / implementing such changes / transcribing orders or test results / communicating with patients / other:
- Triage and diagnosis: primary care / community care / emergency care / secondary care / other:
- Referral of patients for investigation / treatment / monitoring / other:
- Preventive care: case finding / recall systems / other:
- Other – specify:

Type of interaction
- Passive: browsing patient record / browsing material on web site / other:
- Active: giving a prediction / alert or reminder / complex decision support / other:
- Simulation: exploring alternative outcomes to guide choice of therapy / other:
Appendix 4 Taxonomy of information systems with potential to reduce clinical errors

High Street Pharmacy software
A1 Drug interactions
A2 Personal drug history system
A3 Electronic prescribing pilots
A4 Electronic textbook / diagnostic aid for pharmacists

GP software
B1 GP clinical record systems
B2 Electronic health records (EHR)
B3 Prescribing system – drug selection, dose advice, drug interactions etc.
B4 PRODIGY-compliant prescribing guideline systems
B5 Repeat prescribing systems
B6 Electronic prescribing pilots
B7 Booked admission pilots
B8 Patient recall systems – vaccination, elderly screening etc.
B9 Smart card record systems

Hospital/clinical systems
C1 Electronic patient records (EPR) levels 1 to 5
C2 ERDIP projects and software
C3 Laboratory information systems
C4 Order communication systems (OCS)
C5 Pharmacy information systems
C6 Prescribing systems
C7 Clinical applications on hand-holds / PDAs
C8 Patient appointment reminder systems
C9 Smart card record systems
C10 A&E systems
C11 Clinical data repository
C12 Alert or reminder systems
C13 Boiler plate text or template-based discharge summary systems (as opposed to simple word processors)

Other software
D1 NHS Direct decision support tool
D2 Childhood vaccination call/recall systems
D3 Cervical screening etc recall systems

Ineligible systems
• Hospital information support systems (HISS)
• Admission, discharge, transfer (ADT) systems
• Case note tracking systems
• Document imaging systems
• Supplies and CSSD systems
• Financial information systems
### Appendix 5: Types of unambiguous clinical error and low tech or high tech information systems which might prevent them

<table>
<thead>
<tr>
<th>Clinical errors</th>
<th>Information systems which might prevent the error</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category</strong></td>
<td><strong>Low tech and paper systems</strong></td>
</tr>
<tr>
<td>Drug prescribing</td>
<td></td>
</tr>
<tr>
<td><strong>Subcategory</strong></td>
<td><strong>Example</strong></td>
</tr>
<tr>
<td>Dose calculation error</td>
<td>Exceed single / daily dose; give adult dose to child; misplace decimal point</td>
</tr>
<tr>
<td>Drug-drug interaction</td>
<td>Recommending aspirin to patient taking regular warfarin Patient on warfarin takes aspirin they bought in supermarket</td>
</tr>
<tr>
<td>Allergy</td>
<td>Giving penicillin to a patient who is allergic to it</td>
</tr>
<tr>
<td>Wrong drug name</td>
<td>Prescribing azidothymidine instead of azathioprine</td>
</tr>
<tr>
<td>Polypharmacy</td>
<td>Prescribing one drug to overcome side effects of another</td>
</tr>
<tr>
<td>Repeat prescribing</td>
<td>Unduly prolonged course of antibiotics, omeprazole...</td>
</tr>
<tr>
<td><strong>Drug dispensing &amp; administration</strong></td>
<td></td>
</tr>
<tr>
<td>Right drug, wrong route</td>
<td>Drug (eg. vincristine) given by inappropriate route / dose combination</td>
</tr>
<tr>
<td>Wrong drug dispensed or administered</td>
<td>Confusion over drug names, abbreviations (AZT), similar labels on drug ampoules...</td>
</tr>
<tr>
<td><strong>Carrying out procedures</strong></td>
<td></td>
</tr>
<tr>
<td>Incorrect procedure, or incorrect patient</td>
<td>Transfusing patient with unit intended for someone else, operating on the wrong limb</td>
</tr>
<tr>
<td><strong>Patient monitoring</strong></td>
<td></td>
</tr>
<tr>
<td>Monitoring hazardous therapies</td>
<td>INR for patients on warfarin, blood sugar for those on insulin, liver function for others</td>
</tr>
<tr>
<td>Therapies</td>
<td>Function for those on cyclophosphamide; FBC for those on chemotherapy</td>
</tr>
<tr>
<td>---</td>
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</tr>
<tr>
<td>• Junior doctor handbook with checklists for hazardous therapies</td>
<td></td>
</tr>
<tr>
<td>Responding to abnormal test results</td>
<td>Elevated blood sugar in undiagnosed diabetic; ECG which shows MI</td>
</tr>
<tr>
<td>• Lab staff call doctor concerned about life threatening abnormalities</td>
<td></td>
</tr>
<tr>
<td>• Lab report highlights abnormal values</td>
<td></td>
</tr>
<tr>
<td>• Automatic interpreter for lab tests, lung function tests, ECGs etc.</td>
<td></td>
</tr>
<tr>
<td>• Automated email, pager or SMS message about serious abnormalities</td>
<td></td>
</tr>
<tr>
<td>Monitoring patients in acute settings</td>
<td>Obstetric accidents; anaesthetic accidents; disconnected ventilators in ICU</td>
</tr>
<tr>
<td>• Algorithm for interpreting fetal HR traces on delivery room wall</td>
<td></td>
</tr>
<tr>
<td>• Automated interpretation of discrete physiological signals eg. from cardiotochograph, ECG rhythm, capnograph, oximeter, bedside monitor</td>
<td></td>
</tr>
<tr>
<td>• ICU patient data management system</td>
<td></td>
</tr>
<tr>
<td>• Fusion of signals from several sources</td>
<td></td>
</tr>
<tr>
<td>Monitoring patients in chronic illness settings</td>
<td>Maintaining patients with asthma, diabetes, epilepsy, angina, chronic renal failure, psychotic illness, on anticoagulants…</td>
</tr>
<tr>
<td>• Condition-specific paper checklists, eg. &quot;Record asthma therapy, symptoms, days off work, PEFR every visit:&quot;</td>
<td></td>
</tr>
<tr>
<td>• Paper decision tree to classify disease stage, identify patients at high risk</td>
<td></td>
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<tr>
<td>• Data collection, charting, interpretation &amp; advice system eg for warfarin dose</td>
<td></td>
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<tr>
<td>• System to classify disease stage, predict risk of relapse or complications</td>
<td></td>
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<tr>
<td>Communication</td>
<td>Drug with serious adverse effect, novel risk with ventilator</td>
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<tr>
<td>• (Telephone calls – too labour intensive)</td>
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<tr>
<td>• Email alert pointing to document on intranet</td>
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<tr>
<td>Implementing changes in policy</td>
<td>Difficulty identifying patients receiving a drug that has been withdrawn</td>
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<tr>
<td>• GP repeat prescribing system with report generator, mail merge letters</td>
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<tr>
<td>• Retail pharmacy system (if patient ID known)</td>
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<tr>
<td>Transcribing orders, results</td>
<td>Errors writing down patient ID, lab results, drug dose after phone call</td>
</tr>
<tr>
<td>• Email or structured messages to transfer lab results, prescriptions etc</td>
<td></td>
</tr>
<tr>
<td>Communicating with patients</td>
<td>Checking that patient tolerated new drug, attended for test</td>
</tr>
<tr>
<td>• Automated email reminder to nurse to call patient after 1 week</td>
<td></td>
</tr>
<tr>
<td>Diagnosis, triage</td>
<td>Missing serious treatable illness in NHSDirect, GP, out of hours, walk in, A&amp;E settings</td>
</tr>
<tr>
<td>• Information leaflets for patients / carers on recognising serious acute illness</td>
<td></td>
</tr>
<tr>
<td>• Diagnostic / triage systems</td>
<td></td>
</tr>
<tr>
<td>• Annotated library of normal and abnormal images or ECGs on intranet</td>
<td></td>
</tr>
<tr>
<td>• Telemedicine links from minor injuries units to A&amp;E / radiologists at home</td>
<td></td>
</tr>
<tr>
<td>Referral</td>
<td>Delayed referral</td>
</tr>
<tr>
<td>• GP reminders based on referral guidelines</td>
<td></td>
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<tr>
<td>Preventive care</td>
<td>Failure to perform necessary preventive actions</td>
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</tbody>
</table>

Prescribing prophylactic antibiotic, vaccination; ordering mammogram, cervical smear

Case finding systems in GP, community

Reminders based on procedure, patient age, sex, coded preventive care history
## Appendix 6: Sites willing to participate in the proposed R&D programme

<table>
<thead>
<tr>
<th>Name</th>
<th>Organisation</th>
<th>Category of site</th>
<th>Type of system, codes</th>
<th>Incident system; rate pa.</th>
<th>Work-stations / users</th>
<th>Pts per week</th>
<th>Concerns</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paul Charnley</td>
<td>Wirral NHS Trust</td>
<td>Hospital</td>
<td>EPR level 3-4 (C1, C3-C13)</td>
<td>Yes / 4000</td>
<td>1500 / 3500 (120 cons, 600 juniors, 100 pharms, 60 GPs, 2500 nurse)</td>
<td>10000 per week</td>
<td>Confidentiality, Disruption. IPR.</td>
<td>NHSIA funded</td>
</tr>
<tr>
<td>John Thornbury</td>
<td>Walsall HA ERDIP</td>
<td>Health community</td>
<td>EHR, EPR (C1, C2, C3, C5, C6, C8, C10, C11)</td>
<td>Yes / ?</td>
<td>2000 / 830 (60 cons, 100 juniors, 10 pharms, 60 GPs, 300 nurse)</td>
<td>40000 per week</td>
<td>Resources</td>
<td>NHSIA funded ERDIP</td>
</tr>
<tr>
<td>Nick Gaunt</td>
<td>Plymouth NHS Trust - Derriford Hosp</td>
<td>Hospital</td>
<td>Clin. data screens for cancer, cardiology as part of PAS (C11)</td>
<td>Yes / 1440</td>
<td>? / 200 (50 cons, 30 juniors, 120 nurses)</td>
<td>120 per week</td>
<td>None</td>
<td>Prev. ext. R&amp;D funding</td>
</tr>
<tr>
<td>Lindsay Fairbrother</td>
<td>Co Op pharmacy systems unit, Congleton</td>
<td></td>
<td>Eclipse PMR, point of sale system (A1, A2, A3)</td>
<td>No</td>
<td>? / 130 pharmacists</td>
<td>1000 per pharmacy per week</td>
<td>Workload</td>
<td>Error detection rates: drug interaction 2% (5% with system); under / overdose 2% - no change; dispensing errors 0.2% - no change</td>
</tr>
<tr>
<td>Charles Caller</td>
<td>Denchem pharmacy, Denton, M34</td>
<td>Retail pharmacy</td>
<td>Park systems PMR (A1, A2)</td>
<td>No</td>
<td>? / 3 pharmacists</td>
<td>?</td>
<td>-</td>
<td>“I've never been able to quantify ADR rates” – implies would like to</td>
</tr>
<tr>
<td>Adrian Giles</td>
<td>Kitson’s pharmacy, Worcester</td>
<td>Retail pharmacy</td>
<td>Eclipse PMR (A1, A2)</td>
<td>?</td>
<td>? / 4 (2 pharms, 2 dispensing technicians)</td>
<td>400 per week</td>
<td>?</td>
<td>To advise on travel-related risks</td>
</tr>
<tr>
<td>Adrian Giles</td>
<td>Kitson’s pharmacy, Worcester</td>
<td>Retail pharmacy</td>
<td>Traveller (A4)</td>
<td>?</td>
<td>? / 1 pharm</td>
<td>2 per week</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>