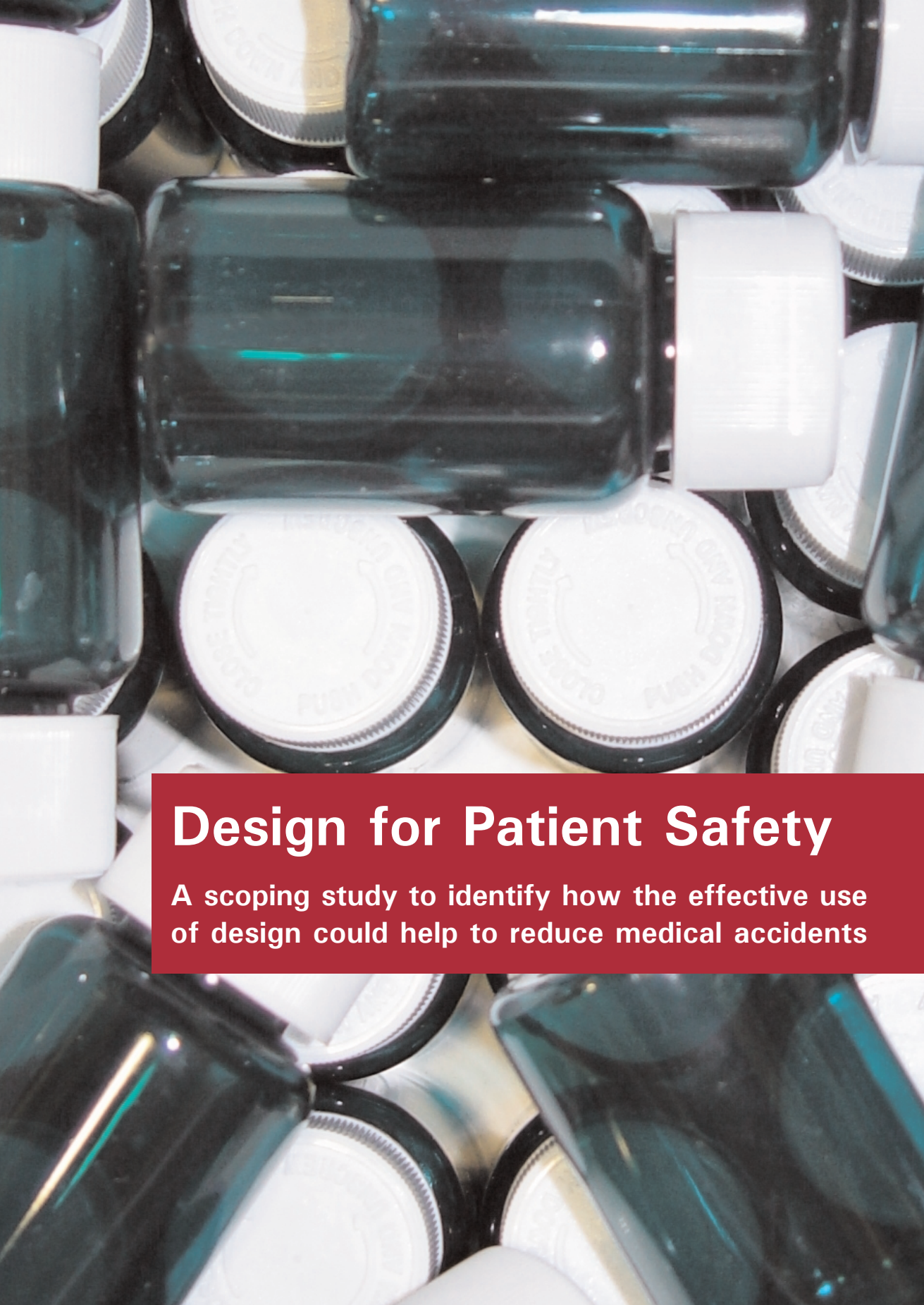

Design for Patient Safety

A scoping study to identify how the effective use of design could help to reduce medical accidents

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A scoping study to identify how the effective use of design could help to reduce medical accidents

A joint report from:

The Robens Centre for Health Ergonomics
at the University of Surrey;

The Helen Hamlyn Research Centre
at the Royal College of Art; and

The Cambridge Engineering Design Centre
at the University of Cambridge.

February 2004

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Executive summary

Why is design a solution to the challenge of patient safety?

The health service is a highly pressured and complex system, where the potential for error and accidents is ever present. Ensuring the safety of people who come into contact with health services is one of the most important challenges facing healthcare today, not just in the UK but worldwide. Medical error in hospitals is now believed to be the seventh most common cause of death in America and perhaps as much as a half of these adverse events are judged to be avoidable (Kohn *et al.*, 1999). In the UK, it has been estimated that around 850,000 medical errors occur every year – equating to some 10% of hospital admissions, the cost of which is suffering for the patients, families & NHS staff involved and £2billion in additional hospital stays alone (DoH, 2001a).

Design is a structured process for identifying problems and developing and evaluating user-focussed solutions. It has been successfully used to transform products, services, systems and even entire organisations. Based on the extensive experience of the aviation, military and nuclear industries, it is clear that effective design thinking can facilitate the delivery of products, services, processes and environments that are intuitive, simple to understand, simple to use, convenient, comfortable and consequently less likely to lead to error and accidents. Confusing, complex and unwieldy designs, which are all too often present in healthcare, are at best less effective than they could be. At worst, they are potentially dangerous to medical staff or the patient - or both. The contribution of design to improving safety in the context of medical systems is an area which remains relatively unexplored.

Government recognition of the role design can play

The importance of effective design thinking in healthcare has now been picked up both by experts and the government. Recent studies, expert panels and government statements have recognised that just as poor design has in the past precipitated accidents, the effective use of design has the potential to deliver a significant reduction in the risk of medical error.

In *Learning from Bristol* (the "Kennedy Report"), the author Professor Kennedy states that although there is a considerable pool of knowledge amongst the various medical agencies and professionals on the effect of design-led solutions on improving safety, it is "well recognised that the adoption of an approach to solving or addressing specific hazards by designing equipment differently is under-explored."[1]

The government has also recognised the key role that design can play. It has recommended in its patient safety strategy, *Building a safer NHS for patients* (DoH, 2001a), that early targeted action should be undertaken to identify opportunities for improved patient safety through the more effective use of design.

The design for patient safety initiative

The Department of Health and the Design Council have jointly commissioned this scoping study to deliver ideas and practical recommendations for a design approach to reduce the risk of medical error and improve patient safety across the National Health Service (NHS).

The study was undertaken over a relatively short period, between March and July 2002, and

[1] http://www.bristol-inquiry.org.uk/final_report/the_report.pdf

explored the potential for improved design interventions in a whole system context focusing on medication error. The subject was approached from three perspectives: medical equipment, the medication process and the care environment. The study has further sought to identify indicative priority problems that are amenable to design solutions in each of the three areas.

The research was undertaken by the Engineering Design Centre at the University of Cambridge, the Robens Institute for Health Ergonomics at the University of Surrey and the Helen Hamlyn Research Centre at the Royal College of Art. To investigate medication error from the three perspectives of medical equipment, medication delivery and home care, the research team employed diverse methods to gather evidence from literature, key stakeholders and experts from within healthcare and other safety-critical industries. Importantly, the team has responded to recommendation 120 of the *Learning from Bristol* report by bringing together managers in the NHS, representatives of the pharmaceutical companies and manufacturers of medical equipment, members of the healthcare professions and the public.

Despite the multiplicity of activities and methodologies employed, a very consistent picture emerged from the research. A complex system of interactions was revealed: between diverse stakeholder groups, the environments in which they work, the care and medication they deliver and the associated information, equipment and packaging, patient and drug records and other information used to track the individual patient and their treatment and medication through the system.

This convergence pointed to the need to better understand the healthcare system and its users, as the context into which specific design solutions must be delivered. Without that broader understanding there can be no certainty that any single design will contribute to reducing medical error and the consequential cost thereof.

The report's key issues and often challenging messages for the NHS, along with its conclusions and recommendations, are based on the research findings interpreted in light of the extensive experience of the research team. These are presented within the body of the report, and are supported by a series of appendices that document the research and stand as evidence in support of the report itself.

Patient safety and the NHS: the scale of the design challenge

During the course of this scoping study the research team came across little evidence of understanding within the NHS of the value and significance of design – especially in relation to managing and implementing design improvements to improve patient safety. The team found cause to question not simply the design of medical devices, products, packaging and information, but the way the NHS as a whole uses, or rather fails to use, design in an effective way, and also fails to understand what design thinking can bring to an organisation.

Furthermore, what this study has confirmed, by taking a number of snapshots across the healthcare services, is that successful design interventions are unlikely to be made without the introduction of a systems approach to design and risk management. The 'big picture' understanding is not present and the highest priority must be attached to remedying this without delay.

In other words, the NHS is seriously out of step with modern thinking and practice with regard to designing for safety. We do not doubt that this issue is by and large shared by other health services around the world. However, there is also little question that a direct consequence of the past failure to put in place an effective design and risk management system is a significant incidence of avoidable risk, error and accidents.

There is much scope for transferring the necessary knowledge and practice from other safety-critical industries. Within the nuclear, aviation and defence sectors, design and design management, and risk assessment and management, are well established and delivered by highly competent specialist professionals capable of taking a 'systems approach' to these subjects. However, it is crucially important that whatever solutions are put in place go beyond short term quick fixes, to deliver consistent and sustainable gains in patient safety in ways that are well established and proven in other high-risk industries. There can be no certainty that specific design solutions will contribute to patient safety, without a sound understanding – from a design perspective – of the healthcare services as a complex system of interacting organisations, professions, care environments, procedures and tasks, and of the way risk arises within that system.

The model: a systems-based user-centred approach to healthcare design

Each year industry invests significant sums of money in design. However, there is currently no mechanism for directing that investment towards patient safety, nor a mechanism for directing research council funding towards the same goal. The research team believe there is a real opportunity to create a virtuous circle whereby a better understanding of the design implications of patient safety can shape purchasing decisions and specifications in ways that will focus industry investment on delivering patient safety. Other high-risk industries have succeeded in sharing responsibility for safety aspects with their suppliers, and this could prove similarly effective and cost-efficient in delivering long-term advances in patient safety.

To be successful any such initiative must be underpinned by a thorough understanding of the complex system of interactions that take place within the NHS. The recommendations of this report are therefore presented within the framework of a design-centred approach, a strategy and a model for managing risk and design at all levels of the healthcare system. The aim is to understand patient and carer-related issues in the context of complex interactions between the many stakeholders and the equipment, medications, environments and other associated products and services that constitute the NHS. This model consists of an interrelated set of key issues to be addressed and goals to be achieved, which is very much in accord with the 'factors that influence the delivery of healthcare' as set out in *An Organisation with a Memory*: 'institutional context; organisational and management factors; work environment; team factors; individual (staff) factors; and task factors'. A list of appropriate actions is also put forward. In the main, these actions require further research directed at plugging significant knowledge gaps, and it is out of these further studies, and the evidence they provide, that specific action plans will emerge. However, given the desire to act speedily that is reflected in the Department of Health response to the Kennedy Report, some recommended actions can be rapidly initiated without compromising the main thrust of this report, which is that ***action without understanding will not address the issue of patient safety.***

Conclusions

It was intended that this scoping study be the first stage of a wider programme of work that aims to identify and demonstrate the potential of a design led approach to preventing medical accidents and to identify the most effective ways of integrating this approach into the everyday working practices and processes of the NHS and across the healthcare industry.

The study has concluded that:

- The NHS is seriously out of step with modern thinking and practice with regard to design. A direct consequence of this has been a significant incidence of avoidable risk and error.
- There are no quick fixes. On the contrary, it is of the utmost importance that single design initiatives are seen in the context of the 'big picture' of the healthcare system as a whole, and the way it impacts on patient safety and risk management.
- The 'big picture' understanding is not present and the highest priority must attach to remedying this without delay.
- On the basis of our investigations there is cause to question, not simply the design of medical devices, products, packaging and information, but the way the NHS as a whole uses (or rather fails to use) design in an effective way, and also fails to understand what design thinking can bring to an organisation.
- There is little evidence of any understanding or practice within the NHS equivalent to those which are commonplace in other safety-critical industries and leading commercial organisations.
- There is insufficient grasp of the value and significance of design, or of how to manage or implement design improvements.
- Understanding is lacking of the value of customer experience, human factors and user-friendliness to the NHS brand, as is a strategy for developing and managing it in the way that successful modern organisations and enterprises do.

Recommendations

The model on the following page serves as a map for the recommendations that we are proposing. They emphasise the systems approach to patient safety and, in places, echo the findings of other recent reports on related issues (e.g. *An Organisation with a Memory* (DoH, 2000; Bristol Royal Infirmary Inquiry, http://www.bristol-inquiry.org.uk)).

In setting out these recommendations, we are mindful of the objectives of this scoping study and of the necessarily limited time and resources that were available for establishing a full body of evidence to support each one. That said, the main body of the report reflects the breadth of methods used, the range of views and information sought and, above all, the consistency of the messages that emerged.

The recommendations respond to key issues we have identified. They are not principally concerned with the design process itself (within the inner box) but with developing knowledge, systems and processes that will provide the foundations for effective design decision making across the health service and industry. In section 4 we set these out in more detail together with possible action points and early projects to achieve the recommended changes. However, in order to develop viable action plans, we believe more extensive consultation is required (with all relevant stakeholders).

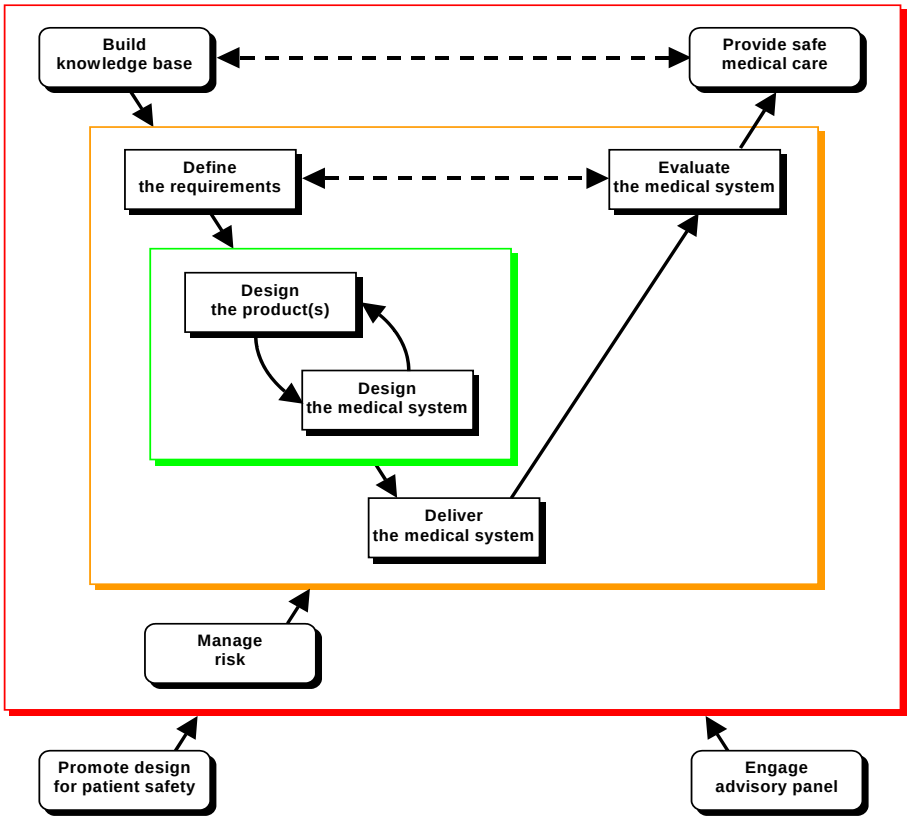


Figure 1: A systems-based user-centred approach to healthcare design

Key to figure:

- **Build knowledge base**: e.g. understand NHS: contexts; organisational components; specific tasks; user needs; information management; developing best practice.
- **Define the requirements**: e.g. purchasing and usability criteria/guidance; involving stakeholders; NHS agencies' synergy.
- **Design the product(s)**: e.g. utilising innovative design, systems engineering and ergonomics.
- **Design the medical system**: e.g. utilising systems engineering, ergonomics to consider the complete problem.
- **Deliver the medical system**: e.g. implementation, process of introduction and management of change.
- **Evaluate the medical system**: e.g. monitoring, auditing, verification, validation.
- **Manage risk**: e.g. prevention, hazard and risk identification, development of standards, safe practices and policies, European Directives.
- **Promote design for patient safety**: e.g. across the NHS; to industry.
- **Engage advisory panel**: e.g. through stakeholders in industry, design and procurement.
- **Provide safe medical care**: The result.

We are aware of a number of initiatives from the Department of Health for which the findings of this report would be of particular relevance. For example, the activities of the National Patient Safety Agency and the changes to the Medical Devices Agency and Medicines Control Agency may provide opportunities to reflect the systems-based user-centred approach to design that has been advocated in this report. We would urge that these initiatives now be reviewed so as to examine how this approach could be effectively integrated into their future work programmes.

The recommendations are:

A: Build an effective knowledge base to underpin better design decision-making.

- Develop a better understanding of:
    - healthcare contexts at each specific point where the system interacts with the patient, so as to inform the design process.
    - how the interactions both within and between healthcare organisations impact on patient safety.
    - what is actually going on in healthcare situations at the level where individuals undertake specific tasks.
    - the user requirements, from which safer designs can be achieved that function as required for all users and across the range of situations in which they will be used.
- Effectively manage knowledge and information, with regard to patient notes
- Ensure the provision of timely and appropriate information regarding use, including monitoring and maintenance, of equipment in primary/ secondary care and the home environment.
- Capture best practice examples of designing for patient safety from around the world, which can be used to inspire change in behaviour within industry and across the NHS.

B: Define effective design requirements for the NHS.

- Enable the design of safe products, packaging, information and services through the setting of more effective design requirements by the NHS.
- Better understand user needs and capacities by actively involving stakeholders in a more systematic way at all stages of the design process, from problem/requirements capture to post-implementation evaluation
- Ensure the effective collaboration of the appropriate agencies in design and risk management so as to improve the delivery of safe products and systems through a seamless representation of drug, device and organisational interests.

C: Effectively evaluate healthcare services and products within a system context with regard to patient safety.

D: Put in place strategies for risk identification, control and management that will deliver effective procedures and protocols for identifying, capturing and reporting risks.

E: Communicate the importance of design for patient safety across the healthcare industry.

F: Establish an advisory panel to oversee the delivery of the design led approach to patient safety.

Early projects

We have also outlined at the end of each recommendation section a series of 'early projects'. These should be seen in tandem with this research work plan, and are intended to provide exemplars of studies that need to be undertaken but that do not compromise the priority for a systems approach. They have been selected to be conflict-free for all stakeholder groups and thus something the health service can unite around. The 'early projects' suggested include:

1. Tackling non-compliance in the community (especially for those on complex drug regimes) through a collaboration with a major pharmacy chain.
2. Developing design proposals for a standard but personalised medication dispenser.
3. Implementation of a single patient ID along with other aspects of an integrated information system.
4. Development of usability criteria for medical device procurement.
5. Developing and designing pharmaceutical packaging and labelling that reflect the needs of all users in the system.
6. Risk assessment of patient safety during defined treatment/care pathways to prioritise a programme of risk containment and design improvements.
7. Identification and publicising of best international design exemplars.

The recommendations, action plans and 'early projects' enable a start to be made in addressing these design issues and patient safety. In order to execute these recommendations the Department of Health will have to acquire expertise in design management, with specific reference to systems design, and in risk assessment and management. To support that work the research team has gone to considerable lengths to provide in the annexes to this report detailed documentation of the research undertaken as a ready resource for those tasked with implementation.

Acknowledgements

The authors would like to thank all the stakeholders since this is as much their report as ours. We hope we have reflected their views and concerns in an objective and sympathetic manner.

Particular thanks are due to those who gave of their time for interviews; the primary/secondary healthcare deliverers, purchasing/manufacturing/pharmaceutical stakeholders, designers and patients who participated so enthusiastically in workshops; the midwives, accident/emergency personnel and cancer/palliative carers who contributed to the focus groups; and the safety critical industry experts who gave us much insight in to how things could be.

Finally, thanks are due to those senior health service and agency personnel who kept us on track, and to the Design Council for their active encouragement and involvement in the generation of this report.

Note: The report and the work it describes were jointly funded by the Department of Health and the Design Council. The contents of the report, including any opinions and/or conclusions reached, are those of the authors alone.

1. Background

1.1 Introduction

The Design Council, which commissioned this study on behalf of the Department of Health, has worked over the years to promote design in industry as a route to innovation, a way to add value, a key communication resource, a way of understanding and engaging with consumers, and as being central to profitability and competitiveness. Design and the effective management of design are recognised as key business resources.

The most forward-looking companies now see the customer experience as fundamentally important to the future development of their brands. The best companies also recognise the importance of and focus down on the performance of human factors and usability issues and in doing so deliver better products and services leading to benefits for their brand. They understand that usability and user-friendliness are essential to the success of products and services and ultimately to the success of the company itself. Major retailers work ceaselessly to develop quality relationships with their customers in order to understand their needs and aspirations, and to respond to them rapidly and positively. They see no conflict between such goals and cost efficiency. For example, Jeremy Lindley, when in charge of the design of retail environments at Tesco, worked constantly to make consumer-friendly improvements that benefited older and disabled customers and reduced costs. Similarly, many safety critical organisations have developed careful specifications based on the needs of their employees and used these as a basis on which to commission new design of, for example, work equipment, new technology and protective clothing.

The potential for introducing similar practical and systematic approaches to the use of design, and importantly design management within the healthcare services is considerable, as is the potential for focusing such developments on patient safety.

The health service is a highly pressured complex system where the potential for error and accidents is ever present. Effective design thinking should result in the development of products, services, processes and environments that are intuitive, simple to understand, simple to use, convenient, comfortable and consequently less likely to lead to accidental misuse, error and accidents. Confusing, complex and unwieldy designs are at best less effective than they could be, and at worst are potentially dangerous to medical staff or patients – or both.

The importance of effective design thinking in healthcare has been picked up both by experts and the government. Recent studies, expert panels and government statements have recognised that just as poor design has in the past precipitated accidents, the effective use of design has the potential to deliver a significant reduction in the risk of medical error.

This was recognised specifically in the *Learning from Bristol*[2] report (the *Kennedy Report*) (Chapter 26, Recommendation 120), which reads: "The proposed National Patient Safety Agency should, as a matter of urgency, bring together managers in the NHS, representatives of the pharmaceutical companies and manufacturers of medical equipment, members of the healthcare professions and the public, to seek to apply approaches based on engineering and design so as to reduce (and eliminate to the extent possible) the incidence of sentinel events."

In particular Kennedy was "impressed by the extensive experience of anaesthetists in applying a 'systems approach' to safety. The work of the Royal College of Anaesthetists and

[2] http://www.bristol-inquiry.org.uk/final_report/the_report.pdf

the Association of Anaesthetists of Great Britain and Ireland deserves to be commended. Through their emphasis on protocols and guidelines, and in their influence on the design of equipment, they have helped to make remarkable advances in the safety of anaesthesia over the past 30 years."

The Government is committed to addressing the challenge of medical accidents and is particularly keen to explore how the effective use of design could help to improve patient safety. The Department of Health's response (DoH, 2002) to *Learning from Bristol* set out a plan of action, which included under item 20, p. 8, "to work with the Design Council to identify opportunities for design solutions to safety problems". This represents a change of emphasis which, perhaps in responding to the urgency implied in the Kennedy Report, appears to assume that specific design interventions could be rapidly identified and initiated and so lead to notable and early advances in patient safety. That assumption has been subjected to investigation in this report.

In order to implement its proposed action plan, the Department of Health asked the Design Council to commission a scoping study to explore this issue further. The focus of the study was to be environmental issues, equipment design and medication prescription delivery and compliance as they relate to medication error. These were chosen as they encompass both clinical and institutional situations, and community and domestic care situations, and the future impact of the ageing population and its increasing demand on healthcare technology.

A joint research team from the Universities of Surrey and Cambridge and the Royal College of Art undertook this work. They brought together expertise in the design process, medical equipment errors and access to knowledge in and experience of related areas such as human factors, the pharmaceutical and medical equipment industries and medical practices and environments. The first task was to understand the nature and extent of the challenge and to interpret the results from a design perspective. The next task was to identify where and how design could be effectively employed to reduce medical errors and accidents. The final task was to map out the scope and potential of a design-led approach to patient safety.

In undertaking this scoping study the research team has been careful to keep an open mind on how design and design management might most effectively be employed by the Department of Health and throughout the healthcare services in order to achieve the goal of 'ensuring the safety of care' as identified by the Bristol Inquiry. In order to fully understand this it has also been necessary to look at how risk assessment and management can most effectively be employed towards the same end.

There is much scope for transferring knowledge and practice from other industries where design and design management, and risk assessment and management, are well established and delivered by highly competent specialist professionals capable of taking a 'systems approach' to these subjects, as was recognised and recommended in the Kennedy Report.

It is crucially important that whatever solutions are put in place go beyond short term quick fixes, to deliver consistent and sustainable gains in patient safety in ways that are well established and proven in other high-risk industries.

The outcomes of this study complement the many initiatives already underway in the UK, build on the experience of the US and other countries, and comprise a series of recommendations for a programme of activities directed at reducing risk, limiting the impact of medical error and promoting patient safety. These are presented within the framework of a design-centred approach. The aim is to understand patient and carer-related issues in the context of complex interactions between the many stakeholders and equipment, medications, environments and other associated products and services that constitute the NHS.

1.2 Scope

Medical accidents, such as those that occur as a consequence of medication errors, rarely happen because of a single failure – they are usually the consequence of a multiple breakdown in the system (Reason, 2000). The study consequently explores the potential for improved design interventions in a whole system context. This is potentially a very broad area of investigation and the initial task for the research team was to work with the Design Council and the Department of Health to give a clear focus to the research. As a result this study has focused on medication error and approached the subject from three perspectives, where each has a direct influence on the prevalence of error:

- medical equipment;
- the medication process; and
- care environment.

The following sections describe these cross-cutting perspectives in more detail.

The study has further sought to identify indicative priority problems that are amenable to design solutions in each of the three areas. These problems included: the design, packaging and labelling of medications; the design of medical devices and equipment; and the design of information relating to patients, treatments, medications and delivery devices.

Medical equipment

Medical equipment is ubiquitous in the diagnosis and treatment of medical conditions in the home, the GP's surgery and in hospitals. It ranges from the simple tongue depressor to the asthmatic inhaler, from the safety-critical pacemaker to the large and complex MRI scanner.

There are different levels of equipment failure. For example, during 2001, the Medical Devices Agency received 7,896 reports of adverse incidents in the UK involving medical equipment (against a background of significant under-reporting). They reported that there were 141 incidents involving a fatality and 650 involving serious injury. For the cases where the investigation was completed in 2001 (MDA, 2002a):

- 40% of the incidents were attributed to equipment problems that had been introduced as a part of the design, manufacturing, quality control, or packaging process;
- 20% of the incidents were simply attributed to user error, rather than inherent design problems;
- 10% of the equipment was recalled or required design changes, suggesting that its design was inappropriate for reasonable use;
- 10% of the incidents required design/labelling/packaging change, suggesting that existing designs were inappropriate;
- and a further 15% required manufacturing changes or improved quality assurance.

Equipment-related adverse incidents can be categorised as resulting from device factors (e.g. manufacture, design, product failure), external factors (e.g. power supply failure, EMI) and user-related errors (e.g. abuse, misassembly, failure to train). A consistent finding in all accident research is that the main cause of accidents is systems induced human error. For example, incidents attributed to equipment use may far exceed those caused by overt equipment failure, and accidents involving human error are as high as 87% of all cases. Indeed, the FDA found that of 582 equipment inspections conducted between 6 January 1997

and 6 January 1998, 27% of companies did not adequately address human factors issues during equipment design.

For this target area it was important to identify those types of equipment related to the supply of medication and patient monitoring that are more likely to contribute to the occurrence of accidents. Since design-related problems were judged to be significant, the design of medical equipment was then investigated with reference to all those involved in the delivery supply-chain to ensure that the experiences of all the stakeholders in the process were covered.

The medication process: supply, dispensing and administration

Around 1,200 patients in England and Wales died in 2000 because of the adverse effects of medicines in therapeutic use in hospital. Of these, around 150 died as a direct result of medication errors. The prevalence of medication errors in primary care is less certain. There is much anecdotal evidence of patients in the home environment failing to comply with prescription instructions, and this is particularly true of the elderly where as many as 50% of those on medication do not take their medicine as intended (RCP, 2000). These cases all represent errors in the medication process, an often complex chain of supply, dispensing and administration.

In order to conduct a comprehensive review of all stages in the process, for this target area it was important that the supply of medication be tracked from pharmaceutical companies to the end users for the primary, secondary and care-home environments. Particular heed was paid to medication design and packaging, and to any equipment used during the manufacturing, prescribing and dispensing process. There is already much activity in this area, both in the UK and the US, and care was taken to identify current initiatives for change from a systems point of view.

Care environment

Healthcare environments are complex. When an adverse incident does occur there are likely to be elements within both the physical and psycho-social environment contributing to the event. In this scoping study, focus was maintained on environment issues related to the supply of medication. Particular attention was given to patients moving from one environment or care sector to another, since initial evidence suggested that designers and manufacturers of medical equipment do not adequately consider the various situations in which such products will be used.

Medical equipment is often transferred with the patient, for example between intensive care and a general ward, to be used by staff with different levels of expertise. This can be especially troublesome when such equipment moves from secondary care to the home environment, and is then operated by the patient or a carer.

1.3 Aims and objectives

Aims:

It was intended that the scoping study would be the first stage of a wider programme of work that aims:

- to identify and demonstrate the potential of a design led approach to prevent medical accidents; and

- to identify the most effective ways of integrating this approach into the everyday working practices and processes of the NHS and across the healthcare industry.

Objectives:

The initial proposal outlined areas of activities that would be explored during this scoping study. These included the development of baseline information. It was noted that these might include examples of international best practice on the efficacy of a design-led approach to patient safety. It was also hoped to make practical and cost effective recommendations for a design-led programme of activity that might deliver a demonstrable reduction in the risk of medical accidents. Finally, it was proposed to engage key stakeholders in the research process so as to encourage them to become agents of change and facilitate the delivery of the recommendations and messages emanating from the study.

In undertaking the study, these general issues were more carefully structured to enable a list of specific objectives to be constructed. These were:

1. mapping the problem;
2. investigation of special cases;
3. identifying problems;
4. identifying best practice;
5. facilitating change;
6. solving the problems;
7. making recommendations; and
8. achieving action through stakeholder engagement.

The following section shows the methods used to enable each objective to be met.

2. Methodology

The methodology adopted to achieve the objectives of the study included:

- developing a baseline of information to inform the planning of the project as a whole;
- the investigation of specific cases through interviews and workshops; and
- a process of iterative review of the final report with the research team, the Design Council and the Department of Health.

It was recognised from the outset that a scoping study such as this did not have the resources to complete a rigorous scientific study on every aspect. It would not, for example, have been realistic to identify a random and representative sample of every primary care health professional to participate in the workshops. Issues of potential bias in the workshop, focus groups and interview samples do therefore exist. However, the study design has attempted to minimise these biases by relying on more than one method to address each of the major study objectives. By identifying areas of agreement resulting from the application of different methods (i.e. using a form of triangulation) greater confidence can be placed in the results. The methods used to address each objective can be seen in the accompanying table. It should be noted that each of the objectives requiring data collection and synthesis (i.e. objectives 1-7) have been addressed by at least three different methods. A short description of each method is provided in this section.

The research team had extensive experience in the fields of medical equipment design, systems engineering and ergonomics. These skills, coupled with input from the Design Council, have enabled a unique skill set to be applied to the methodology, results interpretation and recommendations/discussion elements of the study.

Each of the institutions contributing had a substantial record of undertaking, applying and implementing research and/or design initiatives within industry and other settings. This facilitated consensus on recommendations and actions that were realistic and relevant to be reached.

2.1 Developing a baseline of information

Systematic literature review of peer-reviewed journals

(see ‘Annex 2 – Literature reviews’ for more details)

In order to inform the planning of the project as a whole and to develop a baseline of information, the research team brought together existing knowledge, evidence and best practice from across the world on this issue. There is much published material concerning medical error that has emerged from the UK, USA and elsewhere in recent years. A systematic review of the literature from peer reviewed journals enabled the problem to be mapped. The literature review also enabled specific problems to be identified and indicated how they might be solved. Best practices were highlighted, for instance how using computerised prescriptions in GP surgeries have eliminated some types of medication errors due to poor handwriting (Annex 2).

Literature review, reports and 'grey' literature

(see 'Annex 9 – Bibliography' for more details)

There is an extensive literature associated with the topic of patient safety that is not part of the peer-reviewed journal literature. The research team sought to identify those reports deemed to be of most relevance for inclusion in this review. These included those from the Department of Health and other Health Agencies, as well as a number of authoritative international reviews. In some instances web based materials were also reviewed.

A number of specific cases were investigated to illustrate the range and type of errors that can occur. For example, *Methotrexate Toxicity – An inquiry into the death of a Cambridgeshire patient in April 2000* (CHA, 2000) was used to illustrate a multitude of types of errors, from prescribing to administering, but also communication errors in particular (Annex 2).

Examples of best practice were sought through electronic sources. These helped provide an understanding of the scope for design interventions and hence potential for action at the Government/NHS level, at the institution level and at the GP/domestic care level (Annex 2).

Information exchange with international experts

Throughout the course of the study, contact has been sought and information exchanged with a wide range of experts from across the world. International experts from the United States and the Netherlands confirmed the extent and severity of the problem.

2.2 Investigation of specific cases

Interviews with healthcare practitioners/deliverers

(see 'Annex 4 – Interview results' for more details)

A number of interviews were held with healthcare practitioners/deliverers in and around Cambridge to set the scene and highlight specific medical issues. These included:

1. primary care – general practitioners in both dispensing and non-dispensing practices, practice manager, phlebotomist, head pharmacist in a community pharmacy, nursing policy manager and a social worker; and
2. secondary care – chief risk manager, biomedical equipment manager, staff nurse, infection control nurse, consultant anaesthetist, administrative director, chief pharmacist, principal pharmacist, manager of high-risk medication and a pathology services manager (see also Annex 3).

While some interviews were of a general scene-setting nature, in others specific medical accident issues were highlighted. Views were sought, in particular, in relation to those issues considered to be a priority because of the frequency or severity (in health or cost terms) of the accident/error, and those that were representative of broader types of medical problems.

Further information was elicited on the key design factors relevant to each type of accident and the opportunities for design interventions in each case.

Workshop input from other safety critical sectors

(see 'Annex 6 – Workshop results' for more details)

A number of previous reports have identified the capacity for different work sectors to learn from one another about the prevention of accidents and errors in complex, safety critical, work systems. The project team considered that much might be learned by meeting with experts from other safety critical sectors and discussing how they would approach a number of the problems faced by the health service and, by implication, this study. The safety critical industries represented included: railway, aviation, military and nuclear.

The aims of the workshop were to:

- understand how best practice in safety critical industries could be transferred to the Health Service; and
- suggest where practical system design improvements could be implemented and tested (Annex 5).

Focus groups with healthcare practitioners

(see 'Annex 5 – Focus group results' for more details)

Three focus groups were conducted across the three main areas of Midwifery, Accident and Emergency and Cancer/Palliative Care.

Workshop with primary/secondary healthcare deliverers

(see 'Annex 6 – Workshop results' for more details)

A series of workshops was held to facilitate a better understanding of the challenges facing stakeholders across the healthcare industry.

The participants of this workshop included representatives from across the primary and secondary care sectors. Some of the participants held very senior posts and had a lifetime of experience of healthcare services, others were more junior and had more day-to-day contact with patients.

The specific aims of the workshop were to:

- gain more detailed information of what was thought to be problematic in various care sectors;
- to understand the healthcare deliverers' experience (both positive and negative factors); and
- prioritise the resulting issues, tease out the design implications and identify opportunities for and barriers to effective intervention.

Workshop with supply chain stakeholders

(see 'Annex 6 – Workshop results' for more details)

A key aim of the study was to evaluate how the design process might positively influence the relationship between the designer and manufacturer as well as the supply chain.

The participants at this workshop included representatives from procurement, licensing and

the equipment and pharmaceutical industries.

During this workshop, the issues explored were related to the supply chain (especially medication), existing standards (industry, national and international) and costs and packaging (branding and identity). The information was collected as outlined in the previous section.

Workshop with patient support groups

(see 'Annex 6 – Workshop results' for more details)

This workshop was convened to enable the team to capture the priorities and concerns of various groups of patients, particularly those with long-term or chronic conditions. The workshop enabled the team to:

- engage the participants as a group and tap into their combined expertise, knowledge and experience;
- prepare the ground for future engagement of the participants e.g. as part of an institution or sector-based taskforce or cross-sector advisory group.

Workshop with designers

(see 'Annex 6 – Workshop results' for more details)

The participants at this workshop included representatives from the first three workshops, with two additional industry representatives: the head of a large design group and a product manager. There were also seven design professionals, ranging from current and recent RCA graduates to senior designers with experience of design in a medical context and of major design implementation projects.

2.3 An iterative process

Regular steering meetings and interviews with senior health service personnel aided the project team and provided valuable insights. Presentation and discussion of the study and the report with Department of Health and Design Council representatives were ongoing throughout the research period.

After collecting information from all the above sources, the research team discussed how best to present the findings. Using a Delphi style consensus meeting, decisions were reached on the recommendations, actions and their priorities. This process was facilitated by members of the Design Council. Research team agreement was unanimous regarding the recommendations presented in this report.

Table 1: Methods and objectives

Method \ Objectives	1 Mapping the problem	2 Investigation of special cases	3 Identifying problems	4 Identifying best practice	5 Facilitating change	6 Solving the problems	7 Making recommendations	8 Communicating findings	9 Achieving action
1 Systematic lit review, journals	✓	✓	✓	✓		✓	✓		
2 Lit review, reports and "grey" literature	✓	✓	✓	✓		✓			
3 Information exchange with international experts	✓		✓						
4 Prior experience of res. team	✓		✓	✓	✓	✓	✓		✓
5 Workshop: other safety critical sectors				✓	✓	✓	✓		
6 Input from senior health service and agency personnel	✓			✓					✓
7 Interviews with healthcare practitioners	✓	✓	✓	✓					✓
8 Focus groups with healthcare practitioners	✓	✓	✓	✓					✓
9 Workshop with primary/secondary healthcare deliverers	✓	✓	✓	✓	✓	✓	✓		✓
10 Workshop with supply chain stakeholders	✓		✓	✓	✓	✓	✓		✓
11 Workshop with patient support group	✓		✓		✓	✓	✓		✓
12 Workshop designers					✓	✓	✓		✓
13 Systematic consensus/priority setting by res. team					✓	✓	✓		✓
14 Iterative review of report with Dept of Health and Design Council								✓	

3. Developing a design-led approach to patient safety

"Human beings make mistakes because the systems, tasks and processes they work in are poorly designed"

(Lucian Leape, Harvard School of Public Health)

"If we truly want safer care we will have to design safer care systems"

(Bates *et al*., 1997)

The intention behind the research process for this study was first to understand what is going wrong, and second, to begin to map out a design-led response to medication error that could be broadened out into a mechanism for delivering safer designs to the NHS. What has emerged from our investigations is not a series of discrete design 'problems' to which solutions can be sought in the short and medium term. Instead, a range of more complex and problematic issues has arisen, which requires that design interventions be made against the broader backdrop of a better understanding of the contexts in which medication errors occur, and of the causes of errors, which are often multiple and interrelated.

3.1 The design challenge

The challenge that designers of safety critical products, services and processes face is to:

1. reduce the chance of errors occurring;
2. increase the chance of discovering an error when it does happen (many errors are caught very late, if at all, after passing through several opportunities to identify them); and
3. reduce the effect of an error (e.g. make it less severe or improve the ability to counteract the error).

In addressing this challenge, we must bear in mind that it is generally not possible to design out errors completely – design is still a prisoner of Murphy's Law! Many examples show that no matter what is designed, somebody somewhere will find a way of getting round the system. A recent example of this occurred in mid-January 2002, when two women undergoing cardiac catheterisation in a New Haven, Connecticut, hospital asphyxiated and died because an oxygen flowmeter had somehow been misconnected to a nitrous oxide gas outlet. In this case one of the small tabs on the Ohmeda-style oxygen fitting was "reportedly" deliberately broken off; thus, the fitting was able to be inserted into a nitrous oxide outlet despite the obvious colour and label differences between the flowmeter and the outlet.

But that troublesome law aside, a systematic approach to design is required that actively encourages designers to address all of the above issues in a timely and effective manner.

From a design perspective this means:

- designing to prevent user error from occurring, such as by encouraging simple and intuitive device operation, for example, by reducing the reliance on human memory for device operation;
- designing to take user error into account when it does occur, for example, by introducing warning messages when a user is about to proceed with a possibly dangerous action;

- building in barriers to prevent errors occurring by providing appropriate procedures for use; and
- providing adequate training (since training and maintenance are known to make a significant contribution (MDA, 1998a)).

Human error was frequently referred to in discussion at the workshops, and there appears to be a general assumption of the inevitability of human error as opposed to an awareness of contributing factors that could be Annex amenable to design or other interventions (see *Stakeholder Workshops Conclusions* (SWC) 6). In terms of causes, stress, workload, concentration failure, training, protocol, failing to check/double-check and local non-standard practices were all cited (see full set of stakeholder *Problems and Causes* (P&C) for details – see Table 16, in *Contributors and Datasets*, Annex 6), but there was little awareness of the attention burden imposed by factors such as similarity of names and packs, poor information, cluttered labels, small lettering, etc. In other words, human error was accepted as a root cause rather than the result of a multitude of factors which make it more likely to occur. In tandem with this, 'blame culture' and the disciplinary procedures that go with it, were seen by the stakeholders as significant contributing factors across the system. It may well be that this emphasis on human error is distracting attention from design flaws that could be remedied.

With so many interacting factors it is not possible to point to single causes and design solutions (SWC 6.12). Instead we are faced with a series of issues and the very real possibility that a design solution to one 'problem' could impact adversely on others. In this situation, directives, guidelines and requirements, for say, drug information, are not necessarily improving safety and may be contributing to problems, in the same way as investment in design by the pharmaceutical and medical devices industries could be creating rather than solving problems.

In short:

> *There appear to be deeper problems behind individual instances of medication error that are not being effectively captured by existing reporting systems, and are not amenable to short term or individual design 'fixes'.*

3.2 The example of packaging

Packaging - how do errors arise?

One example of a patient safety issue, that demonstrates the complexity of the issues the health service is having to confront, relates to errors arising from confusion over pack identification, e.g. when the wrong pack is taken from a pharmacy shelf because the name is mistaken, or the dosage is mistaken. This issue is explored in the Department of Health's Chief Pharmacist's report, *Building a Safer NHS for Patients: Improving Medication Safety* (section on "Why do medication errors occur?") (DoH, 2004), the general thrust of which was confirmed by the stakeholder workshops, but with more vibrant detail emerging.

Many interacting factors are involved in such errors – poor handwriting can be misinterpreted; prescriptions do not indicate what the drug is for and hence an additional clue to interpretation is lost; corporate branding enforces visual similarity; colour coding schemes tend to focus on brand identity rather than product differentiation; all forms and strengths of a medication can come in boxes of the same colour and shape (e.g. Tegretol); generic names are often less clear than brand names; proprietary and generic names can look and sound very

similar; changes of supplier can lead to confusion; as can multiple names for the same drug; alphabetical positioning can place similar named drugs from the same manufacturer side by side on the pharmacy shelf (e.g. Atenolol/Azathioprine); and working under pressure can exacerbate any of these factors.

Packaging - potential design responses

An immediate design response to confusion between drugs in the pharmacy could be that standardisation should be introduced. However, what emerges from consultation with stakeholders working within the NHS is that standardisation is not working effectively because it is driven by conflicting imperatives. As a consequence, industry investment in packaging design and drug identity is not necessarily adding to patient safety. Even where an individual manufacturer works hard to reduce confusion, its proprietary system/solution will be one of many, and is unlikely to be generalised or become a standard because of competition and brand issues.

An alternative approach is to explore ways to organise pack information so that it guides pharmacy staff through a desirable series of checks, and to make conformity to such a system a purchasing requirement.

Other design interventions could focus on introducing additional and differentiating marking or other elements to alert pharmacy staff to potential problems. It is interesting to note that in discussions at the creative workshop (SW4) senior pharmacists listed a significant number of factors that helped them identify and check medications prior to more recent advances in both immediate packaging (blister packs etc.) and boxes and other containers. They could differentiate drugs by their smell, by the feel of them to the fingers, the sound they made when poured out on the counter, the dust they produced – what that looked and felt like. These and other factors provided near-subliminal information/confirmation as to the identity of the medication. With modern packaging, not only are these subtle clues no longer available to the pharmacist, but the similarity and the proliferation of proprietary and generic medications and forms means that pharmacists are obliged to correctly identify drugs from amongst an increasing number of presentations, which are becoming less easily differentiated.

In reviewing the design of infusion devices the research team noted that the design of a device and the medication to be used with it needed a systematic approach. Thus, for a device to deliver the correct dose, it requires both the correct strength of medication to be inserted and the correct rate of drug delivery to be programmed. The design of the packaging (being for example specific to a particular brand and model of device to prevent a ‘mix-up’) could assist in reducing the potential for error. In other areas of health care products, the design of the labelling shows what might be achieved. For example, one section of this scoping study deals with a number of illustrations of enhanced visual cues on equipment. Defibrillator pads are used for both adults and children. Those designed for use on children have Teddy-bear shaped connector plugs and children's images on the pads themselves (with diagrammatic location information for pad use).

There is scope here for several design approaches, ranging from adding visual and tactile cues to packaging – embossed elements, say – to obliging manufacturers to add additional warning indicators to packs that are regularly mistaken – say a red spot or band to tell the user to take special care in checking. Bar codes could also be used to address this issue, and the adding of information about what the prescription is for could help confirm (or otherwise) the choice of medication in the pharmacy, and identify errors and confusions arising from the prescription itself.

Packaging - similar issues, different situations

The pharmacy is only one of several situations in which medication errors track back to problems with packaging. Indeed, in many instances packaging issues should be seen in tandem with information issues. The home is another environment in which errors are taking place, and where packaging and information are important factors, particularly in relation to compliance, which is known to be a significant problem affecting a large proportion of medications taken by elderly people. However, the stakeholder workshops indicated that the range of issues faced in the home is significantly different to that faced in the pharmacy (SWC 6.3, 6.8-6.10). In the home, an inability or failure to read or understand the leaflet inside the pack can lead to self-medication errors. This can be ascribed variously to poor eyesight, small type size, the way information is organised and the language used. Other similar problems are associated with legibility and poor durability of printed labels attached at the pharmacy; identifying medications once separated from their original packs; opening blister packs and handling and swallowing tablets, in particular in the case of older and arthritic patients (See P&C, Table 16, under *Contributors and Datasets*, Annex 6). In addition, the P*atient Support Groups* workshop identified other factors, centred on how effectively patients understand and 'own' their own conditions and treatments, which impact on compliance and can interact with the more specific, physical aspects of packaging and information.

3.3 Issues and ideas arising from the stakeholder workshops

Major issues identified by stakeholders ranged from the specific – prescribing, dispensing, administration and self-administration errors, needle stick injuries, misuse of gases – to the systemic, i.e. "assumptions that simplifying the process of a healthcare delivery system will lessen the need for knowledge, skills and experience" (SWC 6.1-13). Each case raises specific challenges. Gases, for example, as used in hospitals, are not subject to the same safety precautions as are those used in industrial settings. Fittings are interchangeable and errors arise because of this. Here a design-led approach would be to adopt and transfer industrial standards in terms of fittings and colour coding to the hospital ward. The Kennedy Report cited recent advances in the field of anaesthetics that address this issue (Gaba, 2000), but noted that in healthcare "it is well recognised that the adoption of and approach to solving or addressing specific hazards by designing equipment differently is under explored." (See also *An Organisation with a Memory*, p. 78.)

In the case of information-related errors the situation becomes more complicated. While the implementation of a single patient ID based on NHS number, as in Scotland, would have an immediate advantage, information-related problems vary significantly from sector to sector and between different healthcare environments, and so a single patient ID cannot be regarded as a complete solution. This corroborates the Chief Pharmacist's report on reducing the risk of medication error (section on safer user of medicines at the interface) where Dr Smith observes that "Timely, effective and unambiguous communications are essential to ensure medication safety as patients move between primary, secondary and tertiary care."

Hotspots

An alternative approach, which was explored and corroborated in the stakeholder workshops, is to identify 'hotspots' in the system – risky situations, risky moments, risky items and risky users – and look for design interventions that can reduce those risks. Such hotspots can be identified:

- in the home – around problems associated with packaging, storage, remembering, reading, understanding, etc.
- in transfer/transit – around associated changes in drugs, protocols, people, equipment, records, etc.
- around the hospital bed – around infusion lines, connectors, notes and record keeping, communication between staff, drug administration procedures, etc.
- when situations, equipment or medications are new or unfamiliar, and when people are working under pressure.
- when information becomes detached ("non-sticky") from its original place – associated with patient identity, records and drug charts, medications in and out of their original packs, when patients move from one sector to another or return to the community.
- in cases of mistaken identity – around look-alike/sound-alike names, branding on packs, changes in packaging, names and terminology, interchangeable connectors for lines and gases, ampoules, equipment calibration and dose delivery, etc.
- in failures to effectively capture errors – where communication is not effective or complete, reporting systems are not in place; there is insufficient understanding of risk and its cause; etc.
- in poor understanding of design, how it can effect risk and safety, and where blame culture mitigates against openness in reporting.
- when problems and causes are confused and conflated – e.g. is non-compliance among older people due to single causes (such as poor communication in surgery or pharmacy, unreadable packs and information leaflets, lowered visual ability or confusion), or to a complex chain of interrelated factors?

Critical users

One place to look for solutions is to identify common problems that occur in different forms and situations, and then select 'critical' users to work with (SWC 7.10-11). By "critical" users we mean those groups most likely to experience or be associated with the more severe or extreme expressions of the problem. For example, if we can solve the major pack-associated problems for older people in their homes, we may be able to solve similar problems for other groups and so deal with the issue in the most effective (and cost effective) way. Similarly, by tackling the major problems for hospital staff and paramedics associated with identifying medications, once they are separated from their packs, we may go a long way towards solving the problem for other less 'critical' groups.

One of the most positive observations to emerge from the research activities was the high level of commitment to finding solutions that was demonstrated at the stakeholder workshops. Engaging people working in the NHS and throughout the supply chain, along with patient representatives, will be crucial in developing a user-centred approach to design for patient safety.

3.4 Addressing the challenge

The research points very clearly to there being no simple solution in all but the most obvious of cases. Rather, there are complex interrelated issues that need to be addressed as a whole, and that are not sufficiently understood to be accessible to rapid solutions. This is borne out by the grouping of factors amenable to design interventions by the workshop participants (SWC 8.1-8), for example:

- around the design of packaging — physical access to medication, accompanying information, the separation of medication from packaging and information and correct identification of pack/contents;
- around patient information and records – drug charts, transfer of records and separation of records from patients; and
- around misadministration – device design itself, complexity, variety of designs and confusion over correct use.

Some general directions were identified that could be incorporated into a design-led approach, but again, few of these can be associated with discrete design solutions (SWC 8.9-13). The list included:

- seeking to increase simplicity of design, to make products more user-friendly and intuitive to use;
- standardisation of products so that users know what to expect of equipment;
- levels of lockout to reduce the temptation to tamper with or modify equipment;
- speeding up support/maintenance for key items;
- keeping the product attached to its package until use in order to retain instructions;
- imbuing products with identifiable features to facilitate recognition even if the packaging changed; and
- methods of record keeping incorporated into the packaging or presentation of medication.

Apart from a few more instances, most of these are of a general nature and point to what some of the goals and priorities of a design-led approach might look like, rather than to the detail. The failure of the workshops to move beyond the general towards more specific solutions points to how deep and multi-faceted the problems are, and to the need to understand some of the complexity of the NHS itself, before moving into detail on what a design-led approach should consist of (SWC 9.1-7).

In this sense, the stakeholder workshops have confirmed the desk research, not just in terms of the range and scale of the overall problem and the key issues within it, but also in terms of the conclusions reached by the research teams from Cambridge and Surrey universities (SWC 1.1-2). In particular:

> *The nature of the problem of medication error within the NHS is such as to require a systems approach to its solution, and any design-led initiative should build upon a systems approach to patient safety.*

Looking at design from this perspective would ensure that individual solutions interact with each other in effective ways that contribute to error reduction and support NHS staff in their everyday work. It would also ensure that the considerable investment in design by industry is

directed towards patient safety by making that a central goal of the system as a whole.

3.5 Why a systems approach to design?

> *"From past work in Human Factors a single standard emerges for judging success in research on error and safety. Research is successful to the degree that it helps recognise, anticipate and defend against paths to failure that arise as organisations and technology change, before any patient is injured."*

Building a Safer NHS for Patients p. 57 (after D. Roberts, past President, Human Factors and Ergonomics Society)

The examples cited above illustrate the need for a systems approach within the healthcare sector. The discipline of ergonomics uses a systems approach to the design of work and workplaces, which could be used as a basis to develop a model for the health system. This approach has developed over the past 50 years in order to address the complex interactions that occur between a worker, their tools, their colleagues and their work organisation. More recently a need to look still further and consider the role of regulations, societal and cultural pressures has been recognised (Moray, 2000).

This appears to be a daunting, but necessary, challenge. It is a challenge that is being met by a number of the safety-critical industries that became involved in this study, including both the nuclear and aviation industries.

The reason why these industries have adopted this approach is that they have realised the dangers of considering only some elements of a system in isolation from others. For example, procurement was raised as an issue during a workshop held with representatives from safety critical industries. It was evident that the defence industry incorporates an integrated systems approach from the very start of its procurement process. Whole lifecycles of products are considered along with other issues, such as available personnel, maintenance costs, attitudes, the competencies of users, training and skill levels needed. All these elements are included in any design costing and a 'requirements capture' method has been developed specifically for this purpose.

The need for such a systems approach within the healthcare sector might be illustrated as follows: A consultant decides on the purchase of a new state-of-the-art infusion device. This is to be used in a research project on his/her patients over a 12-month period. A small team is trained in the use of this equipment. The goals of the research project are met. However, the equipment is then left on the ward to be used by others with no training in its use. The system now contains a latent, and potentially fatal, failure.

Building a Safer NHS for Patients: Reducing the Risk of Medication Errors, §2.3.9, p28, stresses the importance of understanding the causes of errors and the need to undertake a 'systematic analysis of incidents', along with the importance of considering all contributory factors, and the fact that such formal investigations are well established in aviation, oil and nuclear industries.

There is consequently a need to consider the health service as a socio-technical system, and to design within this context. This can be illustrated through reference to the model presented by Moray (2000), (see figure 5).

Healthcare environments are complex. Therefore systematic assessments for accident and error potential are required. When an adverse incident does occur there are likely to be elements within both the physical, technological and psycho-social environments that are contributing to the event (HSE, 1999).

It is important that designers of one component of such a complex system recognise these interactions between different elements of the system. For example, the design of the control panel of an infusion pump must take into consideration the range of potential users, their prior experience or training, their expectations, the operational context, environmental constraints and communication and team needs, as well as potentially important management and organisational parameters.

Failure to take a systems approach to the solution finding process is unlikely to be successful and may generate additional problems and, therefore, scope for errors and adverse incidents.

Each year, industry invests significant sums of money in design. However, there is currently no specific mechanism for directing that investment towards patient safety. Nor is there a mechanism for directing research council funding towards the same goal. We believe there is a real opportunity to create a virtuous circle whereby a better understanding of the design implications of patient safety can shape purchasing decisions and specifications in ways that will focus industry investment on delivering patient safety. Other high risk industries have succeeded in sharing responsibility for safety aspects with their suppliers, and this could prove similarly effective and cost-efficient in delivering long-term advances in patient safety.

To be successful, any such initiative must be underpinned by a thorough understanding of the complex system of interactions that take place within the NHS. In order to achieve this, the research team has put forward a series of recommendations within the context of a design-centred model which draws on the disciplines of systems engineering, healthcare ergonomics and user-centred design. As a consequence it presents a strong case for a systems-based user-centred approach to healthcare design, and will be used as a framework for the recommendations that follow.

3.6 A systems-based user-centred approach to healthcare design

Design is the process by which something is created, whether it be a product, a protocol or a service. It is helpful to consider what design is in the context of systems development, since this will shed light on the role of design in improving patient safety.

Simple models and elements of the design process

There are many models of design that help to describe the nature of the process. One of the simplest may be found in British Standard 7000 Part1. It describes the design process as comprising of three key stages: *design*, *production* and *operation* (these are illustrated in figure 2). This model belies the subtlety of design and paints a rather optimistic view of the process as in reality there can be much iteration.

A better model of design shows the need for *forecasting* and *feedback* within the process. Forecasting is necessary if the designer is to be able to design a product that can be made at the right price and used by the right people. Such forecasting is generally possible only if feedback is obtained about the performance of previous products or prototypes of the emerging product.

This model of design applies to products, services and systems. For example, if a new prescribing form is to be designed, a means must be defined to encourage the adoption of the

form (production). In addition, the layout of the form must encourage its effective use (operation), both in terms of its ability to accurately convey the required information and its ability to be completed (and read) within an acceptable period of time.

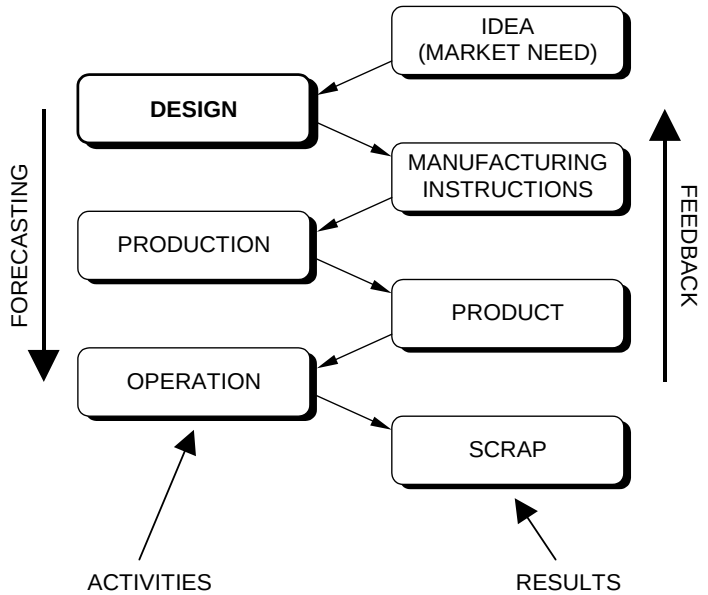


Figure 2: Adapted from the BS7000 product introduction process

Design is often then subdivided into a series of activities that enable the initial *market need* or *idea* to be converted into the *manufacturing instructions* that fully describe the product that is to be made (figure 3).

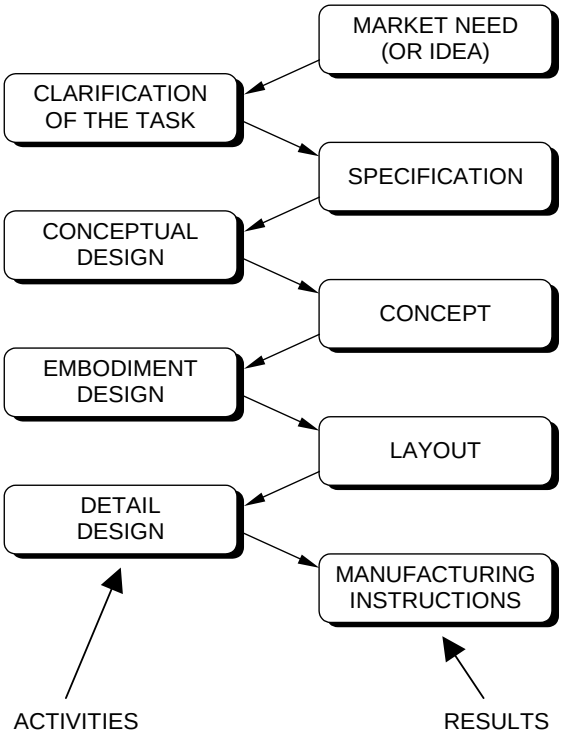


Figure 3: Elements of design

Clarification of the task

The starting point for the design process is an idea or a market need, often stated in vague, and sometimes contradictory, terms. Before the subsequent design phases start, it is important to clarify the task by identifying the true requirements and constraints. The result of this phase is a design specification.

Conceptual design

In this phase, concepts are generated with the potential of fulfilling the overall functional and physical requirements listed in the specification. Early consideration of user interface features is also critical. The result is a concept.

Embodiment design

In this phase, the foundations are laid for the detail design through a structured development of the concept. In the case of a mechanical product, the result of this phase would be a detailed layout drawing showing the preliminary shapes of all the components, their arrangement and, where appropriate, their relative motions.

Detail design

Finally, the precise shape, dimensions and tolerances of every component have to be specified. The result of this phase is detailed manufacturing instructions. These can take various forms, including detail drawings, programs for CNC machines, test schedules, etc.

In reality, these stages are not strictly serial and may show significant overlap. The simple model also hides many significant influences that may affect the design process, a number of which are shown in figure 4. These influences begin to show that product design is not simply

an isolated activity, but is critically dependant upon (and even defines) the business process. Indeed the model presented by Moray (2000) (shown in figure 5), derived from an ergonomic viewpoint, is remarkably similar to that presented by Hales (1993), derived from an engineering design viewpoint (figure 4).

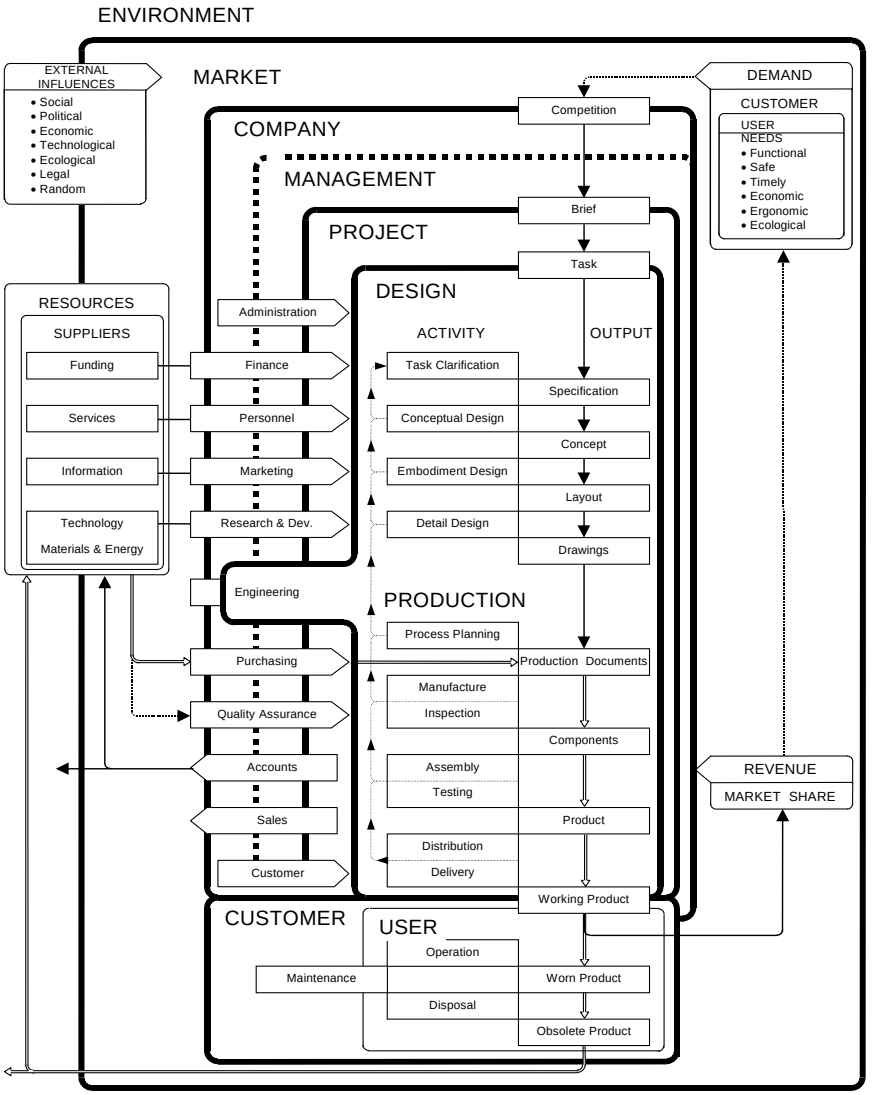


Figure 4: The design process in context (Hales, 1993)

It is important to note that one person's product may be another person's component. For example, the Rolls-Royce Trent 700 jet engine becomes a component for an Airbus 340-500. Thus a product may be made up of a complex mix of components, or may be one of a number of products required to contribute to a particular task or service. For example, the provision of a domestic electricity supply relies on a number of products configured in the generation, transmission and supply system.

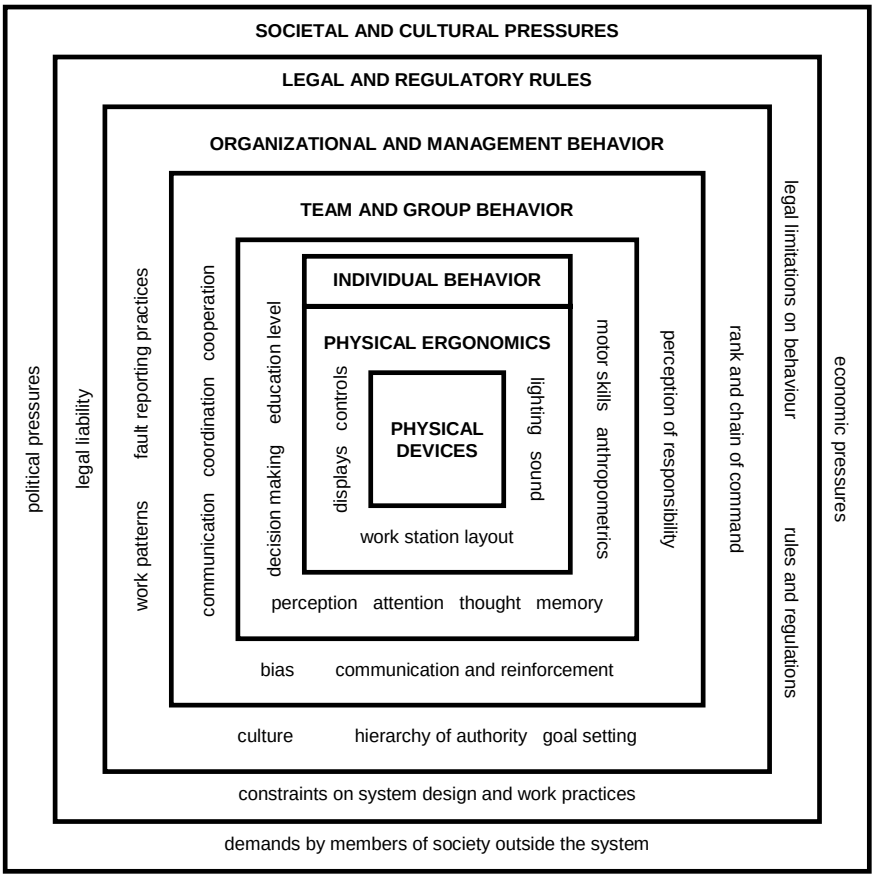


Figure 5. Ergonomics as the study and design of socio-technical systems (Moray, 2000)

Although the stages of design remain the same, as far as design is concerned, nothing is changed in dealing with a system, although there are usually more users, more requirements and generally more demands and influences on the product. However, in the case of systems the simple models of design do not help the design team and more rigorous design strategies are required. In addition, there is a need to develop methods better suited to ensuring the safety of the final product.

Better models of design

Thus far all the discussion has been based on common descriptions of product design. However, they generally do not map well to the requirements of medical device or equipment design. More emphasis is required on the product safety requirements, whether the product be a medical device or medical procedure. In both cases, one way of ensuring safety is to rigorously evaluate the performance of the emerging product or system. Methods adapted from software engineering are useful for this purpose. One such adaptation is shown in figures 6 and 7 (Alexander and Clarkson, 2000a). The first shows the development of a system along with its implementation/manufacturing process, highlighting the need for *validation* of the system and the delivery process.

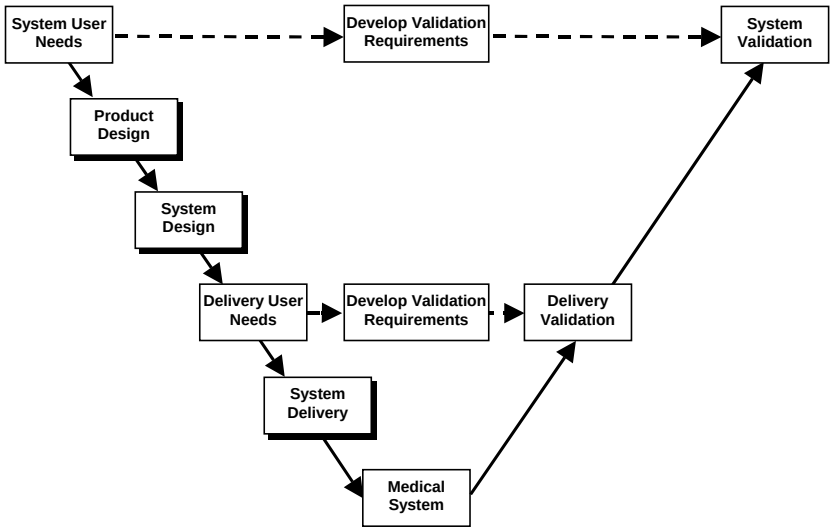


Figure 6: System Validation – is it to specification? (adapted from Alexander and Clarkson, 2000a)

The second shows the role of *verification* in the design of the system and the delivery process. Put simply, verification and validation may be defined by:

- Verification: '*Are we building the thing right?*'
- Validation: '*Have we built the right thing?*'

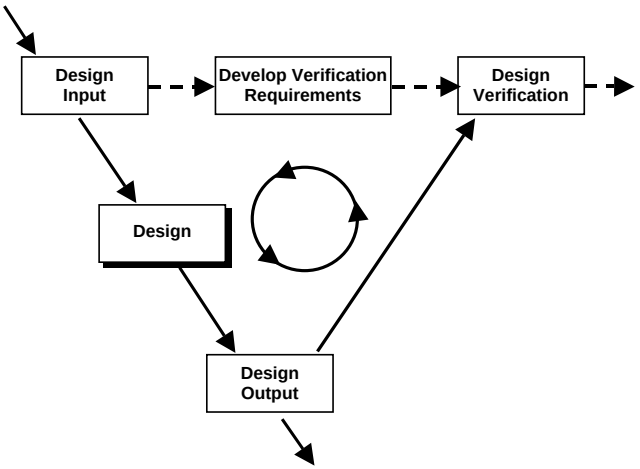


Figure 7: System Verification – does it meet users' needs? (Alexander and Clarkson, 2000a)

Evaluation, in the form of verification and validation, emerges as a critical component of medical device and equipment design, ensuring that evidence of satisfactory performance is available. Of particular importance is the early definition of the evaluation requirements, which in turn may influence the design. In addition, the evaluation of medical devices or equipment must also be done in the context of their expected use. Ideally, this involves a range of tests, including user trials, to provide representative performance data. Where a product is used as part of a system, the full system must be evaluated. The same is true for services, where every part of the service chain should be evaluated. For example, if a new treatment protocol is to be evaluated, all those activities required for the preparation,

execution and monitoring of the protocol should be evaluated. Inevitably, this leads to the evaluation of human/equipment systems.

The systems engineering approach to better design

The International Council on Systems Engineering (INCOSE) states that:

> *"Systems Engineering is an interdisciplinary approach and means to enable the realization of successful systems. Systems Engineering focuses on defining customer needs and required functionality early in the development cycle, documenting requirements, then proceeding with design synthesis and system validation while considering the complete problem."*

Key issues include operations, performance, testing, manufacturing, cost and schedule, training and support, and disposal.

> *"Systems Engineering integrates all the disciplines and specialty groups into a team effort forming a structured development process that proceeds from concept to production to operation. Systems Engineering considers both the business and the technical needs of all customers with the goal of providing a quality product that meets the user needs."*

It can be seen from these definitions that Systems Engineering is no different from what is normally referred to as design. Its distinguishing feature is its complexity, brought about by its multi-disciplinary, multi-product or multi-user approach.

The validation model can be extended to provide the basis for a Systems Engineering approach to meet the needs of the NHS. The model, an extension of figure 6, is based on the definitions and issues presented above (figure 8).

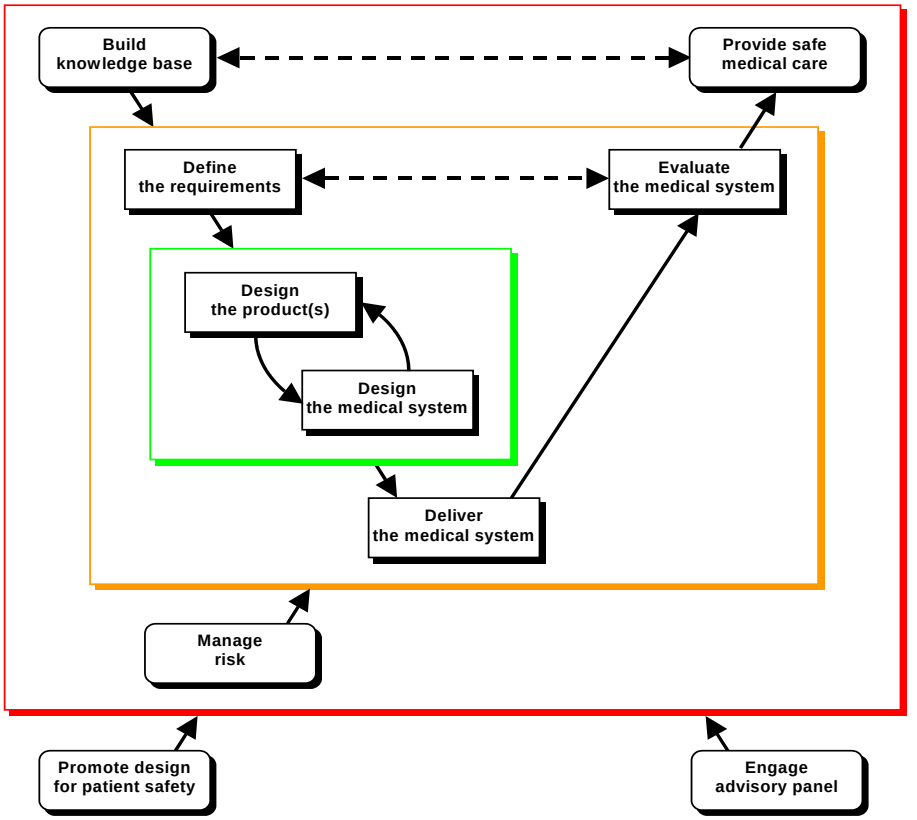


Figure 8: A systems-based user-centred approach to healthcare design

Key to figure:

- **Build knowledge base**: e.g. understand NHS: contexts; organisational components; specific tasks; user needs; information management; developing best practice.
- **Define the requirements**: e.g. purchasing and usability criteria/guidance; involving stakeholders; NHS agencies' synergy.
- **Design the product(s)**: e.g. utilising innovative design, systems engineering and ergonomics.
- **Design the medical system**: e.g. utilising systems engineering, ergonomics to consider the complete problem.
- **Deliver the medical system**: e.g. implementation, process of introduction and management of change.
- **Evaluate the medical system**: e.g. monitoring, auditing, verification, validation.
- **Manage risk**: e.g. prevention, hazard and risk identification, development of standards, safe practices and policies, European Directives.
- **Promote design for patient safety**: e.g. across the NHS; to industry.
- **Engage advisory panel**: e.g. through stakeholders in industry, design and procurement.
- **Provide safe medical care**: the result.

At the heart of this model is the innovation/procurement activity (within the inner box) which represents the design activity shown earlier. This process will be unique to a particular product or service, and should be informed by all the relevant stakeholders and agencies, and be actively managed to minimise technical and commercial risk.

Successful product or service development cannot be achieved in isolation of the system or environment into which it will be introduced. Therefore that system must be well understood, as is illustrated by the *build knowledge base* element. This improved understanding will in turn lead to the setting of more effective design requirements by the NHS, a prerequisite to improvements in procurement and innovation practice. This whole process could be informed and assisted by an advisory panel made up of industry and academic experts.

Figure 8 represents a convergence of views from the fields of ergonomics, engineering design and user-centred design. Thus it presents a strong case for a systems-based user-centred approach to healthcare systems design. The model will be used as a framework for the discussion and recommendations that follow.

Once people are involved in a system a whole range of complexities follows, and delays can occur because people are not as responsive as machines. It is not therefore possible to make direct comparisons between complex mechanical systems like an Airbus, and complex services like healthcare.

In order to better understand these differences and the special conditions that exist in healthcare, many diverse research methods were used to engage with and involve stakeholders in the work. The model recognises the value of that input and its ongoing importance in relation to implementation of the recommendations. Stakeholder – especially user – involvement is an integral part of this process and should inform both the development of specific design solutions (develop the system/product) and the process as a whole. For that reason the final recommendation concerns the involvement of an advisory panel, as was in essence envisaged by recommendation 120 of the Kennedy Report.

4. Conclusions and recommendations

4.1 Conclusions

It was intended that this scoping study should be the first stage of a wider programme of work, that aims to identify and demonstrate the potential of a design led approach to preventing medical accidents, and to determine the most effective ways of integrating this approach into the everyday working practices and processes of the NHS, and the healthcare industry as a whole.

The study has concluded that:

- The NHS is seriously out of step with modern thinking and practice with regard to design. A direct consequence of this has been a significant incidence of avoidable risk and error.
- There are no quick fixes. On the contrary, it is of the utmost importance that single design initiatives are seen in the context of the 'big picture' of the healthcare system as a whole and the way it impacts on patient safety and risk management.
- The 'big picture' understanding is not present and the highest priority must attach to remedying this without delay.
- On the basis of our investigations we have found cause to question, not simply the design of medical devices, products, packaging and information, but the way the NHS as a whole uses, or rather fails to use design in an effective way, and also fails to understand what design thinking can bring to an organisation.
- We came across little evidence of any understanding or practice within the NHS equivalent to those which are commonplace in other safety-critical industries and leading commercial organisations.
- There seemed to be little grasp of the value and significance of design, nor of how to manage or implement design improvements.
- There was little apparent understanding of the value of customer experience, human factors and user-friendliness to the NHS brand and no apparent strategy for developing and managing it in the way that successful modern organisations and enterprises do. By successfully aligning the NHS with patient safety through a properly managed and implemented systems approach, the health service could build on the considerable public confidence it still retains and establish a standard against which other healthcare systems and organisations are measured.

In this scoping study we have advanced a series of recommendations and actions to enable a start to be made in addressing these design issues and patient safety. In order to execute these recommendations the Department of Health will have to acquire expertise in design management, with specific reference to systems design, and in risk assessment and management. To support that work the research team has gone to considerable lengths to provide in the annexes to this report detailed documentation of the research undertaken as a ready-resource for those tasked with implementation.

As previously mentioned, we are aware of a number of initiatives from the Department of Health for which the findings of this report would be of particular relevance. For example, the activities of the National Patient Safety Agency and the changes to the Medical Devices Agency and Medicines Control Agency may provide opportunities to reflect the systems-

based user-centred approach to design that has been advocated in this report. We would urge that these initiatives now be reviewed so as to examine how this approach could be effectively integrated into their future work programmes.

4.2 Recommendations

The recommendations for change follow the model presented in the previous section, with the section letters as shown in figure 9.

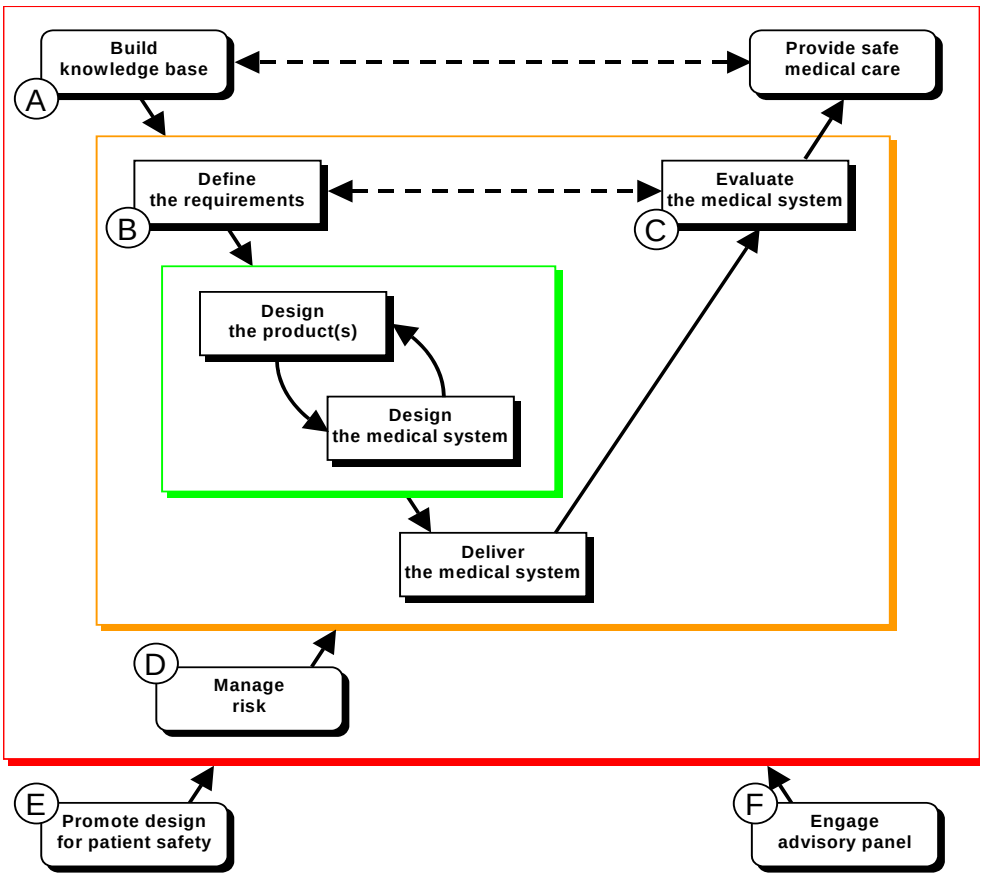


Figure 9: A systems-based user-centred approach to healthcare design

These recommendations emphasise the systems approach to patient safety and, in places, echo the findings of other recent reports on related issues (e.g. *An Organisation with a Memory, 2000*; *The Kennedy Report on the Bristol Royal Infirmary Inquiry, 2001*). It is important to note that the key changes advocated through the recommendations are not principally concerned with the design process itself (within the green box) but with developing knowledge, systems and processes that will provide the foundations for effective design decision making across the health service and industry.

We are mindful of the objectives of this scoping study and of the necessarily limited time and resources that were available for establishing a full body of evidence to support each. The recommendations reflect the breadth of methods used, the range of views and information sought and, above all, the consistency of the messages that emerged. They respond to key issues we have identified, and have been augmented with actions, albeit that we believe more

extensive information gathering and consultation is required to develop viable action plans.

We have also outlined at the end of each recommendation section a series of 'early projects'. These should be seen in tandem with this research work plan, and are intended to provide exemplars of studies that need to be undertaken but that do not compromise the priority for a systems approach. They have been selected to be conflict-free for all stakeholder groups and thus something the health service can unite around. This should be seen as step one in the development and deployment of the NHS brand as:

'*working together for patient safety and well-being*'

An indicative action plan is provided for each of the early projects. However, the details of any final plan must rest on a feasibility exercise to further refine and define the project. A key criterion in this process must be that it does not compromise the priority for a systems approach.

A: Building an effective knowledge base to underpin better design decision-making

Knowledge is the essential foundation upon which the health service can make evidence based decisions. This knowledge is required so that patient safety hotspots and problems can be successfully and systematically identified, prioritised and acted upon. The first stage of the design process is to develop a good understanding of the problem: without an effective knowledge base in place, design briefs and procurement decisions will be flawed and solutions unlikely to be as effective. However:

We have found little evidence of a suitable health system knowledge base to inform the design process nor evidence of a body responsible for such a knowledge base.

The results of this study point to a complex, poorly understood system where little is known about what actually happens – in the home, in the ambulance, in the pharmacy, on the ward – or how different conditions impact on the jobs that have to be carried out. This same lack of information is apparent for the challenges of self-administration of medications under differing circumstances, the functioning and use of equipment in different situations, and how information is recorded, transferred, interpreted and understood by users of differing capabilities in all the situations in which healthcare is delivered. The lack of published information about these contexts results in a poor understanding of what is required in order to effectively deliver safe care.

There is a particular knowledge gap within the home. This is the environment in which the bulk of healthcare is delivered – 75% of prescriptions are issued in the community – and yet this is reportedly the context about which the least is known.

Other safety-critical industries and successful businesses do not have these knowledge gaps. They understand very precisely what happens, when and why, and how individual tasks and elements fit together and interact. They are also aware of the safety implications of these factors and are engaged in a constant process of review and improvement.

A1: Understanding healthcare contexts

A systematic knowledge base must now be developed to gain a better understanding of the

health service's healthcare contexts (e.g. in the home, hospital ward or ambulance), organisational components, clinical tasks and user needs. This is a potentially huge undertaking and so should, in the first instance, look to address the priority areas of concern identified in *Building a Safer NHS for Patients*, 2002: obstetrics and gynaecology; and medication.

Recommendation:

To develop a better understanding of healthcare contexts at each specific point where the system interacts with the patient, so as to inform the design process.

Action 1: ***Create a health system knowledge base relating to primary and community care and patient care in the home.***

This could be undertaken through specific research initiatives in the shorter term and a focused collaboration with the research councils over a longer period in order to complete the requirements capture process. Information capture could be both systematic – through structured observation, recording and reporting – and also based on tapping into the practical experience of OTs, GPs and other professionals, and of voluntary organisations and patient support groups, through workshops focus groups and other methods.

Action 2: ***Compile a health system knowledge base relating to secondary care.***

This should be a simpler task given the greater availability of research studies relating to secondary care. Information capture could focus on such published literature as well as utilising the methods identified above. The result would be a useful, accessible and centrally available knowledge base to inform the design process.

Action 3: ***Map all medical research initiatives and interventions in the home and community to counter medication non-compliance.***

Non-compliance is happening on a large scale, but the reasons for this are poorly understood and key factors have not been adequately identified. It is therefore not possible to identify with certainty where design effort should be directed. An understanding of recent and current research activities in this area is essential if future work is to be efficiently and effectively targeted to those areas deemed to be of particular importance. Design requirements, user needs and other relevant factors must be explicitly stated, so that design solutions can be developed against the background of well-understood contexts in which they will function. This will also enable the solutions to be more easily evaluated in terms of their effectiveness in improving patient safety, supporting care-givers and healthcare professionals in carrying out their work, and enhancing the patient experience.

Action 4: ***Map the medication use process across all healthcare environments.***

Errors occur at many points in the medication use process and are due to a multiplicity of interacting factors, many of which have design implications. Completing the mapping process and fleshing this out with data on, for example, error type, incidence, consequences and associated costs would allow for targeted action. Important evidence lies with the many stakeholders involved. Such knowledge cannot be acquired without their input, and they can identify design-relevant factors that other research may well fail to capture. In our research, a range of methods was used to explore this issue, from literature review to stakeholder

workshops, and hotspots were identified for further investigation (see section 3.3).

A2: Understanding the interactions within and between organisational components

Communication and information flow is vital to patient safety, as are cultural issues and working practices. However:

Our research has found that system design, product design and consequently patient safety are seriously compromised by the lack of understanding of how the components of the health service interact.

The need for our research to map roles, responsibilities, and flow of people, products and information within the system is testament to the lack of existing information. It has only been through engagement with a wide range of stakeholders that we have been able to commence this complex, but essential task (see annexes 4, 5 & 6 for details).

A similar exercise must now be undertaken on a much larger scale so as to more accurately understand the way different parts of the various organisations within the health service fit together, and how these interactions can impact on patient safety. Such an understanding can only be achieved if the organisational structure is known and the interactions relating to people, products and information are understood. Extensive stakeholder engagement is not only the best way to effectively achieve this but it will also help to cultivate a risk-aware culture throughout the healthcare system. This will enable the NHS to move from having an external understanding, for instance through research, to an internal self-awareness on the part of organisations with regard to their susceptibility to risk.

Recommendation:

To develop an understanding of how the interactions both within and between healthcare organisations impact on patient safety.

Action 5: ***Map the roles, responsibilities, and flow of people, products and information within the organisational system.***

Such an organisational map can build on work presented in ‘Annex 3 – Procurement mapping’. This will lead to the need to:

Action 6: ***Identify conflicts between organisational practices, and how these can impact on patient safety elements of the healthcare system interface.***

and to:

Action 7: ***Identify barriers to effective change in the organisation(s) and where and how other safety critical industries have been successful at removing them.***

These objectives can be advanced by engaging the research community, and also by engaging the stakeholders in the process of identifying barriers, obstacles and risky interfaces between elements of the service.

A3: Identifying and prioritising risk-critical situations through a better understanding of healthcare tasks

Complex chains of actions are required to deliver healthcare to individual patients, stretching through the GP's surgery to hospital, specialist clinics and care environments and back to the patient's home. At each stage, safety-critical tasks are carried out by healthcare professionals who are often caring for many other patients at the same time, with very different health conditions and care requirements. Whilst the goal might appear straightforward, e.g. ensuring a patient is provided with the appropriate pharmaceutical drug in the right quantity, the tasks required to ensure this happens may be complex, involving checking and careful attention to detail.

A full understanding of these tasks has long been recognised in other industries (notably in aviation and control-rooms) and many techniques for task analysis have been developed. Such analysis is crucial for the health service where the same piece of equipment, packaging or information can be used in the ward, in a patient's home, on the roadside at night, or under pressure in emergencies. However:

There appears to be no systematic understanding of what is actually going on in healthcare situations. This applies as much to specific tasks as it does to higher levels of system interaction. Without this knowledge it is not possible to effectively undertake or evaluate designs with regard to patient safety.

Task analysis enables goals to be defined, steps that are used to achieve these goals to be accurately assessed, and interactions between the person and the system (including use of equipment) to be identified. The review of the literature has shown a paucity of task analyses of healthcare activities. The membership of the Ergonomics Society similarly knew of very few examples of task analyses drawn from hospital/healthcare settings.

Organisational and regional variations exist in undertaking of routine tasks (as evidenced by workshop participants). The need to learn from these variations and identify 'best practice' requires detailed task analysis from the real world, not paper-based rules, protocols and training materials.

Workshop participants emphasised the need for more knowledge about tasks undertaken around accident 'hotspots' e.g. in the home, around the hospital bed, in transfers, paramedics using shorthand in critical situations and patient records being transcribed with errors, etc. (SWC 9.2).

Examples from workshops showed that confusion over the selecting of drugs occurs (SWC 8.3). Task analysis would identify where such confusion could occur, how individuals vary in their capacity to recognise and to cope with uncertainty and where, for example, better feedback could be given to assist the health-carer (or patient) to recognise whether they are correct (or not) in their decision making.

In other work (e.g. Chisholm *et al*., 2000) the problem of task interruption has been highlighted, with emergency physicians being interrupted more than 30 times in 3 hours. The potential for errors arising from interrupted tasks, broken attention and hand-overs should be further explored.

Task analysis in equipment design:

Understanding task goals and comparing these with tasks undertaken can inform the design process in a pro-active manner. The omission of critical tasks, shortcuts and false assumptions about the state of the system may all be identified using task analysis.

Garmer *et al*. (2002) considered the development of a new user interface for an infusion pump using the human factors/ergonomics approach. Usability analysis was undertaken on existing designs based on observations, interviews, reported incidents and the theoretical basis for memory and human error. A new interface was developed based on a number of ergonomics principles. An evaluation of the reduction in errors was undertaken. The number of errors was reduced but remained significant.

The authors suggest that further tests are needed to improve the interface. They have identified, in particular, the need to provide more effective mode operation (e.g. with the use of spring loaded buttons). With regard to the process for finding solutions, the authors emphasise the importance of usability testing with a wide range of methods. They also emphasise the need to study both competent, experienced users *and* novice or learner users.

Task analysis in training:

Training in safety critical industries should start from the position of a task analysis. Task analytical training systems have been developed for use in the Aviation industry. These enable a thorough examination of the task to be undertaken which then forms the basis of the development of training needs, the training principles and the training materials. It is also important that any training delivered follows well-recognised concepts in the design of training courses. Walter (2000) describes one such programme for use in the aviation maintenance and inspection industry.

Recommendation:

To develop a better understanding of what is actually going on in healthcare situations at the level where individuals undertake specific tasks.

Action 8: ***Identify and prioritise a list of risk-critical situations.***

Various methods could be utilised to achieve this action. The creative workshop began to explore the nature and extent of risk at specific points in patient pathways through the healthcare system, with promising results. There is also a rich source of information in published literature relating the relative prevalence of particular errors. In addition, the mapping of patient pathways in itself can assist the identification of potential 'hotspots' or activities/interactions that might lead to a higher risk of error.

The stakeholder representative groups established during this study (including those from the design and creative sector) offer a valuable resource which could be rapidly built on in the context of a demonstration project as outlined in the section 'Demonstration Projects' below.

Action 9: ***Undertake a task analysis of the prioritised risk-critical situations to inform design and training.***

And to:

Action 10: ***Use the information elicited from task analysis to inform aspects of the system such as interface design, protocols, job and team design, personnel selection, definition of competencies and training needs.***

Often, the process above is used to assess Human Reliability (HRA) (see HSE, 1999). This further enables assessment of what human errors can occur with each task, considers

individual and organisational variability in task execution, examines factors that influence performance of the task, explores consequences of errors and identifies opportunities for detecting and recovering from these errors, and looks at dependencies between errors.

A4: Understanding healthcare user requirements

Developing an in-depth understanding of the full range of user capabilities (be they clinical staff or patients) will enable designers to deliver solutions that are safer to use. However, whilst through the ergonomic literature much is known about human capabilities, this knowledge has been primarily developed around working situations in offices and industry, and for military purposes. More recently such data has been extended to cover older adults and children. However, much of the information is not regularly consulted by designers and decision-makers, either because they are not aware of its existence, or because the formats in which it is presented are not appropriate or designer-friendly.

The requirement for accurate data on user behaviour and characteristics is heightened in healthcare due to the variety of situations in which equipment and information have to function, and the range of potential users. Much work has already gone into developing user-research methods by and for designers, and there is significant potential to transfer that knowledge to the healthcare industries in ways that support and promote patient safety.

Recommendation:

To develop a better understanding of the user requirements, from which safer designs can be achieved that will function as required for all users and across the range of situations in which they will be used.

Action 11: ***Knowing the user: encourage and make available research into user behaviour and characteristics.***

This can be achieved by encouraging designers to work closely with appropriate groups of stakeholders, patients and carers, leading to a better understanding of the users and promoting uptake of research into user behaviour and characteristics.

The maximum benefit is likely to come from the engagement of designers with ‘critical groups’ whose capabilities and working environments present the most critical use conditions and design challenges. Careful observation of and consultation with such groups is desirable as part of the design process. For example, older people and those for whom English is a second language are likely to have problems reading and understanding medication packaging and information leaflets. Paramedics and secondary care workers may experience similar problems under stressful or sub-optimal working conditions.

Building a knowledge base to support these processes will ensure that design decisions are well founded. Making such knowledge readily available in formats suited to decision-makers and designers will ensure it informs professional training and practice.

A5: Improving the management of knowledge and information across healthcare

The design of information, its structure and content, is particularly important if it is to meet the needs of its users and its authors. In addition, the means by which it is captured, stored and retrieved must also be suited to the user needs as well as to the technology available. This is especially true for knowledge management in the healthcare sector, which should focus

first and foremost on the need for accurate and up-to-date patient records. Secondly, it should be used to support the monitoring and maintenance of equipment.

Our research found:

There is a significant opportunity to develop a better understanding of the needs for effective knowledge and information transfer within and between the primary and secondary care communities. The goal being to ensure the information provided is accurate, timely and appropriate.

The understanding developed could underpin major design-led improvements in patient notes, equipment related information and the effective sharing of information between healthcare professionals. Such improvements may yield significant reductions in risk, errors and adverse events. Indeed, the Department of Health's Chief Pharmacist's report, *Building a Safer NHS for Patients: Reducing the Risk of Medication Errors*, stresses the potential to reduce risks through better use of information management and technology.

Patient related information

Patient notes are critical to the continuity of patient care. They should capture a patient's complete medical history and be available to all those medical professionals who need to see them, allowing informed decisions to be made regarding future treatment.

However, access to a complete set of notes is not always possible. In general, separate notes are kept for primary and secondary care, with different sets of notes sometimes held in different parts of a hospital, for example, in maternity and outpatients. The patient is also often responsible for providing the hospital with their medication history – which may not be accurate or complete. This concern was recognised through the research and confirmed in the stakeholder workshops which identified information and records as a top-level challenge with wide ranging implications (see Annex 6, references: SWC 4.6, 6.4, 7.3, 7.6, 7.8, 8.4 and 8.13).

Effective knowledge management is the result of careful design. Patient notes need to be designed to minimise the time taken to record accurate and complete information, and to maximise the information available to others in a coherent form. There is also a need to consider standard forms and reporting syntax to aid accurate searching analysis and diagnosis by computer-based systems as they are introduced. Currently the variations of language used by different medics to describe the same condition can be a significant problem.

A critical requirement of such a system is the capture of treatment rationale so that a clear trail of evidence from patient symptoms to treatment protocol is visible. This is particularly important in the case of medication, where joined-up thinking between primary and secondary care is desirable.

Appropriate technology must be used to ensure access to patient notes at all points in the treatment cycle, including home visits and emergency situations. Critical information, such as allergies, must be immediately available. Pharmacists should also have access, as appropriate, to patient details if they are to check medication regimes.

The first step in defining an information system for patient notes must be an analysis of the information needs of all healthcare professionals involved in patient care, coupled with a survey of current systems and approaches. Protocols for data management can then be defined with the help of those intending to use the system, and trialled using paper-based systems. Ultimately, the requirements for a computerised system will need to be specified.

Immediate progress may be made in the area of patient records for critical medication. It is evident that the integration of medication protocols with the patient medication chart can reduce errors. For example, the provision of dosing details for Warfarin on the 'Warfarin' chart not only reduces the chance of dosing errors, but also provides evidence of the dosing rationale for a particular patient. Although this happens to some extent at the moment, it does so only on a very ad-hoc basis.

Recommendation:

To effectively manage knowledge and information, with regard to patient notes

Action 12: ***Define best practice for the design and use of patient information in primary/secondary care and the home environment.***

It should be noted that the Department of Health's response (DoH, 2002) to the Bristol Inquiry, Learning from Bristol, does make a commitment to implement electronic patient records by 2005 (SWC 8.11-8.13).

Central to the concept of access to patient notes is the need to know that the notes in hand refer to the actual patient being cared for. The use of a unique 'Patient ID', as is being trialled in Scotland, would make such identification much more secure. There is therefore a need to:

Action 13: ***Implement single patient I.D. across the UK.***

As a step towards the improvement of patient notes, there is a particular need to:

Action 14*: Define and implement best practice for the prescribing and administration of critical medications.*

Working with known centres of good practice and professional organisations, such as the Royal College of Nursing, good practice could be defined and disseminated nationally.

Equipment related information

Equipment is increasingly mobile and is transferred between wards, general practice and the home. Consequently, there is an urgent need to actively design a system for recording, maintaining and using information relating to the use, status and maintenance of healthcare equipment.

Knowledge management is a well established discipline in industry and a fruitful research topic in academia. It has found particular favour in industries that develop complex products whose design relies on the knowledge of a number of experts, such as the automotive and aerospace sectors. In many safety conscious industries equipment performance and usage is closely monitored as a part of the process of maintaining adequate levels of safety. For example, the history of any component or system in an aircraft is carefully recorded. This enables design performance to be monitored, maintenance to be planned and particular part numbers to be tracked in the case of suspected design errors.

Knowledge management involves the identification of the knowledge to be captured, and the design of systems to capture, store and retrieve such knowledge. The form of these systems depends upon available technology, particularly in the case of complex products, and must be designed to encourage efficient use by those building and using the knowledge base.

Recommendation:

To ensure the provision of timely and appropriate information regarding use of equipment, including monitoring and maintenance, in primary/secondary care and the home environment.

There is an urgent need to:

Action 15: ***Define best practice for the design and use of equipment information in primary/secondary care and the home environment.***

There is much to learn from the experience of other industries where the use of such information management systems is commonplace. A study to define the requirements of an equipment information system for healthcare would be a good first step.

Understanding information sharing across the NHS

There is a need to establish an effective means for the dissemination of critical information to healthcare professionals. The need to keep information and knowledge up to date is common to all information-intensive professions. Consultants need to know the latest innovations in their field; general practitioners, the latest drugs and drug reactions; pharmacists, the source of the cheapest drugs – to name but a few. This raises the question of how such information should be best disseminated to busy professionals.

There is a need to:

Action 16: ***Survey healthcare professions to establish the current barriers to effective information dissemination and propose alternative approaches.***

and to:

Action 17: ***Learn from other industries that face similar issues and from those in the healthcare profession, such as hospital pharmacists, who already run effective networking activities.***

There are many examples of current good practice to observe, ranging from the provision of information for photocopier field technicians to the publication of warnings by the Civil Aviation Authority.

Dissemination systems need to be designed to ensure effective delivery of critical information, requiring a balance between the amount of information distributed and its visibility. Any solution will have to address the linked issues of how to package the information to be disseminated and how to provide the time for the recipient to assimilate the information.

A6: Developing a body of best practice on designing for patient safety

There is a significant opportunity to develop a body of best practice case studies and benchmark exemplars, along with demonstration projects that encourage industry to compete on the basis of patient safety through design.

While pressure can be put on industry to encourage it to focus on user-centred design practice, industry is unlikely to respond to abstract directives or inducements. What is needed

therefore is a body of exemplar case studies and demonstration projects that show how such an approach can lead to better and more competitive products.

Over the past 10 years, first in the field of age-friendly design, and more recently in the field of inclusive design, much progress has been made in advancing the subject and in successfully influencing industry and the design profession through demonstration projects, competitions and other activities leading to exemplar designs and case studies of good practice.

Two of the research teams involved in this study have been actively engaged in promoting these ideas and advancing study in these areas. They have published widely and disseminated the results internationally through lectures, conferences and the Internet, and engaged in many demonstration projects in collaboration with industry and the public and voluntary sectors.

Major companies such as Ford UK, Dyson, Hewlett Packard, BAA, and voluntary sector bodies such as the British Heart Foundation and the Leonard Cheshire Foundation have collaborated on design-research programmes leading to exemplar inclusive designs, and to new products, services and information campaigns. Other companies such as Consignia have commissioned evaluations to improve the user-friendliness of products and services.

The Design Council has been a partner in this process, and leading design consultancies have become involved in developing best practice exemplars (for an example see figure 10). All this work has created commercial opportunities for the companies involved and helped design and industry in the UK to prepare itself for the impact of ageing populations and the Disability Discrimination Act on consumer expectations.

As a result of this work, the Design Council has published a policy paper on 'Living Longer: the new context for design' which sets out the design challenge of population ageing. It has also taken the same approach to using design as a mechanism for reducing crime.

Much other material is now available to industry and the design professions on the subject of age-friendly and inclusive design, and a British Standard is being drafted on the subject as part of the BSI 7000 series. There is therefore a significant body of successful practice that could be rapidly transferred to the healthcare system and associated industries around the theme of Design for Patient Safety.

Recommendation:

To capture best practice examples of designing for patient safety from around the world, which can be used to inspire change in behaviour within industry and across the NHS.

Action 18: ***Identify best practice through demonstration projects.***

Academics can be encouraged to identify, document and evaluate examples of good industry practice by focusing research funding on the issue.

Design journals can be encouraged to actively seek papers on the subject; design magazines can likewise be encouraged to publicise best practice.

Action 19: ***Identify best practice through a number of exemplar case studies.***

Partnerships can be encouraged between medical and pharmaceutical companies and the UK design schools, for example along the lines of the Helen Hamlyn Research Associates Programme and its current collaborations with GlaxoSmithKlein, Unilever, Waitrose and

B&Q on developing age-friendly equipment, and packaging for food, medication and domestic goods.

This work could be reinforced by creating design industry competitions, sponsored by the Department of Health and others, that encourage the development and publicising of best practice examples, along with collaborations with stakeholders and appropriate research institutions (e.g. along the lines of the Design Business Association collaboration with the Helen Hamlyn Research Centre and the resulting 'Inclusive Design Challenge' which attracts top design consultancies).

In addition, research could be undertaken to identify existing examples of international best practice, which could then be written up and publicised.

Action 20: ***Define guidelines to make healthcare environments and personnel more accessible to design students and staff.***

Steps can be taken to make healthcare environments and personnel more accessible to design students and staff, as at present the obstacles and permissions required do not encourage practical work in the field. Healthcare and medication design issues should also be incorporated into design curricula at all levels.

The above could be facilitated by special arrangements allowing designers and students more ready access to stakeholders and to healthcare environments, in order to carry out user-research and observation as part of the design process.

Early project 1.

Aim: Tackling non-compliance in the community (especially for those on complex drug regimes) through a collaboration with a major pharmacy chain

Short-term objective: To improve treatment efficacy and minimise the potential for adverse incidents and confusion

Long-term objective: To develop integrated user, carer and manufacturer systems

Actions:

- Work with stakeholder users to map their needs (e.g. patients, healthcare deliverers, relatives, manufacturers)
- Undertake risk assessments of existing system for a range of patients, conditions and environments
- Identify mismatches between what is needed and what is provided
- Classify mismatches and deficiencies
- Develop criteria to overcome these deficiencies using established ergonomic and other best practice
- Use criteria to inform new designs in conjunction with creative designers, manufacturers and other stakeholders
- Test and validate new designs with small group studies
- Implement and monitor effectiveness
- Evaluate changes in performance and cost-effectiveness of the system

Stakeholders:

- Research team (expertise to include design, systems engineering, ergonomics)
- Healthcare providers, managers
- Patients and patient groups
- Other representatives of healthcare workers
- Manufacturers

Early project 2.

Aim: Developing design proposals for a standard but personalised medication dispenser.

Short-term objective: To improve reliability of dispensing and reduce potential for error

Long-term objective: To develop integrated health system culture with patient as the essential focus

Actions:

- Work with stakeholder users to map their needs (e.g. patients, healthcare deliverers, relatives, maintenance operatives)
- Undertake task analysis of existing need for patient information, format, quantity, etc.
- Identify mismatches between what is required (and hence expected) and what is actually provided
- Classify mismatches and deficiencies
- Develop criteria to overcome these deficiencies using established ergonomic and other best practice.
- Use criteria to inform new designs
- Develop new designs (in conjunction with stakeholders)
- Test and validate the design with small group studies
- Implement and monitor effectiveness
- Evaluate changes in performance and cost-effectiveness of the system

Stakeholders:

- Research team (expertise to include design, systems engineering, ergonomics)
- Healthcare providers, managers
- IT specialists
- Patients and patient groups
- Other representatives of healthcare workers
- Manufacturers

Early project 3.

Aim: Implementation of a single patient ID along with other aspects of an integrated information system

Short-term objective: To reduce potential for error

Long-term objective: To develop integrated health system culture with patient as the essential focus

Actions:

- Work with stakeholder users to map their needs (e.g. patients, healthcare deliverers, relatives, maintenance operatives)
- Undertake task analysis of existing need for patient information, format, quantity, etc.
- Identify mismatches between what is required (and hence expected) and what is actually provided
- Classify mismatches and deficiencies
- Develop criteria to overcome these deficiencies using established ergonomic and other best practice.
- Use criteria to inform new design options
- Test and validate the design with small group studies
- Implement and monitor effectiveness
- Evaluate changes in performance and cost-effectiveness of the system

Stakeholders:

- Research team (expertise to include design, systems engineering, ergonomics)
- Healthcare providers, managers
- IT specialists
- Patients and patient groups
- Other representatives of healthcare workers
- Manufacturers

B: Defining effective design requirements for the NHS

Medical equipment, medications, packaging and information have to function across a wide range of situations and for users with very different capabilities. If these are not all taken into account at the requirements capture and specification stages of development patient safety may well be compromised.

Our research found that:

There is no proper understanding of the design requirements of products, packaging, information and services, across the range of situations in which they will be utilised, and consequently no safety-conscious way to evaluate such designs.

B1: Delivering effective design requirements for patient safety

The study has revealed serious gaps in the knowledge necessary to design and develop safe products, packaging and information. It has also revealed a lack of awareness of how this can impact on patient safety.

For example: in cancer treatment and associated palliative care, infusion devices may be used in the hospital, the hospice and the patient's own home or community. The patient may also be following a complicated schedule of orally administered drugs. A range of carers may be involved, from specialist hospital staff through community and Macmillan nurses to family members. The patient may also need to understand and interact with the devices, and self-administer medication, while the medication and the condition itself may have a significant impact on the patient's physical and mental capabilities.

Effective design solutions to these complex systems will require an in-depth understanding of the range of potential users, how they function in different environments, and how design-related factors impact on each other.

Specifications and regulatory requirements must also take other commercial factors into account. For example, pharmaceutical manufacturers tend to regard drug information sheets as a defence against litigation more than an aid to patients and carers. Consequently the information presented may be complete, but not readily accessible due to text size, layout, ordering of information and use of language and symbols. The Chief Pharmacist's report, *Building a safer NHS for patients: Improving medication safety* makes several recommendations with regard to packaging and labelling, all of which were confirmed by the stakeholder workshops, but with added vibrancy of incident and detail.

The stakeholder workshops identified many instances of work practices and events that challenged design assumptions. For instance, in group discussions at the creative workshop, it was established that paramedics remove ampoules from their original, single medication, packaging and repack them in mixed batches that are more convenient to carry. However, in this condition, most of the more obvious clues to identity have been removed. A designer working with paramedics would very quickly begin to explore ways in which this risky practice could be made safer without losing the convenience of packing ampoules in small quantities, for example, by developing a new container, by introducing colour coding, and so on. A manufacturer that was prepared to implement such solutions would gain a competitive advantage if it could be proved that their product and associated packaging was safer in use.

Other instances included the transfer of notes from primary to secondary care; the identification of drugs brought in by patients; and storage in patients homes, along with many others (P&C).

There is evidence from the stakeholder workshops that designers and manufacturers of medical devices and equipment do not adequately consider the various situations in which such products will be used, especially outside the secondary care environment (SWC 9.3). Such factors mitigate against transferring patients from secondary to primary care and could result in prolonged in-patient care and consequential costs.

All three workshops identified the large percentage of patients that do not know or understand enough about their medication (SWC 9.5). Several reasons were cited, including a failure on the part of the GP to adequately explain to the patient, a failure on the part of the pharmacist to adequately explain, and a failure on the part of the carer, especially relatives and friends to adequately understand and communicate with the patient (P&C). Although this appears a complex and challenging problem, two of the three groups at the creative workshop identified it as a key issue and developed a range of ideas that could help address this particular challenge.

There is much evidence that user-involvement in design leads to better products. However, the involvement of all stakeholders is crucial if this benefit is to be maximised. Therein lies the challenge: how to involve users in a cost-effective manner.

Purchasing criteria, standards and guidelines and effective design briefs are both at the heart of the problem and an important part of the solution. Without a clearer understanding of how the many and diverse purchasing policies of the NHS impact on the promotional strategies adopted by manufacturers, the NHS will not be in a position to favourably influence manufacturers and hence the design of their products with regard to patient safety issues. Given that the majority of expenditure on design is made by industry, not the NHS, this is a very significant issue.

Recommendation:

To enable the design of safe products, packaging, information and services through the setting by the NHS of more effective design requirements.

Action 21: ***Develop usability criteria for procurement.***

One way to achieve common industry and NHS objectives for the procurement and delivery of safer services and products is to develop clear criteria for usability based on system requirements capture, task analysis and stakeholder/patient involvement. Were procurement decisions based on such criteria, then competition between manufacturers would be redirected towards meeting those criteria in cost effective ways, while improvements in usability would lead to error reduction, and lighten the load on hard pressed staff.

Usability criteria should be applied across the board – from devices, through packaging, to information and the form of medication itself – and developed for all situations in which the system interacts with the patient, with as much emphasis on use in the home and the community as in secondary care.

Action 22: ***Undertake NHS initiatives to develop specifications for equipment based on improved patient safety.***

Safety assessments and in-use monitoring of performance with regard to associated errors and risky events offer an evidence-based route to differentiating between specific designs and design features. Using such assessments as the basis of specifications for equipment would further focus attention and industry design spending on delivering measurable improvements in patient safety.

Cost-benefit analysis would add realism and a rational base to purchase choice which is currently driven by lowest cost comparisons and the subjectivity of senior doctors and consultants. This could also offer an alternative to standardisation which may not always

deliver the required improvements in patient safety.

Action 23: ***Define guidance on the role of through-life (life-cycle) costing in the delivery and procurement of products and services.***

Current purchasing criteria are based on cost rather than patient safety. A better approach would be to consider through-life costs. Although the initial purchase price of a particular piece of equipment may be lower than a competitor, once durability and reliability are taken into account the picture may change. Many other factors impact on the through-life costs of equipment, including the training required to ensure safe use, potential for errors in use, acceptability to the user, and so on.

Cost-benefit analysis allied to through-life costs would offer a more rational basis for purchasing decisions. As a result, product requirements could be more accurately stated and industry would compete to deliver value-for-money against those requirements. Much progress has already been made in this direction in terms of life-cycle analysis with regard to environmental impact and sustainability. There is therefore an existing knowledge-base of through-life evaluation that can be applied to patient safety and reliability of task performance.

Action 24: ***Provide adequate guidance and control for packaging design.***

Our study has found that recurrent confusions arise from similarities of name, brand identity, colour, box size, shelf position, and inconsistent and confusing colour/packaging of medication (e.g. all forms and strengths of Tegretol anti-epileptic drugs have same coloured boxes).

Action 25: ***Develop a better understanding within industry of the importance of system design needs in the healthcare services through the provision of guidance on the role and application of system design in the development and delivery of safe services and products.***

Successful product or service development cannot be done in isolation of the system or environment into which it will be introduced. However, there is little proper understanding within healthcare of the importance of system design in the development and delivery of safe products and services.

B2: Involving stakeholders and understanding their needs and capacities

There is potential to involve stakeholders at all levels of the design process of identifying, understanding and addressing risk within the healthcare system. However, our research has found that:

There currently appears to be no systematic feedback between users, purchasers, designers and manufacturers of equipment. As a consequence significant opportunities to reduce risk through better design are being lost.

Stakeholders can be considered to include: medical staff, academic and other related health experts, design consultants and in-house professional designers, design collaborators and commissioners, experts in ergonomics/human factors, government agencies, experts from other high-risk non-healthcare setting environments, and patient groups.

Our work with focus groups found that most nursing staff had little involvement with respect

to purchasing decisions and many considered the situation to be consultant dominated. Manufacturers too were found to listen to the needs of clinicians (e.g. regarding technological advances to devices) but rarely to more basic usability needs of other health carers.

A better system would require close liaison with end-users throughout the commissioning period, identification of potential problems through appropriate risk assessment, feedback to procurement and manufacturers and the adoption of appropriate strategies for the implementation of change within the organisation. The benefits of such a participatory approach to design are well documented (e.g. Haines and Wilson, 1998) and the methods used in this study for engaging with stakeholders further demonstrates how participants, from different perspectives within the health-care system can provide rich data to inform the prioritisation, advancement and ownership of solutions. This approach enabled the researchers to tap into over 1,000 years of collective stakeholder experience and 150 years of experience in medicine, health, packaging, product and information design. This represents an impressive and readily available resource that must play a key role in a design and stakeholder-led approach to patient safety.

Recommendation:

To better understand user needs and capacities by actively involving stakeholders in a more systematic way at all stages of the design process, from problem/requirements capture to post-implementation evaluation

In order to achieve this there is a need to:

Action 26: ***Provide guidance on how to successfully use/engage stakeholder knowledge.***

The engagement of stakeholders is considered to be a crucial factor in the long-term success of any programme of change including assisted solutions.

This study has used a number of methods for understanding and recording their experiences. The methods for mapping the healthcare system and orientating the participants have enabled the systematic capturing of problems and possible sources of errors, as well as increasing the understanding of participants of the real patient issues. Such approaches allow the stakeholder teams to have ownership and enable them to understand the importance of their role in tackling errors.

The process of participant selection/invitations and how each workshop was organised and facilitated has been recorded and could form the basis of future studies.

Action 27: ***Ensure that feedback loops are available within the stakeholder community to enable the effective evaluation of equipment, for example, to be undertaken.***

General principles should be applied including close liaison with end-users throughout the commissioning period, identification of potential problems through appropriate risk assessment, feedback to procurement and manufacturers and the adoption of appropriate strategies for the implementation of change within the organisation.

In addition, the approach used in this study has provided the means to:

Action 28: ***Identify and resolve conflicts of interest through participation in stakeholder workshops.***

The use of a professional facilitator is advanced in this respect. The observation that in excess of 90% of those invited actually attended the workshops, is strong evidence of stakeholders' commitment to resolving the challenge of medical error (SWC 2.1). Their positive participation and suggestions for action provide further evidence of the workshops' successful approach to: capturing the problems, understanding the challenges, looking for solutions, compliance and other patient group issues, and design-related factors in the creative workshop (SWC sections 6, 7 & 8).

B3: Involving the appropriate agencies in design and risk management

Our study found that there is a significant opportunity to effectively involve agencies along with the National Patient Safety Agency in the harnessing of design to reduce risk and improve patient safety. A common focus with regard to all aspects of product/service evaluation and control, ranging from product approval and recall to the provision of advice on good purchasing practice, will have the potential to make a significant impact on patient safety.

Learning from and integrating the appropriate agencies at each stage of the process (i.e. from problem/requirements capture to post-implementation evaluation) will ensure the delivery of safe products and systems through a seamless representation of drug, device and organisational interests. It is important that the agencies' responsibilities map clearly against those issues that relate directly to patient safety. This will help both designers and the agencies to appreciate their respective roles in the provision of safe products/services.

In the 1990's, the Food and Drug Administration moved towards a partnership approach with manufacturers. This led directly to a reduced time to market and an improvement in the quality of products. This in turn served the patients better, enabling the FDA to satisfy their own objectives. The provision of better guidance for product/service development and accessible advice is intended to result in a "least burdensome approach" for manufacturers. However, manufacturers are still failing to detect quality issues in a timely fashion, often due to a lack of appropriate interaction with the regulatory authorities. Flawed products are being approved, resulting in cost for the authorities to deal with the subsequent problems.

A review of the current remit and responsibilities of the agencies in the healthcare sector, with respect to patient safety, design and risk management, will provide a clearer picture of the extent of current guidance and controls. Where gaps or omissions in the responsibilities of the agencies are evident it will be important to clearly define a change of remit and responsibility of the appropriate agencies.

Recommendation:

To ensure the effective collaboration of the appropriate agencies in design and risk management so as to improve the delivery of safe products and systems through a seamless representation of drug, device and organisational interests.

Action 29: ***Review the remit and responsibilities of appropriate agencies.***

A review of the current remit and responsibilities of the agencies in the healthcare sector will provide a clear picture of the extent of current guidance and controls.

Action 30: ***Map agency responsibilities against designing for patient safety requirements and identify any gaps/omissions.***

It is important that the agencies' responsibilities can be seen to map clearly against those issues directly related to patient safety. This will help designers and the agencies to appreciate their respective roles in the provision of safe products/services.

Action 31: ***Refine the remit and responsibilities of the agencies, as necessary, to meet the requirements for designing for patient safety.***

Where gaps or omissions in the responsibilities of the agencies are evident it is important to clearly define a change of remit and responsibility of the appropriate agencies.

Early project 4.

Aim: Development of usability criteria for medical device procurement

Short-term objective: Inform procurement strategies

Long-term objective: Influence design of healthcare products

Actions:

- Commission study to establish usability criteria for a class of equipment/products (e.g. infusion devices)
- Work with stakeholder users to map their needs (e.g. patients, healthcare deliverers, relatives, maintenance operatives)
- Undertake task analysis of existing use
- Identify mismatches between what is expected (i.e. required) and what is actually provided
- Classify mismatches and deficiencies
- Develop criteria and good practice guidance to overcome these deficiencies using established ergonomic and other best practice
- Validate the guidance with small group studies
- Implement the guidance
- Monitor effectiveness with National Patient Safety Agency and Medical Devices Agency/Medicines Control Agency data sources
- Evaluate cost-effectiveness of improved procurement strategy
- Provide designers/manufacturers with the guidance to inform future design changes and marketing strategies

Stakeholders:

- Research team (expertise to include design, systems engineering, ergonomics)
- National Patient Safety Agency, Medical Devices Agency/Medicines Control Agency
- Patients and patient groups
- Representatives of healthcare workers
- Manufacturers

Early project 5.

Aim: Developing and Designing pharmaceutical packaging and labelling that reflect the needs of all users in the system

Short-term objective: To reduce potential for error

Long-term objective: To develop a culture whereby the health service leads initiatives in the design of healthcare products

Actions:

- Work with stakeholder users to map their needs (e.g. patients, healthcare deliverers, relatives, manufacturers)
- Undertake task analysis of existing needs and problems for a range of patients and conditions
- Identify mismatches between what is required and what is actually provided
- Classify mismatches and deficiencies
- Develop criteria and to overcome these deficiencies using established ergonomic and other best practice.
- Use criteria to inform new designs
- Test and validate the design with small group studies
- Implement and monitor effectiveness
- Evaluate changes in performance and cost-effectiveness of the system

Stakeholders:

- Research team (expertise to include design, systems engineering, ergonomics)
- Healthcare providers & other representatives of healthcare workers
- Patients and patient groups
- Manufacturers

C: Evaluating the service or product

A healthcare industry standard guide for practical system evaluation, to ensure patient safety, needs to be developed as:

There is a lack of practical guidance on how to evaluate the design of services and products either individually or in their interactions with other elements within the system. There is also a lack of effective procedures for monitoring and auditing the performance of existing designs, and evaluating their effectiveness (and relative cost-effectiveness) in terms of patient safety. The implications of this are disturbing.

This is particularly important if a system is changed, as with the adoption of new working practices, or when a new system is introduced, for example, a new patient monitoring device. In each case it is important to evaluate the effect of the change and to ascertain whether the new system meets its safety and operational requirements. For example, this may be through a formal validation process in the case of a new drug, or an informal study for a new prescribing protocol. In this respect there is a particular need to establish a common language of reporting for evaluation - much success in this area has been achieved in the US.

Evaluation is generally confined to that required for new medical equipment where practices are often adopted with no evidence of improved patient safety. Product evaluation is better understood, however, when the new product is being introduced with similar functionality to products already on the market.

Existing standards and guidelines regarding evaluation generally describe *what* has to be rather than *how* it should be done. In addition, evaluation is often seen as a means to gain regulatory approval rather than a route to ensure patient safety.

Much is written on device and drug validation, most of it focusing on the requirements of the validation process rather than on practical guidance for evaluation. In general, there is little guidance available on the informal evaluation of new systems outside of the software industry and even less on the evaluation of the effects of change. In addition, the guidance that exists is usually very specific to a particular industry sector. In practice, the evaluation method must be chosen, and often adapted, to suit to the system undergoing change or development. Ideally this should be a risk-driven process with the most effort expended on those factors which are critical to patient safety. However, this can be difficult if the appropriate balance between the cost of evaluation and its benefit is to be maintained.

Recommendation:

To effectively evaluate healthcare services and products within a system context with regard to patient safety.

Action 32: ***Define guidance on how to evaluate the effectiveness of change, e.g. as a result of new equipment or revised operating protocols.***

Evaluation begins with the specification of a new system, where the evaluation needs of the system must be defined. Evaluation then continues throughout the whole life of the system, until it is removed from use. It is important that any such evaluation is consistent with and therefore comparable to other major healthcare systems.

Action 33: ***Ensure a common understanding of the definitions of medical/ medication errors, causes and contributing factors, e.g. as with the NCCMERP system in the US.***

A study of evaluation approaches in other industries would be of benefit to help define appropriate guidance. In practice, however, it is important to define a simple risk-based approach that can be utilised by the users/maintainers of the system. This places interesting demands on such an approach and further research will be necessary to develop practical guidance based on initial work from the University of Cambridge. Such evaluation often requires reference to historical data/information relating to other similar systems.

Action 34: ***Encourage and require in-use auditing of existing products, and validation of designs.***

By validation we mean to establish that the design solution does what it is required to do – that we have built the right thing; to establish how effectively we have done this; and to identify scope for improvement. Validation, both during design development and post-production is essential if task analysis and user-research are to prove effective in improving usability and reducing risk and error. Validation should be part of an iterative process whose goal is to constantly seek improvement in performance against agreed criteria.

Action 35: ***Provide a body of evaluation data/information to inform system evaluation.***

A database of evaluation methods and guidance describing their appropriate use, would prove useful for industry and the NHS. This would lead to a common understanding of what could be achieved through evaluation and those methods that should be used in a particular case. Such a database might also include advanced simulation methods along with relevant baseline data – an approach being pursued by the EPSRC in the setting up of a national Health Technology Assessment centre. In addition, a database of evaluation results might assist the evaluation of comparable products.

Early project 6.

Aim: Risk assessment of patient safety during defined treatment/care pathways to prioritise a programme of risk containment and design improvements

Short-term objective: To risk assess patient safety during defined treatment/care pathways

Long-term objective: To develop a culture of risk assessment, surveillance and prevention

Actions:

- Commission study to study the effectiveness of risk assessment and prevention
- Define common patient pathways
- Develop, with the end-users, appropriate risk assessment system (to include strategy, guidance, training)
- Validate method
- Apply method to a number (up to 4) patient pathways using a representatives sample of patients and settings (home/hospital/care environments/transfers)
- Identify and classify the nature of the risks and hazards
- Prioritise the interventions re. system design
- Map the prioritised areas to National Patient Safety Agency data for their validation
- Make appropriate interventions
- Re-assess to measure effectiveness
- Disseminate results to influence training and culture

Stakeholders:

- Research team (expertise to include risk assessment, design, systems engineering, ergonomics)
- Stakeholder representative groups established during this scoping study of design and patient safety, including patients and patient groups, National Patient Safety Agency, Medical Devices Agency/Medicines Control Agency, and representatives of healthcare workers, including trust-based risk assessors.
- HSE advisers

D: Putting in place strategies for risk identification, control and management

Safety- critical industries and successful businesses tackle the issues of hazard and risk within the context of prevention. This means avoiding risk wherever possible, evaluating the risks that cannot be avoided, combating the risks at source and adapting the work to the individual. This can only be achieved by developing a coherent prevention policy that covers the individual, the job, the technology, the working conditions and the organisation. European Directives and Health and Safety Executive guidance exist to support this approach, but this study found little evidence of such cohesive and systematic thinking within the healthcare sector.

Indeed:

There currently appears to be no systematic commitment to risk identification, control and management across the NHS.

As a consequence of this lack of a consistent strategy, significant opportunities to identify risk are being lost - e.g. risky situations, risky moments and risky items of equipment - that could be addressed by design.

Representatives of other safety-critical sectors have pointed out that the NHS does not appear to see itself as a 'high risk' industry, therefore it has a poor safety culture. Accordingly, the NHS needs to first understand the risks embedded in its complex structure and in its interaction with patients at all stages of their care pathway.

It is heartening that the health service is moving to a system of reporting adverse incidents, but it is worth noting that in the defence and nuclear industries the emphasis is on more proactive systems where the reporting of *potential* incidents is required. This approach also generally provides more detailed information than adverse incident reporting. And whilst confidential reporting systems are a useful way of involving stakeholders in the risk management process, other industries have successfully moved to open reporting of potential incidents. These open reporting systems have been instrumental in building and maintaining a safety culture.

Professor Kent Woods points out that: *"The reality is that for the next decade at least the NHS will be attempting to develop safe systems in an environment which, for historical reasons, is ill-suited to the human factors approach. The unpropitious starting point makes it even more important that system safety is urgently addressed."* (The Prevention of Intrathecal Medication Errors, 2001 p.6).

It is also worth noting that other high risk industries share the common characteristic of being answerable to a powerful independent regulatory body; often spend much time and money on generating quality systems and clear audit trails; and provide regular refresher training for their operatives (with evaluation) and may even require that operatives re-qualify at set intervals.

The NHS, by comparison, is a highly fragmented organisation largely lacking unified standards, procedures and protocols – the problems associated with which are dramatically amplified by the movement of staff, e.g. junior house officers on rotation during their training, and the increasing employment of staff from overseas who have not been exposed to the NHS *modus operandi* before.

Other industries have identified the need to define and specify equipment requirements and to transfer responsibility for safety aspects to the manufacturers. The defence industry uses a whole life cycle approach when buying equipment and incorporates human factors at an early stage. This informs and drives the design process. No such approach seems to exist in the health service. Indeed, evidence from the primary/secondary care workshop indicates frontline staff have little or no involvement in purchasing decisions and it is not uncommon to find up to six different types of device in a unit all performing the same function.

Standardisation was identified in the primary/secondary care workshop as a means of reducing risk (SWC 4.5). This included standardised training across all trusts. Standardisation of commonly used or high volume items of equipment would assist with training and usage of equipment. Using standardised forms in the labelling of drugs was also identified as a way to reduce risk (SWC 8.7). Standardisation of training is an important safety feature in the nuclear industry.

To conclude, the NHS now needs to implement effective risk management strategies at all levels of the healthcare organisation, which can build on best practice in other industries and healthcare services internationally.

Recommendation:

To put in place risk identification, control and management strategies that will deliver effective procedures and protocols for identifying, capturing and reporting risks.

Action 36: ***Provide guidance and training in risk awareness and assessment amongst staff in primary and secondary care.***

For example, frontline staff (nurses, doctors, pharmacists, paramedics) are trained to recognise/diagnose and respond to various patient conditions. However, their professional training does not equip them to recognise the other factors in the work system that may compromise their professional competence. Many routine procedures have an element of risk and healthcare professionals need training in risk assessment techniques so they are able to make the appropriate decisions.

Action 37: ***Ensure that feedback loops are available within the stakeholder community to enable effective risk management.***

High risk work areas and activities need to be identified and processes put in place to protect patients from injury. Some activities are obvious sources of risk such as staff using complex equipment for which they have not been trained. Some aspects of risk identification are less apparent, for instance not knowing a patient when writing a prescription (Dean, 2002). It is not uncommon for one type of stakeholder (e.g. nurses) to feel the effect of a problem that originated further upstream in the course of patient treatment. Such a problem may be caused by a different set of stakeholders than those that felt its effects (e.g. the nurse may receive insufficient patient information on transfer of a patient from one ward to another). Communication must therefore be capable of crossing boundaries if risks are to be tackled effectively.

Having identified and taken steps to control the risk of hazardous events, there needs be continuous management to prevent a resurgence of accidents. The same approaches and techniques should be applied to other key areas outside direct care giving situations.

Action 38: ***Apply the risk management process to the medications and equipment procurement chain, engaging experts from other industries.***

and to:

Action 39: ***Apply the risk management process to a map of patient pathways through the healthcare system.***

There is an opportunity to work with the stakeholder groups established for the purpose of this study to make an early start on the process of risk identification and control. See demonstration projects below.

E: Promoting design for patient safety across the healthcare industry

Currently, more often than not, price determines which items of equipment are used to treat patients. Safe equipment may be available from manufacturers but is often more expensive; and because economic considerations drive the market, designers have limited incentives to improve design for the purposes of patient safety.

Our research has found that:

There is little proper understanding in the NHS of the importance of the delivery process on the provision of safe products and services by decision makers in the healthcare industry.

The research revealed significant conflicts of interest, in particular between the safety needs of patients and the corporate goals of companies supplying the health service. Manufacturers are motivated to seek differentiation for their products within the market place as a way of enhancing sales and profits. They respond to what the NHS demands – least cost design solutions – but are not motivated to advance patient safety because there is no incentive for them to do so. An example of such a false economy from the focus groups is the case of replacement leads for a piece of equipment. The cheapest are usually bought, but do not last as long as more expensive ones and are more prone to failure (for other cited examples of poor design, see Annexes).

In his report to the Chief Medical Officer on preventing intrathecal medication errors, Professor Kent Woods stated that:

> "*Manufacturers have in the past been reluctant to develop design modifications of high volume, low cost products such as needles and syringes in the absence of a known market for them. A design initiative of the scale required here would have to be customer-led, using the resources of the NHS Purchasing and Supply Agency to put the work out to tender. Since the manufacturing base is global, the size of the market offered by the NHS would be an important factor for companies. Contracts would need to provide the scale and duration required to cover product development costs*" (The Prevention of Intrathecal Medication Errors, 2001 p.14).

Safer products should be demanded by the NHS from manufacturers. When buying in bulk the NHS has sufficient leverage (3% of world sales) to influence the market and this should be exploited to coerce manufacturers to change their marketing strategies and make patient safety a priority. But awareness raising measures, the sharing of best practice knowledge and other incentives also have an important part to play.

The NHS needs to develop an understanding of what drives industry and how that differs

from the needs of healthcare services and actual patient requirements, and to look at ways in which these conflicts can be resolved to increase patient safety and focus design and procurement efforts on factors which address user needs.

Recommendation:

To develop a common understanding of the importance of design and procurement approaches within industry and the NHS for the delivery of safe services and products.

Action 40: ***Understanding the needs of the information user: encourage research into how to effectively communicate design for patient safety research to designers and design decision makers in industry.***

Action 41*: Quantify industry spend on design in the pharmaceutical and medical devices sectors.*

Considerable investment is made in design by industries associated with medication production and administration. Currently much of this expenditure is focused on branding and differentiation as a route to increased sales and profitability. A significant proportion of this design activity could be redirected towards patient safety. Understanding how much is spent, why, and towards what ends could identify opportunities for design improvements and tap into significant funds at a relatively low cost to the NHS and Department of Health.

Action 42: ***To encourage manufacturers to innovate and improve their designs to reflect a greater emphasis on patient safety, in the knowledge that such improvements are important to the NHS.***

The establishing of well-founded criteria for purchasing decisions need not be prescriptive if the criteria are related to usability and delivering patient safety. Such criteria should stimulate innovation and competition around patient safety, which manufacturers will be able to see as a means of differentiation not just in marketing to the NHS, but to other healthcare markets.

Action 43: ***Undertake NHS initiatives to encourage the use of collective purchasing power to influence manufacturers' designs.***

Despite the financial and other constraints it works under, the NHS retains a high degree of trust as a brand in its own right, and could act as a world leader in developing such criteria to drive purchasing and R&D. On this basis some purchasing could be centralised, but purchasing by individual trusts could still carry a collective weight if a common and transparent set of criteria is adhered to, and maintained in light of new developments.

Early project 7.

Aim: Identification and publicising of best international design exemplars

Short-term objective: To provide examples of innovative design

Long-term objective: To develop a new climate of synergy between design expertise and healthcare system needs

Actions:

- Identify existing international design exemplars
- Generate opportunities for designers and healthcare personnel to work together to common goals
- Publicise the benefits of systems-based user-centred approaches to design
- Develop models of good design processes (as well as good product design)
- Evaluate designs with respect to performance and cost-effectiveness of the system
- Undertake a dissemination and awareness-raising campaign with key stakeholders/ industry

Stakeholders:

- System designers
- Product designers
- Healthcare providers
- Patients and patient groups
- Manufacturers

F: Establishing an advisory panel to oversee the delivery of the design led approach to patient safety

There is a significant opportunity to capitalise on the goodwill and commitment of stakeholder groups across the healthcare services, in industry and design, and at all stages of the procurement chain. This potential now needs to be focused through an advisory panel on designing for patient safety.

Neither the NHS, the Design Council, the DTI, nor the government commissions, supports or carries out design work within the medical domain in any significant way. Industry is driven by profitability and share value, not, in general, by patient safety. Consequently its design spend is focused on these goals, not on patient safety (SWC 9.6). There is therefore a huge obstacle to determining and/or implementing any design improvement. This situation is unlikely to change unless industry competition and design spend can be redirected towards the goal of patient safety (SWC 8.8).

Similarly, apart from this study, little research effort has been directed towards understanding and determining the design implications of medical errors and adverse events. Researchers tend to be driven by their own interests, and while some good and relevant work is funded by the research councils, (for instance the EPSRC EQUAL programme is exploring healthcare issues with relation to older and disabled people in their own home and public environments; EPSRC 4th EQUAL call), there is no systematic research into patient safety and related matters. This situation is unlikely to change unless the research councils can be encouraged to support bids that set out to deliver the necessary information, which requires an authoritative body to define what those research questions should be.

The Engineering and Physical Sciences Research Council (EPSRC) programme Extending Quality Life Initiative (EQUAL) provides a suitable model. In developing the scope of the EQUAL project on Prolonging Independence in Old Age, the EPSRC sought advice from a number of different sources such as the Ageing Population Foresight Panel, the academic community, charities and other funding agencies. The scope for a co-ordinated initiative that embraced a number of research councils as well as manufacturing groups is evident.

An independent reference body, actively working with the National Patient Safety Agency on fleshing out and implementing the recommendations of this and other similar reports would give focus and drive to a design-led approach to patient safety.

Recommendation:

To establish an advisory panel to oversee the delivery of the design led approach to patient safety.

Action 44: ***Define guidance on the formation and engagement of advisory panels.***

The exact workings of this panel are beyond the scope of this report to recommend, but considerable steps have already been taken in this direction as part of the supporting research, and these should act as a starting point for any such initiative. However, it is assumed that such a body would be an active working group, meeting as required, and hopefully extending its expertise to industry and other NHS agencies.

To ensure the effectiveness of such a group, it would need to be given status and respect

within both design and healthcare communities, the participants should be properly recompensed and attendance should be facilitated by employers as a matter of high priority and as part of a wider commitment to dealing with these important issues of national interest.

Action 45: ***Establish an advisory panel drawn from the stakeholder and design communities with a brief to further consider and assist those responsible for following through on the recommendations of this report.***

The value in this stems from both the wealth of relevant experience brought to bear on the matter, and from the potential to add value to National Patient Safety Agency and other initiatives. This could be done by beginning the process of redirecting industry spend on design towards issues of patient safety, and by identifying questions for the research community to address with support from the relevant research councils.

The advisory group should be tasked with working to ensure that significant sources of error and adverse events are explored from a design perspective and that:

- relevant information is fed back to industry and NHS procurement agencies in order to focus future design investment on patient safety;
- future design decisions are made on the basis of appropriate and sufficient information to enhance patient safety;
- design solutions are evaluated and improved on the basis of good evidence of their ability to reduce risk and error; and
- purchasing decisions are made on the basis of sound evidence of value for money when the consequential costs of adverse events are taken into account.

Annex 1 – Definitions

Medication errors

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) http://www.nccmerp.org in the USA defines a *medication error* as:

> *"any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems including: prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."*

The medication use process

The medication use process is a complex continuum that requires the successful interaction of multiple allied health professionals, technology and the patient. It can be described as a succession of joined but distinct processes, each of which is in itself a system. The medication use process may be summarised by the following:

Prescribing

- Evaluate patient
- Establish need for medicine
- Select right medicine
- Determine interactions and allergies
- Prescribe medicine

Documenting

- Transcribe prescription
- Pass to patient/pharmacy

Dispensing (or preparation)

- Review prescription
- Review warnings, interactions and allergies
- Confirm transcription, if necessary
- Contact prescriber about discrepancies, if necessary
- Prepare medicine
- Pass medicine to patient/ward

Administering

- Review prescription
- Confirm transcription
- Review warnings, interactions and allergies
- Evaluate patient
- Administer medicine

Monitoring

- Assess patient's response to medicine
- Report and document results

Each part of this process presents an opportunity for the prevention of medication errors.

The product design process

Design is the process by which something is created, whether it be a product, a protocol or a service. It is often then subdivided into a series of activities that enable the initial *market need* or *idea* to be converted into the *manufacturing instructions* that fully describe the product that is to be made.

Clarification of the task

The starting point for the design process is an idea or a market need, often stated in vague, and sometimes contradictory, terms. Before the subsequent design phases start, it is important to clarify the task by identifying the true requirements and constraints. The result of this phase is a design specification.

Conceptual design

In this phase, concepts with the potential of fulfilling the overall functional and physical requirements listed in the specification are generated. Early consideration of user interface features is also critical. The result of this phase is a concept.

Embodiment design

In this phase, the foundations are laid for the detail design through a structured development of the concept. In the case of a mechanical product, the result of this phase would be a detailed layout drawing showing the preliminary shapes of all the components, their arrangement and, where appropriate, their relative motions.

Detail design

Finally, the precise shape, dimensions and tolerances of every component have to be specified. The result of this phase is detailed manufacturing instructions, which can take various forms including detail drawings, programs for CNC machines, test schedules, etc.

Evaluation

Evaluation, in the form of verification and validation, is a critical component of medical device and equipment design, and ensures that evidence of satisfactory performance is available.

The system design process

The International Council on Systems Engineering (INCOSE) states that:

> *"Systems Engineering is an interdisciplinary approach and means to enable the realization of successful systems. It focuses on defining customer needs and required functionality early in the development cycle, documenting requirements, then proceeding with design synthesis and system validation while considering the complete problem."*

Key issues include operations, performance, testing, manufacturing, cost and schedule, training and support, and disposal Systems Engineering integrates all the disciplines and specialty groups into a team effort forming a structured development process that proceeds from concept to production to operation. Systems Engineering considers both the business and the technical needs of all customers with the goal of providing a quality product that meets the user needs.

For note, the dictionary definition of a system includes the following:

- *a group or combination of interrelated, interdependent, or interacting elements forming a collective entity*
- *a method or complex of methods*
- *any assembly of electronic, mechanical, etc., components with interdependent function*

It can be seen from these definitions that Systems Engineering is no different from what is normally referred to as design. Its distinguishing feature is its complexity, brought about by its multi-diciplinary, multi-product or multi-user approach.

Annex 2 – Literature reviews

A systems engineering view

Each year in the UK an estimated 850,000 people are involved in an adverse event caused by a medical error. Each year, the Department of Health (DoH, 2000) receives tens of thousands of written complaints about all aspects of treatment in primary care and a similar number of written complaints about aspects of clinical treatment in hospitals. Annually, the Medicines Control Agency receives reports of around 20,000 adverse drug reactions and the Medical Devices Agency receives around 7,000 reports of adverse incidents (DoH, 2000).

The evidence of adverse incidents is almost entirely based on occurrences in secondary care (Leape *et al.*, 1991; Leape *et al.*, 1995; Wilson and Sheikh, 2002). Research is emerging about the type of problems occurring in primary care but not the prevalence (Wilson and Sheikh, 2002). Prescribing is the area about which most is known. Three to five per cent of all prescriptions cause potential problems and of these (ibid) one third would be considered serious.

Drug-related adverse events are not always caused by drug related errors but may result from aspects of the patient's condition. Categories of drug errors identified by Leape (1994a) are shown in table 2.

The most frequently cited contributing factors to an adverse incident in an intensive care unit were (Buckley *et al.*, 1997): inadequate assistance, deviation from standard technique, inexperience, error of judgement, distraction, haste, stress, fatigue, lack of knowledge, inadequate communication and an unfamiliar environment. According to Weingart *et al.* (2000) patients who are more seriously ill, who are subjected to multiple interventions and who remain in hospital for longer, are more likely to suffer serious injury as a result of medical mistakes.

Table 2: Categories of drug error (Leape, 1994a)

Error types	**Error**
Diagnostic	• Error or delay in diagnosis • Failure to employ indicated tests • Use of outmoded tests or therapy • Failure to act on the results of monitoring or testing • Technical error – performing a procedure/test
Treatment	• Error in administering the treatment (including preparation) • Error in drug dosage or in method of drug use • Avoidable delay in treatment or in responding to an abnormal test • Inappropriate care (treatment that takes no account of patient's condition) • Failure to provide indicated prophylactic treatment

Error types	Error
Preventive	• Inadequate monitoring or follow-up of treatment • Failure in communication • Equipment failure
Other	• Other systems failure

Models of error

Active failures are unsafe acts (errors and violation) committed by those at the sharp end of the system (surgeons, anaesthetists, nurses, physicians, etc). They are the people at the human-system interface whose actions can and sometimes do, have immediate adverse consequences (Vincent and Reason, 1999). This is the person centred approach which views unsafe acts as arising from aberrant mental processes such as forgetfulness, inattention, poor motivation, carelessness, negligence or recklessness. Counter-measures are directed at reducing the unwanted variability of human behaviour but may not recognise that there may be situational traps caused by latent failures. Latent failures result from decisions made by managers or directors within organisations. The consequences of such decisions may not be apparent for some time and may lie dormant for years, only to become evident when they are combined with local triggering factors (Vincent and Reason, ibid).

Ideally all the defences separating hazards from potential losses should be intact. In reality they are full of holes, like slices of Swiss cheese (figure 11). The gaps are continuously opening, closing and shifting position. They are created by active failures and latent conditions. Serious danger arises when a set of holes lines up to allow a brief window of accident opportunity. Highly technical systems such as nuclear power plants have many barriers and safeguards. In clinical practice there are very few protective barriers (Reason, 1994).

Buckley *et al.* (1997) give examples of the types of error that may occur when setting up a ventilator. If the ventilator system is connected incorrectly this constitutes a human error. The error is a violation if the ventilator breathing system was not checked prior to use. Incorrectly connecting the system to the patient would constitute an active error which may be due to a slip or lapse. However, using equipment that can easily be connected incorrectly amounts to a latent (systems) error.

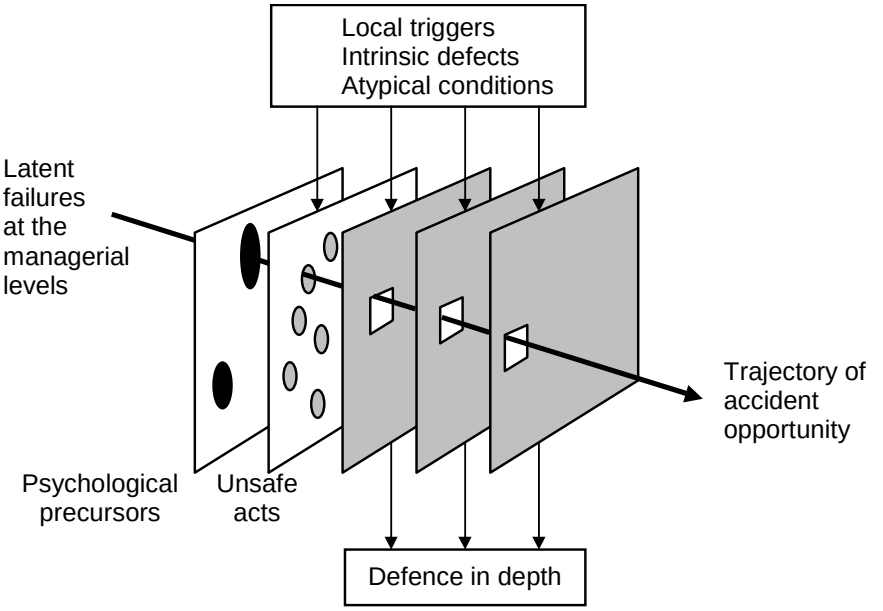


Figure 11: Model of how defence, barriers and safeguards can be penetrated by an accident trajectory (Reason, 1990)

According to Moray (1994), the relevant information needed to reduce error in the design of equipment to be used by humans is readily available. However, even when all the ergonomic knowledge is applied to design of equipment the probability of error cannot be completely eliminated. The factors at work in a complex human-machine system have far greater potency for causing errors than do ergonomic factors. It is these factors that call for the notion of systems design. Moray's model (figure 12) is a representation of the causal structure of a complex hierarchical human-machine system. It is very general and is able to encompass bureaucratic organisations as well as the systems in which humans interact with complex machinery.

Physical devices

At the centre of the system is the physical device or tool being used. Literature abounds with examples of device related error (Hyman, 1994; Obradovich and Woods, 1996; Buckley *et al*., 1997; Brown *et al*., 1997a; Kempen *et al*., 2000). Infusion devices are often a cause for concern as they are widely used, have been known to cause stress (McConnell *et al*., 1996) and are frequently cited in adverse incident reports (Williams and Lefever, 2000). Incorrect infusion rates have included incidents of setting infusion devices at the wrong rate, so that the device infused more rapidly than the prescribed rate. Confusion may exist between mg/hr and ml/hour when setting the infusion rate (Poster and Pelletier, 1988). This is because users tended to be hindered by a lack of feedback from the display and were frequently unable to detect which operational mode they were in (Garmer *et al*., 2002).

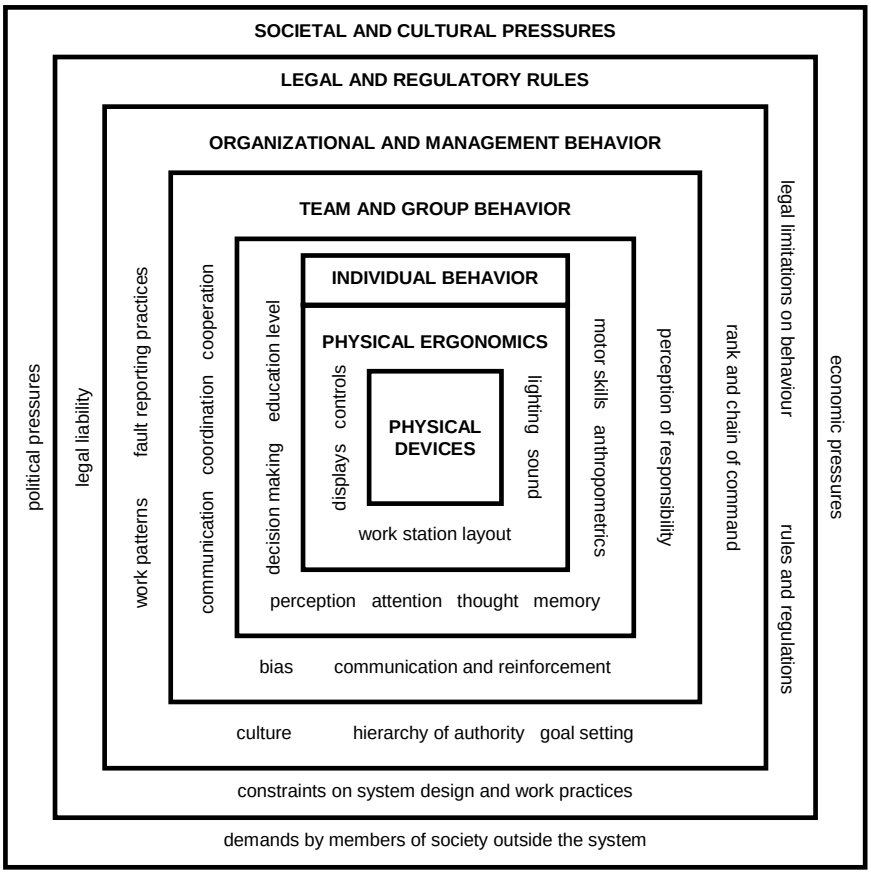


Figure 12: A generic hierarchical systems oriented approach to design and analysis (source Moray, 2000)

Other aspects related to using physical devices are: the legibility of labels on bottles and equipment or confusion over the identity of bottles of similar shapes and colours. According to Orser *et al.* (2001) 47.3% of anaesthesiologists report reading ampoule labels most of the time. This study revealed that label colour was the most important secondary cue to identifying the medication (reported by 50.7% of respondents). However, 26.9% of respondents said there was not one feature on the label that helped them. The colour of the ampoule and its label were cited as ”extremely important” for ampoule recognition, as were the colour of the vial and cap. The text colour and external packaging were the most important features for pre-filled syringes, whilst for self-prepared syringes, the drug label and syringe size were the most important features.

Factors affecting the individual

Omissions were identified as the most common type of error (Poster and Pelletier, 1988). Another commonly occurring problem is giving drugs to the wrong patient. This is frequently connected with failing to check the patient’s identity bracelet and is often associated with distractions from other patients or interruptions because of the high level of ward activity. Administering the incorrect drug is most often associated with failing to read (or failure to understand) the prescription chart or the drug label correctly and a lack of knowledge of a particular drug (Gladstone, 1995).

Noise levels in working environments may cause messages to be misunderstood and can lead to interruptions. Chisholm *et al*. (2000) carried out a study to determine the number and type of interruptions occurring in emergency departments. In this study an interruption was defined as any event that briefly required the attention of the subject but did not result in switching to a new task. A “break-in-task” was defined as an event that required the attention of the physician for more than 10 seconds and subsequently resulted in changing tasks. The study demonstrated that emergency physicians were frequently interrupted (about 31 times in 180 minutes) and that many of these interruptions resulted in an average of 20.7 breaks in the primary task over a time period of 180 minutes. In primary care settings, practice nurses reported that interruptions were distracting, affected patient flow and that the confidential nature of some consultations was irrevocably damaged by constant disturbances (Paxton *et al*., 1996). In a study by Dearden (1996), 20% of patients rated the interruptions as having a "bad effect" on the consultation, 40% believed that it would have been better not to have been interrupted and 18% expressed negative feelings about the interruptions.

Other factors contributing to adverse drug events include poor handwriting (Gladstone, 1995), poor mathematical skills of nurses (O’Shea, 1999) and poor knowledge of medications amongst new graduates in both medicine and nursing. This lack of knowledge can lead to inconsistent abbreviations, unclear dosage directions and confusing brand names. Personal factors mentioned by doctors as possible contributors to drug errors were feeling tired, hungry or unwell (Dean *et al.*, 2002). An absence of knowledge of drug dosage was also a contributing factor and the use of brand names rather than generic names caused confusion. Pharmacists are most likely to intercept drug errors. Typically, between one fifth and one quarter of inpatient prescription charts are amended by pharmacists (DoH, 2000).

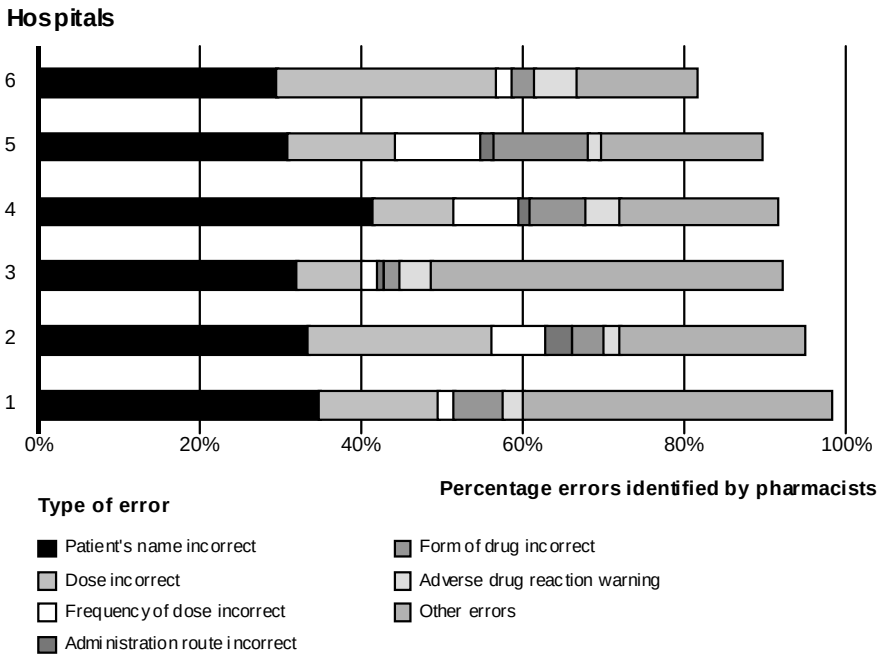


Figure 13: Nature of errors on medicine charts identified by pharmacists (DoH, 2000)

Team and group behaviour

Much of the literature focuses on errors made by individuals, but most people work within some kind of healthcare delivery team and are subject to factors such as communication,

supervision and responsibility. Absence of, or poor communication between and within teams is likely to contribute to errors (Dean *et al*., 2002). The most junior medical officer is usually called upon to take a patient's medication history on admission. In addition, junior doctors are often called upon to prescribe drugs and do so without asking questions under the assumption that this is the correct procedure. In some instances junior doctors felt that supervision was inadequate and non-distinct. Overlapping responsibilities between teams were also factors that contributed to errors (Dean *et al*., 2002).

West, commenting on communication in groups, states that traditionally, information flows vertically through a hierarchy and orders are sent from the top down with the expectation that lower levels will implement them. Adverse events can occur because individuals of lower status experience difficulties challenging decisions of a person of higher status (West, 2000). This may be because doctors' informal social networks are 'dense', that is, the networks are dominated by other doctors who have frequent contact. The density of these networks creates a strong boundary between doctors. Senior doctors (and to some extent senior nurses) when discussing various issues during informal settings are unlikely to encounter ideas that are strikingly different from their own. For this reason senior staff are reluctant to accept input from junior staff (Sexton *et al*., 2000).

Effective teamwork and communication leads to fewer and shorter delays in treatment and increase staff morale, job satisfaction and efficiency (Sexton *et al*., 2000). There is a relationship between perceptions of teamwork and status within a team. Surgeons are more likely to support steep hierarchies in which junior staff do not question senior staff. Surgeons are also more likely to perceive teamwork and communication in the team to be of a higher quality than other team members. The position is similar in intensive care where doctors perceived teamwork with nurses to be of higher quality than did nurses with doctors. Comparing medicine with aviation Sexton *et al*. (2000) suggest that poor communication is the equivalent of poor threat and error management. Effective cockpit crews use one third of their communications to discuss threats and errors in their environment whereas poorly performing teams spend about 5% of their time engaged in this activity.

Organisational and management behaviour

Although factors affecting individuals have been highlighted, there is limited value in focusing on individual activity as this tends to perpetuate a blame culture. The focus needs to widen to include systems issues underlying the problems that are present in any complex work environment (Anderson and Webster, 2001).

Leape *et al*. (1995) carried out a study to identify and evaluate the systems failures that underlie drug errors and give rise to potential and actual adverse drug events. The first seven systems failures were identified as:

- defects in drug knowledge;
- dissemination, dose and identity checking;
- availability of patient information;
- order transcription;
- allergy defence system;
- medication order tracking; and
- inter-service communication.

These failures were underpinned by impaired access to information and resulted from design faults. These included defects in conceptualisation and planning, failure to recognise service needs and failure to adapt systems to changing demands and changing technology. The authors identified other systems failures such as issues surrounding device use, standardisation of doses and frequencies, standardisation of drug distribution within the unit, standardisation of procedures, preparation of intravenous medications by nurses, transfers/ transition procedures, conflict resolution, staffing and work assignments and feedback about adverse drug events.

Poster and Pelletier (1988) conducted a retrospective study over a 12 month period to evaluate the effects of two medication administration systems looking at error in terms of frequency, type and reason for error. The two systems were a functional medication administration and a primary medication system. Within the functional medication system, one nurse is designated to administer all medications on each shift. Whilst in the primary medication system, each nurse administers medications to his/her designated patients during the shift. The error rate was higher in the units using the functional system.

System failures are sometimes difficult for "front line" staff to recognise because the decisions underpinning these systems may have been made in the past by those at a higher level of the organisation (Leape *et al*., 1995). Suggested system changes to reduce errors include: adjusted work schedules, simplifying work systems and enlisting the help of frontline personnel.

Legal and social pressures

The behavioural options available to those working in a system may be tightly constrained by regulatory rules (Moray, 1994). Only certain drugs may be administered or procedures undertaken. Regulations describe what should be done in as many foreseeable occasions as possible but cannot cover absolutely every situation.

Primary care

Much of the published literature focuses on adverse events in secondary care. However, Wilson and Sheikh (2002) have identified common themes emerging in primary care. These issues related to prescribing drugs, communication and organisational characteristics of primary care. The major problems linked to prescribing were: prescription of contra-indicated drugs, errors in dispensing, disregarding known allergies and prescribing the wrong drug. Breakdown in communication was also a common cause of harm to patients and often symptomatic of organisational problems. Transcription of information (for instance when dictating referral letters) proved to be an additional source of inaccuracy and offered a major opportunity for error. Wilson and Sheikh (2002) make the point that primary care does have a tradition of strong teamwork. However, the evidence that this makes a positive contribution to safety is unclear.

In a Dutch study, Conradi and de Mol (1999) conducted interviews among 17 GPs. Sixteen GPs admitted having made errors and provided over 100 examples. Errors with fatal or disabling consequences were cited by 14 GPs. 78 per cent of the cases involved faulty diagnosis. The authors identified four chronological phases of the interaction between the GP and patient: contact, diagnosis, therapy and follow up. In the contact phase error is likely to develop from lack of clarity regarding appointments. Communication is often by telephone to the surgery where the practice assistant makes the choice between an emergency call, an appointment or advice over the phone. Errors can be made in diagnosis because patients either

inadvertently or deliberately fail to disclose information thus inappropriate therapy maybe chosen. There may not be a period of follow up because, after treatment, the patient feels better and does not recognise the need to return. Another source of error is through informal contact at social or everyday events. Patients feel reassured even though the GP does not have all the necessary information to make an accurate diagnosis.

Use of complex equipment in the home is the focus of a study by Obradovich and Woods (1996). This study highlights some of the issues involved in using equipment designed for hospital settings at home. The areas highlighted were: the context of use, how the characteristics of the device increased the potential for error and how the users developed strategies to prevent errors. The device in this case was a computer-based infusion pump used for Terbutaline therapy to prevent pre-term labour. The problems identified in its operation may be applied to other complex medical equipment used in the home. The pump was operated by four buttons, each one having multiple functions depending on the sequence of key presses. The pump had four modes of operation, multiple displays and several auditory alarms. This treatment regime needed extensive support from hospital nurses who developed a user help manual of procedures, checklists and information for the patients.

The study by Obradovich and Woods (1996) provides an illustration of the fact that although technology makes it possible to transfer aspects of critical care medicine into the home, the risks do not disappear; rather, the distributed system for healthcare becomes more complex. People have new roles and the need for effective co-ordination and communication between the different agents increases.

Error mitigation

Errors are an inevitable aspect of human activity and times of accidents cannot be predicted. However, the form that errors will take can be predicted and it is this factor that should be addressed. Senders (1994) advocates the use of failure mode analysis as a means to identify error. Each medication packaging or medical device should be subjected to failure mode analysis during the design phase. Briefly the designer asks: what incorrect actions can people do; what adverse result can arise from these incorrect actions; how can these actions be prevented from being completed? Failure mode analysis provides designers with the opportunity to identify and analyse all the possible ways in which products can be misused and to subsequently use design to remove these failures. This process can also be applied to information and work systems.

Use of constraints

Devices can be designed to make it difficult for errors to occur. For instance, using different types of Luer connectors for intrathecal and IV administration routes. Anderson and Webster, (2001) suggest that patient controlled analgesia (PCA) machines could have lockouts of greater than five minutes so that patients do not overdose themselves.

Standardisation

Standardisation is advocated by Leape (1999), Vincent and Reason (1999) and Nolan (2000). West (2000) suggests standardisation and formalisation of tasks in an effort to reduce the complexity of work. In a hospital this might mean having a similar layout for each ward thus facilitating the work of bank or agency staff. Formalisation of tasks requires clarification of roles, rules and procedures and could have the effect of reducing the cognitive load required to perform the task. Leape (1999, p34) gives a drug related example of standardisation. Rather

than have nurses calculate how much potassium to give a patient according to serum levels, it would be better for them to give a standard dose.

Many errors stem from the absence of controlled vocabulary for use in the medical setting (Senders, 1994). All communication of medical orders, the names of medical preparations and devices could conform to the standards of a controlled vocabulary. This would reduce the number of prescription errors due to the use of non-standard abbreviations.

Using technology

In a prospective study, Raschke (1998) evaluated a computer alert system designed to correct errors that might have led to adverse drug events and to detect adverse drug events before the occurrence of injury. The alert system was triggered 1116 times and of these 596 were true-positive alerts. 44% of the true-positive alerts were unrecognised by the physician prior to the alert notification.

The use of decision support tools can lead to less reliance on memory (Leape, 1999; Nolan, 2000). Nightingale *et al*. (2000) describe how a rules based computerised drug prescribing and administration system was used to guide medical and nursing decision making. A high proportion of doctors and nurses found the system easy to use (86% and 88% respectively) and 82% preferred the computerised system to hand written prescribing. The system ensured that all prescriptions were complete and legible, transcription errors were eliminated and patient prescriptions were readily available. There were added benefits of using this system in that treatment protocols were introduced and the process of drug prescribing was simplified.

Johnson *et al*. (2002) describe how a bar code medication administration (BCMA) system could be used to reduce drug administration errors. This is an automated system using wireless, point of care, technology with an integrated bar code scanner.

In primary care the use of electronic prescriptions reduces the scope for error resulting from poor hand writing or incomplete prescriptions (Wilson and Sheikh, 2002). Extending this system to include referrals would reduce the number of transcription errors.

Education

Lester and Tritter (2001) suggest that teaching students to accept responsibility for their mistakes could lead to constructive changes in clinical practice. Doctors also need to learn to accept the idea that some error is inevitable. This view is supported by Pilpel *et al*. (1998) who suggest that medical education emphasises the importance of avoiding error in clinical practice and that student doctors do not learn quality assurance skills that would enable them to be aware of medical negligence. Changes in the curriculum to emphasise team working, communication skills, evidence-based practice and strategies for managing uncertainty are potentially key components in helping future doctors to discuss, cope with and commit fewer errors (Lester and Tritter, 2001).

Conclusion

This literature review was not exhaustive due to time and resource constraints. In order to fully understand the systems issues underlying patient safety we have highlighted models of general error and used a hierarchical conceptual model (Moray, 2000) to identify the key issues. The focus centred mainly on medication errors since these account for a large proportion of adverse incidents. Consideration was also given to equipment, as increasingly complex devices are used both within and outside hospital settings.

Not all errors can be eliminated and because of this it is necessary to increase the probability of self-detection of errors before they cause harm. This can be achieved by training, through the design and purchase of safer devices and containers and through consideration of the error, including aspects of the social and physical environment in which errors occur (Senders, 1994).

A medical error view

Hundreds of reports exist on medical errors, the majority of which focus on medication-related errors. Such investigations (and particularly those into medication-related errors) are well-warranted because:

- Medicines are becoming more powerful.
- Expenditure on medicines is rising.
- Pressure on medical staff to perform complex tasks quickly is increasing. Due to better reporting and more thorough investigations, a greater percentage of errors are being uncovered and more is being learned about the true scale and nature of the problem.
- The NHS has seen a vast increase in litigation over the last few years (placing a considerable burden on the NHS budget).

Definitions and reporting systems

Reports define medical errors in a number of ways. Some, for example, define such errors as those which cause actual harm. Others simply define them as departures from intended practice. These differences make it difficult to make comparisons between report statistics. Varying settings for error investigations and methods for collecting and categorising the errors also lead to problems in making such comparisons. The data in the following sections should therefore be seen in the above context.

Scale and nature of the problem

According to a UK Department of Health report, *A Spoonful of Sugar*, around 1,200 deaths occur per year due to problems with medication (DoH, 2001b). The majority of these are due to adverse effects of drug use and are not defined as medication errors (according to the NCC MERP definition) as they may not be avoidable.

A variety of data show the scale of the problem:

- Adverse incidents in 10% of hospital admissions in England (Australia – 17%) (DoH, 2000).
- 850,000 incidents per year in England (1.3 million in US) (DoH, 2000).
- Consensus is that 50% are preventable (UK and US) (e.g. DoH, 2000).
- 1/3 lead to moderate or greater disability or death (UK) (Vincent *et al.*, 2001).
- Medical error is a highly significant cause of death in the US, resulting in the deaths of as many as 98,000 people per year (Phillips *et al.*, 2001).
- Costs of US$20-75bn/year (FDA, 1998a), notwithstanding the human cost (individuals and families, etc.).

- Clinical negligence claims backlog of approximately £2.4bn in England – and still increasing (DoH, 2000).

Medication-related figures:

- 25% of negligence claims are due to medication errors (DoH, 2001a).
- 10% of medication errors are fatal (US) (Phillips *et al*., 2001).
- 10,000 adverse drug reactions per year (UK); 275,000 in US (Phillips *et al*., 2001).
- 7,000 deaths per year due to medication errors (US) (Kohn *et al*., 1999).
- 500-600 deaths per year due to labelling/packaging/naming issues (US) (Leape *et al*., 1991).
- As many as 50% of older people do not take their medicine as prescribed (RCP, 2000).

More figures on medication-related incidents may be found on page 19 of *A Spoonful of Sugar* (DoH, 2001a).

Medical errors – a summary from three studies

In order to provide more focus on what sits behind these figures, three key reports were studied in more detail: a study by Phillips *at al*., research by Leape *et al.* (the "Harvard Study") and, in most detail, work by the United States Pharmacopoeia.

Phillips *et al.* (Phillips *et al*., 2001)

Phillips *et al.* report on a study of 5,366 medication error reports from across the world, between 1993 and 1998. The vast majority of these reports were from the US (<6% from the UK) (Phillips *et al*., 2001). 68% of the errors were judged to be "serious", comprising a total of 469 deaths. The following types of error contributed to these deaths:

- Wrong dose – 40.9%;
- Wrong drug – 16.2%;
- Wrong administration route – 9.7%;
- Wrong strength – 5.7%; and
- Wrong rate – 5.6%.

Behind these types of error, the most common causes were found to be:

- Human factors (e.g. poor performance or lack of knowledge) – 65.0%;
- Communication (e.g. misinterpretation of order) – 15.8%;
- Medicine name confusion – 8.9%;
- Labelling on medicines – 5.4%; and
- Packaging and design of medicines – 4.6%.

Harvard study (Leape *et al*., 1991)

In over 30,000 hospital records made in New York state in 1984, adverse events (defined in this case as those involving actual harm, rather than near misses) occurred in 3.7% of

admissions. The leading cause of error was found to be drug complications. Due to their definition of adverse incidents, the resilience of patients and the fact that many errors may have been caught before they reached the patient, it is likely that this figure is a low-end estimate. Indeed, other studies of medical error have arrived at higher figures than these.

United States Pharmacopeia (USP, 2002)

The United States Pharmacopeia has been monitoring medication errors through its MedMARx programme since 1998 and publishes a report each year on the findings. During the year 2000, 184 facilities in the US filed a total of 41,296 medication error reports, which have been analysed in a recent publication (USP, 2002). This is worth a good deal of scrutiny due to the size and contemporary nature of the study. Future reports from the USP are likely to involve a considerably greater number of error reports in the following years, judging by the current rate of increase in reporting. Key findings are summarised below.

Origin of errors:

- Prescribing – 13%;
- Transcribing – 27%;
- Dispensing – 17%;
- Administering – 42%; and
- Monitoring – 1%.

Of these, 63% of the errors reached the patient and 3% reached the patient and caused harm or fatality. Administering is the most common node for discovering errors. This is not surprising as it is the node closest to the patient.

Types of error included:

- Omission error – 29%;
- Improper dose/quantity – 23%;
- Unauthorised drug – 15%; and
- Prescribing error – 10%.

Where causes behind these errors included:

- Performance deficit (i.e. when an error could not be explained) – 42%;
- Procedure/protocol not followed – 20%;
- Transcription inaccurate/omitted – 14%; and
- Documentation – 13%.

Across all categories of effect, 40% of records reported more than one cause per record. For those errors that resulted in harm, the majority (53%) had more than one causal factor. Communication problems and knowledge deficits were particularly significant causes in errors that resulted in harm.

Other contributing factors included:

- Distractions (53%);
- Workload increase (21%);

- Inexperienced staff (18%); and
- Shift change (7%).

Issues from other studies

Prescribing

According to one study, errors occur in around 1 in 20 prescriptions for medicine, with 1/3 representing major safety concerns (Wilson and Sheikh, 2002). There have been found to be discrepancies between what has been prescribed and what has been received by patients in the community in around 40% of cases (Duggan *et al*., 1996).

Labelling/packaging

Under their old system of reporting, (now superseded by the MedMARx programme) 5% of 5751 reports to the United States Pharmacopoeia associated with drug problems, were due to inappropriate design of the product's delivery system, labelling and/or packaging (USP, 2000).

Between 1992 and the end of 1997, the FDA's Center for Drug Evaluation and Research had received 6000 reports of medication errors, with some 50% of these being caused by confusion in the labelling or packaging of the medication (FDA, 1998a). These errors involved 1,273 serious events and 326 deaths.

Errors caused by name confusion, for example, Tamoxifen/Temazepam and Flomax/Volmax, were not uncommon findings in the study by Phillips. A review of literature on medicine labelling shows the need to consider both the format and the content of information presented on the label (Sless, 2001). A further study has shown that changes in packaging can cause many dispensing errors (Cox and Marriott, 2000).

High-risk drugs

Anticoagulants (e.g. Warfarin and Heparin), chemotherapy agents, opiates (e.g. Morphine), Insulin, Potassium Chloride and antibiotics, to name but a few, are generally regarded as high-risk medicines. Some of these (such as Warfarin) have a narrow therapeutic index, meaning that toxicity results if only twice the minimum therapeutic concentration is reached. There is also a variability in patient response to treatment, which further complicates the matter.

The study by Phillips shows central nervous system agents as causing the highest number of deaths, followed by cancer treatment and cardiovascular drugs (Phillips *et al*., 2001). The MedMARx report listed, in order of frequency, Insulin, Heparin, Morphine, Warfarin and Potassium Chloride as the drugs associated with the most harm.

Pharmacy

Little research has been conducted in the primary care sector regarding risks in a pharmacy setting (Cox and Marriott, 2000) or the primary sector in general (Wilson and Sheikh, 2002). A study in 1996 of practice in four pharmacies in the UK showed a medication error rate of 1% (Kayne, 1996). Approximately 1 in 5 of these errors were potentially serious, although none actually left the pharmacy. Findings from a UK survey of prescription errors show that (Shah *et al.*, 2001):

"…errors were found on 140 of the 1,373 handwritten items presented during the study

period (10%) compared with the 1,233 of the 33,772 computer-generated items (8%)…"

Where handwritten prescriptions were used, there were 30% more errors compared with computer-generated prescriptions.

Issues associated with information access and transfer

"Most errors are caused by the prescriber not having immediate access to accurate information about either the medicine (its indications, contraindications, interactions, therapeutic dose, or side effect); or the patient (allergies, other medical conditions, or the latest laboratory results)" (DoH, 2001b)

Many other errors are due to the need to gain the right information in the right format at the right time. Other studies have shown handwriting, transcription and communication errors to be major causes of errors. In the study by Phillips, dose miscalculations were found to be the third highest cause of error (Phillips *et al.*, 2001). Written communication errors, such as handwriting errors, were not uncommon, accounting for around 6% of causes of errors.

Errors of omission have been found to be particularly high (Leape *et al*., 1991), suggesting that systems should provide reminders to ensure actions are carried out whenever possible.

Purchasing issues

The NHS Purchasing and Supply Agency (PASA) purchases goods and services for the NHS. A number of issues concerning PASA, which are relevant to this report, are stated below (Warrington):

- The NHS spends 18% of its budget on clinical supplies and services, 11% on drugs and gases and 7% on general supplies and services. Clinical supplies and services represent the largest single expenditure group.
- There are one million "requisition lines" per week, 30,000 requisitioners in NHS procurement, 3,500 purchasing staff in 300 hospitals. 25,000 suppliers, with as many as 8,000 for a single NHS Trust.
- Trusts have too many suppliers, leading to a lack of efficiency. Unnecessary increases in the range of products can also lead to confusion for users.
- "Money flow is currently based on organisational and departmental budgets not around healthcare costs or patients."
- There is a general lack of training in the use of new products.
- There is no apparent systematic and realistic assessment of risks and benefits associated with new products. The evidence-base that exists may be wildly inaccurate due to evidence gathering by manufacturers or those sponsored by manufacturers, who may have a vested interest in collecting favourable results.
- There appears to be some reluctance by manufacturers to improve patient safety through innovative design, where this leads to an increase in the product's cost. This is especially the case when purchasing strategies will mean that the cheapest device is often used. There is therefore little incentive for product design improvements to be made.

Current initiatives and institutions tackling the problems

Much can be learned from the approaches in the US, as they appear to be some way ahead of the situation in the UK. Below is a brief summary of some of the efforts. It is by no means

intended to be an exhaustive study:

Many organisations now exist which are investigating and tackling issues associated with medical errors. Almost all are from the United States. Many other professional societies also have medical error sections. In particular, the following are worth investigation:

- The Agency for Healthcare Research and Quality (AHRQ) is the USA's lead Federal agency for research on healthcare quality, costs, outcomes, and patient safety.
- The American Society of Health-System Pharmacists (ASHP) states that their mission is to advance and support the practice of pharmacists in hospitals and the health and serve, and to act as their collective voice on issues related to use and public health.
- The FDA's Center for Drug Evaluation and Research (CDER) states that their mission is to assure that safe and effective drugs are available to the American people. CDER promotes, protects, and enhances the health of the public through the drug development and evaluation process. It now reviews names of new drugs with their Labelling and Nomenclature Committee, focusing predominantly on reducing errors associated with look-alike or sound-alike names of medicines.
- The European Foundation for the Advancement of Healthcare Practitioners (EFAHP) has been established due to the need for a multi-disciplinary European platform that can address issues of quality improvement in the care of patients, through a working approach.
- The Institute for Healthcare Improvement (IHI) was created to help lead to improvement of healthcare systems. IHI conducts courses, convenes national meetings, and coordinates research to improve quality and efficiency in healthcare.
- Institute for Safe Medication Practices (ISMP) is an organisation which works closely with healthcare practitioners and institutions, regulatory agencies, professional organisations and the pharmaceutical industry, to provide education about adverse drug events and their prevention. The ISMP provides an independent review of medication errors that have been voluntarily submitted by practitioners to a national Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP). Information from the reports may be used by the USP to impact on drug standards. All information derived from the MERP is shared with the FDA and the pharmaceutical companies whose products are mentioned in reports.
- The NCC MERP intends to mount a campaign for medication error reporting and prevention that will promote recommendations broadly to colleges, schools, and state associations of medicine, pharmacy, and nursing; national professional associations; managed care organisations; and third-party payers.
- The Quality Interagency Coordination Task Force (QuIC) was established in 1998 in accordance with a US Presidential directive to ensure that all Federal agencies involved in purchasing, providing, studying, or regulating healthcare services are working in a coordinated manner toward the common goal of improving quality care.
- The United States Pharmacopeia (USP) endeavours to promote public health by establishing state-of-the-art standards to ensure the quality of medicines for human and veterinary use. The USP also develops authoritative information about the appropriate use of medicines.

Design solutions

> *"If we truly want safer care we will have to design safer care systems"* (Bates *et al*., 1997).

Errors are usually caused by multiple factors. Telling practitioners to try harder is often symptomatic of a failure to understand the causes of errors. The consensus of opinion in accident research is that many errors are caused by poorly-designed systems. Engineering design has some useful basic ideas which can be applied to the design of systems, as well as products. Designers should aim to:

1. Reduce the chance of errors occurring;
2. Increase the chance of discovering an error when it does happen (many errors are caught very late, if at all, after passing through several opportunities to identify them);
3. Reduce the effect of an error (e.g. make it less severe or improve the ability to counteract the error).

From a design perspective this means:

- designing to prevent user error from occurring, by encouraging, for example, simple and intuitive device operation, by reducing the reliance on human memory for device operation;
- designing to take user error into account when it does occur, for example, by introducing warning messages when a user is about to proceed with a possibly dangerous action;
- building in barriers to prevent errors occurring by providing appropriate procedures for use;
    - providing adequate training (it is widely regarded that there is no substitute for reading the label) since training and maintenance are known to make a big difference (MDA, 1998a).

When all else fails, should an error occur, and assuming that it is reversible to some extent, training and equipment should be provided to mitigate against the effect of the error.

It is generally not possible to design out errors completely. Design is still a prisoner of Murphy's Law and many examples show that no matter what is designed, somebody somewhere will find a way of getting round the system. For example:

- One UK-based manufacturer's syringe driver has two models, one with the infusion rate set in hours, the other set in days. Despite clear marking of the equipment, healthcare practitioners can still become confused regarding 1 hour or 24-hour pump selection, meaning that a 24x overdose in drug delivery speed can occur.
- Anaesthetic gases are prone to misconnection even where the design should physically prevent such a condition.

Design merely leads to products and systems that remain dependent upon human behaviour for their proper operation. Good design attempts to pre-emptively minimise the consequences of human failure. However, it is difficult to predict how resourceful people can be in finding ways to bypass patient safeguards.

For example, in mid-January 2002, two women undergoing cardiac catheterisation in a New Haven, Connecticut, hospital asphyxiated and died because an oxygen flowmeter had somehow been misconnected to a nitrous oxide gas outlet (http://www.ecri.org). In this case

one of the small tabs on the Ohmeda-style oxygen fitting was reportedly broken off. Thus, the fitting was able to be inserted into a nitrous oxide outlet despite the obvious colour and label differences between the flowmeter and the outlet.

There are no easy solutions. Medical errors usually occur due to a combination of many reasons, both organisational and design-related. In the USP's Drug Product Problem Reporting (DPPR) report (USP, 2000), only 5% of reports concluded that errors were due to "inappropriate design". It is possible that this low figure is due to a failure to recognise that the design caused the error, since the professionalism of many healthcare providers leads them to 'get working' any system such that healthcare can be given to patients, despite design flaws.

In addition, design can create more problems than it solves (e.g. colour coding or over-reliance on the design to prevent error, i.e. not checking the label). Solutions to such problems can simply shift the boundaries. Consider, for example, alerts on medication warning systems (e.g. potential overdose). Practitioners can simply become trained to ignore them. Such a shift can result in an even more unfavourable situation than before, as responsibilities, assumptions and working practices may be affected. Over-reliance on the system can be a serious problem. There is often no 'perfect' solution – there is simply too much diversity to satisfy all situations perfectly.

Information Technology

Many incidents are related to information management due to the constant need to access or change information into a new form (e.g. dose calculations). Such information must be accessible during a multitude of functions that a nurse or doctor must perform in various locations. The use of an international standardised system for bar-coding on the packaging of medicines would contribute to a reduction of incorrect identification. The FDA is engaged in rulemaking that would remove existing barriers to the use of such a system (FDA, 2001a). The FDA has also proposed new regulations that will improve the format and content of prescription drug labelling (FDA, 2001a).

Risk analysis

Although Senders recommends the use of failure mode and effects analysis (FMEA) on devices (Senders, 1994), risk analysis methods should also be used to assess both medical errors in general and the systems problems behind them. Due to resource limitations it can be the rare but severe incidents which tend to be investigated, leaving a gap in learning from the more common and less severe incidents (CHI, 2002). This is a missed opportunity, but little can be done until resources are increased.

Failure Mode and Effects Analysis is becoming more and more common in the engineering community, particularly in the design of medical devices (BSI, 2000). However, this method can be applied to many other areas, including accident prevention and investigation. It is a bottom-up method, which begins by investigating each step in a process.

Methods such as root cause analysis are also good approaches which can be used to detect design errors.

Trends

Many changes are occurring in the healthcare system:

- Increase in pressures on staff, including more distractions, more complex treatment,

under-staffing: greater chance of error.

- Increase in medical device complexity, types and models from different manufacturers, giving the potential to increase the error rate.
- Medical treatment becoming more safety-critical, giving the potential for increasing the severity of errors when they do occur.
- Increase in litigation, leading ultimately to an increase in healthcare costs.
- Improvement in design, leading to more frequent use of better tools and techniques such as risk analysis and human factors engineering.
- Increase in use of devices in the home setting. Such devices must be designed in such a manner that they can be used safely and effectively by poorly-trained users, or those with limited skills.

Conclusions

There is much scope for improving healthcare systems design. Poor systems design is usually the problem, where budget problems and a lack of training are key contributing factors. However, there is still much work needed to identify the leading causes of errors.

A number of key issues have emerged which lead naturally to a number of potential recommendations for improvement. These are:

To ensure a common understanding of the definitions of medical errors / medication errors, and the reporting of causes and contributing factors as well as what happened. Consideration should be given to using the NCC MERP system developed in the USA.

- To explore the correlation between the quality of medical team communication and the quality of care.
- To review the use of hospital equipment (designed for use by healthcare professionals) in the home.
- To encourage the wider use of investigative methods such as failure mode and effects analysis for analysing the potential for error in all areas of healthcare.
- To investigate the effect of standardisation of products and medical language.
- To extend the powers of the Medicines Control Agency to review medicines names and packaging for good design.
- To encourage the use of specialised drug charts for high-risk drugs such as Warfarin. These are cheap to produce and easy to use, providing the right information necessary to calculate doses and record administrations.
- To encourage the introduction of a more balanced purchasing policy across the NHS, where patient safety is given prominence over immediate savings on cost.
- To encourage manufacturers to *innovate* and *improve* their designs to reflect a greater emphasis on patient safety, in the knowledge that such improvements are important to the NHS.

Annex 3 – Procurement mapping

The medication supply chain

The British pharmaceutical drug industry is one of the country's leading manufacturing industries worth an estimated £11 billion, exporting £7.25 billion and raising a trade surplus of £2.3 billion in 2000. With around 350 manufacturers, 12,000 pharmacies and around 800 hospitals to cater for, the industry employs 70,000 people and generates another 250,000 jobs in other related industries. To put this in perspective with other UK industries, it adds the largest value of all industries in the UK, i.e. the greatest value of output minus the cost of all inputs.

Research and development is taken very seriously within the pharmaceutical industry. On average 20% of pharmaceutical companies' gross output is spent on R&D, which again is a huge proportion when considered against other industries. Figure 14 displays the proportion of the industry's manufactured output supplied to various pharmaceutical outlets. The graph displays the relative volume of 'prescription only medicines' and 'over the counter' medicines.

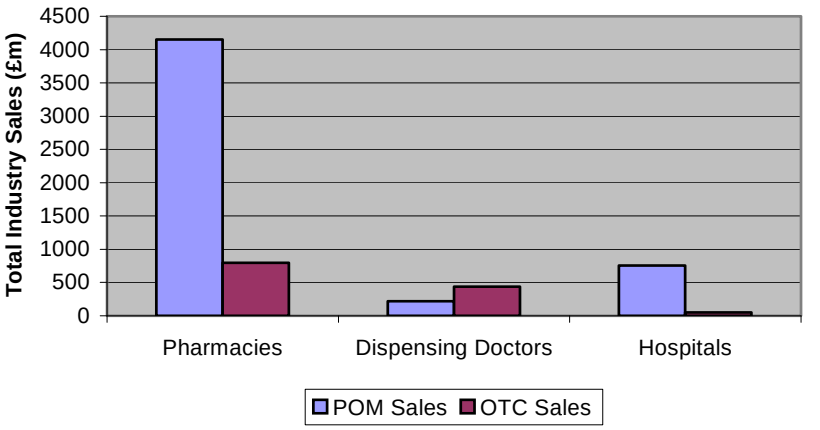
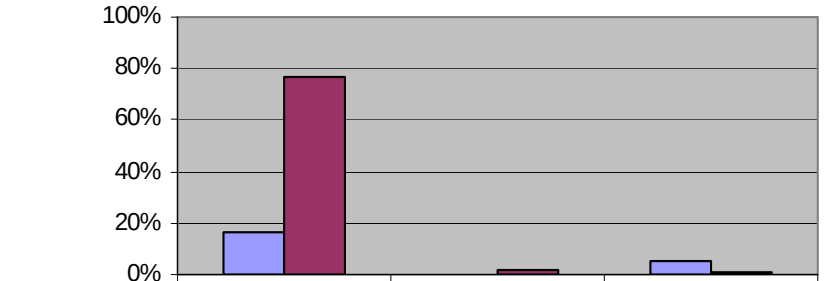


Figure 14: Proportion of manufacturer's output to different outlets

Figure 15 displays the total manufacturers' output reaching the major types of pharmaceutical outlets. 97% of wholesalers' turnover is accountable by sales to pharmacies, with 2% to dispensing doctors and the remainder to hospitals. Hospitals currently buy 40% of their medication through wholesalers, a figure which is increasing significantly in relation to their direct purchases from manufacturers.

One of the most fascinating parts of this project has been to get an in-depth look at the supply of pharmaceutical drugs from the distributor, through the wholesaler right down to the individual pharmacies at a community level. In order to be consistent, a large group including pharmacies, distributors and wholesalers, who in turn own 11% of pharmaceutical outlets in the UK, was used as the focus of the study.



	Pharmacies	Dispensing Doctors	Hospitals
Manufacturer	16%	0%	5%
Wholesaler	77%	2%	1%

Figure 15: Supply proportions for pharmaceutical outlets

What follows in this section is a discussion of the findings that have been observed from various sources of information. Findings from the manufacturing and distribution of medication are covered and various errors are highlighted in the summary at the end of the section.

Findings from medication manufacture

This section deals with the findings from web-based research and information from visits to various drug manufacturers. Apart from large manufacturers who benefit greatly from economies of scale, there are also drug manufacturers who deal with 'specials' manufacture. The report covers information based on interviews with a large morphine manufacturer, and a company that prepares these special formulations of drugs. We look first at the market drivers in manufacturing a drug, then at errors pertaining to manufacturing based on findings from web research and finally identify errors in the preparation of specialist drugs.

Marketing and market drivers for new pharmaceutical products

In order to ascertain what the major factors are in producing a new drug, an interview was conducted with the UK's leading manufacturer of Morphine, who has currently secured 95% of the oral slow-release Morphine tablet market. It was suggested that the primary driver for producing a new medication was obviously to produce profit. New drugs are produced via extensive research and development, with a focus on finding new drugs within their speciality or improving existing drugs.

The main targets for marketing are the doctors and healthcare professionals that prescribe the drugs and the pharmacists that dispense the drugs. Pharmacists have a choice of which medicines to supply to the patient when the doctor has prescribed a generic drug. They do not have a choice when the doctor prescribes a certain brand and so *must* supply that drug. Doctors are targeted by direct advertising in journals and promotions/displays from the manufacturers so that they are encouraged to prescribe a particular manufacturer's drugs.

It was mentioned that a 'brand-personality' is very important for identification of the brand and packaging is very important in implementing this.

There is also a difference in primary and secondary care emphasis, in particular for palliative care. As we have seen from figure 15, it is evident that the major focus for manufacturers will be on community pharmacies. In palliative care, patients will need to return continuously for

repeat prescriptions. It is very unlikely that the drug ever changes, so once a doctor prescribes that drug initially, the patient will always return for the same drug. This is where manufacturers will target doctors in primary care by several methods to ensure they prescribe their drugs. This way, when the patient passes into secondary care, community pharmacists must dispense the same brand.

A future development that we might be seeing in this country is 'Direct-to-Consumer' marketing. This is commonplace in the US and utilises all the usual D2C channels, such as television, to target patients. The idea behind this is that patients will ask for a specific brand when the doctor prescribes the medication. The company believed that D2C is inevitable in the UK and that it will be only a matter of time before it is allowed.

Errors in the manufacture of drugs

Once the manufacturer's advertising has been successful and a drug is prescribed, the implications of errors creeping in at the manufacturing stage have potentially huge cost implications for the pharmaceutical companies involved. If we take the example of the automotive industry, it is clear that regulatory bodies have a comparatively strong influence. On the identification of an error within the design of a released automobile, it is common knowledge that major car manufacturers will not always recall the product without first conducting extensive risk analysis. If the cost of recalling the product is less than the cost of litigation when balanced with the likelihood of the malfunction occurring, the product will remain on the market without recall. This is certainly not true for drug recalls in the pharmaceutical industry. The MCA and RPS have the authority to withdraw a drug from the market even on the most trivial of findings.

There are also error-reporting schemes such as the 'Yellow Card Scheme' within the British National Formulary and 'MIMS'. The cards are also available in the 'MIMS Companion' and the 'ABPI compendium of datasheets and summaries of product characteristics'. They enable practitioners to advise the MCA of adverse reactions to drugs and issues relating to drug quality.

The American equivalent of the Yellow Card Scheme is the 'MedMARx' system. This enables practitioners to report similar errors, but also those relating to administration. It uses the MCC MERP definition of medication error. This scheme superseded the USP's 'Drug Product Problem Reporting' (DPPR) program that focussed mainly on improving defective and potentially unsafe drug products (USP, 2000). The DPPR uncovered some interesting findings which can be found in table 3.

Table 3: Summary of the 1999 Information Submitted to MedMARx (USP, 2000)

Problem Reported	***Number of Reports (n=5751)***	***% of Reports***
Adverse drug reaction	1166	20.3
Product does not contain the labelled quantity	572	9.9
Foreign material in the product	407	7.1
Mechanical failure of product's container	348	6.1
Therapeutic effect lacking	309	5.4
Product's delivery system, labelling, and/or packaging missing	307	5.3
Design of product's delivery system, labelling, and/or packaging inappropriate	295	5.1

It is likely that some of these errors will be passed down to the patient and not necessarily picked up by the healthcare professional. The report goes into some detail as to the most common drugs and administration routes that are to blame. These are covered in the relevant sections later in this report.

These large manufacturing corporations greatly contrast the preparation of 'special' medications. Specialist producers work on a much smaller scale and are expected to tailor their products to suit individual needs. They are however still prone to error as we shall now see.

Specialist drug preparation

Specialist drug providers create bespoke medications as prescribed by specialists and consultants. An important information flow problem was presented at a meeting with one of their head pharmacists. They are contracted by community pharmacists when 'special' formulations of drugs are prescribed or when they lack the appropriate mixing apparatus. Figure 16 displays the communication within this specialist drug delivery chain.

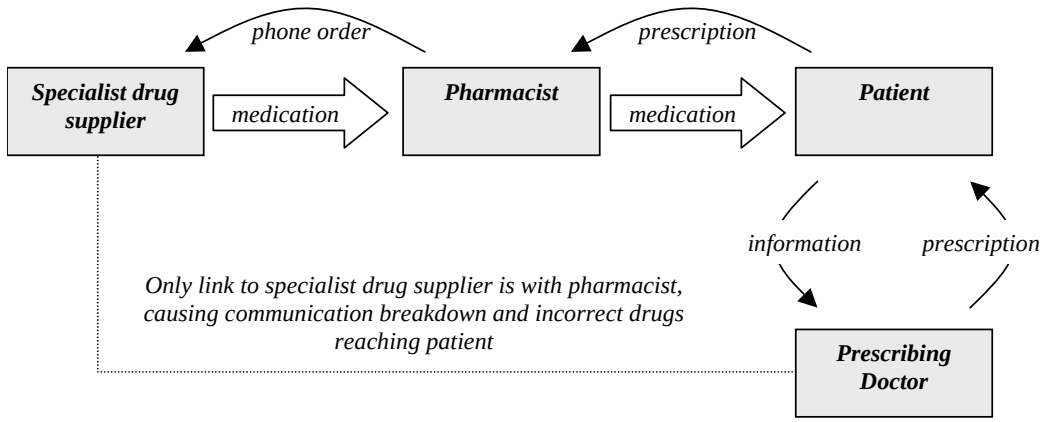


Figure 16: Communication within specialist drug supply

The pharmacist initially receives a prescription from the patient and decides whether it can be formulated in house. If it cannot, the pharmacist phones or faxes the supplier with the specification of the formulation. The supplier prepares the drug and despatches it accordingly, usually within 24 hours.

If the doctor prescribes a preparation that is not chemically possible, the only point of contact that the supplier has is with the pharmacist. Because there is no communication between the supplier and the doctor, they cannot consult him/her on a more appropriate formulation. It is seen as bad practice to "go behind the pharmacist's back" by talking to the GP directly and they fear the loss of business if they were to adopt such practice. Hence, in the majority of cases, the formulation is made even if it is useless and the patient receives an incorrect medication. Obviously harmful formulations will not be considered, but on the whole, formulations are for skin preparations that are for topical use only.

Findings from medication distribution

Once the drugs have been manufactured, they must be supplied to the various pharmaceutical outlets. Medication distribution in the UK is a big business and orders require a very fast response to ensure that patients receive their medication within 24 hours. The main wholesalers are: AAH/Lloyds (Gehe); Boots and Moss (Unichem) who supply to both group

pharmacies; and independent pharmacies.

The wholesale distribution system is first investigated. Next, the pharmaceutical pricing structure as a whole is described, and after this, foreign imports or 'parallel imports'. The section concludes by looking at international examples of good practice.

The order processing system and logistics

On first inspection, the pharmaceutical industry would appear to be fairly straightforward and undemanding. However, upon visiting the AAH wholesale distribution warehouse, it was evident that pharmaceutical distribution is a seriously responsive logistical operation. From observations by the Design for Patient Safety research team, roughly three orders were filled per minute on a highly automated distribution line.

Figure 17 gives an impression of the scale of operation that most group-wholesalers work on with an 'A-frame' capable of holding hundreds of different drug types. The A-frame comprises of the racking shown and an automated picking system which places all selected drugs onto a conveyor. Behind the workers, you can see the handpick racking used for less common drugs. Figure 18 shows the apparatus used for filling the boxes that get sealed and consequently delivered. Although it is not entirely clear from the picture, boxes pass from left to right of the picture and the conveyor runs perpendicular to this. The boxes are then vibrated to ensure that the drug packages settle in the box.

Deliveries are made once a day. There is no need for any more deliveries than this because the nature of their customers, i.e. the wholesaler, is relatively undemanding. Vans are used and orders are checked off the computer system accordingly.

Distributors need to process orders rapidly to meet deadlines and deliver twice daily to their pharmacy outlets. Orders come through from the pharmacies automatically everyday at 5.15pm and are delivered the next morning at 10.30. There is also an afternoon order at 12.15 which arrives at 3.30pm leading to a three hour response time. Because of the rapid nature of deliveries it is unsurprising that pharmacists regularly receive incorrect orders. This poses no threat to patients as long as the error is picked up by the pharmacist.

Figure 17: 'A-frame'

Figure 18: Filling boxes

Errors in the distribution of drugs

During this study it has been very hard to find information pertaining to errors in the supply of drugs. There is obviously a finite number of routes in which errors may occur in distribution, including the confusion of orders, a failure to track the medicines correctly and supplying the wrong medicine. All of these may have implications on patient health, but should be picked up by the pharmacist in the dispensing of the product.

One of the main sources of information in this area has been from interviews with drug distributors who specialise in pharmaceutical distribution. More specifically they are the UK leaders in temperature controlled drug distribution, an area which is critical for the integrity of some medications. On consultation with the managing director, the following findings present us with topics for further consultation.

Drug tracking is an area that has led to confusion and mix-ups in medication in the past. Figure 19 focuses on the link between the distributor and the wholesaler and the crossover of tracking systems used.

Figure 19: Tracking used between supply chain nodes

When the drugs arrive at the wholesaler, the tracking system is swapped and hence a mix-up can, and sometimes does, occur on entering the order into the computer system.

An example of a mix-up was highlighted to the DPS team researchers. Because the drugs were ordered especially and the incorrect vaccine was received and administered by the practice nurse, he/she expected the correct medication to have been delivered. The drug name was not double-checked which led to the incorrect administration of Rubella instead of the MMR. A combination of factors are therefore to blame: tracking, failure to follow protocol and human error.

Batch numbers are also an area for concern. It is mandatory for a batch number to be included on the medication packaging, but there is no specified way of imprinting this on the pack. Batch numbers that are embossed on packaging without ink are open to interpretation. Another scenario highlighted was that in which a 'picker' has to break through several layers of cellophane wrapping in order to see an embossed batch number. This obviously leads to the possibility of batch confusion and damage to the drugs.

Payment structure

Price competition is evident at manufacturing and wholesaling levels for generic medication. A pharmacist can choose any generically equivalent drug if specified on the prescription. This is obviously not so for branded drugs.

Figure 20 shows the pharmaceutical payment structure and how reimbursement from the Prescription Pricing Authority (PPA) works. The manufacturer must sell the medication to the wholesaler at a fixed price of 87.5% of the NHS list price. The wholesaler is then free to pass the drugs on to the pharmacy with a variable discount, usually resulting in selling the medication at 93% of NHS list price.

The pharmacist is under pressure to choose the cheapest generic drugs because of 'clawback'- a variable amount that is returned to the NHS at the end of the financial year. Clawback is calculated based on the cheapest generic available. Therefore if a pharmacist has been using an expensive generic, the difference in price between that and the cheapest is 'clawed back' by the NHS.

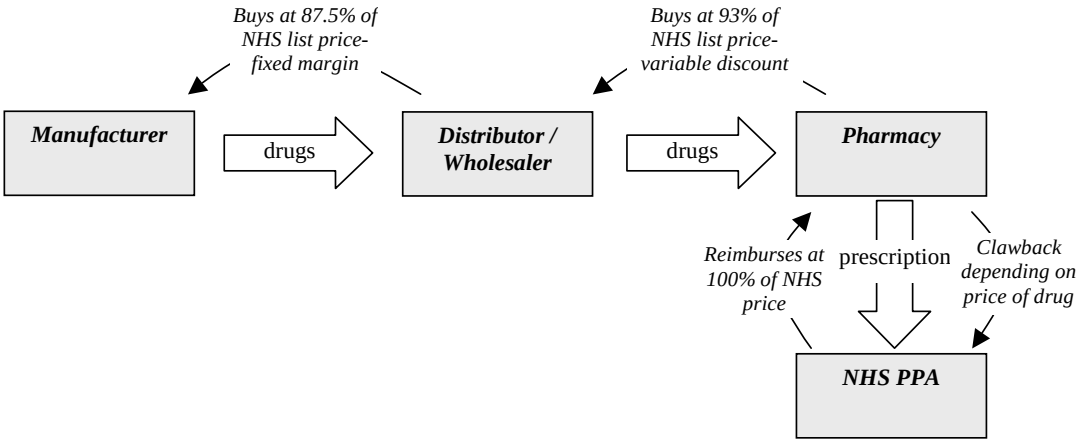


Figure 20: The pharmaceutical payment structure

The NHS makes payments to the pharmacies based on three factors: reimbursement for the ingredient costs of prescribed drugs, a dispensing fee and a professional allowance. The level of reimbursement for the ingredient costs is made up of the list price of the item dispensed less the clawback. This pricing structure has opened up a new channel of cheap foreign alternative drugs via 'parallel importing' which we shall now investigate.

Parallel imports

Parallel importing occurs when a product placed on the market in one country is bought by an intermediary who exports it to a second country. These imports are initially intended for the country that they are manufactured in and are imported by the UK as cheap alternatives because of the pricing structure. Medication typically comes from France, Spain, Italy and Belgium. For parallel trade to exist, profits for the trader have to be sufficiently large to be attractive; i.e. when there are significant price differences between countries or currency fluctuations. The medicines market operates on a different basis from most other competitive markets and most EU countries control pricing, but the ways in which they do so result in wide variations.

Other than parallel importers, very few benefit from the trade. It has been estimated that for every pound that the NHS saves, the pharmaceutical industry loses £6 and more than one in eight prescriptions in the UK are now filled with a parallel imported product. There are also implications in terms of the safety and quality of medicines. This practice also brings about an increased risk of counterfeiting and piracy.

Clearly, on importing the medication, it will have to be repackaged to ensure that writing is in English and aligns to the MCA's guidelines. A possible source of error is in the brand names associated with the drugs. For example, it was found that foreign brand names for UK equivalents are not necessarily always the same, which can lead to confusion. It is not unlikely for patients or pharmacists to contact manufacturers to ascertain if the imported drug they have is in fact the same as their product.

International practices

This payment structure is certainly not the case in Canada. Patents on drugs are prohibited and hence price competition is fierce, thus lowering the ultimate price borne by the consumer/health authority. Brand names do still exist, but generic equivalents are allowed which, on average, cost 50% less than their branded equivalents.

Another example of lowering drug costs that we can draw from the French is in the licensing of drugs. Their MCA equivalent will resist any branded drugs, or indeed generic drugs that are deemed to be too expensive. Obviously they will not disallow the drug on the market, but they extend the amount of time in granting a licence. This means that manufacturers need to price their drugs reasonably so that they do not lose revenue in getting the drug to market.

Information flow throughout the supply chain

We now shift our focus onto the information flow in the supply chain. Figure 21 maps the distribution supply chain and the information flows within it. It was found that there are four main methods of communication: phone/fax/internet, electronic data interchange (EDI), paper and face-to-face oral communication, each of which carries a different level of risk.

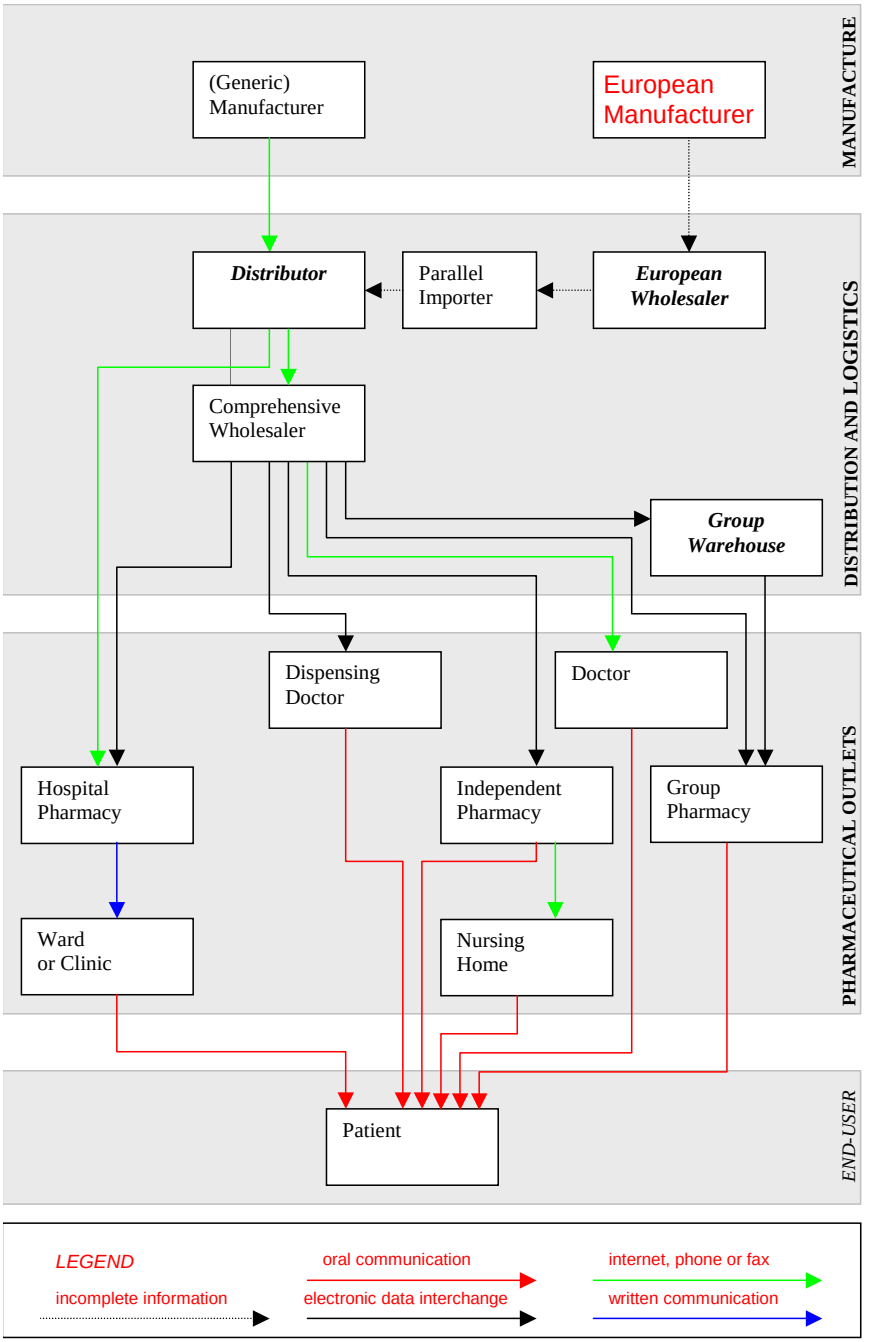


Figure 21: Information flow in the drug supply chain

In general, all pharmacies are linked to their wholesaler electronically using an EDI or phone line. This is mainly due to the fact that orders are generally complex and large in number; therefore an electronic system is necessary to cope with the intricacy of the ordering process. A phone or fax communication method is sufficient between manufacturer and wholesaler since there are a relatively small number of companies that a wholesaler sources their drugs from.

Due to a lack of information on parallel importing, it was not possible to get a feel for the communication with overseas suppliers. From observations of errors in general and case

studies, the following areas are cause for concern:

- oral and written communication;
- changeover of communication method; and
- changeover of data type.

Oral and handwritten communication methods such as prescriptions have room for interpretation, and, because of human nature, errors will result. A changeover in communication method is also risky, an example being the change from EDI to phone or fax between the manufacturer, supplier and wholesaler. Again, there is room for interpretation and errors can creep into the process.

As we have seen from the example of the MMR/Rubella mix up, it is clear that changeover in data type can present room for errors to occur. This relies on the correct input into a computer system, and again, human error can lead to mix ups. The implications of this are far reaching since one error at an early stage in the supply chain can affect thousands of packs of the same product.

It is clear that suppliers and wholesalers recognise these areas of confusion since double-checking is used profusely in medication tracking. An example of this can be found in the 'Pick Sheet'. The "Pick Sheet" is used when an order is processed and gives a list of medication required for a worker to pick. The form ensures that the correct batch number, lot number and pallet number are used so that mix-ups with different drugs do not occur. The computer system also ensures that the stock is not out of date and meets customer requirements in terms of shelf life. Stock taking is one of the most important aspects of the business and is carried out by at least two designated personnel on a continual basis.

Conclusion

As we have seen from this section, the pharmaceutical industry is certainly more complex than one would first suspect. It is clear that the different types of manufacturers leave scope for various errors, the majority of which are based on communication and human error. In summary, the main findings of this section are:

- Branding is extremely important in the manufacture of drugs which can potentially lead to negligence on the part of the manufacturer.
- The manufacture of drugs is not always perfect and errors are evident at the production phase of the supply chain in both large-scale and 'specials' preparation.
- The UK pricing structure has led to an increase in the use of parallel imports, increasing the likelihood of translation and repackaging errors.
- Information exchange between nodes of the supply chain is prone to confusion and there are various different areas that can lead to tracking errors.

Medication and information flows

Now that we have covered the top end of the supply chain, we can now turn our attention to the tail end and discuss the information and medication flow between the healthcare professional and the patient. If we focus on the information and material flows in the environment in which the drug is administered, i.e. the hospital, in the home or at the doctor's surgery, we find some interesting patterns. The following archetypes generalise the circumstances of this administration:

- Self-prescribed, administered at home by patient.
- GP prescribed, administered at home by patient.
- GP prescribed, administered at home by carer.
- Doctor prescribed, administered at hospital by nurse.

In this section, the archetypes listed above will be investigated in more detail. Information, medication and prescription flows are mapped out and numbered 'hotspots' between the nodes are identified. Hotspots above pharmacy level are ignored since this has been covered already in the report. If a hotspot is not numbered, the issue is common to a number of archetypes and is covered later in the section, namely software.

Figure 22 shows the key used in all the subsequent diagrams. 'Hot spots' are marked with a circular red dot and discussed under the diagram in more detail. The section concludes by looking at a case-study and identifying issues in the crossover from primary to secondary care.

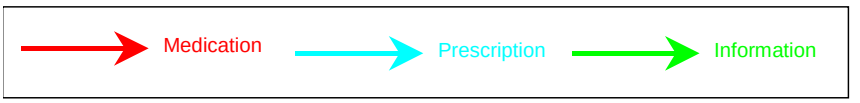


Figure 22: Key to supply archetypes

Self-prescribed, administered at home by patient

This archetype covers 'over-the-counter' (OTC) drugs only, and hence contraindications and adverse drug reactions will in general be mild unless there is a serious misunderstanding in the administration of the medication.

Hotspot 1: Prescribing errors

Figure 23 displays this archetypal situation. Hotspot 1, between the patient and the pharmacist, is indicative of patient history being communicated ineffectively. A pharmacist should always ask a patient if they are likely to suffer an ADR with the drug by checking their past history. However, misunderstanding and an incomplete patient history might lead to confusion.

An example of OTC drugs being potentially harmful in this way is if the patient is taking Warfarin and then gets OTC aspirin. This would result in a potentially lethal adverse drug reaction. It should be noted that aspirin is readily available off the shelf without any pharmacist intervention.

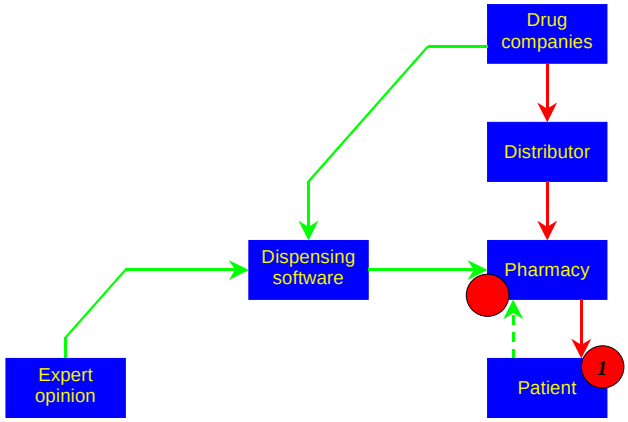


Figure 23: Medication and information flows for self-prescribed drugs administered at home

GP prescribed, administered at home by patient

Figure 24 offers the most hotspots of all archetypes. The fact that the patient is responsible for the transfer of the prescription from the GP to the pharmacist leads to a wide scope for errors to occur.

If we focus in on the interaction between the pharmacist, GP and patient, we find there are many hotspots evident. It should be noted that this assumes that the manufacturer does not carry any risk in terms of packaging and incorrect drugs being supplied. In this section, we will follow up on the errors highlighted in figure 24 and categorise them according to who is involved in the interaction. Of these errors, it will be most beneficial to ascertain those which occur most frequently and determine whether the consequences are severe enough for further investigation. Where there has been information available, each error has subsequently been investigated and a frequency assigned accordingly.

Hotspot 2: Prescribing errors

This hotspot covers the issues related to prescribing errors. Communication between the patient and GP are outlined in hotspot 2. The remainder of this section will cover:

- Miscalculation of drug amount and frequency.
- Prescribed wrong type of drug.
- Prescribed wrong timing of drug.
- Dispensed wrong strength of drug.
- Dispensed wrong amount of drug.

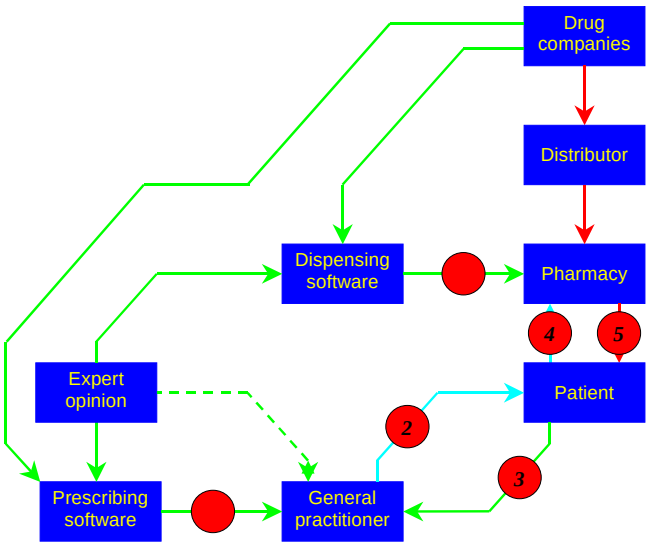


Figure 24: Medication and information flows for GP prescribed drugs administered by the patient

The miscalculation of drug doses, leading to the dispensing of the wrong amount of drug, is a cause for concern, especially in paediatric cases where complicated equations are necessary to determine the correct dosage. Table 4 highlights the most common errors related to miscalculation and their frequency (Lesar, 1998). "Errors in the prescribing of medications are the most common cause of preventable adverse drug events," (Bates *et al.*, 1995) 15% of these errors are due to dosage equations.

The study covered hand-written prescriptions only for drugs of special formulation. The prescriptions or 'medication orders' were then entered into a computer system before dispensing. The system that was used had "standard automatic checking facilities for dosage range, allergies and drug interactions.

Table 4: Errors in the miscalculation of doses on prescriptions (Lesar, 1998)

	No of errors (%)	***No of serious errors (%)***	***Errors per 1000 'special' prescriptions***	***Serious errors per 1000 'special' prescriptions***	***Errors per 100 admissions***	***Errors per 100 patient days***	***Serious errors per 1000 patient days***
Paediatric	139 (69.5)	43 (51.2)	**4.94**	**1.53**	3.56	4.34	1.1
Adult	61 (30.5)	41 (48.8)	0.13	0.09	0.43	0.26	0.3

Because we do not have any firm figures on the ratio of 'special' prescriptions to normal prescriptions, we cannot scale up this error rate. Clearly there will be differences in UK and US protocols which will affect these results.

The report delves deeper into the exact nature of these errors, the results of which can be seen in figure 25, covering 119 individual reports. Clearly, 'factor of ten' errors are the most common errors.

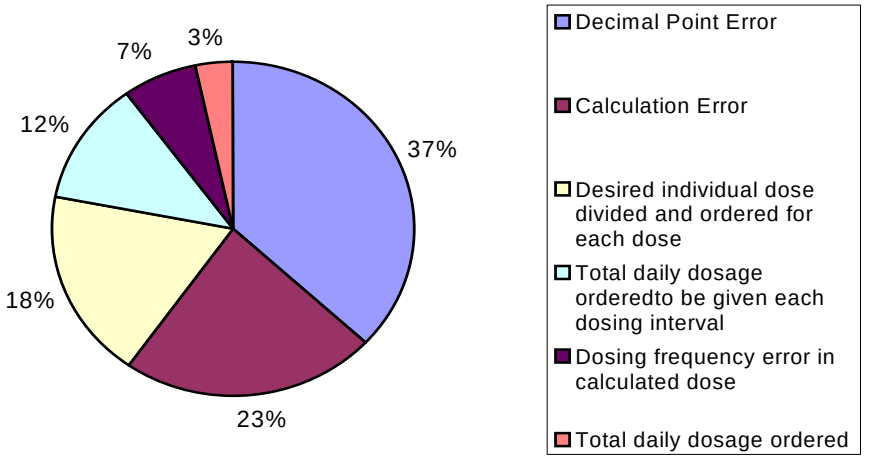


Figure 25: Most common equation error causes, taken from Lesar (1998)

Table 5 below shows the result of a recent survey conducted in late 2001 in the UK (Shah *et al.*, 2001). The survey investigated prescribing errors and covers the remainder of the errors due to interaction between GP and patient. It was found that errors were evident on 7.5% of prescriptions, 16.5% of which were identified by the patients or their representatives.

Table 5: Prescription errors (Shah et al., 2001)

Category of Error	***Type of error***	***Number of errors***	***Error Rate per 1000 prescriptions***	***Percent of total errors***
Incorrect strength prescribed	Strength missing where no guidance available in BNF	260	6.9	9
	Wrong strength prescribed, and subsequently changed	18	0.5	<1
	Strength was not clear where existing in various strengths	12	0.3	<1
	Total	*290*	*7.7*	*11*
Prescribed wrong timing of drug	Directions not mentioned at all	715	18.9	25
	Prescribed quantity was not clearly written, too large, or missing	229	6.1	8
	Directions incomplete, not legible or written 'as directed'	321	8.5	11
	Directions were potentially hazardous and subsequently changed	20	0.5	<1
	Total	*1285*	*34*	*45*
Prescribed wrong type of drug	Prescribed item was not requested	510	13.5	18
	Prescription for any discontinued medicine, or wrong medicine due to a transcription error from a hospital discharge letter	25	0.7	<1
	Potentially hazardous drug interaction, changed after consultation	14	0.4	<1
	Total	*549*	*24.5*	*20*
Dispensed wrong amount of drug	More than one month's supply prescribed where not requested	306	81	11
	Patient suffered from short supply of medicine due to special pack rules	17	0.4	<1
	Total	*323*	*81.4*	*12*

It should be noted also that the wrong amount of drug can also be dispensed due to blister packs and 'original pack dispensing'. These issues are covered later in the report.

Hotspot 3: Patient communication errors

Here we cover the issues relating to:

- Improper communication of symptoms.
- Improper communication of medical history.
- Instructions not followed properly.

The Department of Health has released some interesting data based on the ability of patients to communicate their symptoms and follow instructions as necessary (RPSGB, 2001). Table 6 outlines some of the most significant findings relevant to this interaction.

It is perhaps disturbing reading to find that only half of the population tells the pharmacist if they are taking another medicine although the study does not cover whether this information is dealt with when the medication is prescribed.

Table 6: Significant findings from "Your medicines matter" (RPSGB, 2001)

Survey question topic	***Percentage of Survey***
Patient always tells pharmacist if taking another medicine	54%
Patient does not always follow all kinds of directions i.e. how often, duration and how to use	42%
Patient admits to having stopped taking medicine before the end of course	33%
Patient failed to take medicine they were prescribed	18%
Patient admits to not always sticking to instructions for prescription medicines	17%

Hotspot 4: Transaction of prescription to pharmacist

This hotspot covers the errors pertaining to the transfer of the prescription to the pharmacist from the patient. Obviously the main error in this transaction relates to prescription misinterpretation and so handwriting errors are clearly a large area for concern. As described in the section in this report entitled "A medical error view", findings are covered in a UK survey of prescription errors, stating that:

"…errors were found on 140 of the 1,373 handwritten items presented during the study period (10.2%) compared with the 1,233 of the 33,772 computer-generated items (7.9%)…"

Hotspot 5: Transfer of medication to patient

The last hotspot within this archetype covers the risk involved in dispensing the wrong medication to the patient. Clearly the trigger for this will largely be due to prescribing errors, but drug confusion can occur due to similar packaging. This is covered in more detail later in the report.

GP prescribed, administered at home by carer

Figure 26 displays the information and medication node linkage in a situation where a carer is necessary for administration, i.e. for elderly or immobile patients. In this archetype, it would be easy to consider the carer as a skilled individual who can be relied upon to double check medication before administration. This is, however, not always so since there are vast differences in carer skill level and an extra level of complication can result.

Hotspot 6: Communication with carer, patient and GP

The hotspot in this archetype has been placed on the carer, rather than on the interfaces. This is because the carer acts as an intermediary between the patient and GP and hence introduces a wider scope for communication error. One way to integrate the pharmacist more with the patient is by integrating them with the care team used in palliative care. A recent article describes the beneficial effect of using properly trained carers and community pharmacists in palliative care as opposed to not using a pharmacist (Needleham *et al*., 2002).

The study followed the interventions made by community pharmacists to 14 patients in palliative care with a terminal illness. Each intervention made by the pharmacist was documented and reviewed at the end of the care period. An example of the interventions made would be to alter their medication dosing regime depending on the level of pain the patient was feeling. Table 7 classifies the results of the interventions made by the pharmacist, leading us to the conclusion that most interventions made by the pharmacist are beneficial to the patient's well-being.

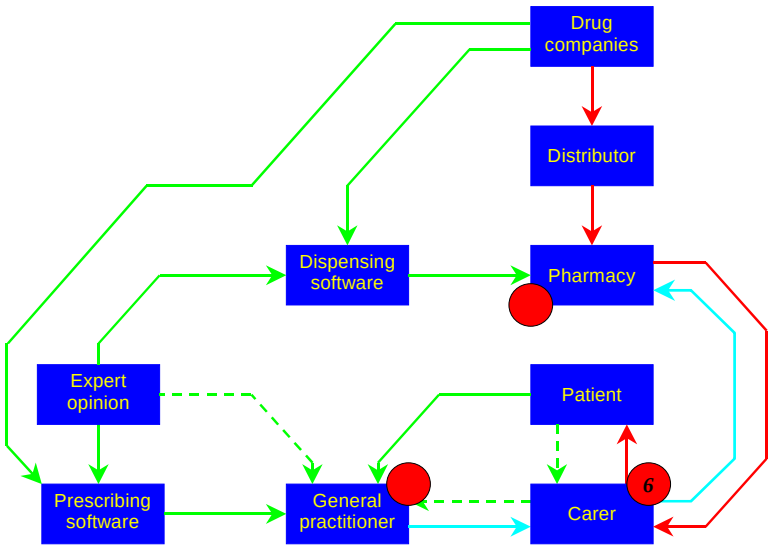


Figure 26: Medication and information flows for carer-administered drugs prescribed by a GP

Table 7: The effect of community pharmacist intervention in palliative care (Needleham et al., 2002)

Case	***Percentage of interventions***
Intervention was likely to improve symptom control	31%
Intervention was worthwhile but effected no change	28%
Intervention was likely to improve patient compliance	13%
Intervention was likely to prevent deterioration of the patient	9%
No agreement reached by expert panel	8%
Intervention was unnecessary/ inappropriate	6%
Intervention was likely to be detrimental to the patient's well-being	3%
Insufficient information available to allow categorization	2%

Doctor prescribed, administered at hospital by nurse

The final archetype presents a complex interaction involving many different people including nurses, doctors and pharmacists. It is further complicated by the fact that the patient is in hospital on a constant basis and invites risks associated with staff-changeovers. Prescription information in the hospital ward is carried on hospital charts which are handwritten. The majority of drugs included on the chart are available in ward stock. However, if a special drug not carried on the ward is needed, a separate prescription is written and taken to the pharmacy and the information is duplicated onto the chart.

Hotspot 7: Specialist prescription transfer

When a drug is needed for a patient that is not carried in ward stock, a separate prescription is written by the doctor and is transferred to the hospital pharmacy by the ward nurse. The nurse is then responsible for administering the drug. There is scope for error when the medication chart is not updated with this information and results in the patient's file not being updated.

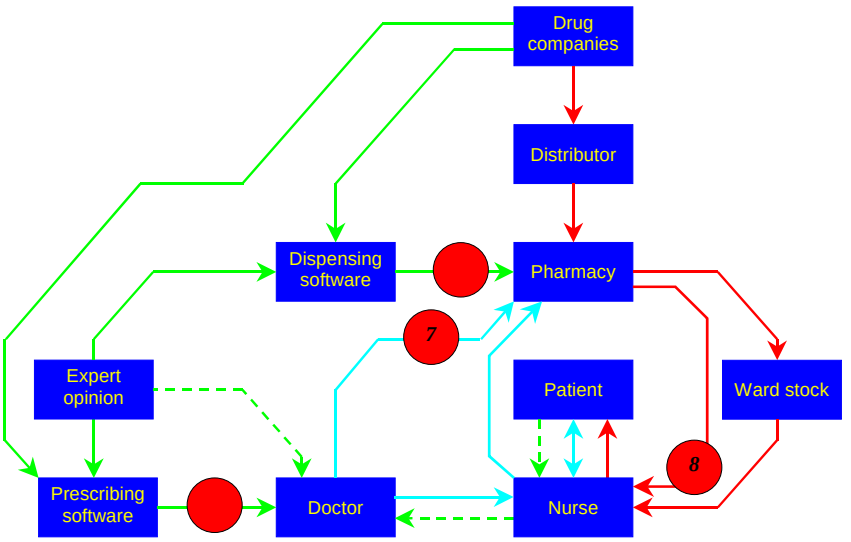


Figure 27: Medication and information flows for doctor-prescribed drugs administered in hospital

Hotspot 8: Medication charts

The main source of information on a patient is carried on the patient's medication chart. It is perhaps worrying that the care of the patient relies on a paper-based system since the nature of drugs prescribed and administered are more complex than in a community pharmacy, noting of course that the vast majority of GP prescriptions are computer-generated.

Again, it has been difficult to obtain information about prescribing using the medication chart, but on inspection, it seems as if the chart is both large and complex. The information carried on the charts has led to specific occurrences where the patient has suffered or even died as a result of an error.

Prescribing and dispensing software

The most commonly used software for prescribing is 'EMIS', or the 'Egton Medication Information System'. It is hoped that this system will be recognised as the national standard in prescribing software and covers all types of healthcare.

EMIS supplies software to primary care, secondary care, community nurses and for health authorities. It is updated weekly via 'patches' to the EMIS Drug Database which contains all information pertaining to prices, new drugs and drug directions and warnings. Information comes to the system from:

- The Department of Health;
- "Requirements for Accreditation" (RFA) from the NHS;
- Chemist and Druggist magazine;
- MIMS;
- British National Formulary;
- Drug Companies; and
- Importing Companies.

It should be noted that it is not mandatory for drug companies to inform EMIS of an update, but ultimately it is in their interests if a new drug is developed and they want it to be prescribed. The RFA requirements stem from the NHS and cover testing of the system. An example of one requirement is for a doctor to be able to prescribe a generic equivalent drug with one keystroke.

New drug requests received are added to the EMIS central database and placed on the distribution update system within eight hours. Approximately 60% of sites collect a patch update within 48 hours, with over 14,000 GP's receiving the update within eight working days of release. It is hoped that the electronic transfer of prescriptions will remove this risk.

Conclusion

To summarise this section on medication and information flows, we will highlight the hotspots that present the most threat to patients:

- Self-prescribed drugs available off the shelf are a potential source of harm for patients. There is however very little that can be done other than to change all off-the-shelf medicine to OTC medicine and to possibly improve patient information leaflets.
- Communication between the GP, pharmacist and patient is a great cause for concern. The interactions based on prescription information and oral communication leave a large scope for errors to be made.
- Prescribing issues including decimal point calculation errors are of the greatest concern. This is where double and triple checking of prescription information is essential since the rate for this kind of error is very high.
- The hotspot relating to carer communication is a potential major issue as an extra node in the supply chain is introduced. If the carer is not well trained, this relay of information could lead to confusion.
- Hospital charts are another cause for concern since the nature of medication information carried on them is both large in quantity and more risky than community prescriptions. This is an example of safety critical information being relied on by a hand-written communication method.
- Lastly, the crossover of care from secondary to primary care and vice-versa can lead to complications and confusion. Since there is currently no central record of patient

information, errors can easily happen as we have seen from the Methotrexate case study.

Focus on administration of medicines

This part of the report will tackle the issues surrounding drug administration. Drug administration can be described as the route that a drug takes in getting into the body and covers everything including the administrator responsible, the administration route, the drug used and also the environment in which it is conducted. As we can see, these factors lead to many different circumstances surrounding the administration of medicine, and it is the aim of this report to 'pluck out' those which present the most risk when weighed up against that route's frequency.

There are several different methods of administration associated with medical devices such as inhalers, intravenous syringes and transdermal patches, each carrying their own respective risk, some more than others. There are, too, many different types of healthcare professional who are capable of administering POM drugs, including nurses, doctors, GPs and in some cases the patients themselves.

The 1999 Summary Report of information submitted to MedMARx (USP, 2000) found that administering drugs caused the greatest number of errors as can be seen from figure 28. The most common errors within administration were "omission" of medicine and "improper dose", caused by "performance deficit" and the "protocol not [being] followed". The reasons for this were because of "distractions" and "workload increase".

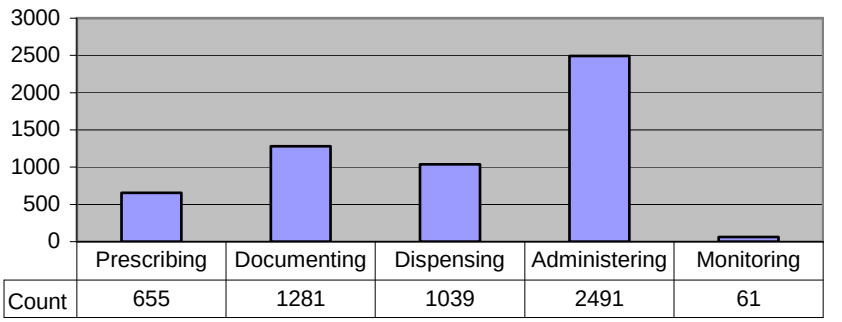


Figure 28: Node where most errors have been reported (USP, 2000)

In this section, we will start by looking at the risks involved with the administration route, drawing on studies (mainly from the US) and moving on in turn to look at risky medication. The section concludes by tying the drug and administration method together in a risk matrix which is followed by a summary of what we have learnt.

Administration route risks

In order to assess the risk of an administration method, there are several factors that need to be taken into account. There are inherent risks associated with the administration route, such as the speed of absorption of the drug into the body, as well as risks associated with the environment of administration, i.e. administration location and the healthcare professional responsible.

A matrix was used to measure the risk of an administration method in relation to the administration circumstances. Obviously some combinations of environment and administration method will not occur at all, for example, applying a morphine patch in an

emergency environment opposed to an intravenous injection.

Each administration route has been given an *absolute* measure of risk, identifiable at the top of each heading (H- High, M- Medium, L- Low). This score is based on the following factors:

- Relative speed of absorption.
- Risk of contamination.
- Ease of confusion during administration.
- Types of drugs available via that administration route.

When plotted against the administration environment and circumstances, there is a *relative* measure of risk assigned based on the same scale as the absolute risk. These scores were then taken and multiplied out on a scale of 1 to 9. For example, a highly risky procedure (H) in a risky environment (H) will score 9, whereas applying a nicotine patch (L) in home use (L) will score 1. Table 8 summarises the most risky methods of administration circumstances which scored 9/9.

Table 8: Most risky administration circumstances based on risk matrix

Administration Route	***Circumstances***
Intravenous	Surgical Procedure
Intravenous	Critical Care
Intravenous	Ambulance/Paramedic
Intravenous	General Ward
Intrathecal	Surgical Procedure
Tablets	Dispensing GP
Tablets	OTC at pharmacy
Tablets	Off the shelf, no pharmacy
Oral Mask	Repeat prescription

As we can see, intravenous and oral tablet administration pose the greatest threat under different circumstances. It should be noted that the information has largely been formulated from background reading and limited conversation with professionals. It would certainly be preferable to talk to more healthcare professionals about mapping these risks more thoroughly, but obviously resources and time are at a premium.

Now that the more risky areas have been investigated, a frequency should be assigned so as to determine the most important areas for further investigation. Unfortunately, data for each specific administration circumstance is very hard to find from an external standpoint and the only real data that is available is that displayed in figure 29. This is merely general data on the relative frequency of each administration route and does not give us any information on the administration circumstances.

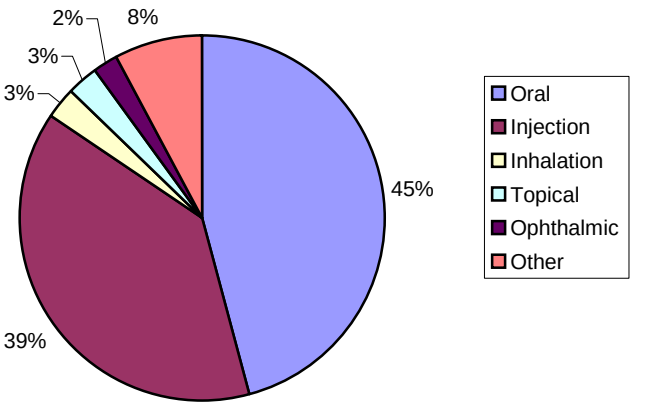


Figure 29: Reports by route of administration (USP, 2000)

Reported errors pertaining to administration route

Now that various administration-related circumstances have been investigated, it is beneficial to look at studies which have delved into specific occurrences to explore further the accuracy of the findings described so far.

The DPPR report from the USP (2000) agrees that the vast majority of all errors reported involve tablets and intravenous injection. Figure 29 demonstrates the full results; the main conclusion being that these routes of administration need more focus than any other.

The National Coordinating Council for Medication Error Reporting and Prevention (NNCMERP) in the US provides us with the last relevant piece of research. It describes fatal errors reported to the FDA's Adverse Error Reporting System between 1993 and 1998. A total of 5366 reports were received and table 9 displays the most common causes.

Clearly overdose and the confusion of drugs are the major errors that arise, but information on the frequency of occurrence would be beneficial. Unfortunately there are very few studies that apply in this situation. It is perhaps unfortunate that the majority of information related to this subject stems from American research. Obviously different protocols and procedures will affect the figures to a certain degree, but we can certainly get a general 'feel' for where there are causes for concern.

Table 9: Types of Error (Phillips et al., 2001)

Category	***Error***	***Number of Reports (%)***
Improper Dose	Overdose	216 (36.4)
	Under dose	8 (14.2)
	Extra Dose	6 (1.0)
	Not classified	13 (2.2)
	Total	*243 (53.8)*
Wrong Drug	*Total*	*96 (16.2)*
Wrong Administration Route	Intrathecal opposed to IV	14 (2.4)
	IV instead of Oral	8 (1.3)
	IV instead of Intramuscular	4 (0.7)
	Intramuscular instead of IV	1 (0.2)
	Other	30 (5.1)
	Total	*57 (9.7)*

Problematic medications

Certain administration circumstances will invite different kinds of medication to be used. From studying various sources, it is apparent that there are certain drugs that present more risk than others, either by inherent risk of drug composition, drug administration method or via ease of confusion during administration.

By mapping certain drugs through the matrix in figure 30, it is possible to ascertain the risks involved. The NCC MERP's MedMARx report contains data relating to the drugs that have caused the most errors and the severity of these. The report categorises error types on a severity rating from A – I. Categories A – D involve potential errors and errors that cause no harm, whereas categories E – I involve actual errors which cause harm.

The incidents were reported voluntarily by healthcare professionals registered with the scheme and are categorised into these severity ratings. Table 10 shows the drugs that were responsible for incidents categorised into these ratings; the top 5 drugs are shown for each rating. If a drug was found to be in the top 5 of both ratings, it is given a rating of A –I.

Table 10: Most commonly reported drugs (USP, 2000)

Drug	***No of Reports***	***Within Top 5 in Severity Level:***
Warfarin	155	A – D
Insulin	151	A – I
Heparin	129	A – I
Cefazolin	98	A – D
Vancomycin	96	A – D
Lorazepam	82	A – D
Potassium Chloride	72	A – D
Meperidine	68	A – D
Furosemide	62	E – I
Famotidine	61	N/A
Morphine	No data	E – I
Fentanyl	No data	E – I
Propofol	No data	E – I

Administration risk matrix

Having found the most 'troublesome' administration routes and the most risky drugs, we can now get a feel for the most risky administration circumstances. The objective of this investigation has ultimately got to be to help reduce deaths by medication error. Therefore, if we can find a way of quantifying the amount of deaths caused by a certain type of administration, or for a certain drug, we can generate specific targets for further research. This is important because a lot of publicity has been given to high-profile cases that only happen very rarely, whereas the most impact can be made where accidents are occurring frequently but perhaps on a less severe scale (i.e. do not necessarily cause death).

Figure 30 is a crude representation of this information; examining the medication risk, administration risk and frequency of administration method. The medication risk uses the drugs listed in table 10. Using the BNF to find information on administration techniques for each medication, a level of risk is assigned to each based on:

- Number of different administration methods for that drug.
- The total number of hazardous adverse drug reactions listed with a "•" in the BNF.
- Severity ratings based on the MedMARx data in table 10.

The administration method risk is derived from table 9, and the frequency is plotted drawing on information from figure 29. It is unfortunate that the actual frequency of the specific route and administration method cannot be found, but the matrix does serve as a rough guide for ascertaining which drugs/administration method combinations are the most risky.

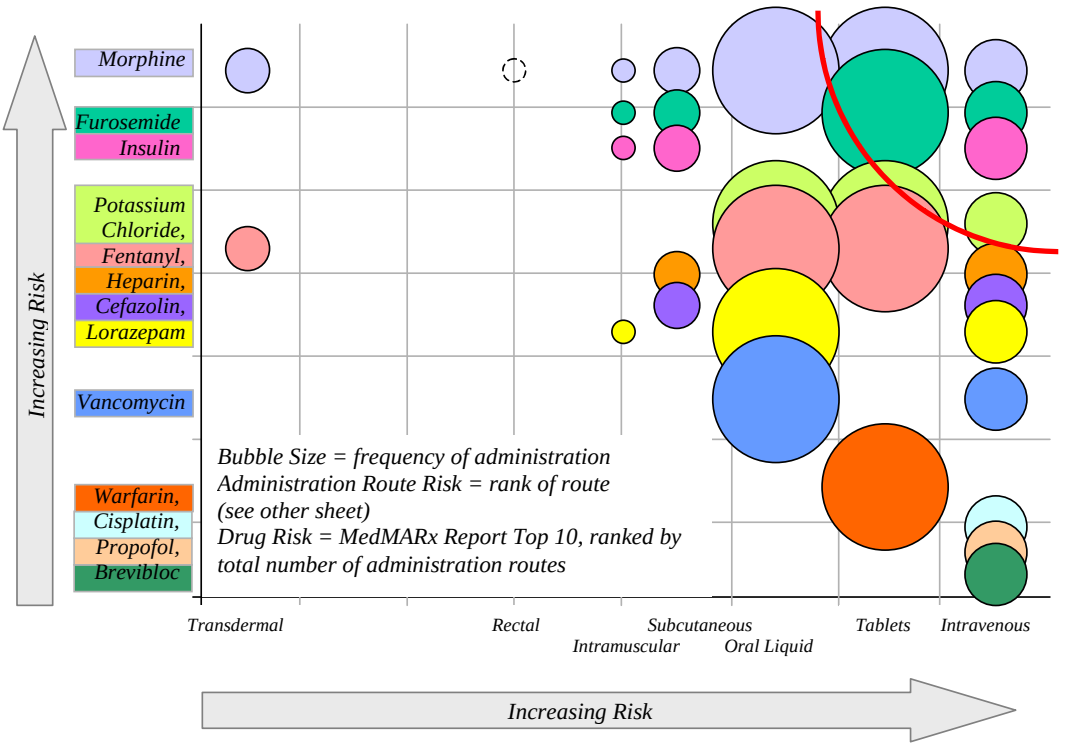


Figure 30: Medication/administration route matrix

From figure 30, we can draw an 'isobar' (in red) of risk and can conclude that the following combinations are the most risky:

- Tablet and intravenous administration of Morphine.
- Tablet and intravenous administration of Furosemide.
- Intravenous administration of Insulin.
- Intravenous administration of Potassium Chloride.

Clearly with full information and total knowledge on the different risks, we can be more sure of these risk areas as it is a very crude estimation at present. One piece of evidence that this may well be a fairly accurate model comes from the 'Working Group on Labelling and Packaging of Medicines' report (DoH, 2002). The recommendation outlines the use of black caps on the top of potassium chloride (KCl) syringes so that confusion does not occur. There are several reports of confusion occurring between KCl and Furosemide, another of the risky drugs mentioned above. The report also mentions guidelines on the use of Warfarin and Morphine further fortifying the results of the above analysis.

Conclusion

To summarise the findings of this section, we can begin by saying that the analyses are a

crude estimation of the real challenges in drug administration. It is however a good starting point for further analysis using more accurate data. In order to build up more of a complete picture on administration *circumstance* risks, it is suggested that:

- Further advice should be taken in order to ensure that the risks have been scored correctly.
- Frequency of specific administration route and circumstances be acquired and investigated further.

The same can also be said for frequency data pertaining to the frequency of administration of specific medications. However, we can draw the following findings:

- Oral tablets and intravenous injection administration methods are the most risky and most often reported methods associated with errors.
- The most common error pertaining to each administration route is ‘improper dose’, with ‘overdosing’ being the most commonly reported error.
- When combined, we see that the intravenous administration of Morphine, Furosemide, Insulin and Potassium Chloride are the most risky combinations of method and drug.
- These findings are reinforced by independent sources from the UK.

Medicines packaging and design

One area where design can be used most effectively and have a great impact has to be in the packaging and design of drugs. Confusion of drug packaging and tablet design has led to incorrect dispensing at the pharmacy and incorrect administration in the hospital ward. The consequences have been fatal as we have seen recently in the confusion during the administration of Vincristine via the intrathecal route. This has occurred 14 times in as many years and has been the focus of much attention as a result.

We begin this section by identifying the current problems with pharmaceutical packaging and identifying the resulting errors. The final part of the section identifies current technology and initiatives that are being developed to address these sources of error.

Current problems with packaging

Packaging of pharmaceutical medication must take into account several factors including pack size, room for labelling, branding, clarity and so on. As a result of inappropriate packaging design, there are many complaints that are evident. These include:

- Like-sounding names.
- No obvious differentiation between strengths of the same drug.
- Brand names are more obvious than the information about the drug itself.
- No barcode or obvious batch numbers.
- Inappropriate designation of space for pharmacist labelling.

We will now go through each of these design flaws and investigate their likelihood and implications. The majority of the confusions could be corrected with more thoughtful design and research of current products on the market.

Like-sounding names

Figure 31 displays an extreme example of poor packaging for two generic medicines. This gives us an example where the NHS refunding structure for generics leads to the need for manufacturer identity. Here, Norton Pharmaceuticals have aligned their packaging so that the two different drugs look exactly the same. This establishes a 'brand identity' which is the only competitive advantage that the company can sustain in the choice of a generic medicine.

Figure 31: Example of poor 'sound-alike' and 'look-alike' packaging

Obviously, confusion would lead to the wrong type of drug being administered. It should be noted that from observations in Lloyd's pharmacy drugs are arranged in alphabetical order and hence would invite confusion by familiarity.

An online database, "Simpack", has been set up by UCL to diagnose the most common forms of medication errors because of packaging confusion (For further information, see Simpack at www.emmsys.com). From analysis of the information on the database, it was found that 64% of incidents reported were due to confusion in the name of the drug. Although the database has collected a relatively small amount of data so far (101 reports to date), 43% of reports were due to mix-ups with tablets and 22% pertaining to an injection of some kind.

No obvious differentiation between strengths of the same drug

Another error that occurs frequently is the confusion of drug strengths. Again, analysis of the Simpack data tells us that 34% of errors were due to confusion over strengths of the same drug. As we can see in Figure 32, there is very little difference in the packaging for different strengths of medicine. Figure 33 shows an example of good packaging using colour to differentiate between strengths of drug whilst still retaining a corporate identity. It might even be argued that the strengths are still not labelled in words clearly enough, but the possibility of confusion is largely reduced by the use of colour.

Figure 32: Example of poor packaging for different strength medicines

Figure 33: Example of good packaging

No barcode or obvious batch numbers

Bar-coding of packaging is something that is a necessity if proper tracking of the drug is to be conducted. There are many instances in hospitals where barcodes are covered over by in-house barcodes which can obviously invite errors if confusion occurs. 'Tracleer', a new drug which has recently been licensed by the MCA lacks a barcode and therefore the ability to be tracked effectively.

Stamped batch numbers are also a cause for concern. As we have seen earlier in the report, this can lead to confusion of product and also potential harm in the warehouse where cellophane packing material must be removed to see the printing.

Brand names are more obvious than the information about the drug itself

Because of the issue relating to corporate identity in generic differentiation, it would suggest that the brand name and manufacturer's details are going to be important to manufacturers when designing their packaging. Findings from the Pharmaceutical Packaging Audit would certainly suggest so (The Pharmaceutical Packaging Audit, http://www.patientpacks.com). Figure 34 displays an analysis of an extreme example, where corporate identity takes the majority of the pack's total surface area.

Inappropriate designation of space for pharmacist labelling

Figure 35 shows an example of where poor design does not allow space for the pharmacist to put their own labelling on the pack. Clearly a large amount of information is lost when the label is applied and is very common in pharmaceutical packaging.

Breakdown of Surface Area for Information on Pack	
Manufacturer's Details	46%
Product Brand Name	2%
Drug Form	0.8%
Generic Description	0.7%
Generic Name	0.2%
Quantity	0.2%

Figure 34: Pack information breakdown

Figure 35: Poor pack design

Current initiatives

Now that we have investigated these common errors, it would certainly seem strange if there was nothing currently being done to reduce the occurrence of such events. The section

concludes by identifying the most recent examples of initiatives that are being conducted to reduce errors.

Original pack dispensing

To begin, we investigate 'Original Pack Dispensing' (OPD). This is something which has been suggested by the "Spoonful of Sugar" report and is something that certainly has many benefits. In a letter to the Pharmaceutical Journal (2002), Fox outlines the benefits that OPD has:

- Integrity of pack, expiry date, batch number, contents, quantity and quality.
- Cutting foils not only runs medicinal risk but also can cause physical damage to the elderly or unwary if sharp edges are not blunted. OPD eliminates this risk.
- Packs broken to fill exact quantities are an expensive waste. Dispensing 30 as prescribed from two packs of 28 warrants payment for 56 tablets.
- The Prescription Pricing Authority would have a much easier task with greater inherent accuracy calculating costs on whole packs.
- Patient compliance, confidence and information are increased. Broken packs are inelegant, unprofessional and confusing for patients, particularly if used alongside calendar packs tailored to requirements.

Unfortunately, one-third of NHS trusts are spending less than 25% of their medication expenditure on original packs (DoH, 2001). The main driver for this may be that OPD packs can be more expensive due to increased complexity during manufacture and sourcing decisions are largely based on the lowest cost alternative.

The pharmaceutical packaging audit

The Pharmaceutical Packaging Audit is an independent organisation that has laid out some easy-to-follow guidelines for the effective packaging of medicines. Although their presence is relatively small in comparison to the working party for the Department of Health, their recommendations are clear and give manufacturers a useful checklist for package design. For more information and examples of poor packaging, their website has all the details, www.patientpacks.com. Their guidelines, called the "Golden Rules" are displayed in table 11.

Table 11: PPA's recommendations to the pharmaceutical industry in safe packaging design, taken from www.patientpacks.com

PPA's "Golden Rules"	
Recognise first the essential information for product and pack identification	*The brand name, the form of drug, the strength, the variant*
	The generic name
	The pack size (contents)
Always present this information on every face of the pack…	*…using an area of the pack's surface devoted exclusively to content description*
	…ensuring that this area is in proportion both to its importance and to the overall size of the pack
	…employing a style and size of print that is adequate
	…giving due consideration to an appropriate order of emphasis
Take proper and full account of the practical requirements that the design is expected to fulfil…	*…insisting that the pack meets all criteria for Child Resistant Closures*
	…remembering that the prime object and essential function of product presentation is that of establishing product identity. Establishing it without ambiguity, establishing it rapidly and establishing it clearly

"Number-plating" of packaging

It was within the context of *An Organisation with a Memory* and the recent Vincristine mal-administration that the Committee on Safety of Medicines established a working group on the labelling and packaging of medicines.

One of the group's recommendations was the 'number-plating' of medication packaging. The number-plating system recognises the need for pharmacies to apply their own labelling for information on administration and also the need for manufacturer's brand information. The number plating system is however far from settled since it has had a lot of resistance from the Association of the British Pharmaceutical Industry (ABPI). Andrew Curl, Deputy Director General of the ABPI has said that *"there is no evidence that current pack labelling has caused inappropriate drug administration or any patient deaths. The number plate system will make packs look more alike and could increase confusion"* (Curl, 2002). Instead, the ABPI believes that the *"likely causes of prescribing errors lie in system failures and human error, sometimes due to inappropriately trained staff."*

Industrial pressure

As we have seen, the number-plating of packaging is not settled and nothing will be finalised until the ABPI buys into the system. So, who can make a difference? Boots the Chemist says it has used its buying power to change unsafe packaging design. In a recent article, it was found that: *"If Boots believed a product could compromise patient safety (e.g. through the use of similar packaging for different strengths of the same product) it would approach the*

manufacturer, usually a generic firm, requesting that it be changed. If the firm did not agree, Boots would seek an alternative supplier."

Conclusion

It is clear that pharmaceutical packaging is an area where a large impact can be made. The challenges facing improved packaging lies in the ability to overcome resistance from manufacturers to take the costly and time-consuming steps to improve their existing designs. The pressure must be exerted by the MCA since this body ultimately decides which products are allowed to reach the market. It is apparent that the current guidelines in place by the MCA are not aligned to the reduction of errors by improved packaging design.

In summary, the main findings of this section are:

- The most common errors from inappropriate packaging design are from name and strength confusion.
- There are many factors that need to be taken into account when designing pharmaceutical packaging, but the use of colour and differentiation can be used to reduce confusion in dispensing.
- There are many initiatives that are being conducted currently to reduce confusion in packaging. The most topical being the 'number-plating' of packaging which the ABPI strongly opposes.
- Lastly, it is important for large corporations to use their buying power to encourage good package design. It would seem that Boots are currently leading the way in this initiative.

Patient pathways

Following on from the patient interaction archetypes presented above, further work has been done to try and extend the maps presented in figures 23, 24, 26 and 27. One of the issues to be resolved is the representation of patient pathways that cross between archetypes. Figure 36 shows one attempt to represent such a map.

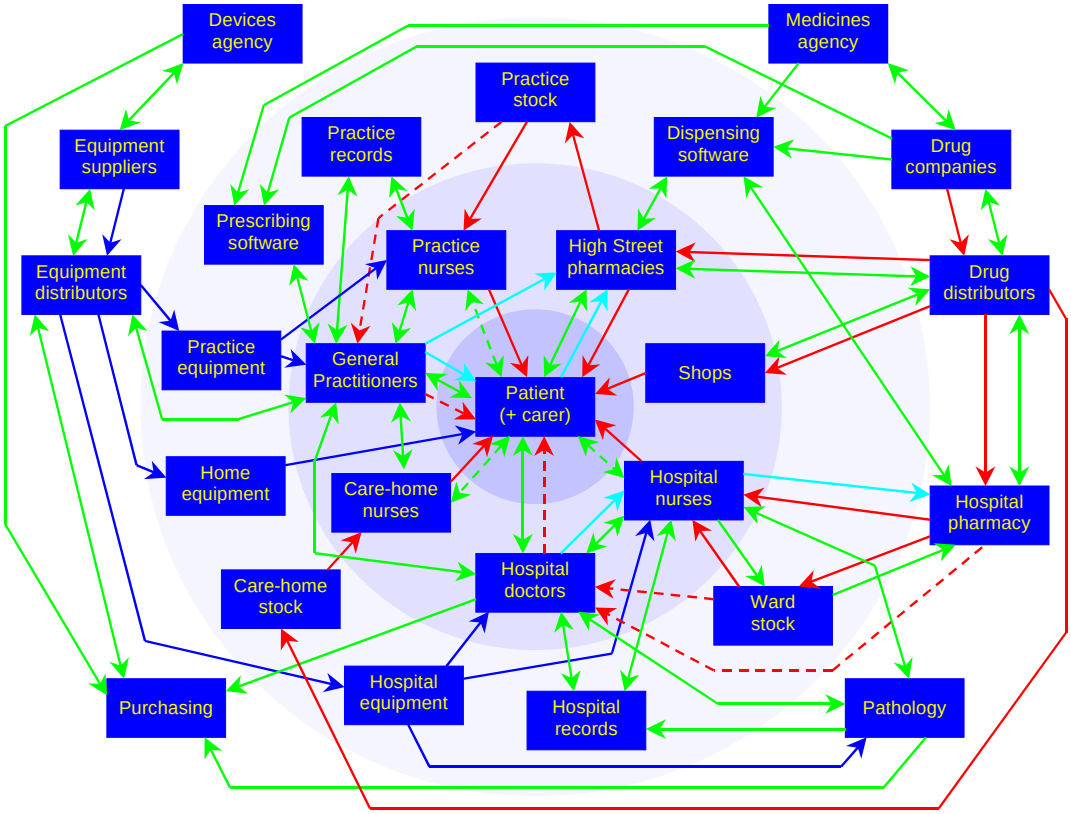


Figure 36: A patient-centred map of the healthcare system

At the centre of the map is the patient, surrounded by healthcare professionals who might interact directly with them. Further out lies a layer of equipment, software and medication stock. The outermost layer comprises companies and organisations involved in the healthcare supply chain. The interconnections show, as before, the flow of medication (red), prescription (blue) and information (green).

Whilst this map is more comprehensive than the earlier figures, showing as it does, connections between primary and secondary care, it is more difficult to read. One solution is to highlight only those parts of the diagram engaged in a particular pathway. For example, figures 37 and 38 show the patient pathways for self-prescribed drugs and GP prescribed drugs respectively.

The advantage of such maps is the clarity they bring to the many interactions present in the healthcare system. However, much further work is required to complete these maps and to identify the real hotspots.

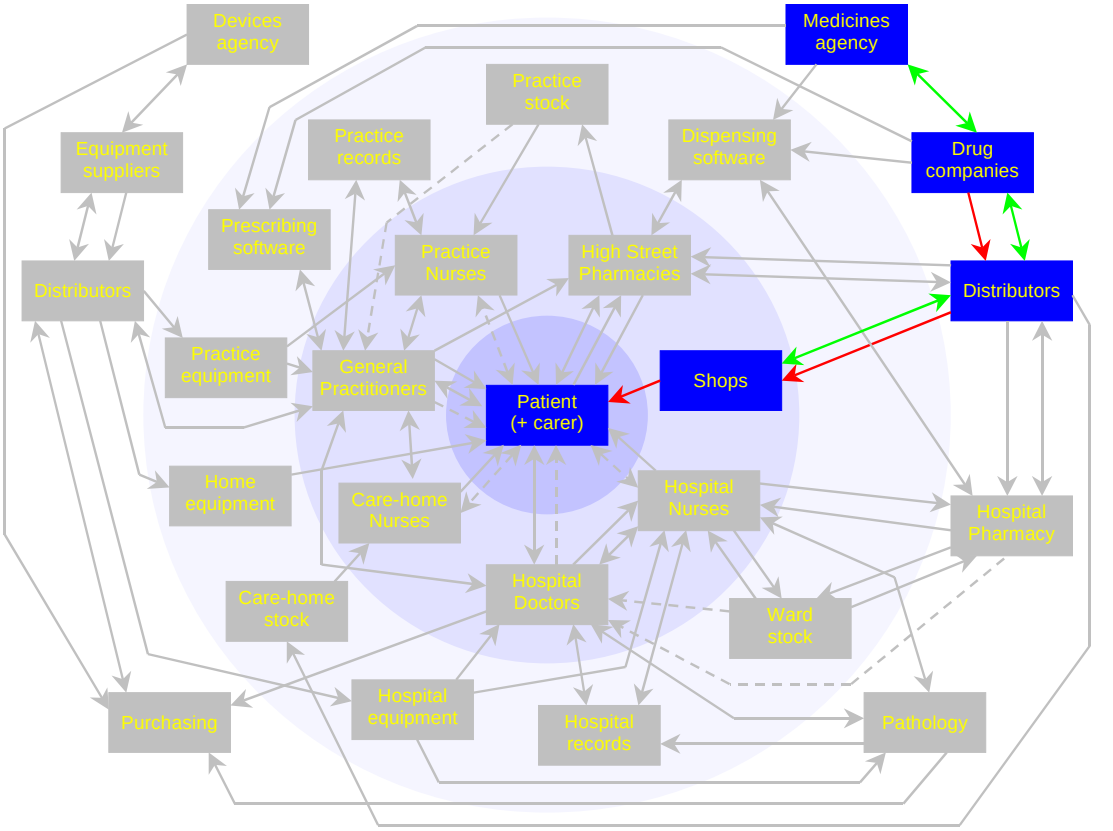


Figure 37: A map for self-prescribed drugs administered at home

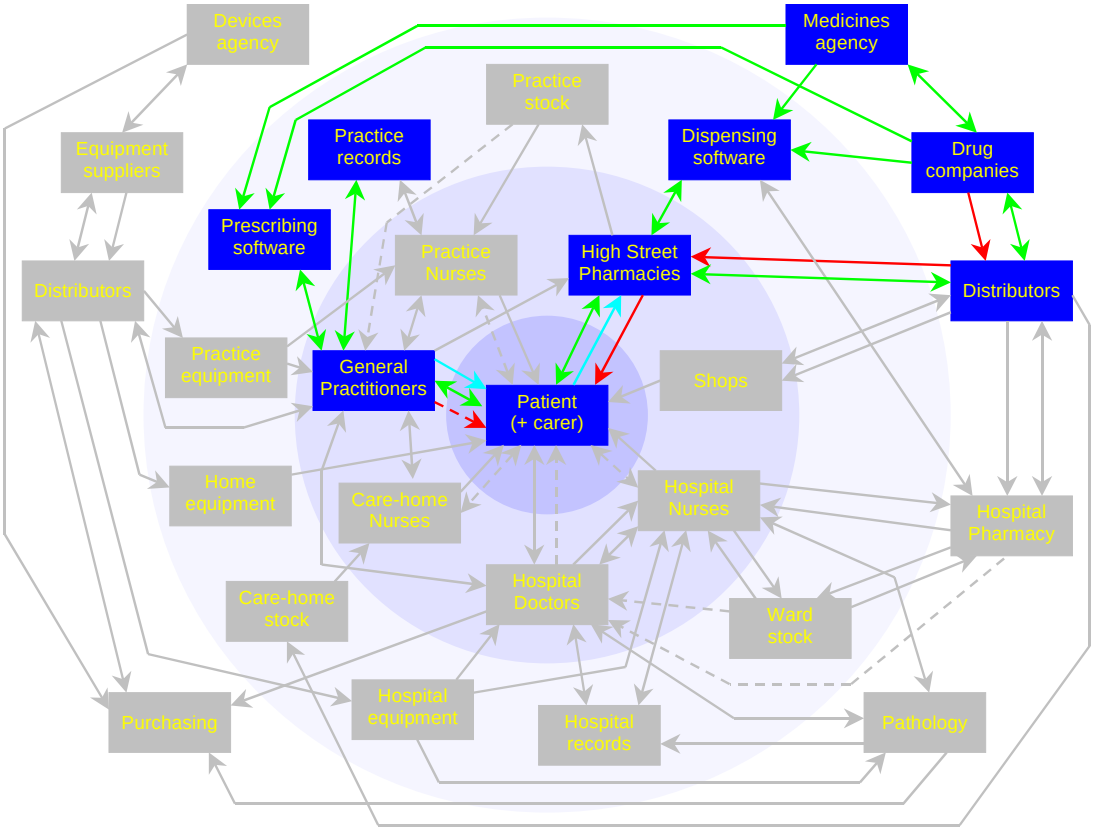


Figure 38: A map for prescribed drugs administered by the patient

Annex 4 – Interview results

This section describes the output of an extensive interviewing process with healthcare professionals in primary care and secondary care. The primary and secondary care interviews focused on the medication use process, looking for good practice, problems and opportunities for change.

Interviewees in primary care were taken from the local community in and around Cambridge. The secondary care interviewees where focused on Addenbrooke's, a large teaching hospital serving Cambridge and the surrounding area.

The medication use process described on page 74 of this document is used below as a basis for reporting observations made during the interviews.

Primary care

A number of interviews were undertaken with the following: General Practitioners in dispensing and non-dispensing practices; Practice Manager; Phlebotomist; Head Pharmacist in a community pharmacy; Nursing Policy Manager; and Social Worker. A number of key observations emerged which may be summarised as follows:

Prescribing

Little time was spent discussing the practice of diagnosis. However, the related topic of Continuing Professional Development (CPD) was raised. At present CPD appears to be rather ad-hoc and unstructured, and considered optional. It may consist of simply reading the BMJ and occasionally attending a conference.

The majority of GPs now use software tools when prescribing. Such software provides up to date information regarding available medication and dosing regimes, flags up warnings of contraindications for medication prescriptions (e.g. Ciclosporin), and checks medications are prescribed within accepted limits.

The use of prescribing software has led to a situation where most patient notes are now kept on hand-written and computer records. New details may not be added to both, so there may be contradictions and contraindications that may not be flagged. Doctors need quick access to key information (e.g. high risk medication that a patient is taking) . An example of good practice is the use of a 'blue' sheet on the front of the notes to record key information.

In practice, there are not that many drug interactions that have to be considered. Another safety net is the fact that the doctor tends to know their patients quite well and is aware of the important points about their treatment or history. However, the increasing use of out-of-hours schemes brings unfamiliar GPs into contact with patients, often without any knowledge of their medical history.

Little or no information seems to be fed to GPs with regard to medical errors (Methotrexate is an exception). Contrary to this, information overload is a problem, and GP's don't have time to read all that is sent to them. One surgery had a 'high risk' chart of drugs in reception.

The variability in GP's practice was highlighted. There are few mechanisms for sharing good procedures and experience beyond the bounds of the surgery. Examples of good practice included the printing out of computerised patient records before conducting home visits (problems occur when medical history is not accessible when on a home visit, such as drug-drug adverse reactions). In another case, lessons learnt from a particular error were written up

and distributed to all local practices.

Documenting

Handwriting remains a problem with GPs. Although the number of hand-written prescriptions has been reduced by the introduction of prescribing software, notes on the whole remain hand-written as do requests for tests sent to pathology laboratories.

Patient notes are kept on hand-written and computer records. New details may not be added to both, so there may be contradictions.

Dispensing

Medication errors were judged not to be a problem, particularly due to current computerised ordering systems and warnings given by computer software. However, software warnings often provided information overload to the point where they were ignored.

In a rural dispensing practice where the pharmacist knows the GP's idiosyncrasies, prescribing adjustments might be made. Fewer errors are detected since the advent of GP's prescribing software.

Pharmacists had received guidance on Methotrexate dispensing, but no other general or specific guidance on medication errors.

Administering

No general guidance was forthcoming on how to ensure good practice in helping patients to take their medicines properly. There may be a mismatch between expectations of the GP and the actual actions of the patient – for example, the GP may think patient is taking X, whereas the patient is actually taking Y.

Disposal of unused medication is a particular problem. The medicine cabinet will not always be an accurate representation of the medication currently in use. In addition, the most recent dosing regimes may not be accurately reflected by labels on older prescriptions.

Confusion arises when packaging is changed, particularly regarding the form of tablets where a supplier may be changed to another with a different colour or shape of tablet, but identical medication. Suppliers may sometimes be foreign, with stickers put over the initial labels with information in English. There is also confusion over medication with similar packaging.

Blister packs are all very well for the able-bodied, but can be hard to use for people with poor grip or those needing to select small tablets. Tops can be hard to open. Sweetex are better for those with only one hand, but the danger is not knowing how many you have taken, especially as there is a tendency to fiddle with the delivery mechanism.

Compartmentalised boxes are sometimes used for patients with complex medication regimes. However, they take time to fill – as a result the chemist may be reluctant, leaving the task to untrained family or friends. For patients with poor eyesight or co-ordination, it may be difficult to access pills. Generally, the compartmentalised box was regarded as a sound idea. Some privately-available compartmentalised boxes have alarms which sound when the medication is due to be taken, which stops sounding only when the medication has been administered.

There are particular issues with the increasing number of patients unable to self-administer. Social services even have to hide stores of medication to prevent patients taking too much. It

is also difficult to assess when they are unable to safely self-administer. In addition, when patients are admitted into hospital, they may not be assessed to see whether they can competently self-administer. When discharged from hospital, they may not remember the reason behind taking medication that was given to them, usually in haste, by a discharge nurse. A problem occurs if medicines need to be taken two or three times a day, where a social worker can only visit once due to resource limitations.

Monitoring

Patient monitoring is often undertaken during a visit to the GP, but may be the responsibility of visiting healthcare professionals. In practice, most monitoring is undertaken by the patients themselves, or by family or friends. Results of such ad hoc monitoring in the home are seldom documented.

Specific tests may be requested to monitor treatment. These may involve direct measurement from the patient or the passing of a sample to the nearest pathology laboratory. Errors can arise due the difficulty of matching patients with samples at the laboratory, a direct consequence of bad GP hand-writing, incomplete forms or multiple instances of a similar name in the local area. Bar codes are increasingly used to identify the primary care practice.

Secondary care

A number of interviews were undertaken with the following: Chief Risk Manager, Biomedical Equipment Manager, Staff Nurse, Infection Control Nurse, Consultant Anaesthetist, Administrative Director, Chief Pharmacist, Principal Pharmacist, Manager of High-risk Medication and Pathology Services Manager. A number of key observations emerged which may be summarised as follows:

Prescribing

Little time was spent discussing the practice of diagnosis. However, the associated process of prescribing is where the biggest risks are encountered. Doctors often work with an incomplete data set, having to piece it together from disparate sources. Detailed patient notes from primary care are seldom available, with referral letters often focussing on the immediate problem rather than the patient's general history. In addition, doctors may move from ward to ward or from hospital to hospital, be under pressure and not be properly inducted. The most junior doctor is thrown at the bulk of the work, with little training.

Of particular concern is the transfer of patients to and from secondary care. Where admissions are unexpected, patients often cannot provide a full picture of their current medication. Even if they endeavour to bring all their medication to the hospital, some items may be forgotten. Other problems involve labelling of medication. The most recent dosing regimes may not be accurately reflected by labels on older prescriptions. In addition, labelling on the back of blister packs may be incomplete or at best confusing in the absence of the original packaging.

Standard patient charts are often of poor design with no provision made for recording the rationale for the prescription. In contrast, specific charts for high-risk medication such as Warfarin, are of better design. Such charts include normal dosing recommendations and calculation procedures for the specified medication. However, they are usually designed for use only on a particular ward.

Documenting

Handwriting remains a problem with doctors. Most prescriptions are hand-written on the patient's notes, although many requests for tests sent to the pathology laboratory are now computer generated.

As noted earlier, patient notes are kept on hand-written and computer records. New details may not be added to both, so there may be contradictions.

Dispensing

The majority of dispensing in secondary care is done on the ward from ward stock. However, a sizeable minority of medication is dispensed from the hospital pharmacy.

When a new order is received at the pharmacy they assess the adequacy of the prescription. A team of people would then generate the label and "assemble" the medication. It is then checked. Normally checking is done independently, but a pharmacist will be working alone after 7pm at night, and also in the afternoon at the weekends.

Prescriptions may be hand-written, requiring interpretation by the pharmacy. Labellers will have varying levels of skill and experience in such cases. No central dictionary for drug names exists, which can result in confusion when writing or reading prescriptions.

Addenbrooke's deal with about 800 items per day. Figures indicate that 7% of orders are changed by the pharmacist, but the actual percentage may be higher. Current figures are estimates since not all incidents are reported due to lack of time. They estimate 15,000 potential intervention reports per year throughout the hospital (presume the prescription is right, but the dose may be wrong) leading to 5 potentially fatal errors per month and 15-20 potentially serious errors per month. In the case of a "serious" intervention the originator for the prescription would be contacted by phone.

The pharmacy does not have access to the medical notes, and hence do not know the rationale behind treatment. Therefore some mistakes in prescribing cannot be uncovered. In general the pharmacists tend to be more risk-averse than the doctors.

Resources can be limited, with the result that medication errors on the ward may not be discovered by pharmacy staff during the weekend. In addition, bank staff tend to have limited training, or even inappropriate training in that they have been exposed to different working practices in other NHS Trusts, or even overseas.

There is a big push towards automation, using robotic equipment to pick, label and dispense products. Eighty percent of pharmacy stock could be dispensed in this way.

Ready-to-use syringes reduce dosing error problems. Syringes with retracting needles may save needle-stick problems. Blister packs for tablets eliminate the need for loose tablets. The pharmacy has also moved to original pack dispensing, however, the packaging can still be confusing. Pharmacies have little power in changing the packaging from manufacturers.

Issues relating to medical error are actively discussed in the pharmacy. In addition, there are regional networks which come together to discuss such issues and share good practice. For example, a review of the medication supply chain has been completed and the risky areas are being redesigned.

Most medication is dispensed on the ward. Protocols are used to aid error free dispensing and preparation areas help to reduce interruptions during dispensing. Concentrated medications which require dilution are increasingly restricted to the pharmacy. Pharmacist Ward stocks

are replenished regularly. Incorrect medications can be brought up to the ward from pharmacy.

Administering

Within secondary care many patients require assistance to administer their medication. This assistance may be indirect, in terms of providing the right medication at the right time, or direct, where the medication is administered by a doctor or nurse. Each has its potential problems.

For example, if a patient brings their own medication to hospital, and the prescription changes whilst in the hospital, the previous instructions on the bottle may be out of date and will not be updated until discharge.

There are also rare cases of patients receiving medication meant for others. New schemes, such as the use of bar-coded wrist bands to aid blood matching to the patient, will help to eliminate such errors.

Infusion pumps are the topic of many a conversation regarding medication administration. However, it was also suggested that most were not difficult to use, but that the problem is that there is a huge variety of pumps, giving rise to confusion. Equipment often moved with the patient from ward to ward. There were also some examples of poor design – a syringe driver which measures the dose in *mm*, not *ml*! Various sizes of syringe can be used, providing the potential for an inadvertent underdose or overdose. Poor staff training can also be a problem, particularly for temporary staff.

Problems with equipment were usually down to user error, a direct result of too much device variety, poor design and inadequate training. The setting up of complex equipment posed particular problems, likely to be accentuated in a smaller hospital with fewer 'expert' users. Equipment alarms were a particular problem – how do you disable unwanted alarms or hear device alarms when out of room (e.g. low battery warnings).

Equipment purchase was often dictated by the ward rather than hospital policy, thus leading to such a plethora of similar, but different, devices. Frequently, it was the consultant who specified the equipment that others in the team would use. There was generally no contact between equipment designer and users, and no feedback on the effectiveness of equipment.

Monitoring

Monitoring in secondary care takes several forms, from the direct observation of the patient to the use of remote tests to determine the patient's condition.

Results from direct monitoring are recorded in the patient's notes. Form design is again critical here. Forms also need to remain with the patient. At any point in time, up to 20-30% of charts on a particular ward may not be at the bedside. They are removed for legitimate purposes, for example, to write up notes and new prescriptions.

Copying the paperwork is not appropriate, since there is the danger that the wrong version, i.e. not the latest, is subsequently reviewed. In addition, test results are increasingly produced by computer and equipment, to be attached to the notes. Similarly, pathology reports may be recorded in the patient's electronic record, only to be printed and added to the paper notes. Most patient files are cumbersome and lack any noticeable structure, thus needing more time to be read thoroughly. There may even be more than one set of patient notes in a given hospital – for example, for maternity and for general admissions.

Remote tests in the majority of cases go to the pathology laboratory. A request for a test is generated on the ward via a computerised system which prints out a card with the details of the test and a sticker with the patient's name and bar code to stick on the sample tube. With the potential for many of these stickers to be printed in one sitting, it is possible that the wrong sticker can be stuck onto the wrong tube and on occasion the patient is wrongly identified. Some doctors (particularly old-school consultants) refuse to use the computer system and rely on hand-written instructions instead. In addition, samples can degrade, however, only the time that the sample was received is logged, not when it was requested.

Samples are received at pathology and are given a unique bar code, which is specific to the hospital. This bar code is taken from a reel and manually stuck on to the bottle and also onto the form. Using such a bar code is required by the analysers, which is different from the bar code generated when the initial request is made. Next they are manually checked against the stored request on the computer. The bar code is scanned or the information entered manually. It is possible to overlook part of the request on the form, particularly when there are 'special requests' added to the standard requests on the form.

Tests are then completed with varying levels of automation – haematology is highly-automated (97-98% of samples) with results of high integrity returned directly to the computer records, but histology is at the other end of the scale (10%), and suffers from subjectivity in interpreting the samples. Life-threatening results will be telephoned through to be acted upon immediately rather than being left in the internal system.

Patient monitoring on discharge from hospital is difficult. There remains the issue of whether the patient can competently self-administer. When discharged from hospital, they may not remember the reason behind taking medication as given to them in passing by the provider doing the discharge. In addition, unless full details of the patient's condition in hospital are communicated in the discharge notes, subsequent monitoring may not provide complete continuity of care.

General comments

The key problem is a lack of resources; the system is grossly under-resourced. The hospital is aware of many problems, but has insufficient resources to tackle them. This has direct consequences for risk and design management. If you want people to do a risk assessment, you need to provide examples of where such an activity has resulted in a benefit, such as in the case where someone has identified poor equipment, and the budget has been provided to procure new equipment as a result. People need to know that such new approaches will provide a greater chance of freeing up money to purchase new equipment.

Infection control is becoming an ever more important issue. Hospitals need to know who is a high-risk patient in terms of potential introduction of infections (e.g. those newly arrived from other hospitals or anyone in the hospital who has MRSA) but accessing this information is difficult as it has to be done on a patient-by-patient basis, rather than a general search. There is a need for more isolation facilities and controls to prevent further infections. In particular, devices need to be designed to make them easier to clean.

Conclusions

A number of conclusions may be derived from the interview responses, including:

- Handwriting remains a problem with GPs, although the number of hand-written prescriptions has been reduced by the introduction of prescribing software.

- Patient notes are kept on hand-written and computer records. New details may not be added to both, so there may be contradictions.
- Medication errors were judged not to be a problem, particularly due to current computerised ordering systems.
- Of particular concern is the transfer of patients to and from secondary care where patients often cannot provide a full picture of their current medication.
- Standard patient charts are often of poor design with no provision made for recording the rationale for the prescription.
- The pharmacy does not have access to the medical notes, and hence do not know the rationale behind treatment.
- Problems with equipment were usually down to user error, a direct result of too much device variety, poor design and inadequate training.
- Equipment purchase was often dictated by the ward rather than hospital policy, thus leading to such a plethora of similar, but different, devices.
- Patient monitoring on discharge from hospital is difficult.
- Infection control is becoming an ever more important issue and hospitals need to know who is a high-risk patient in terms of potential introduction of infection.

Annex 5 – Focus group results

Introduction

The human, whether as a manager or as an operator within a work system, has a considerable influence on the safety and reliability of that system. This is amply illustrated in *Reducing Errors and Influencing Behaviour* (HSE, 1999) where numerous examples are provided of accidents, industries, consequences and the contribution of human error and other causes to major events such as the Herald of Free Enterprise, Piper Alpha and the Space Shuttle Challenger. In attempting to understand these failures various models have been proposed including that by Reason (1991). In the Type-Token Accident Model (see figure 39) individual errors can be mapped on to management failures and a clear distinction made between so-called types and tokens (see Redmill and Rajan, 1997).

Types are defined as general classes of organisational and managerial failure, while tokens are more specific failures relating to individuals at the human system-interface.

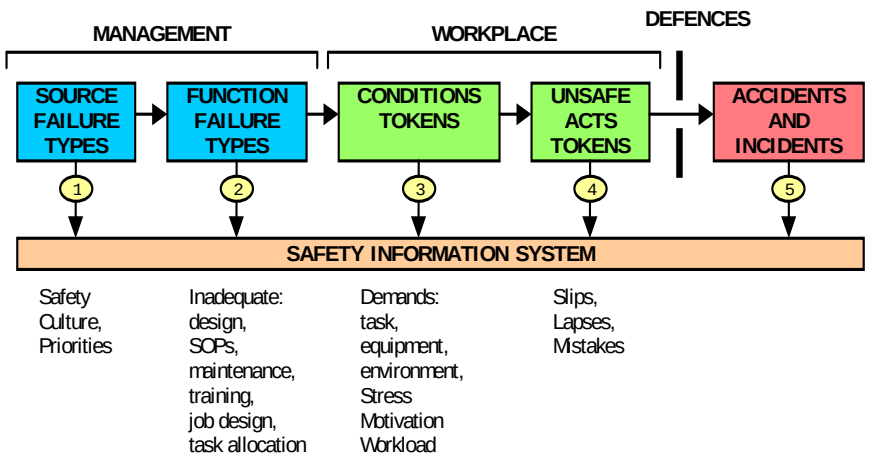


Figure 39: Type-token accident model

Types or organisational and management factors include such problems as:

- Hardware defects
- Design failures
- Poor maintenance procedures
- Poor operating procedures
- Systems goal incompatible with safety
- Organisational failures
- Communication failures
- Inadequate training, etc

Types and tokens are subdivided as follows (see Redmill and Rajan 1997 for details):

Types can be source types (see figure 39) associated with the decision-making failures of policy makers or function types associated with line management decision making failures.

Similarly tokens are divided into condition tokens and include: psychological and situational precursors to unsafe acts and unsafe acts themselves. Condition tokens cover performance-influencing factors such as the human-equipment interface, cognitive or information processing factors such as attentional capacity, memory load and knowledge etc. Table 12 shows examples of performance-influencing factors and figure 40 provides a summary of the Type-token Accident model (see Redmill and Rajan 1997 for details).

Table 12: Typical performance-influencing factors

Task demands and characteristics	Instructions and procedures	Environment	Displays and controls	Stresses	Individual	Socio-technical
frequency, workload, critical nature, duration, interaction with other tasks, perceptual, physical, memory, attention, vigilance	accuracy, sufficiency, clarity, level of detail, meaning, readability, ease of use, applicability, format, selection and location, revision	temperature, humidity, noise, vibration, lighting, work space, movement restriction, control of environment	compatibility, ease of operation, reliability, feedback, sufficiency, location, readability, identification, distinctiveness	time pressure, workload, fatigue, high-risk environment, monotony, isolation, distractions, shift work, incentives	capacities, training and experience, skills and knowledge, personality, physical condition, attitudes, motivation, risk perception	manning, work hours and breaks, resource availability social pressures, conflicts, team structure, communication, roles and responsibilities, rewards and benefits, attitude to safety

In attempting to investigate whether such a model is relevant to the healthcare setting, the main focus will be on source and functional failure types and the extent to which, when combined with Condition Tokens, they influence human behaviour to make incidents and near misses more likely. A secondary issue is whether this reactive approach to understanding incidents and near misses might be made much more proactive. It would also be beneficial to know to what extent currently existing types and tokens might prevent such a proactive approach in becoming the norm.

Research method

Three focus groups were conducted across the three main areas of midwifery, accident and emergency and cancer/palliative care. In total some 21 staff participated.

Midwifery: Seven midwives participated with a mean of 20.0 years of experience (SD 3.95 years).

Accident and Emergency: Six A&E staff participated with a mean of 7.25 years of nursing experience (SD 4.9 years) and 2.45 years of A&E experience (SD 1.1 years).

Cancer/Palliative Care: Eight nurses participated from a range of backgrounds including the Community, Hospice and District General, Cancer and Oncology. They had a mean of 17.5 years nursing experience (SD 6.5 years) with 5.7 years of cancer/palliative-care experience (SD 4.6 years).

All focus groups were presented with the overall objectives of the scoping study and each participant signed the Informed Consent Forms, including an agreement that the session would be recorded. A series of questions were prepared in advance and the discussions centred on these. The sessions were recorded in the form of hand written notes and with a tape recorder. Analysis of the transcripts was made using Reason's (1991) types and tokens model.

Each focus group commenced with the topic of "equipment", prompted by questions 12 and 13 from the bank of questions as shown below.

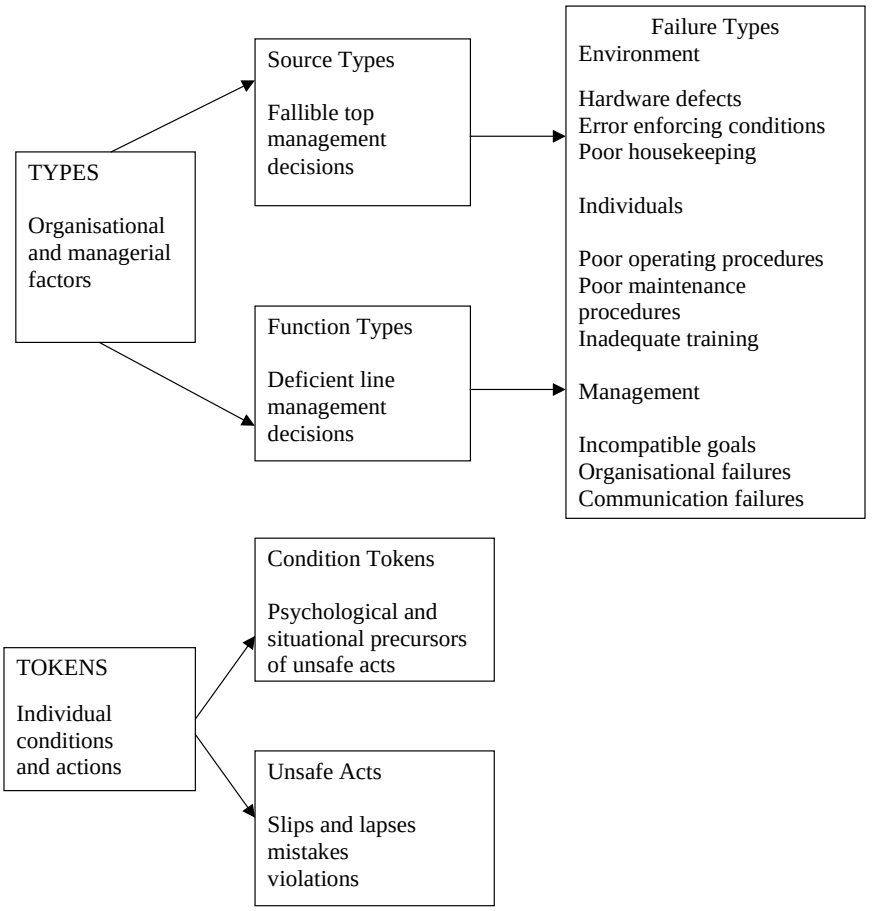


Figure 40: Types, tokens and failure types

Research results

The three focus groups identified only a limited number of good pieces of equipment. However, numerous problems were described across the full type-token accident model.

These included:

"*Good when you know how to use them [equipment] but training in their use is essential, including calibration and maintenance and training appears to have evaporated"*

"*The mix of machines on the wards (up to six sorts) and the non-standard recording paper needed for each, and different calibration procedures and leads that are not interchangeable, resulting in pin damage especially in the middle of the night, cause all*

sorts of problems"

"Bare minimum of equipment held within the Department and others have to be obtained via the equipment library, which can be a major problem at night, wrong equipment sometimes delivered to the ward"

"We have little involvement in purchasing decisions"

"A and E overload and patients in corridors where there are no plugs for our equipment"

"One problem with equipment is that the staff change and confusion between syringe drivers can occur"

With respect to error reporting, each group was prompted by question 8 (see end of section) and typical responses were as follows across the three focus groups:

"Many nurses feel stressed and on edge because of the apparent blame culture"

"Gaining a bad reputation for being a troublemaker if you do fill in trigger forms and because there are so many incidents where they could be used, they are usually only used for the more severe incidents where someone is injured"

"Feedback is very limited unless it was someone's fault or unless a box [on the form] hasn't been filled in"

"Don't do it as it will only get you into trouble"

A limited number of examples of good practice were highlighted, although they appeared to be more examples of good management per se. The need for better management training was emphasised with respect to learning from and communicating lessons from incidents and near misses.

Limitations

It is noted that the main emphasis here has been on Type-Token Failure within Healthcare as opposed to Unsafe Acts.

In this context Source Failures (Safety Culture, Priorities etc) may open the way for Unsafe Acts in the same way as Condition Tokens (Demands of Equipment, Tasks, Stress etc) and Functional Failure Types (Design, Maintenance, Training etc) may influence human behaviour, making incidents and near misses more likely (see Introduction).

Conclusions

The three focus groups across the clinical areas of midwifery, A&E and cancer and palliative care reflect the thoughts and concerns of those participating in these scoping exercises.

However, the sample group is small and the degree to which the themes that emerge are representative or may be generalised to the wider nursing population is unclear. The issues of recall bias, influence of the interviewer and other factors mean that some caution is required when interpreting the outcomes. On the other hand the approach does enable some insight into an holistic and realistic picture of the world of healthcare as perceived by the participants and validated by two senior managers. On these bases the following are areas where further attention might be focussed, although no attempt has been made to prioritise them.

Equipment

The following are highlighted:

- The need for improved equipment design with end-user involvement and a reduction in the variety of similar equipment seen within Departments and Hospitals. Such improvements would reduce existing tokens and sources and functional failure types.
- The need for improved training/competencies in equipment use including calibration and arrangements for maintenance (i.e. existing functional failure types) to enable the effective use of equipment as valuable aids to clinical work.

Error Reporting

The following are highlighted:

- the need for the recognition and ownership of risk throughout the organisation (i.e. source failure type);
- the need for positive and supportive management throughout (further source failure type); and
- clearer reporting procedures for incidents and near misses and effective and constructive feedback are needed (i.e. existing condition tokens and source and functional failure types) if a more proactive approach to errors is to be advanced and sustained.

Possible areas of follow-up

- Wider range of experience for the three groups studied and the inclusion of those clinical areas not considered.
- More in-depth study of examples of "best practice" where these are identified. For example, an incident was described where a wrong drug dose had been drawn and on checking this was confirmed. This was reported. The nurse concerned was not reprimanded but rather the lessons learned were shared and communicated to prevent others from doing the same.
- Case study examples of "good" and "poor" "reactive and proactive" approaches to medical incidents and near misses.

Focus Group Questions

1 In terms of patient safety, what is the most risky procedure you carry out?

2 What would you say was the most difficult part of your job?

3 Does anyone have an example of a near miss? (would need to define)

4 Is anyone involved in patient risk assessment?

- If yes how do you go about it
- Make recommendations
- Are recommendations implemented

5 Protocols are present for many procedures, can you think of any procedures that have no protocol?

- Why do you think no protocol exists?

6 In instances where protocols exist can you give examples of when they cannot be followed?

7 What is management support like (if not managers)

- (If good) does this help?

8 Is the ‘blame’ culture still apparent?

- How could this be changed (for people already in service)
- How do you feel about reporting near misses?
- What would be the reaction to “I’ve made an error”?

9 How do you feel about supporting change?

10 How could this be changed (for those already in service)?

11 Which procedures are examples of “safe practice”? Why do you consider them to be good?

12 Is there any equipment that you think is well designed and easy to use? Why?

13 Is there any equipment that you think of as poorly designed and difficult to use? Why?

14 What, if any, are the barriers to communication?

Annex 6 – Workshop results

Learning from other industries

Introduction

A number of previous reports have identified the capacity for different work sectors to learn from one another about the prevention of accidents and errors in complex, safety critical, work systems.

The project team considered that much might be learned by meeting with experts from other safety critical sectors and discussing how they would approach a number of the problems faced by the health service and, by implication, by this study.

The breadth of such an exercise could have been extensive. To match the resources and time available it was deemed necessary to limit the topics for discussion. The topics selected for discussion were chosen from a more extensive list and following wider debate on their suitability with other project team members.

(Notes: 1. All workshop participants agreed to the Chatham House Rule and the confidentiality of all participants and the identity of their comments has been recognised in this report. 2. All participants gave freely of their time for this project as they each recognised its societal importance. 3. Throughout this section of the report the words *ergonomics* and *human factors* are used synonymously).

Aims

The aims of the workshop were to:

1 Understand how best practice in safety critical industries could be transferred to the Health Service.

2 To suggest where practical system design improvements could be implemented and tested.

Background

A general discussion at the start of the workshop led to a number of important general observations. These were related to the current position of the health service and were considered important in providing a general context in which patient safety and error reduction had to take place. Two major problems were thought to inhibit the development of safer work systems in the health service. These were that:

1 The health service does not acknowledge that it is a ‘high risk’ industry, therefore there is a poor safety culture. Interestingly, it may be more acceptable to approach changing this culture through looking at systems/equipment malfunction, possibly because people are more willing to blame equipment and systems than to blame themselves.

2 The dramatic shortages of permanent staff prevents dedicated training time. Agency and short contract staff have no commitment to improving their performance.

The NHS was also thought to suffer from being a measure of the government’s current success. The resultant, very high, profile in the media means ‘one off’ accidents are over-emphasised.

It was also apparent that rather than there being an occasional "major" accident that might have the effect of heightening awareness, there was instead a steady flow of accidents and adverse incidents at "everyday" level that seemed to encourage acceptance and cover-up.

Following these initial points, three areas for discussion were presented.

These were:

1 What is an appropriate system for "safe" procurement of equipment and what is required to achieve this?

2 How, in a safety critical industry, should equipment be risk assessed and what organisational structures are needed to deliver risk assessment?

3 How might the Health service learn from errors?

What is an appropriate system for "safe" procurement of equipment and what is required to achieve this?

Those speaking on behalf of the defence industries, and the MOD in particular, pointed out that they try to incorporate thinking about human factors issues at the very start of its procurement process. Whole life-cycles of products are considered along with other issues, such as available personnel, maintenance costs, attitudes, the competencies of users, training and skill levels needed. All these elements are included in design costing. The use of a requirements capture method was advocated by the MOD. The need for an NHS equivalent of Manprint (as developed for the MOD) was discussed.

Specifications for equipment are defined and responsibility for safety is transferred to the manufacturer. The rationale for this is that the MOD owns its manpower and invests substantial resources in the time and money for training. The requirement is for systems and equipment to optimise its investment.

Penalty clauses are incorporated into contracts to ensure supplies keep within budgets. The MOD has sufficient influence with manufacturers to induce them to conform to its requirements for safe competitively priced products because it does not have to compete with numerous other clients. Similarly the NHS may be in a position to bargain, as not many competing clients would purchase equipment on the same scale.

Although economic concerns are the biggest driver, safety is becoming increasingly important as there is greater awareness that accidents are expensive.

The railway industry (Railtrack) ensures human factor issues are considered thoroughly by their design teams, along with the individual purchasing needs for each system. However, in terms of cost-benefit it may not always be possible to point to the human factors input and say it does have a positive influence. Operational safety is also the subject of external regulations, as is human factors activity.

The nuclear industry (BNLF) has a very tight system of procurement, with funding dependant on the acceptance of fulfilment of criteria at gateways throughout the management of the whole project.

Currently within the health service procurement of equipment is on an *ad hoc* basis.

Equipment manufacturers are now faced with 400 or so NHS 'customers' who are not in a position to negotiate over price or safety features. It was felt that manufacturers were largely resistant to change even if they could benefit by increased sales. This resistance could be overcome by having contracts that contain clauses related to safety.

It was felt that the NHS had contracts that were large enough to make safety a "lever" with the Purchasing Agency and had sufficient influence with manufacturers to insist on a specification. A need was identified for the procurement system to look beyond "buying off the shelf" and towards the integrated systems design.

It was pointed out that in some industries there is a partnering relationship to bring procurement, research and development together. Some of these issues have been dealt with in the other workshops held as part of this study. The proposed EPSRC Health Technology Assessment centre might be a further opportunity to consider the development of this approach.

Much of the equipment used within the health service has to be operated by a wide range of users, unlike other safety critical industries. For this reason a much greater emphasis might need to be placed on procurement (and design) for usability.

One member of the workshop proposed a study to consider the effectiveness of an improved procurement process. The suggestion was made that it might be possible to identify a sample of purchasing scenarios and try out an ergonomics assessment on each to establish how it might change the selection process. This would also reveal the potential cost benefit of applying user-centred decision making in the equipment procurement process.

Compared to the nuclear industry the medical model for the design process was seen to be very poor. The CE mark is considered ineffective in terms of safety and makes no guarantees. An example of this is that any software used in devices is not guaranteed to be error free. The validation process for design was also thought to be very poor. Process industry standards take six years to come into effect, whilst medical standards are implemented within a few months. A model (see figure 41) of the design process related to safety significant plant and equipment at BNFL was presented. The potential benefits of using such an approach within the health service should be evaluated. A number of BSI committees should be reviewed with a view to their potential impact on the health service. These include, BSI Technical Committee GEL65- Measurement and control, BSI Sub-committee GEL65/1-Systems Considerations, and also Functional Safety committees IEC 61511 and IEC61508.

Standardisation of devices within healthcare would assist with training and usage of equipment. Reference was made to "the McDonald's approach", where each product is specified and the procedure for producing the goods is also laid out. These processes are not subject to local variations. In theory it is possible to place a McDonald's employee from one country into the branch of another and they would produce a uniform product.

In response to the question as to whether there was a process for standardisation of equipment regarding the health service, the reply from those closely involved with health service delivery was that the regulations concerning medical devices are broad and that regional standardisation used to exist but that these now exist at local level.

How, in a safety critical industry, should equipment be risk assessed and what organisational structures are needed?

This area for discussion had, to some extent, become pre-empted by the previous. This was because most of the workshop discussants stated that, within their safety critical sectors, much of the risk assessment takes place ***before*** the equipment is procured. However, in was noted that within the health service the risk assessment of equipment seemed to be limited. For example, it was felt that in the NHS, no risk assessment is carried out for infusion devices. The underlying assumption is that the manufacturer has already done this.

Any risk assessment needs to consider usability. This in turn requires human factors/ergonomics skills. The question arose as to where these skills exist within the health service. It was felt that currently there are not enough human factors/ergonomics trained personnel in the health service at a suitably high level.

The need for the risk assessment to include the intended user was imperative. This is because changing practices within the health service now mean that the intended user might be anybody. Due to this it has also become necessary to ask the manufacturer exactly ***who*** the equipment is designed for and, conversely, ***who should not*** be allowed to use it (or use it only under supervision).

How might the Health service learn from errors?

Reporting systems

The advantages/disadvantages of reporting systems were discussed. A need was recognised to empower those working within these systems to recognise a just culture. "Open" reporting systems were seen to be preferred in those safety-critical industries represented at the workshop. In the nuclear industry, committees exist with the specific task of ensuring that the organisation learns from experience by looking at incidents and taking action. Data are gathered through extensive reporting systems. The safety culture is such that concern is present even in non-critical areas such as preventing slips and trips in office areas. Accident reporting in this industry is the norm.

The reporting system in the NHS should be open as this would be a more effective way to end the no-blame culture. Confidential reporting can lead to open reporting as confidence grows. However, it was considered important to talk about a "just" culture rather than a "no-blame" culture. This is because no blame allows the negligent to get away with poor performance. As risk managers have different perspectives, they need to draw together their experience and provide a systematised background through an educational experience.

Accident analysis and learning from adverse incidents

Root cause analysis was thought to be helpful but gave rise to a number of questions:

- What will happen to the report?
- How will the organisation take on the findings?
- How will they do this themselves and who is available to help?

These questions need urgent consideration in light of the proposed NPSA developments in this area.

Other points raised included:

- The use of proactive teams to look for problems.
- The need to train local champions, these individuals would require training in ergonomics/human factors.
- Basic ergonomics audit could eliminate some risk of misuse.
- A safety diary kept over a week heightens safety awareness.
- Safety improvements could be tested by small groups of users.

- The reporting of ***potential*** improvements should be encouraged, whilst recognising that people may only see improvements in their own sphere, and may be unaware of potential ill-effects elsewhere in the system.
- The NHS should be aiming to have expertise to make root cause analysis.
- Encourage reporting of 'accidents waiting to happen'.
- Take account of technical v human errors when collecting data.
- The possibility of appointing an 'independent assessor' should be investigated.
- Analysis of data should be centralised to give a national picture and trends should be identified. Many data already exist, but have not been analysed and no action has been taken.
- Data must be collected with a view to analysis and feedback given to others working in the environment.
- Managers need to drive the change process whilst front line personnel need to recognise situations where errors or accidents might occur by looking beyond their immediate task.

Local trusts should try to identify risks in the design process using, for example, focus groups as necessary. Local trusts also need to develop the skill base to learn from adverse events and to capture bigger trends across the NHS. A culture change can be achieved through the empowerment of people within the organisation. This process could begin by persuading people to try to see areas within their work area where accidents or incidents might occur.

Error Recovery

Strategies for error recovery were discussed. These include:

- The provision of other modes. For example, if equipment fails or performance is lowered, other tools are employed to complete the task (the usefulness of such strategies within healthcare systems may be limited by the relative lack of detail in healthcare systems compared to other safety critical industries).
- Use of intelligent knowledge-based systems to help define recovery strategies.

Techniques need to be developed and applied to show high-risk areas and recovery at high level systems to find out what happens if things change.

Checking

The question of checking was raised. Perfunctory checking was considered dangerous and double-checking did not necessarily enhance error detection and could have the opposite effect.

Training

Correct use of training data has relevance for safety issues (Rejman,1996) Techniques of error profiling during training can be used proactively in accident prevention. Many organisations are unaware that they routinely collect such data or of its potential value.

However, within the health service more serious training issues exist. Whilst there was a reasonable budget for staff training, staff shortages often preclude dedicated time for training and night staff frequently miss out. Training agency staff and short contract staff was often seen as a poor investment.

Safety managers should have practical experience looking at those using equipment over a period of time.

Conclusions

There was general consensus that there was much to be learned from other safety-critical organisations and industries.

Much of the equipment used within the health service has to be operated by a wide range of users, unlike other safety critical industries. Therefore, a much greater emphasis needed to be placed on procurement (and design) for usability. The purchasing power of the NHS should be used to encourage designers and manufacturers to address these issues. The need for standardisation of equipment throughout the organisation in the longer term was raised.

For this to happen, other industries had found that human factors/ ergonomics must become embedded within design teams. The question was raised of how much ergonomics input there was to the design teams for the health service. More human factors experts should be employed as they are not evident in sufficient numbers at present. A cost-benefit analysis of the ergonomics/human factors team would also be necessary.

Whilst improved procurement strategies and a greater input to the design process were required, systems should be set up to improve the risk assessment of what is already in place.

Training in, for example, equipment use or risk assessment was essential and needed to be designed in accordance with usability needs. Although there may be a reasonable budget for staff training, the actual training that healthcare professionals receive may be less than that intended. The situation may be worse in the case of training agency or short-contract staff. The ability of the health service to learn from errors requires an open reporting system and a “just” not a “blame” culture. Learning from adverse incidents was considered as important, and many important issues to be addressed were noted. Becoming proactive in the reporting of potential problems and moving towards a safety culture that looked to consistently improve the work system was also recognised.

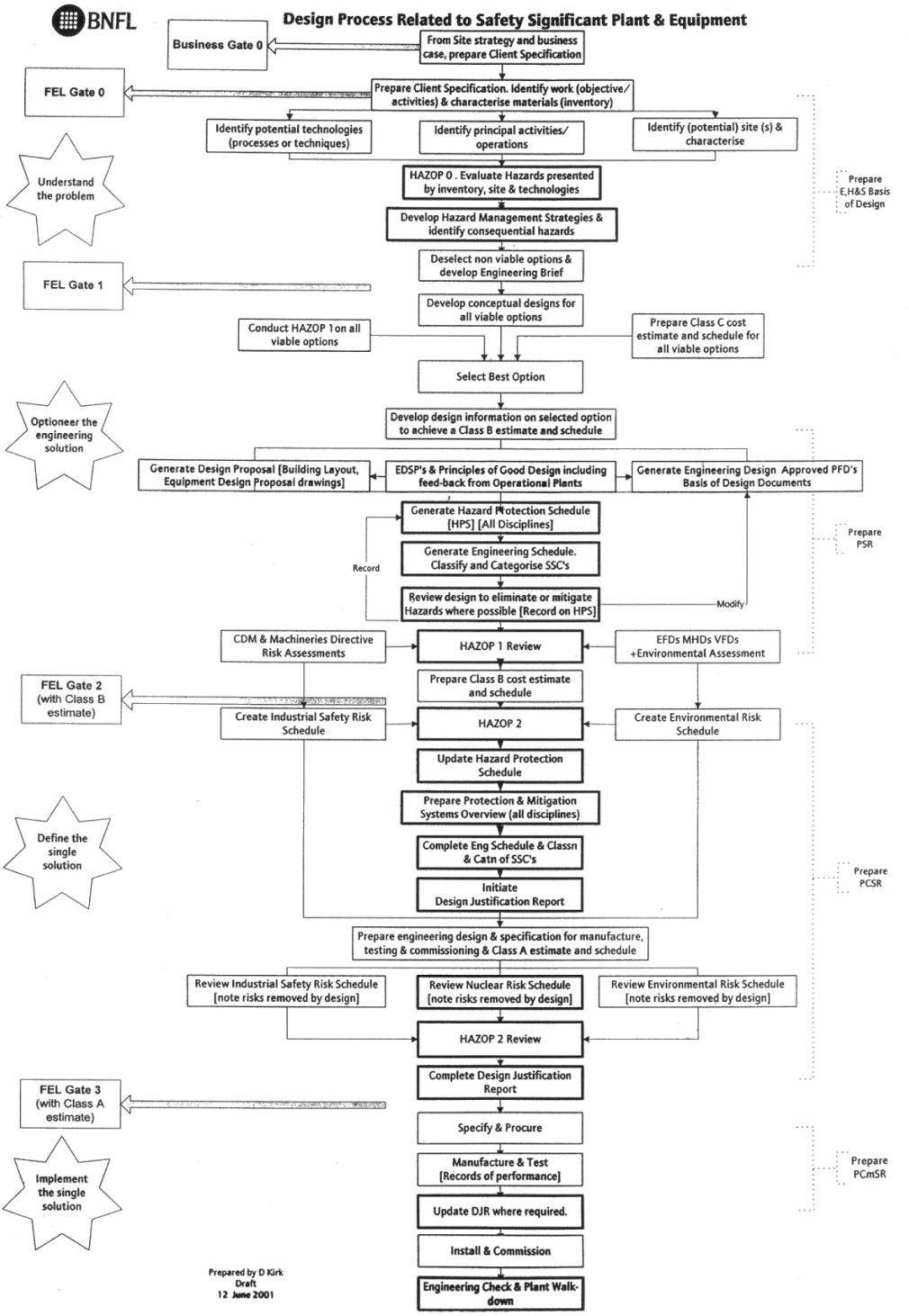


Figure 41: Design process related to safety significant plant and equipment

Stakeholder workshops

A series of workshops was held with the intention of better understanding the challenges facing stakeholders across the healthcare industry, and their priorities and concerns. The workshops were informed by the results of baseline desk-research emerging from the work of the teams at Surrey and Cambridge, and were constructed in order to:

- elicit information to flesh out the 'big picture' of what is going wrong from the various care sector perspectives, what the user experience is like (both positive and negative factors), and where the obstacles and possible solutions lie;
- prioritise the resulting issues, tease out design implications and identify opportunities for effective intervention;
- engage the participants as a group and tap into their combined expertise, knowledge and experience in exploratory and creative ways; and
- prepare the ground for future engagement of the participants e.g. as part of an institution or sector-based taskforce or a cross-sector advisory group.

Overview

A total of four workshops took place at the Design Council offices and the Helen Hamlyn Research Centre. These were conducted under the 'Chatham House Rule", which participants were asked to sign, in order to encourage openness and the sharing of information and experience. Workbooks and other data-capture methods were constructed so as to preserve anonymity. Although it is possible to identity authorship of the problems/errors and causes from the raw data for research purposes, this report maintains the confidentiality of the participants.

Two full-day structured events were organised for a cross section of representatives from primary and secondary care services, purchasing and licensing, and equipment and pharmaceutical industries. These events were professionally facilitated and data was captured using workbooks, maps and note-taking. A facilitated two hour discussion group session was held with patient group representatives, with data capture by note-taking. The data from these sessions were analysed and used to inform and focus a final one-day 'creative' workshop which included a sub-set of participants from the first three events working alongside design professionals from the fields of information, product, communication graphics, and packaging design. Data were captured by means of flip charts and note-taking.

The process

Mapping the system

The participants at the first two workshops included 20 representatives from across the primary and secondary care sectors (time of service ranged from 8-42 years, with an average of 26.9 years) and 17 from procurement, licensing, and the equipment and pharmaceutical industries (professional healthcare related experience ranged from 3-45 years, with an average of 23.3 years). Collectively the participants brought over 1,000 years of experience to the table, with a range of 3-45 years and an average of 23.9 years. Some of the participants held very senior posts and had a lifetime of experience of healthcare services, others were more junior and had more day-to-day contact with patients. Each workshop began with a simplified map of the healthcare system, based on the work of the Cambridge team (literature reviews

and stakeholder interviews). Participants were asked to complete a short personal profile, give some detail on their reasons for attending, and position themselves on the map. Additional elements of the system and relationships were added to the map as requested by the workshop participants.

The map was based on concentric rings, with the patient and carer placed at the centre. In the first ring, beginning at the top and moving in a clockwise direction, came: hospital doctor; hospital nurse; community pharmacy; off-the-shelf medication; care house nurses; community nurses; general practitioners. In the next ring came: purchasing; hospital pharmacy; ward-stock; pathology; dispensing software. In the outside ring came: equipment suppliers; drug companies; distribution; government agencies; trade associations; expert opinion; medical devices agency and medicines control agency.

Over the course of the two workshops and the patient groups discussion session, the following were added to the inside ring: patient consent; patient support groups; care providers; occupational therapists; alternative therapists; clinics, in particular diabetes; consultants; emergency rescue and first aid; and a lack of communication with patient support groups by hospital doctors and nurses was noted.

To the second ring were added: prescribing software; hospital management; equipment training; investigation processes; the hospital environment; and a differentiation was made between purchasing of equipment and medicines.

To the outside ring were added: NHS agencies; trade unions and professional bodies; the Internet; government; self-help groups; the research community; device manufacturers; service providers; drug delivery design and buying from drug companies on behalf of community pharmacies.

Capturing problems and sources of error

The participants were then asked to list actual and potential problems/errors and likely causes they were aware of or had direct experience of, and attach red dots to the map indicating where these problems/errors were situated within the overall system, thus identifying hotspots for medication error. After that, meeting in sector-specific groups, they prioritised problems/errors, chose the top four problems from each sub-group and presented these back to the full group.

Next, the top level findings of the baseline research were presented to the full group and also positioned, as hotspots, on the system map. This brought the participants up to speed with the baseline research and provided an opportunity to compare the research results with stakeholder experience. After that, the participants split into 2 cross-sector groups and worked on identifying potential solutions/design opportunities to the top eight problems/errors prioritised in the earlier session. These were presented back to the full group in a plenary session, and the workshops concluded with a feedback session which allowed participants to reflect on the day.

Understanding patient issues

An evening session was held with four representatives from patient support groups, with the discussion led by the workshop facilitator. Although small in number the participants were extremely articulate and very effective in the role of patient advocates. They were also aware of a number of factors that, although not strictly concerned with medication error, contributed significantly to that and other healthcare problems and issues. The session included a discussion of the system map which helped to flesh out those areas which sit outside the

formal healthcare structure but have an important part to play in the patient experience of illness and medical care.

A creative approach

A fourth 'creative' workshop was held in the Helen Hamlyn Research Centre at the Royal College of Art. This brought together a sub-set of nine participants from the first three workshops, giving a good spread across the stakeholder groups. There were two additional industry representatives; the head of a large design group and a product manager, who did not attend the earlier workshops; and seven design professionals, ranging from current and recent RCA graduates to senior designers with experience of design in a medical context and of major design implementation projects including the Sheffield Super Tram and the BA ticketing system. Between them the designers had over 140 years of experience, ranging from 9-37 years, with an average of 24.2 years. The atmosphere was informal and the event was structured along the lines of 'user forums' and 'brainstorm' sessions, common working methods within user-centred design research and practice. Two research team members were present but no other observers attended, making this very much a relaxed and collaborative 'working' day for all concerned.

Headline results from the baseline research and initial reflections on the first three workshops were fed back to the participants to give a context for the day. This was then focused on a series of drawings of patient-centred situations/environments that charted the patient journey through the healthcare system, from the home, through the GP surgery or rescue services, to entry to hospital, in-patient treatment and outpatient return to community-based aftercare. The non-designer participants identified and discussed issues and problems/challenges in each situation, and these were captured on flip-charts by the designers.

The participants were then broken up into three mixed groups of two or three designers and three healthcare professionals, plus industry representatives. Each group was given an open-ended brief, related to either patient information/records, pack information/access, or medical devices and drug administration. The groups were tasked with developing three ideas each, and then selecting down to a single preferred 'solution'. They worked on the briefs for over two hours, and then presented their conclusions to the full group. Discussion followed during which obstacles and other factors were identified for each of the 'solutions'.

Stakeholder workshops conclusions (SWC)

The stakeholders workshops were highly successful in identifying a broad range of issues and understanding the details behind them. This section provides an overview of some of the key characteristics of the workshops and the general issues which were raised.

1 Triangulation

1.1 Given the short time frame of the scoping study, a range of methods and techniques was used to investigate the subject from different perspectives.

1.2 The results of the mapping and problem capturing exercises demonstrate a strong correlation with the baseline desk research and other methods employed, and with similar studies (e.g. the draft report 'Reducing the Risk of Medication Error' prepared by the Chief Pharmacist, Dr Jim Smith). Understanding of the issues and problems/errors by stakeholders is extensive and consistent.

2 Stakeholder involvement

2.1 The fact that a good cross section of stakeholders could be brought together at very short notice and with an attendance rate in excess of 90% demonstrates a significant degree of commitment to addressing the issues of medication error and patient safety across the many sectors of the UK healthcare system.

2.2 Stakeholders have a wealth of detailed experience which throws fresh light on how and why errors occur. They are particularly keen to improve practice and patient safety in their specific fields and have much to contribute to the process.

2.3 Overall, there is a real potential for the successful and cost-effective engagement of stakeholders in the process of error reduction and improving patient safety, and a willingness among the stakeholders to be part of that process.

2.4 Small groups of designers and stakeholders working together in an informal setting can rapidly identify and explore problems and move towards solutions. However, more detailed information is required if solutions are to be effective and actually improve patient safety.

3 Mapping the system

3.1 In fleshing out the map of the system the participants added layers of complexity, both in terms of stakeholder groups and the interconnections between them. What emerged was a system whose intricacy surprised the participants and pointed to key underlying problems related to fragmentation, parochialism, and lack of communication and integration.

3.2 The number and diversity of interfaces between stakeholder groups created opportunities for errors to emerge, in particular those associated with information transfer, conflicts of interest, differing protocols and working practices and conflicts of status and seniority.

3.3 By positioning their problems on the same map, hotspots emerged, which helped to identify risky situations and activities, and focus discussion around them. This confirmed conclusions reached by the other research teams.

4 Consensus was reached on some issues

4.1 The NHS was considered to be a fractured, complex organisation.

4.2 Surprise was registered that the NHS is not more forceful in its purchasing.

4.3 It was felt that mistakes occurred under pressure which is endemic in the system.

4.4 Blame culture was seen as a considerable obstacle to change.

4.5 It was felt that there was considerable scope for collaboration and standardisation across sectors.

4.6 Concern was expressed over issues of information, packaging and labelling.

4.7 It was felt that the NHS needs to be innovative in tackling error and patient safety, learn from other industries and take a multidisciplinary approach to this.

5 Sectoral differences emerged over other issues

5.1 Those within primary and secondary care are more aware of specific problems and instances as they experience them, whereas those within industry, purchasing and licensing tended to see the issues in terms of generalities.

5.2 Those closest to implementing or specifying solutions had least contact with patients and first hand experience of things going wrong, while those closest to the problems, and patient contact, had the least contact with design and designers.

5.3 This indicates a considerable opportunity for the capture and transfer of safety-relevant information up the supply chain, and for designers, specifiers and purchasers to learn from end users and those in direct contact with patients

6 Capturing problems

6.1 A significant range and diversity of problems was captured during the workshops, and a wealth of detail exposed in discussion.

6.2 The problems can be grouped under six major headings: self-medication errors; prescription errors; dispensing errors; administration errors; information and records errors; and equipment and devices.

Top level challenges included:

6.3 Around the design of packaging – access to medication, accompanying information, the separation of medication from packaging and information, and correct identification of pack/contents.

6.4 Around patient information and records – drug charts, transfer of records, separation of records from patients.

6.5 Around misadministration – device design itself, complexity, variety of designs, confusion over correct use.

6.6 These categories reflect the results of the literature searches, case studies and interviews undertaken, and confirm that direct consultation with stakeholders is an effective way of identifying problems and errors.

6.7 The creative workshop generated many issues centred around specific healthcare environments. While covering the same territory as other workshops, these results are much richer from a design perspective, giving specific details of actual incidences, contexts and practices, with further depth of information emerging in the group working sessions.

6.8 A wealth of anecdotal detail on aspects of non-compliance, especially in the community, emerged from creative, primary, secondary and patient support group sessions.

6.9 The patient group identified a range of issues, from support (or lack of it) to medication delivery by carers, through information flow, checking of medication, especially on transfer from one sector or care environment to another, to the need for patients to take ownership of their health conditions and treatments.

6.10 In general it was thought that patients do not know enough about their medication.

6.11 Issues of human error versus culture and practices arose in all workshops. There was particular emphasis on variations in protocols between providers/services/sectors; confusions about responsibility; stressful situations; hierarchical and autocratic behaviour; and conflicts of interests between industry and healthcare system.

6.12 Many interrelated factors contribute to the major instances of error, and these occur in many variations with there being no clear cut differentiation between problems and causes. This reflects the complexity of the overall problem, and the varying experiences and perceptions of different stakeholder groups.

6.13 From a design perspective the richness of detail and the range of viewpoints and contexts described is both interesting and valuable. As a process, similar stakeholder workshops could help designers better understand the complexity and range of factors to be taken into account.

7 Understanding the challenges

7.1 The problem breaks down into complex interactions between risky situations, risky moments, risky items, and risky users.

Such 'accident hotspots' can be identified:

7.2 in the home, around problems associated with packaging, storage, remembering, reading, understanding, etc.

7.3 in transfer/transit around changes in drugs, protocols, people, equipment, records, etc.

7.4 around the hospital bed and infusion lines, connectors, notes and record keeping, communication between staff, drug administration procedures, etc.

7.5 where situations and equipment or medications are new or unfamiliar, and when people are working under pressure.

7.6 where information becomes 'non-sticky' and gets detached from patients, packaging, medication, or ineffectively or incompletely transferred, e.g. to pharmacists.

7.7 in cases of mistaken identity related to names, packs, connectors, ampoules, infusion pumps, non-standard equipment and so on.

7.8 in failures to effectively capture errors or information that is design-relevant.

7.9 where problems and causes are confused and conflated, especially around non-compliance and there is a tendency to blame – the patient or the manufacturer or the doctor or carer, rather than unravel the complex, interrelated chain of causes and resulting problems.

7.10 solving the major pack-associated problems for older people in their homes may also solve similar problems for other groups.

7.11 tackling the major problems for hospital staff and paramedics, associated with identifying medications once they are separated from their packs may solve similar problems for other less critical groups.

8 Looking for solutions

Specific recommendations:

8.1 Administration of drug by wrong route requires, for example: reducing the complexity of devices; reducing the number of makes and models; better labelling of equipment, instruction manuals and control panels; using non-interchangeable parts; using protocols for storage and providing better training.

8.2 Errors in drug administration require, for example: bar coding to correlate labelling with patient information; ways to link diagnosis with treatment as a checking mechanism, and systems to alert physicians when the wrong drug is selected.

8.3 Similarity of names and packs requires, for example: having a standard sized drug name; using colour coding and pictograms in labelling; including BNF category number; national standards for expressions and concentrations; pre-filled syringes; plastic rather than glass vials; reducing the number of daily dosages.

General recommendations:

8.4 A national medical information system is a priority.

8.5 More evidence-based feedback is necessary and this should be acted on.

8.6 There should be cost benefit analysis that takes into account all the consequential costs of errors and adverse events in order to calculate the true value for money of error avoidance measures and design improvements.

8.7 Standardisation at a national level would be a step forward and should extend to language used, drugs usage and equipment.

8.8 The financial power of the NHS is great but is under-utilised in this respect, while the inertia resisting effective change within the NHS is great.

Other options/opportunities:

8.9 Levels of lockout to reduce the temptation to tamper with or modify equipment.

8.10 Speeding up support/maintenance for key items of equipment.

8.11 Keeping the product attached to its package in order to retain instructions.

8.12 Imbuing products with identifiable features to facilitate recognition even if the packaging changed.

8.13 Methods of record keeping incorporated into the packaging or presentation of medication.

9 Barriers and obstacles to change

9.1 Overall there is a need to better identify and alert people to factors associated with adverse incidents which could be addressed by design interventions.

9.2 Not enough is known about what happens around hotspots, in particular in the home, and also where confusion and mistaken identity occur.

9.3 Different issues arise in different situations, but this is not well understood. Designers/industry do not understand, nor consider the complete range of situations in which devices, packaging, information, medication, etc., are used.

9.4 Work practices challenge design assumptions, e.g. paramedics repackage mixed ampoules in a single box.

9.5 Patients do not know enough about their medication. Information is not effectively communicated, understood and owned.

9.6 Manufacturers are reluctant to innovate in ways that impact on safety as this is not well enough understood, not owned by them as an issue or goal, and not seen as a route to profitability. Instead they look for profitability through differentiation, brand presence and market share based on other factors, which can have an adverse impact on patient safety.

9.7 A major obstacle encountered at the creative workshop was the lack of specific knowledge. Although the participants had no difficulty in outlining possible ways in which the problems might be tackled, they hit a barrier in arriving at solutions because of a lack of knowledge about the system itself, and how elements of it interact.

Detailed results

Motivation and engagement

Assembling a representative cross section of healthcare professionals and NHS agency and industry representatives was a challenging task, given the workloads and job priorities of such people, and the very short time allotted to the project as a whole. The participants were assembled through contacts, referrals and suggestions from the research team, from key Department of Health contacts and through other routes. Almost all the participants engaged positively with the process, and the majority volunteered to return for the creative workshop.

Structured workshops

Reasons for attending stakeholder workshops included:

- Interest in people using medications and also an interest in literacy skills – lack of literacy can be a potential area for danger.
- Broaden my understanding of safety issues.
- Community staff e.g. home care are being asked increasingly to supervise and assist in the administration of medicine to service users in their own homes.
- Personal experience and frustration at medicine package design causing errors.
- Involvement in promoting design and safe use of equipment and environments in which patients may require to use them.
- Wish to contribute to the reduction in adverse incidents involving medical equipment throughout NHS.
- To understand issues affecting patient safety and how this can be improved through the design of the actual environment.
- Interest in ensuring the NHS buys safer medical devices.
- Understand some of the safety issues facing patients.
- Interested in patient safety in our products.
- Dealing with aspects of medical device safety and drug compliance issues as an integral part of new drug delivery projects.
- Increasing awareness of medical devices being used by patients and nursing staff in the home healthcare environment.

Feedback at the end of the workshops indicated that the stakeholders were interested and stimulated:

- Very interesting day. Thank you
- Enjoyed the experience.
- Very interesting mix of people with a wide breadth of knowledge and experience.
- Thanks for a thought-provoking day. I enjoyed the discussion greatly. I hope it provided some good data/areas for follow up.

The majority of the stakeholders felt they had benefited from the day and the range of

comments bears this out:

- There are many problems, but few key themes – mainly packaging and communication, but people are very keen to work towards solutions.
- Problems are widespread and varied, but there is a common theme. Staff try hard, but the volume of work and the pressure they feel under create an environment in which mistakes occur. All sectors (hospital doctors, nurses, GPs, pharmacists) perceive similar pressures.
- Wide ranging issues under the heading of 'design'. Pleased there is a general consensus on some of the solutions.
- How fractured and complex the NHS is! Need a step-by-step strategy to incorporate design at different levels and to achieve different things. Focus effort on areas that will give the greatest return on risk/safety. Design around a common/min spec for high volume/common kit, that is based on good ergonomic principles. Patients involved in design of kit that they will use/be used on them.
- From the limited time I was able to be present I found a broad range of views regarding issues which was stimulating, but the process of achieving not identified.
- I have a limited insight into the issues facing both the NHS and industry in terms of the procurement and administration of medicines and treatments. I am somewhat surprised that equipment providers and pharmaceutical companies lead the process by supply and demand, not the NHS with demand and supply.
- No clear outcomes BUT: NHS needs to be innovative in looking at problems. Learn from other sectors/industries – multidisciplinary. This is an imaginative start – a beginning. The NHS does not utilise designers appropriately, or if it does this is in 'pockets'.

Participants also suggested action for the NHS and industry, including:

- NHS to: Act on some of the issues raised today and drive the pharmaceutical industry in certain areas.
- NHS to: Think and act constantly to put safety first. Standardise where possible. Research more deeply into safer systems/solutions.
- NHS to: Look at standardisation across all trusts' training.
- Industry to look at: Clearer labelling and identification of drugs.
- NHS to: Get manufacturing industry to buy in to the need for pack design to meet the common and disparate needs of prescribers, suppliers (wholesalers, central stores, pharmacies) and patients.
- NHS to: Link up the MCA with NHS purchasing and be more forceful in what is purchased – implications for independent contractors. Make sure IM+T take on board the agenda.
- NHS to: Discuss publicly causes and circumstances of errors.
- Industry to: Address information problem – e.g. patient leaflets orientated as a defensive document for the manufacturer.
- NHS to: Better procedure for reporting of clinical incidents allowing for dissemination of lessons learnt. Abolish local clinical steering committees such that national standards can be applied.

- Industry to: Focus on safety and need. Develop greater collaboration and standardisation to increase safety and reduce costs.
- NHS to: Ensure NPSA can fulfil its objectives – particularly in relation to feedback/dissemination of good practice – but also consider what can be achieved at a local level to reduce error.
- Industry to: Rethink drug purchasing and information. Simple logo for categories. Clarify drug dosage information on ampoules. Design equipment for safe administration.
- NHS to: Standardise, use market position to dictate to industry on what it needs e.g. generic packaging.

Creative workshop

At the creative workshop, all the participants engaged enthusiastically with the process and found the day stimulating and interesting. The atmosphere was informal and the event was structured along the lines of 'user forums' and 'brainstorm' sessions, common working methods within user-centred design research and practice.

There was a general sense of 'ownership' of problems and challenges, and a real commitment to finding solutions. The multi-sector nature of the event was found to be stimulating and there was considerable interest in ways in which problems vary from sector to sector, and also in the issues that were common across many healthcare situations.

Capturing the problems

Several methods were used to capture and prioritise problems and errors, including workbook sheets, maps of the healthcare system, illustrations of patients in different care situations, and group-working sessions. This helped focus attention on different aspects of the patient safety and also gave some indication of the strengths, weaknesses and effectiveness of the different methods.

Over 140 errors and problems were identified in the first workshop. These break down into about 30 problem groups, which can be further broken down into errors associated with e.g. self-medication, prescription, administration, etc. The analysis is not clear cut, in particular when causes are looked at along with errors. The participants were asked to give causal factors related to the errors/problems identified, and an examination of these reveals a significant degree of overlap. Problems are cited as causes of other problems, revealing a chain of interrelated factors, for example, the use of small and/or difficult to read fonts, in combination with computer generated labels that tend to deteriorate rapidly with handling, create difficulties for large numbers of patients in reading instructions. In the case of older patients this is exacerbated by long-sightedness and reductions in visual acuity, leading to errors in following instructions and confusion between medications, which in turn leads to compliance failure, over- and under-dosing, and contributes to adverse reactions in combination with off-the-shelf medication.

In this instance the problem is identified variously as 'patient takes same drug more than once', 'medication taken inappropriately', 'wrong drug administration', 'patient confusion', 'patient unable to read labels' , 'inappropriate storage in home', 'elderly confused patients with several drugs failing to adhere to medication instructions', etc. While causes include: 'older patients; poor labelling; poor consulting', 'impaired vision, small print on labels, poor durability of labels', 'cannot read or understand leaflet', 'forgetfulness, too much confusing information, too many decisions', 'patient doesn't know what drugs are for'.

What is clear is that many interrelated factors contribute to the major instances of error, and that these occur in many variations. For instance; self-medication errors and failures can be associated with: reading and understanding; complicated regimes; storage; patient confusion); access to packs and packaging; information (on and off the pack; knowledge/understanding of the purpose and function of the medication and the dosing regime. Likewise, administration errors and failures can be associated with: wrong dose/dilution; misinterpretation and confusion; poor information/communication; daily instead of weekly dosing; administration route; connection and misconnection; rate and failure of delivery.

Although problems and causes can be grouped in several ways, the overall picture is one of major groupings with:

- significant sub-sets: self-medication; prescription; dispensing; administration;
- significant but less readily sub-dividable groupings: information and patient records, transfer of patients from one situation/environment to another, checking in wards, sharps-related incidents, syringes and contents, over-infusion, misconnection and misadministration of gases; and
- other singular or less significant instances.

This grouping of problems closely reflected what was emerging from the literature study and case study research, and tended to confirm that direct consultation with stakeholders is an effective way of identifying problems and problem areas. It is also helpful in focusing on those areas in which interventions could make a significant difference. In addition, it is interesting to note that although rare but high profile errors were recorded,(e.g. intrathecal administration of Vincristine), they did not feature with undue frequency, suggesting that stakeholders have a well-balanced understanding of the importance and frequency of error. Vincristine was mentioned specifically only four times in the 140+ instances of errors cited.

Ten of these errors were due to ‘wrong route administration’, which was associated with a range of issues including:

- Luer connectors;
- connection standards;
- the lack of regulation of hospital doctors’ working practices;
- staff exceeding or lacking appropriate training;
- inadequate labelling of pre-prepared drugs;
- availability of personnel; and
- lack of familiarity.

Such a level of detail in the comments further indicates the participants’ in-depth understanding of the broader context and issues and their ability to identify error-related factors with an impact beyond a single instance of error.

From a design perspective, this richness of detail is both interesting and valuable. It gives an insight into the complexity of interacting factors contributing to, in this instance, mistakes in administration routes. As such, it could help designers better understand the range of factors to be taken into account, and so identify viable solutions. For example, in the case of Vincristine misadministration, a complete solution would need to address more than ‘the ability to connect Luer syringes to CSF access devices’ and take into account the other issues identified above, which are more to do with familiarity, understanding, working practices, and

the environment within which the equipment is used and the drug administered.

The 'creative' workshop also featured a session during which patient safety factors were captured and shared by the group by means of drawings and flip chart sheets. This generated 93 factors or issues in the space of one hour. The issues centred around the following specific healthcare environments:

- the patient's own home/community GP/nurse etc.;
- the local pharmacy; surgery and day-care;
- the rescue services/paramedics;
- entering hospital;
- operating theatre;
- intensive care unit;
- hospital ward;
- patient after-care back in the community, via a care home, home care or other services.

Although covering essentially the same territory as the earlier problem capture exercises, these results are much richer from a design perspective as they move into specific details of actual incidences, contexts and practices. These are significantly more revealing than more general, abstracted, top level problems which typified the earlier workshops.

Understanding the challenges

In order to better understand where the key 'hotspots' for error lie, participants were asked to locate their problems and errors on the map with red dots, producing the following results. Not all problems were positioned on the map (113 of 142) as some participants assumed that multiple problems at a single site required only one dot. In a small number of cases problems were associated with relationships (or lack of) between one group and another, in which case they are counted twice.

Key clusters were associated with:

- hospital doctors and nurses;
- patients and their immediate carers both at home and in secondary care;
- drug companies;
- community pharmacies;
- hospital pharmacies;
- the MCA;
- general practitioners;
- ward stock;
- off-the-shelf medication; and
- purchasing.

Although the hotspots identified do not match with the numerical incidence of error identified in the baseline research – and it should be remembered that participants were asked to identify

error types rather than frequency – this exercise reveals a strong association of error with those prescribing and administering medication, including self-administration, followed by those supplying medication.

Human error was referred to frequently in the data captured and in discussion at the workshops, indicating a general assumption of the inevitability of human error as opposed to an awareness of contributing factors that could be amenable to design interventions. In terms of causes, stress, workload, concentration failure, training, protocol, failing to check/double-check and local non-standard practices are all cited, but there is little or no awareness of the attention burden imposed by factors such as similarity of names and packs, poor information, cluttered labels, small lettering, etc. In other words human error is accepted as a root cause rather than other factors which make it more likely to occur. In tandem with this, 'blame culture and the disciplinary procedures that go with it are seen as a significant factor by the stakeholders, across the system, and it may well be that this emphasis on human error is distracting attention from design flaws that could be remedied.

Stakeholder priorities

These observations are supported by the results of a further prioritisation exercise undertaken by stakeholders working in sectoral groups. Each group was asked to identify its top four national issues requiring urgent attention. Results are presented in Table 13. (P = primary care; S = secondary care; P&L = purchasing and licensing; I = industry).

Table 13: Key problems/errors and causes

	Key problems/errors	**Causes**
P	Similarity of names and packs	Confusion; lack of differentiating features; working under pressure; the way medications are stored: in pharmacies, on wards, in the home
P	Communication including language and non-verbal	Assumptions; working under pressure; staffing changes; native language and cultural factors; hierarchical culture in NHS; misinformation
P	Information provision is quirky, not systematic	Commercial influence; no central system or single accredited source of information; variations between suppliers; information leaflets protect against litigation rather than provide the right information in appropriate forms for different users
P	Physical access to the contained medications by professionals and users/carers	Pack design; patient ability; conflicts with child and tamper resistance; prompts repackaging of drugs; problems with blister packs
S	Drug identification – difficulty of ensuring use of correct drug.	Highlighted by Vincristine, in particular due to severity of outcome in the event of misadministration, but also occurs in the case of tablets and ampoules. Causes include: similarity of packaging; repackaging; use of colours; renaming of brands; changes of medication name e.g. adrenaline now ephedrine; label size and legibility; using drugs in difficult/stressful situations

	Key problems/errors	Causes
S	Lack of/inaccessibility of systematic information about causes that can be used to inform solutions.	Contingent workforce – temporary staff; structure of nursing and medical workforce; staff shortages – changing hours; frequency/severity of disciplinary action; fear of litigation; complex reporting systems; failure to share information
S	Administration of drug by wrong route	Equipment; variation/lack of variation; wrong route 'selected' by giver; warning systems; individual 'initiative' (purchasing adapters); human error; poor communication; reporting feedback mechanisms
S	Repetitive error in drug administration.	Prescription charts – legibility; environment – distractions; failure to follow protocols; poor verbal communication; poor record keeping; role of 'checker'; lack of error reporting (blame culture); staffing – experience, temporary, skill mix; cultural aspects – dr./nurse relationship; human error
P & L	Packaging. labelling, presentation, recognition. Differentiation	Size/shape; lack of specification and testing against it; commercial pressure; poor labelling, esp. legibility; incorrect interpretation of instructions
P & L	Inadequate understanding of how to use device. And lack of understanding of information about abuse.	Design; complexity of devices; variety of makes and models; supporting information or lack of it; human factors; lack of training; poorly designed documents
P & L	Environmentally aware design solutions (lack of); taking the demands of working situations and stresses into account as part of the design challenge.	Lack of collaborative working + joined up thinking; distance between industry and designers and the actual care environment; industry's need for differentiation; tendency to look for accuracy rather than suitability for purpose as easier to quantify.
P & L	Awareness of secondary risks of e.g. sharps, medical gases, administration, equipment	Lack of training; lack of risk-awareness; over-complexity of safety systems
I	Non-compliant patient/carer/physician	Patient: reluctance to take medication; confusion; forgetfulness; supervision; carer/physician: training; inappropriate expertise; administration
I	Confusion between medications	Delivery systems not differentiated; similar packs/labels; similar names; elderly confused patients
I	Information flow – lack of	Records not with patient – main problem; incorrect modality prescribed; poor handwriting
I	Users override design safety features	Patient plays with device; paramedics in emergency situations; medication separated from pack; cannot understand

Compliance and associated issues

The patient groups session took the form of a free-flowing discussion with relatively light-handed direction from the facilitator. The participants were well-used to patient advocacy and although each had a specific perspective, in terms of the patient group represented, they were highly motivated to explore common issues and problems. However, some issues were seen as significant, even if they were associated with specific patient groups. For instance: people with long-term conditions are concerned with the way side-effects and other aspects of medication impact on quality of life; while for people with depression and suicidal tendencies, the possibility of overdose and self harm is important.

Overall, the discussion reinforced and also supplemented the outcomes of the other workshops. It was particularly informative on the question of compliance in the community, and the carer's part in that. This is a key issue which, although not so directly related to patient safety as some of the hospital-based issues, has a significant impact on the success of treatment outcomes and the consequential costs of treatment failures. Other important, general factors were seen as the tendency to think in terms of the negatives of adverse effects and events, rather than the positives of improving life-quality through effective partnership, and the engagement of patients and carers in delivering successful treatments.

Key issues

1. Complexity

Compliance is a complex issue with many contributing factors, including: side-effects and lack of understanding of them, understanding what is prescribed and why, problems with swallowing and manipulating medication, changes in the presentation and names of medication; and uncertainties about when to take medication – for example, for people who do not eat at regular four-hourly intervals. Expectations of the effect of medication are also important, especially as doctors tend to view patients as having a collection of symptoms to treat, while patients expect medication to have an immediate effect. Patients are reluctant to take medications in public, and to be seen as 'ill', leading both to non-compliance and to life-style restrictions.

2. Support to medication delivery

People without the support of a carer are often not able to properly understand and self-administer medication. There are may reasons why this can be problematic, ranging from physical issues such as reduced vision and dexterity to confusion and lack of understanding of the purpose of the treatment, and on to issues associated with the medication form – ear and eye drops in particular are difficult to self-administer.

3. Alternative therapies

Herbal and other alternative remedies/treatments are regarded as 'harmless', and often not mentioned to GPs, while over-the-counter medications are not regarded as drugs. As a consequence there is considerable scope for adverse interactions. Pharmacists pick up many of these problems, but there is a need here for more effective information transfer on interactions and other dangers associated with alternative and OTC treatments.

4. Information flow

Compliance problems are also due to ineffective flows of information and communication breakdowns. These can be associated with failing faculties – reading/understanding labels and hearing/comprehending advice from doctors and pharmacists – and with the way information is presented on packaging and accompanying leaflets. All these factors can be compounded

by patient anxiety, reticence in the face of the perceived authority of doctors and pharmacists, by inappropriate advice from informal carers, family members, etc., and by the fact that special care needs to be taken with older people and young people as some drugs can be contra-indicated and there can be considerable variation between individuals and tolerance/effective dosing levels.

5. Checking and transfer

Another important issue relates to checking medication. This can be difficult when an individual is admitted to hospital, and again when the person returns to the community. The GP might not have details of the drugs given in hospital and thus the patient may be prescribed a different set of drugs. In essence, there is no consistent 'pocket' supply of information of the drugs a person is taking and the reasons why they are taking them. In addition, there are problems associated with the issue of aids and adaptations, and the conditions/situations in which medical devices are used in the community. Overall there is a need to treat these issues holistically if we are to fully understand why medication compliance failures occur.

6. Patient support groups

These have the potential to fill information gaps and have advisors who give patients information about their medication. They also talk to drug companies, and work to strict policies about not endorsing drug companies. However, there is reluctance among GP and community healthcare groups to refer patients to support groups, as healthcare professionals tend to be suspicious of them. As a result such groups and their advice services are not as well utilised as they might be. In addition, it is difficult for patient groups to engage with or deliver any service into hospitals, except at the lobbying level. On the other hand, while healthcare professionals seem concerned to 'defend' their own patches against patient groups, pharmacists are much more open to engage the community and the resources offered by patient groups.

7. Trust and communication

Patients tend to place a high level of trust in advice given by the medical profession, but have low levels of trust in drug companies. Patient information comes from many sources, both formal (from drug/medication, information leaflets, the medical profession, pharmacy leaflets, etc.) and informal, including the Internet, books and word of mouth. Patient groups also give information and have the potential to act as a respected and authoritative (and therefore effective) information channel as well as a valuable resource for patients. Tapping in to trust and improving communication with patients could offer significant benefits in terms of compliance and successful treatment outcomes.

8. Patient as expert

Giving power back to the patient could also offer compliance and other benefits as patients are frequently expert in their own condition. Expert patient trials have been carried out at Stanford University and are currently under way in the UK. However, if progress is to be made in this direction, initiatives will need to be started to prepare medical staff and other professionals.

Additional patient support issues relate to whether or not patients feel in control of, or engage with, their treatment. Such issues include: the reluctance of people with long-term illnesses to present themselves as ill; deliberate non-compliance by patients as a way of resisting what they see as a form of control; and the way in which professionals can propose treatments (e.g. HRT), allowing little space for challenge and/or discussion by patients. There is a need to

respect the patient's preference for a particular drug and to understand why some patients refuse drugs. There is also a need for some form of monitoring of symptoms, especially as drug effectiveness is often not followed up. Elderly patients are particularly at risk in hospital because they can be ignored or not taken seriously by busy staff. They can starve because they cannot reach food or eat it without assistance, and become dehydrated for similar reasons.

At the interface between primary and secondary care, especially where consultants are involved , and in particular in the case of long-term conditions, there can be confusion about who is ultimately responsible, and little or no space for the patient, especially the older patient to own or control their own care, or to understand who is in charge of it.

9. Other issues

These included the impact of mental conditions on patient compliance and safety; the lack of formalised systems for the transfer of patient information; and the translation of information, often by children, in minority communities, which is particularly associated with older patients who can be on complicated medication regimes.

Design opportunities

The discussion was more informative on the relationship between compliance and patient support, or lack of it, than it was on design-related issues, as was to be expected, given the stakeholder groups involved. However, some opportunities did emerge, in particular in relation to patient information. These included: making better use of the label space on medication packs; more effective ways of keeping information with medication outside the pack; involving patient groups in the dissemination of information; making information in general more accessible and more understandable; dealing with language and literacy issues through better design; improving packaging design in terms of access to medication, making it easier for people to take medications in public; and addressing the issue of complex medication routines by making compliance easier for patients.

Looking for solutions

The challenges identified range from specific (e.g. medication related errors, needle stick injuries and disposal of sharps, injuring patients with misuse of gases) to systemic (e.g. assumptions that simplifying the process of a healthcare delivery system will lessen the need for knowledge, skills and experience). At the systemic level causes of the problem were identified as: lack of under-standing of the impact of change; desire to improve access to care (e.g. reduce waiting times); lack of investment in education and training; assumptions made in redesign and lack of 'team' involvement in re-design.

The prioritisation exercise moved on in a further session to identify a number of key factors, some of which were felt to be amenable to design interventions, and had implications across the NHS.

These factors included issues:

- around the design of packaging – access to medication, accompanying information, the separation of medication from packaging and information, and correct identification of pack/contents;
- around patient information and records – drug charts, transfer of records, separation of records from patients; and

- around misadministration – device design itself, complexity, variety of designs, confusion over correct use.

Although not all issues were covered in the process, some general directions were also identified for design solutions, including:

- seeking to increase simplicity of design, to make products more intuitive to use;
- standardisation of products so that users know what to expect of equipment;
- developing user-friendly products;
- levels of lockout to reduce the temptation to tamper with or modify equipment;
- designing equipment to be as foolproof as possible;
- focusing on fitness for the purpose;
- given the fact that some equipment is in constant use, speeding up support/maintenance for key items;
- keeping the product attached to its package up to use in order to retain instructions;
- imbuing products with identifiable features to facilitate recognition even if the packaging changed – or making packaging transparent;
- changing the shape of tablets to make them easier to swallow; and
- methods of record keeping incorporated into the packaging or presentation of medication.

A small number of specific challenges were also explored in an attempt to identify possible solutions from a stakeholder perspective. These included:

Administration of a drug by the wrong route

Problems related to the administration of drugs featured frequently and ranged from the misuse of equipment, such as syringe drivers and infusion devices, to the wrong drug being dispensed and reducing the complexity of devices and the variety of makes and models.

Errors in drug administration

Using a bar coding system would allow labelling to be correlated with current available patient information. This solution has implications for training and electronic prescribing systems, which need to be failsafe. IT solutions would be most effective in the field of primary diagnosis. For instance, a system could be developed to link diagnosis with treatment, thus acting as a checking mechanism. Such systems could also be set up to alert physicians when the wrong drug is selected from the listed drugs.

Similarity of names and packs

A number of issues arose regarding the appearance of healthcare products. These included:

- effectively using the available space on the package (e.g. having a standard sized drug name);
- colour coding;
- pictograms in labelling (e.g. using a heart for cardiac tablets in conjunction with the BNF category number);

- establishing national standards for expressions and concentrations to reduce the need for calculating doses;
- pre-filled syringes;
- plastic rather than glass vials; and
- reducing the number of daily dosages.

These solutions have implications for training, equipment design, the MCA, and the pharmaceutical industry, and would require the involvement of stakeholders from across the system.

Inconsistent information provision

Setting up a national medication information system could deal with this issue, but would require the involvement of all potential users to ensure effective implementation, training and operation.

General observations

Overall it was felt that if design becomes an integrated part of manufacture, products will become more intuitive thus reducing the need for training. The lowest price should not be the main criterion when selecting products. The reduction of potential risk can justify increased costs and this is becoming more acceptable to those making procurement decisions. There should be a cost benefit analysis that takes into account *all* the consequential costs of errors and adverse events in order to calculate the true value for money of error avoidance measures and design improvements.

Standardisation at a national level would be a huge step forward and would extend to language used, drugs usage and equipment. The financial power of the NHS is great but is under-utilised in this respect, while the inertia resisting effective change within the NHS is great. While some problems occur at the national level, improvements could be trialled locally with small investments and then generalised if successful. More evidence-based feedback is necessary and this should be acted on. Not everything that is technically possible is in the patient's best interests.

Confirmation of desk research

The issues generated by the workshops were confirmed by desk research findings from the Cambridge team (see below) and fed back to the 'creative' workshop in the form of general observations from the workshop organisers and design briefs for the creative teams to work on.

Design-related factors – the creative workshop

From the point of view of the research team, and thinking in terms of design-related factors, some generic issues and situations emerged from an examination and consideration of the workshop results and the Cambridge research. These were fed back to the 'creative' workshop participants as a stimulus for the day.

Key issues brought to the table

- The problem breaks down into complex interactions between risky situations, risky moments, risky items, and risky users. Overall there is a need to better identify and alert

people to factors associated with adverse incidents which could be addressed by design interventions.

Such ‘accident hotspots’ can be identified:

- in the home – and are focused around problems associated with packaging, storage, remembering, reading, understanding, etc.
- in transfer/transit – and are focused around associated changes in drugs, protocols, people, equipment, records, etc.
- around the hospital bed – and are focused around infusion lines, connectors, notes and record keeping, communication between staff, drug administration procedures, etc.
- where situations and equipment or medications are new or unfamiliar, and when people are working under pressure – and are associated with work environments, communication, personnel issues, equipment, drugs, names and corporate branding/differentiation strategies, etc.
- where information becomes ‘non-sticky’ – and are associated with patient identity, records and drug charts, medications in and out of their original packs, the repackaging of medication or temporary storage, e.g. in theatres, when patients move from one sector to another, return to the community, become an outpatient, appear at A&E, etc.
- in cases of mistaken identity – which are focused around look-alike/sound-alike names, branding on packs, changes in packaging, names and terminology, interchangeable connectors for lines and gases, ampoules and other drugs separated from original packaging, equipment calibration and dose delivery, administration routes, local non-standard practices, etc.
- in failures to effectively capture errors – which are focused around the fact that the people near problems are far from solutions and vice versa, communication is not effective or complete, reporting systems are not in place; there is insufficient understanding of risk and its cause; etc.
- in poor understanding of design – where the people near problems have little contact with design or designers; where there is little understanding of what design is and how it can effect risk and safety; where blame culture mitigates against openness in reporting and actively looking for solutions and sharing them.
- where problems and causes are confused and conflated – and are focused on issues such as ‘is non-compliance among older people due to confusion, or is the wrong drug taken or the right one misadministered due too poor communication in surgery or pharmacy, or to unreadable packs and information leaflets, or to printed labels where the lettering runs off, or to confusion between names and pack design, or to older eyes and lowered vision, or to medication being separated from packs by a carer or relative who is helping?’. This is compounded by a tendency to blame – the patient or the manufacturer or the doctor or carer, rather than to begin to unravel the complex, interrelated chain of causes and resulting problems.

One place to look for solutions is to identify common problems that occur in different forms and in different situations, and then select ‘critical’ users to work with, by which we mean those groups most likely to experience or be associated with the more severe or extreme expressions of the problem. For example, if we can solve the major pack-associated problems for older people in their homes we may be able to solve similar problems for other groups and so deal with the issue in the most effective (and cost effective) way. Similarly, by tackling the

major problems for hospital staff and paramedics, associated with identifying medications once they are separated from their packs, then we may go a long way towards solving the problem for other less 'critical' groups.

Homing in on solutions

The capture method used at the creative workshop proved very effective in terms of eliciting specific and detailed information about how and why problems occur at different locations. To facilitate this process a large drawing of the patient journey/experience was prepared, and used as a trigger for discussion of 'site-specific' issues. Participants were open and very forthcoming, and the atmosphere of the group was one of collective participation and involvement. Several factors influenced this, such as the informality of the venue, the general tenor of the event, which was hands-on and practical in orientation, and the fact that participants had been told explicitly to expect a working session and to dress accordingly. An additional feature was the relatively high proportion of creative people at the event and the level of seniority and experience they had between them, covering both medical device and information design and an involvement with important projects like the design of the BA ticketing system.

Over 90 issues were gathered in little more than an hour of extensive and focused discussion, giving useful detail in relation to: care at home involving GP, community nurse etc.; the local pharmacy; the surgery and day-care centre; the rescue services; entering hospital; the operating theatre; intensive care; the ward; and patient aftercare. Headline details from just two areas give a feel for the quality of this information, although the discussion and later expansion in smaller teams went well beyond the capture process. For example:

At the local pharmacy:

- people are reluctant to take medicine due to stigma, etc.;
- there are problems associated with effectively communicating with patients;
- there is inconsistency between individual pharmacists;
- patients can chose to go to any pharmacy and so errors occur and patients are confused by differing presentations of medications;
- presentation forms change frequently even if the patient goes to the same pharmacist;
- changes also occur to brand, trade and official names of medications; and
- self-medication problems occur in correct dosing with eye or nose dropper - very difficult/impossible to get it right.

On the plus side:

- pharmacists act as a checking process (though this is impeded);
- pharmacists share information between pharmacies from different chains; and
- pharmacists are undervalued but often visited first in the case of illness.

At the surgery/day-care centre:

- Drug interactions occur due to different groups of prescribers;
- increasingly nurses are acting as prescribers of medication;

- some unifying information system is needed, smartcards perhaps;
- there are problems associated with the completeness (or lack of it) of doctors' interactions with patients;
- pharmaceutical companies push products at doctors, who are encouraged to prescribe them;
- there are too many drugs to choose from;
- there is a lack of feedback and two-way flow of information;
- there is a lack of awareness and availability of BNF information;
- patients can be reluctant to raise issues with their GP, or to query them, as they tend to be in awe of the doctor;
- there are significant differences between surgeries that prescribe and those that dispense; and
- there are recurring issues about access to medication, problems with packaging, and so on.

Design solution teams

More detailed information and mini case studies emerged in the team working sessions which were organised around three simple briefs. Participants were asked to come up with 3 illustrated ideas/scenarios to improve patient safety in relation to: patient records and information; medication/packs and associated information; and drug administration and associated kit and devices. They were then asked to select one idea to present in depth to the whole group. The team leader introduced how the group approached the brief, where it looked for solutions, and the non-preferred ideas, and another person presented the selected idea. As the team leaders were all designers, this ensured that both designers and non-designers presented back to the assembled group.

The brief

The briefs were purposefully open to encourage maximum sharing of information and discussion of issues, directions and possible solutions. The teams were asked to come up with ideas and directions rather than specific solutions, and the overall intention was to discover how well the process could work. In normal circumstances, the designers would go on from such an intensive user or 'stakeholder' forum to develop more specific and in-depth solutions, which would then be tested and re-tested with users as part of a process of homing in on and working up the detail of final proposals. There was not time to take the process through to this stage, but in the context of a scoping study that was not thought necessary.

Solution spaces

Typically, after quite lengthy general discussion to establish a focus and priorities, the teams moved onto discussing very specific and in-depth problems. There was a strong sense of ownership of these by individuals and a very practical desire to reach combined solutions to more than one problem. In several instances, such detailed information pointed to design solutions, for example:

- Paramedics repack ampoules in a handy (mixed) format using existing larger quantity packs – scope for smaller volume supply or special containers designed for paramedics

which give better visibility and identification.

- Information fails to transfer properly from one environment to another, for instance: ambulance drug records are hand written under pressure and using abbreviations/codes and are therefore often mistranscribed – scope for the use of peelable bar-codes in the recording of drug information in many situations including the home. These could be peeled off from medication packaging, or from a sheet and stuck to the patient record, allowing for accurate, swift and keyless transcription to computerised records.
- Patients, paramedics and other carers are often unaware of what medications are for – scope to add this information to prescriptions and labels on dispensed drugs, as an aid to identification and a way of better informing patients, to be pointed out to patients at the pharmacy.
- Pharmacists who remember dispensing drugs from large quantity containers, counting tablets, etc., point out the extent to which they were aware of the smell of different drugs, their appearance, the feel of them to the fingers, the sound they made when poured out on the counter, the dust they produced and other factors that provided near-subliminal information/confirmation as to the identity of the medication. With modern packaging, not only are these subtle clues no longer available to the pharmacist, but the similarity and the proliferation of proprietary and generic medications means that it is increasingly difficult for pharmacists to correctly identify drugs. There is scope here for various design approaches, ranging from adding back visual and tactile cues to packaging to obliging manufacturers to add an additional warning indicator to packs that are regularly mistaken. Bar codes could also be used to address this issue, and the adding of information about what the prescription is for could help confirm the choice of medication in the pharmacy.

This process led naturally to practical ideas for solutions, which included:

- a patient information system building on patient/doctor interaction and the recording of what their medication was prescribed for, as an aid to communication between e.g., patients and pharmacists;
- a national patient/drug information system that would give correct information and encourage trust between patient and prescriber/carer;
- simple redesigns of line connectors to eliminate incorrect connections;
- a customised individual drug administration/packaging system to aid medication compliance, particularly for complicated regimes;
- improved pack designs to keep information with medication, both inside and outside the pack, and to facilitate identification of drugs and their use;
- a simplified drug recognition/information system tailored to different users, e.g. patients; community carers and hospital nurses in the ward and in intensive care;
- ways in which peelable barcodes could be used to update patient records both in stressful situations like rescue, and in the ward and the home; and
- ways in which smartcards can be used in hospitals, by paramedics and in the home, to check, monitor and reassure.

Given the nature of the study, and the short space of time allotted to the workshop, none of these solutions has been explored in depth, and the participants themselves rapidly came up with challenges and further issues. The solutions are not therefore proposed as viable as they stand, but the potential effectiveness of the process has been well demonstrated.

Contributors and datasets

Workshop participants

Primary and secondary care – workshop 1

- a diabetes nurse and health visitor from Norfolk
- paramedics from Liverpool and London
- a disability services manager from Leeds
- a GP, recently retired, from Cambridgeshire
- an ex-GP and principal medical officer from London
- a representative of the National Pharmaceutical Association
- the Head of Medicines Management from a Bristol PCT
- an R&D officer from the College of Occupational Therapists
- the Head of Clinical Quality from a major community pharmacy chain
- a representative from the Royal College of Nursing
- an A&E doctor from a London hospital
- the Medical Director of an acute hospital in the north of England
- a representative from the Royal College of Anaesthetists
- an intensive care sister from an Essex NHS trust
- an anaesthetist from Preston
- a palliative care nurse from Cambridgeshire
- a clinical risk advisor, Leicester
- the principal pharmacist from a Cambridgeshire hospital
- a representative from the NPSA

Procurement, licensing and medical/pharmaceutical industries – workshop 2

- the chief pharmacist of a London hospital
- the Head of Clinical Engineering at a Cambridgeshire hospital

and representatives from:

- the NHS Modernisation Agency
- the MDA
- NHS Estates
- the MCA – product information
- the PASA – pharmaceuticals and medical devices

- the ABPI – commercial affairs
- the ABHI – medical technology policy
- Carillion Building Special Projects
- Cambridge Consultants
- Armstrong Medical
- Southern Medical Alliance
- Glaxo SmithKline
- Owen Mumford Ltd.
- Medi Scott Consultants

Patient support group representatives – workshop 3

- Depression Alliance
- Carers National Association
- Age Concern London
- Long Term Medical Conditions Alliance

Designers – workshop 4

- Working Solutions in Design
- ISIS
- Gill Scott Design
- Point 9
- Wire Design
- RCA Design Products and alumni

In the two full day workshops participants were asked to cluster the problems they had identified on large wall maps of the healthcare system which were populated over the course of both workshops. The clustering was helpful in identifying and stimulating discussion of error 'hotspots'.

Table 14: Error and problem clusters from mapping process

Hospital Doctors	20
Hospital Nurses	15
Patient/Carer	13
Drug Companies	12
Community Pharmacy	11
Hospital Pharmacies	7
Medical Control Agency	5

General Practitioners	5
Ward-stock	4
Purchasing	4
Off-the-shelf Medication	3
Care Provider	3
Distributor	2
Drug Delivery Design	2
Equipment Suppliers	2
Equipment Training	1
Investigation Process	1
Pathology	1
Government Agencies	1
TU and Professional Bodies	1
Hospital Management	1
Service Providers	1
Community Nurses	1
Care House Nurses	1

Selected issues from the desk research were introduced by a member of the Cambridge team. These were positioned by him (using 'post-it' notes) on the map as a way of introducing the workshop participants to the clustering activity (see above). This stimulated discussion on problems, causes and associated 'hotspots'.

Table 15: Key issues from Cambridge desk research

Syringe driver	Calibrated in millimetres not millilitres
Follow-up of progress of tasks (e.g. pathology results)	Long time hanging on the phone – increases stress and wastes resources
Patient notes	Proliferation and adherence or lack of to patient; past history; conditions; adverse drug reactions; current medication, from paramedics; etc.
Transfer of information (and equipment)	To and from primary/secondary and between wards (e.g. from surgery to general or specialised ward, or recovery). Also consider home visits.
Rationale for treatment	As patient's care is passed between different healthcare providers, rationale for treatment becomes lost.

Labelling issues	Packaging confusion; changed packaging resulting in confusion; cluttered labels; lettering too small; looks the same (e.g. black 12 pt Arial on white label for all drugs); concentration of drug issues (take wrong concentration); also consider similarity of tablets
Pharmacy	Addenbrooke's: 15,000 intervention reports per year (5-10%); medication names.
Training	Lack of resource; constant fire fighting
Purchasing	Lack of standardisation of products and suppliers – 25,000 used in UK, is that really necessary?; confusion between different makes of infusion pump as a good example; purchasing based on price; no incentives for industry to improve design.
Tubes and equipment issues	Suction tubing can be wrongly connected (suction in surgical procedure); lack of colour-coding; too many tubes (e.g. many infusion pumps in ITU – which is which?); wrong tubes or adapters (also with power connectors).

Creative workshop issues

Large cartoons of key points on patient journeys were used to stimulate discussion of related issues. Brainstorming techniques were then used to capture these. Full lists are given for each situation.

Care at home (GP/Nurse…)

- Lose control over drugs/patient
- Patient understanding medication – what it does, how to use it
- Can't see pill in blister packs – random dispersal of medication
- Doubt – people afraid to ask for more information
- Expert advice needed – no font of knowledge for patient
- Place undue weight on advice of friends/relatives
- Few visits from GPs
- BNF 41 – electronic version needed
- No priority of information
- Writing rubs off pharmacy printed labels when handled
- Language misleading
- 50% of patients do not know about their own medication – don't take ownership

Pharmacy (local)

- People reluctant to take medicine – stigma, etc.
- Communicating with patient

- Inconsistency between individual pharmacists
- Patients can go to any pharmacy
- Tablets and presentation changes
- Brand/trade/official name
- Self-medication dosing with eye or nose dropper – very difficult/impossible to get it right
- Pharmacist as checking process
- Pharmacists have no way to access patient information
- Can't network between pharmacies (one chain to another etc.)
- Pharmacists undervalued – often visited first
- Pharmacists make mistakes, too

Surgery/day-care

- Drug interaction – different groups of prescribers
- Nurse prescribers
- System needed – smartcards
- Completeness of doctor's interaction with patient
- Pharmaceutical companies push products – doctors encouraged to prescribe
- Too many drugs to choose from
- Lack of feedback
- BNF information (availability/awareness)
- Mistaken identity issues
- GP-identity
- Not identifying patients
- Patients reluctant to raise issues
- Query GPs – patient in awe
- Difference between surgeries that prescribe and those that dispense
- Access to medication issues – packaging etc.

Rescue services

- Identifying what patient is actually taking
- Previous history reactions
- Less controlled environment – identification of phials/ampoules under pressure
- Small ampoules don't signal risk
- Pack sizes don't contain quantity required (bulk supply, large packs)

- No site specific packs – paramedics make up their own mixed packs – possibility of confusion
- Patient records completed by hand, shorthand/codes used – incorrect transcribing of record
- Space problems mean medications removed from original packs
- 90% of ambulance visits to homes/private property

Entering hospital

- Poor records of pre-hospital drugs
- Poor communication between GP and hospital
- Patient lacks knowledge of drugs
- Generic names of drugs patient is taking
- Poor transfer of information
- Bringing in drugs without packaging
- Drugs taken away from patient – doses missed, patient anxiety
- Booking systems of patient rely on patients' knowledge of drugs
- A great deal of time between admission and seeing GPs

Theatre

- Labelling
- Ampoules
- Changing presentation of drugs
- Pack confusion
- Different labelling systems (colour coding)
- Loose ampoules – re-storing, mixing them up
- No constant checking – no double-checking
- Patient identification
- Devices – wrong inlets/connectors
- Adapters (from manufacturers)
- Working under pressure
- More output demanded from less resources

Intensive care

- Multiple infusions
- Equipment failures
- Identification of access

- Putting things into wrong access point
- Syringe drivers available, but expensive technology
- Calculating doses complicated – e.g. drops per minute, ml. per hour
- No shared platform for machines – IP leads to nonconformity. A common platform would reduce mistakes.

Ward

- Patient I.D.
- Drug and dose identification – prescriptions poorly written
- Confusions with handwriting, especially national conventions of writing numerals – 7 with a slash through (7), etc.
- Decimal points and dilution ratios
- Changing shifts
- Medication records
- Adult dose supply in paediatrics (measuring, calculating)
- 2 nurses on drug round

Patient after care

- Emphasis of communication may change from care at institution
- Devices problematic – not necessarily designed for home environment
- As patient goes through cycle of care, situation often worsens
- Effort priority – home care to patient to GP
- What is the criteria for priority?
- Designers/producers do not consider usage of devices/medication – e.g. can't get it through the door
- Litigation – patient to company, patient to doctor in hospital
- Blame culture – entrenched in system
- Medicines act

All participants at the two one-day workshops were issued with personal workbooks. These were used in a variety of ways, with sheets being torn out and pinned to the wall as part of the mapping process, and later sorted by groups of participants to identify and cluster priorities and issues. A key part of the process was a 'brain dump' whereby participants were encouraged to identify as many 'problems' and 'causes' as possible. Each participant had a unique number, which allowed the researchers to map back responses to individuals whilst preserving anonymity. The following table records the full set of responses, as given. Multiple causes (where given by the participants) are separated by semicolons.

Table 16: Full set of stakeholder problems and causes (P&C)

	Problems	**Causes**
1.1	**Self-medication error**	**Reading, understanding**
P	Medication taken inappropriately	Cannot read or understand leaflet inside package
S	Wrong drug administration	Age (deteriorating eyesight means small letters hard to read); small lettering on ampoules; poor contrast on fonts; engraved/etched labelling can be hard to read
P	Patient unable to read labels	Impaired vision; small print on labels; poor durability of labels
I	Patients confused by medication names and/or appearance	Lack of standardisation
I	Elderly patients unable to read instruction on packs and/or dispense medication from pack	Ergonomics
P	Patient error in frequency/dosage of medication	Poor durability of computer printed labels affects legibility. Deficient instructions by GP regarding 'as required' medication; removal of tablets from original packs by patients.
P&L	Patient confusion: failure to remove wrapper on suppositories, muddling up drugs; doses; timing	Older patients; poor labelling; poor consulting; poly pharmacy?; dangerous combination of potent drugs and low awareness patients. Also administration by family members acting as carers
P&L	Removal of suppositories without removing wrapping	Inadequate user information. P.I.L. and package legibility
P	Over the counter medication 'not harmful' often not seen as medication	Lack of knowledge/awareness
I	Non-compliance taking asthma medication i.e. Sevetide, particularly under-dosing	Forgetfulness; patient knows best (drug holidays); patient feels better; education
P&L	Inadequate dosing of respiratory products via inhalers	Over-complex design + operation requirements
I	Operating inhalers: co-ordination (aerosols) and complex steps; high forces for children and infirm; when to renew; flow rates	Technical constraints; available technology; cost constraints
I	Accurately measuring liquid formulations (at home)	Lack of suitable delivery systems; unintentional misuse
P	Patient doesn't take medication when given – pills found in the bed, on the floor, etc.	Lack of supervision, patient non-compliance, swallowing difficulties, patient can't handle dispensing format
I	Inaccuracy of drug delivery in relation to diabetic insulin delivery	Users not properly trained in administration of product; non-compliance due to patient error

	Problems	**Causes**
P	Inappropriate or inadequate counselling of patient with regard to taking/handling medication	Knowledge; communication inadequacy; time resource; environmental inadequacy
P	Patient misunderstanding of relationship/ interaction between prescribed and over-the-counter medicines	OTC medicines often not perceived as potent
1.2	**Self-medication error**	**Storage, confusion, complicated regimes**
P	Reuse of insulin needles leads to hypo-dystrophy and/or needle breakage	Saving money
P	Inappropriate storage in home	Lack of knowledge by patient
P	Storage of medicines in patient's homes; child access	Packaging design
P	Storage of medicines in patient's homes; temperature control	Poor instructions
P	People having lots of different bottles of medication – out of date/current/not relevant – can take wrong one	People keep old medication, don't throw it away
I	Elderly confused patients with several drugs failing to adhere to medication instructions	Forgetfulness; too much confusing information; too many decisions; poor/no aids to assist with correct and timely dispensing
P	Identification of drugs (taken in overdose)	Drug names printed on the reverse of blister packs are not readable once the tablet is removed; drug packs hoarded by patient
P&L	Patient self medicating, takes wrong drug from a number prescribed	Patient doesn't know what drugs are for, cant read label, removes blister from carton
P&L	Patient takes same drug more than once	Brands plus generic version available but patient doesn't realise they are the same and takes both
I	Patients failing to comply with prescribed treatment due to too many medicines to remember	Complicated drug regimes causing confusion/error; variety of packaging/poor quality labels/instructions;
1.3	**Self-medication error**	**Access and packaging**
P	Access to packs and bottles	Not getting the balance right between impaired/elderly requirements and child safety
P	Patients unable to manage packaging	Elderly; muscular/skeletal; psychological/confusion; poor pack design; prescriber unaware of user needs/pack types
P	Older and arthritic patients unable to open packaging – container or blister strip split off	GP systems ordering non pack size (30 when comes in 28). Rules say if not a calendar pack (no day/week on foil) the exact quantity should be supplied, hence odd 2 tablets supplied, difficult to manipulate

	Problems	**Causes**
P	Older people will get a third party to open packaging and leave open – can't open 'child proof' tops so leave off. May lead to deterioration of contents	Manufacturers reluctance to think of new ways of packaging
1.4	**Self-medication error**	**Information, knowledge**
P	Patient/carer lack of knowledge leads to errors in managing medication in community – take too much, too little, wrong time or combination	Lack of awareness/understanding by presenter; unreadable information in packaging
P	Incompatible or contrary information supplied to patient by healthcare professional – GP, Pharmacist, nurse, Internet, relative	Poor communications
P	Care provider not understanding about the medicines they are supervising/assisting in administering	Lack of training/information sharing
2.1	**Prescription error**	**Wrong drug**
P&L	Prescription error	Human failure; system failure: wrong prescription or patient or record interrogated; 2 doses to one patient
I	Poor handwriting/transcription errors/illegibility	Lack of awareness of risk hazards; poor investment in IT
P	Wrong patient gets script	
P	Prescribing drugs outside normal experience	
P	Incorrect prescription because of confusion of generic names	Generic names often less clear than brand names; similarity of generic names of very different medications; computer 'pick lists' problems for prescriber
P	Misprescribing of drugs with similar names	Partly the MCA, especially with co-names
P	Ignoring decision support e.g. prescribing software etc	Information is available but not used
2.2	**Prescription error**	**Communication, follow-up**
P	Inappropriate information from drug company reps etc.	GPs using reps for education
P	Errors in communication with patients (by GPs and pharmacists e.g. on how to take inhalants)	Lack of appreciation that it is a problem
P	Interactions with over the counter products	Poor history taking by GPs
P	Audit trail for controlled drugs (once they have reached the patient)	Drugs left in patients possession are 'owned' by patient; no formal route for disposal
3.1	**Dispensing error**	**Wrong drug**

	Problems	**Causes**
P&L	Wrong drug dispensed	Label not read correctly by HCP; similarity in packaging; busy pharmacy; poorly written prescriptions
P	Dispensers/pharmacists dispensing wrong medication pack	Design of packs conforming to manufacturers corporate ID despite different medications, dosage, strength; similar generic names causing confusion
P	Wrong medication/strength supplied against GP/dental prescription	Process control; pack design/clarity
S	Wrong drug given in error	Identical packaging by drug company of different drugs; Pharmacy stock constantly changing supplier
P	Mis-pick medicine	Similar pack; word shape; similarity of drug name; distraction
P&L	Dispensing/administration error	Poor medicine labelling; poor pack design
S	Inconsistent colour/packaging of medication	Lack of direction centrally; importing
I	Incorrect product selection by nurse/pharmacist prior to administration	Similarity of labelling/packaging; lack of training/awareness
S	Pack selection; All along the supply chain	Design of packaging; shelving for storage
I	Sound-alike and look-alike names of medicines causing incorrect product selection	Difficulty in finding unique nomenclature
P	Confusion of drug identity with multiple names for the same drug	Lack of clarity if the actual drug name on some packages – some very similar names used to identify different drugs
3.2	**Dispensing error**	**Specific confusions**
P	Norton/Ivax – Atenolol 100 mg prescribed for blood pressure; Azathioprine 50 mg supplied (an immunosuppressant)	Manufacturers pack design – same colour, size box, sit next to each other in continental drawer system – typeface size where label applied is small – both white tablets so patient takes one before noticing difference
P	Prochloperazine 5 mg on prescription, Procyclidine 5 mg supplied	Norton/Ivax packaging is same colour, size, font and lie next to each other; corporate colour coding scheme focused on brand identity rather than product identity, colour now changed
P	Wrong profiled insulin pen given to/used by patient – 42 fast as opposed to 42 basal	Poor information on script; GP not giving enough information; pharmacist not asking; patient not realising difference
P	Tegretol anti-epileptic drugs – all forms and strengths have same coloured boxes	Manufacturer, and all their other products are in the same coloured packages
3.3	**Dispensing error**	**Mislabelling**
P&L	Dispensing errors: incorrect selection; incorrect labelling; incorrect supply	Human failure; confusion: not reading label; misreading; choosing by sight (colour coding)

	Problems	**Causes**
P	Mis-labelled medicine	Knowledge; Distraction; Label system shortcomings
P	Dispensing Medications in the community; mis-labelling by pharmacy/dispensing doctor	Process control
3.4	**Dispensing error**	**Stock control**
P	Stock control, out of date drugs	Short shelf life of some products
P	Out of date fluids given – saline, dextrose	Staff under pressure have not carried out proper safety checks. Most fluid bags look the same, dates on fluids in small font not distinctive
3.5	**Dispensing error**	**Incorrect supply to pharmacy**
P	Wrong supply to pharmacy	
P	Amiodarone 200 gm supplied by wholesaler (anti-arrhythmic for heart) Trimethoprin 200 gm ordered (antibiotic)	APS packaging same colour; manufacturers packaging designs identical and same strength. Only drug name differs; untrained staff and language problems loading automatic A frame system
P	Availability of some drugs, changes in packaging and presentation	Supply and distribution
3.6	**Dispensing error**	**Clinical trials**
S	Dispensing of active medication for a clinical trial when placebo medication called for	Trial design; unfamiliarity; out of hours; trial supplies
4.1	**Administration error**	**Wrong dose/dilution**
P	Uncertainty of drug doses, especially in paediatrics	Different methods of calculating doses – age, size, weight – adult/child vary according to drug
P	Use of paediatric drugs in pre-hospital care – ambulance paramedics	Environment is stressful, only two staff to complete multiple tasks, time constraints; draw up exact amounts of drugs
S	Error of drug dilution in paediatrics	Paediatric doses
S	Error in dose prescription and failure to identify this, resulting in incorrect drug being administered to child	Volume of workload/dependency of sick children on the drug
P	Standard doses for adults given to elderly people – with different rates of drug metabolism/absorption.	
4.2	**Administration error**	**Misinterpretation, confusion**
P	Misread prescription – dose drug, etc.	Knowledge, training; distraction, personal issue; unclear direction, illegibility

	Problems	**Causes**
P&L	Dispensing errors (personal); incorrect administration – solution, dose, rate of administration	Poor labelling; not reading labels; human error, prescription error
S	Misreading of decimal point on prescription – nurse gives too much drug	
S	Confusion and delays in giving emergency drugs	Change of name - adrenaline to epinephrine; staff too often unfamiliar with description of concentration e.g. 1:1000 etc.
P&L	Medication errors caused by 'human factors' e.g. fixation, routine, stress, poor processes	Lack of awareness; low levels of education /training; cultural issues – 'way we do things round here'; poor standardisation; multiple variety in applications
S	Drugs wrongly prepared (concentrations)	Difficult to find preparation information and no info about how long to give drugs over; 'Information for patients' included in drug packaging is often inappropriate and does not include practical instructions.
S	Wrong drug +/- wrong dose	Illegible prescription
S	Miscalculation of prescribed dose	Problems re interpretation of prescribing information and local documents/charts
P&L	Administration error	Confusion around colour coding; poor labelling; small print; can't read in dark; similar drug names; mcg confused with mg; confusion over measures/ratios: 1:1000, 0.1%, 1 mg/ml
P	Having to dilute drugs in the field increases risk of error	Some drugs supplied in dried or concentrated form needing dilution with saline or water
P	Supply quantity is larger than normally carried on an ambulance/by a paramedic meaning drugs are often removed from a box and even put into other drug boxes	Supply quantity does not relate to normal pre-hospital doses
I	Medicines being separated from their original containers/packaging prior to use	Convenience/speed; poor design/storage facilities/packaging
4.3	**Administration error**	**Information/communication**
S	Nurse takes verbal instruction from doctor – incorrect medication given	Availability of doctor; agreement by nurse
S	Failure to give prescribed drug by nursing staff	Pressure of wards; prescription charts; organisation of one-off medication
S	Miscalculation of drug to be administered from a correct prescription	Inexperienced staff; staff in unfamiliar working environment
S	Incorrect drug dispensed to patient	Unable to read prescription; not checking drug with patient
P	Hand medicine to wrong patient	Distraction; patient reaction; violation of procedures or inadequate procedures

	Problems	**Causes**
S	Drug prescribed but wrong drug given to wrong patient	Illegible hand writing; incorrect checking of drug chart
S	Nurse fails to check patient name, patient confused and confirms (mishears) name – given drug intended for another patient	
4.4	**Administration error**	**Methotrexate**
P&L	Methotrexate intended for weekly dosing, but patient takes it daily	Lack of knowledge on the part of HCP about use of Methotrexate; lack of information to patient about how drug should be used
S	Oral weekly Methotrexate given daily	Labelling, training, packaging, knowledge (lack of)
4.5	**Administration error**	**Route**
P&L	Administration error: rate; route	Poor training/ignorance; pump used incorrectly; injection intravenously not intrathecally and vice versa; confusion – mis-supply of product and/or not reading label
P	Incorrect route of administration in emergency (resuscitation usually) situation or incorrect dosage	Ampoules difficult to read – shiny small print on shiny glass ampoules – especially in emergency situation. Complexity and small print of data sheets
S	Drug delivered by incorrect route (intrathecally rather than intravenously)	Pre-prepared drugs not labelled
S	i-v administration of drugs intended for another route	Prepared infusion in solution bag virtually identical to normal intravenous solution
I	Poor process control – inexperienced staff being put into situations of risk (to patients) e.g. cytotoxic chemotherapy administration/spinal procedures by junior hospital doctors	Cultural; availability of personnel; lack of perceived risk
S	Vincristine (chemotherapy agent) wrongly given intrathecally instead of intravenously. Patient dies.	Many (extensive report published); Doctors in hospital are a surprisingly unregulated group in terms of strict working practices
S	Vincristine administered intrathecally	Connection standards; unfamiliarity; accreditation
S	Administration of potent anticancer drugs (Vinca alkaloids) into central nervous system instead of intravenously	Failure to check medication carefully; staff exceeding their training and responsibilities; Interchangeable connectors
P&L	Accidental intrathecal injection of Vincristine	Multiple, but the ability to connect ‘Luer ‘ syringe to CSF access devices is one. If this were impossible this error couldn’t happen
P&L	Misconnection of medical devices resulting in inappropriate administration of drugs, or failure to deliver drugs	Widespread use of ‘Luer’ connectors on a wide range of medical devices

	Problems	Causes
4.6	**Administration error**	**Rate/connection**
P&L	Mistake in administration of infused drug and/or user error in setting up or use of equipment – generic problem often with no clear cause	Technology seen as secondary to answering patient requirements. Busy, stressed clinical staff; inadequate training in use of equipment
P&L	Misuse/abuse of e.g. infusion devices, syringe drivers	Poor labelling of equipment; poor design of control panels; poor instruction manuals
P&L	Inappropriate drug delivery rates when using infusion pumps and similar devices. Results in over/under infusion	Complexity of current devices; variety of types/makes/models; poorly understood by users; user training
P&L	Lack of standardisation of devices – wide variety available – potential for staff to use unfamiliar devices	
I	Incorrect administration of medicines due to lack of understanding of equipment e.g. syringe drivers/pumps	Lack of training; inexperienced staff; complicated design features
P&L	Drug administration errors due to incorrect interpretation of instructions and wrong device connected	Incorrect interpretation of instructions; potential for different types of medical devices to be connected allowing inappropriate drug delivery
4.7	**Administration error**	**Misconnection/delivery**
S	Interruption in life-sustaining drug infusion	The design of syringe drivers, some reduce rate of delivery towards the end of the infusion (KVO); insignificant alarm noises - should alert nurses to nearing completion of infusion – some sound like feed pumps.
S	Syringe becoming detached from syringe-driver. Delivery of incorrect dose	Poor design
P&L	Plunger of pre-filled syringe falls out as syringe is connected to intravenous cannula	Human failure – poor technique; lack of familiarity in use of glass syringes
I	Patient ‘plays’ with drug delivery device, resulting in drug build-up and subsequent overdose	Non compliant patient – no effective design response
5.1	**Information and records**	**Continuity between sectors**
P	Continuity of care	Not all drugs are available in all places, meaning that a patient is moved from one location to another. Often a suitable range of medication is not available in care homes. Only a list of drugs, or their prescription chart may travel with a patient.
S	Inadequate information flows regarding errors/near misses	Nationally: lack of co-ordinated system (that being piloted has changed direction and looks to become less effective than desired); locally: poor or poorly used systems, poor feedback, inappropriate management responses

	Problems	Causes
S	Poor secondary/primary care communication re medication monitoring	Poor recording/transmission in the NHS; inadequate emphasis in medical training; shortage of staff e.g. clerical; inadequate use of modern technology
P	Different drug protocols used by different care providers/ambulance services – 'postcode care'	Local paramedic steering committee
5.2	**Information and records**	**Drug charts**
S	Medications not clearly prescribed on drug charts. Allergy box not completed	Doctors under heavy workload pressure
S	Nurse fails to record drug as given on drug chart – another nurse assumes drug not given and gives further dose	Work pressure; lack of compliance with protocol
5.3	**Information and records**	**Checking in wards**
S	Nurse and checker doing drug round with controlled drug – checker called away by another patient – other nurse continues, gives wrong patient drug	Work pressures; distraction; non-compliance with protocol
S	Nurses (usually) have a 2nd person check drugs – dose/expiry date etc. Doctors don't. Generally they are subject to less regulated practice than nurses.	Long-standing cultural differences of the domain of nursing and medicine. Arrogance of some doctors
S	Nurse tells doctor that he/she has prescribed wrong drug (usually junior doctor and senior nurse). Doctor ignores expertise and knowledge of nurse	Culture, hierarchical relationship; individual personality
6.1	**Equipment and devices**	**Sharps related incidents**
P	Needlestick injuries from used intravenous cannulas or lancets	Administration of intravenous/intramuscular drugs in sub-optimal environments; cost of 'needle safe' devices
P&L	Sharps injuries to medical staff	Inappropriate disposal of used syringes, needles, etc. 're-sheathing' syringes
P&L	Disposal of sharps used in medication delivery – problems created by injuries to staff and patients	Improper disposal of sharps after use, and injuries from accidents while sharps are in use
6.2	**Equipment and devices**	**Confusion, mistaken identity**
S	Nurse hands syringe to colleague to give injection – colleague thinks it is a clear fluid, in fact syringe empty	Attention/distraction; failure to check

	Problems	**Causes**
S	A&E department, minor procedure taking place. Nurse hands doctor 5 ml syringe that he thinks is saline and is in fact Lignocaine. He injects, the patient is fine but could have had cardiac arrest	Poor communication; poor labelling of syringes/equipment; lack of protocols
S	Antimicrobials diluted with KCl instead NaCl	KCl kept in same place as NaCl; ampoules look/feel similar; writing small
P&L	Lignocaine selected for flush rather than saline/water in theatres	Similarity of packaging; poor storage of drugs – small containers outside fully labelled packaging; poor lighting; emergency situation, rapid response required
S	Giving the wrong drug on occasion to a patient	Picking up the wrong syringe and failing to check the label properly. It is part of an automatic process, and if distracted it is easy to do, with multiple syringes in use.
S	Busy junior ward doctors being the only people eligible to give intravenously. Being in a hurry, giving the wrong drug to the wrong patient	Not enough time; not enough care; lack of protocols; over reliance on 1 person to give all i-v medication
S	Over-pressured doctors with inadequate knowledge of individual patients	Increased pressure/turnover; decreased junior doctor hours - often compounded by transient nursing staff
6.3	**Equipment and devices**	**Over infusion**
S	Over infusion of drugs	Using incorrect infusion device, one that infuses over 1 hour instead of 24
6.4	**Equipment and devices**	**Gases**
P&L	Traumatic patient injury arising from inappropriate delivery of medical gases	Equipment poorly understood by users; poor manufacturer instructions; inadequate training
S	Nitrous oxide given, not oxygen – death of child	Confusing equipment, doctor error
6.5	**Equipment and devices**	**Peculiar to anaesthesia**
S	potential for contamination (accidental or deliberate) of volatile anaesthetic agents	At least two of the volatiles come in screw-top bottles and could be contaminated. Most of the vaporisers have a ‘key-filler’ system to prevent misfiling of a vaporiser, but on one of the newest vaporisers the system can be by-passed
6.6	**Equipment and devices**	**Insufficient differentiation**
I	Drug companies are turning to proprietary delivery systems to differentiate their products in the market. This means that the patient may have a range of drugs in very similar containers/systems	Insufficient differentiation of drug delivery systems due to: costs of retooling to differentiate drugs by design solutions, inventory costs, timescales and costs to evaluate system
7.1	**Other**	**NHS modernisation**

	Problems	**Causes**
P&L	Redesign of healthcare system that simplifies the process BUT then assumes that the need for skills/knowledge/experience in the process is lessened	Lack of understanding of impact of change; improve access (waiting times); lack of investment in education/training; assumptions made in redesign; lack of team involvement in redesign

Annex 7 – Case studies

The following studies reflect the range of good and bad product/systems design evident within the NHS. The first study describes the case of a Cambridgeshire woman who died as a result of medication error. The second reviews the design of the infusion pump, while the third briefly reviews a number of good and bad products.

Medication error – a case study

The following case study describes the events leading to the death of a patient in Cambridgeshire. It serves to illustrate how a single tragic event is the result of a number of significant and seemingly insignificant errors. The patient had originally been prescribed a weekly dose of 17.5mg of Methotrexate for rheumatoid arthritis. Due to a prescribing error this dose was increased to 10mg daily. This high daily dosage had severely compromised the patient's immune system, leading ultimately to death.

A subsequent inquiry mapped out the events leading from the initial error to the patient's death. Figures 42 and 43 summarise the main events during this time. There are a number of initiating errors, some more serious than others, that evade detection leading to problems for the patient. Most notable is the incorrect prescription for Methotrexate that goes undetected for 16 days.

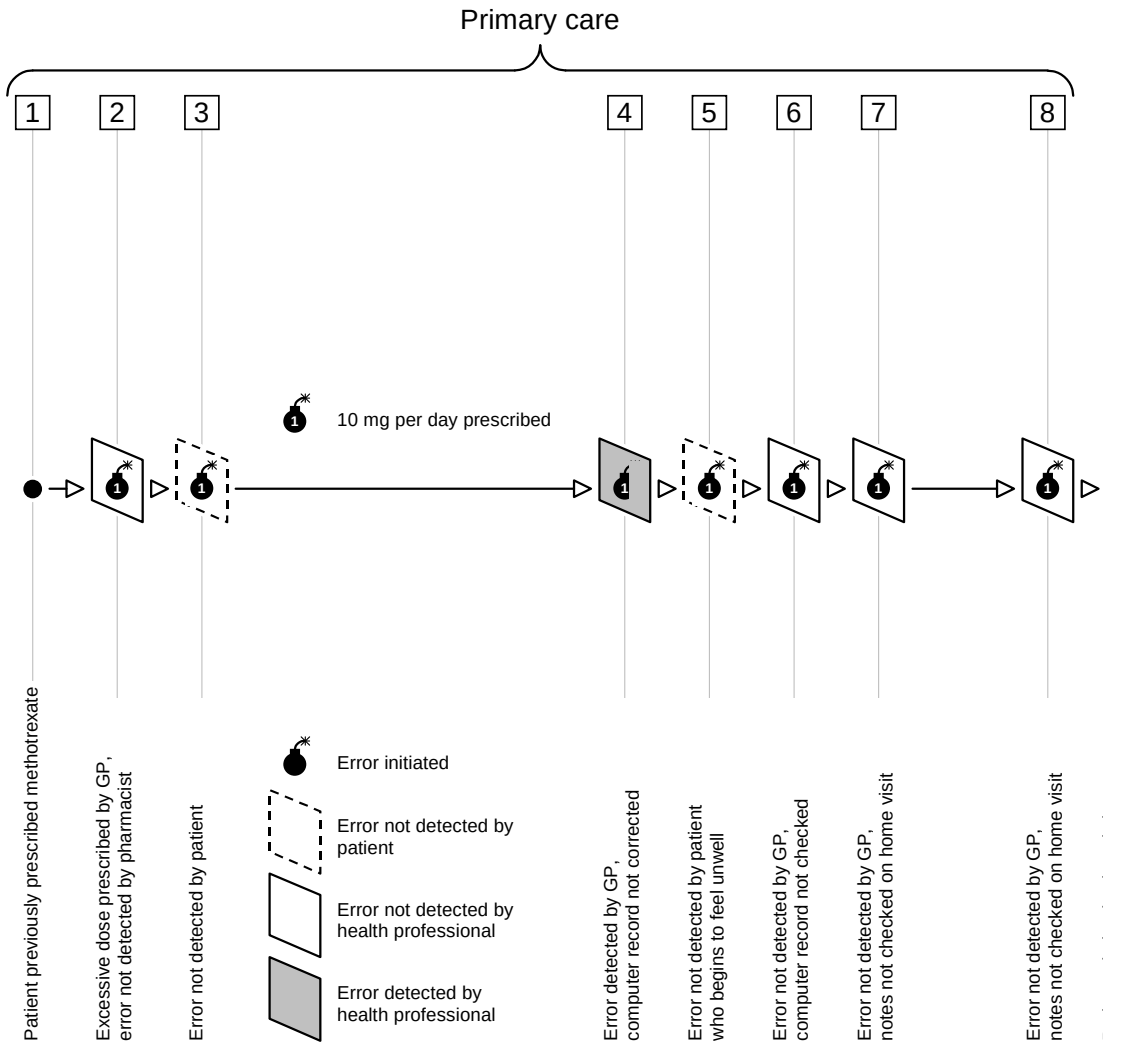


Figure 42: Methotrexate errors in primary care

There were more than a dozen opportunities for the initial error to be discovered. Indeed, on one occasion a GP found the error, but thought its so unlikely that the medication had actually been prescribed that insufficient action was taken to resolve the problem. The first part of the diagram shows events occurring while the patient was in primary care. Admission to secondary care was prompted by symptoms of a sore throat, a side-effect of the incorrect medication.

The second part of the diagram (figure 43) shows events occurring while the patient was in secondary care. Further errors were initiated until finally the cause of the patient's illness was discovered.

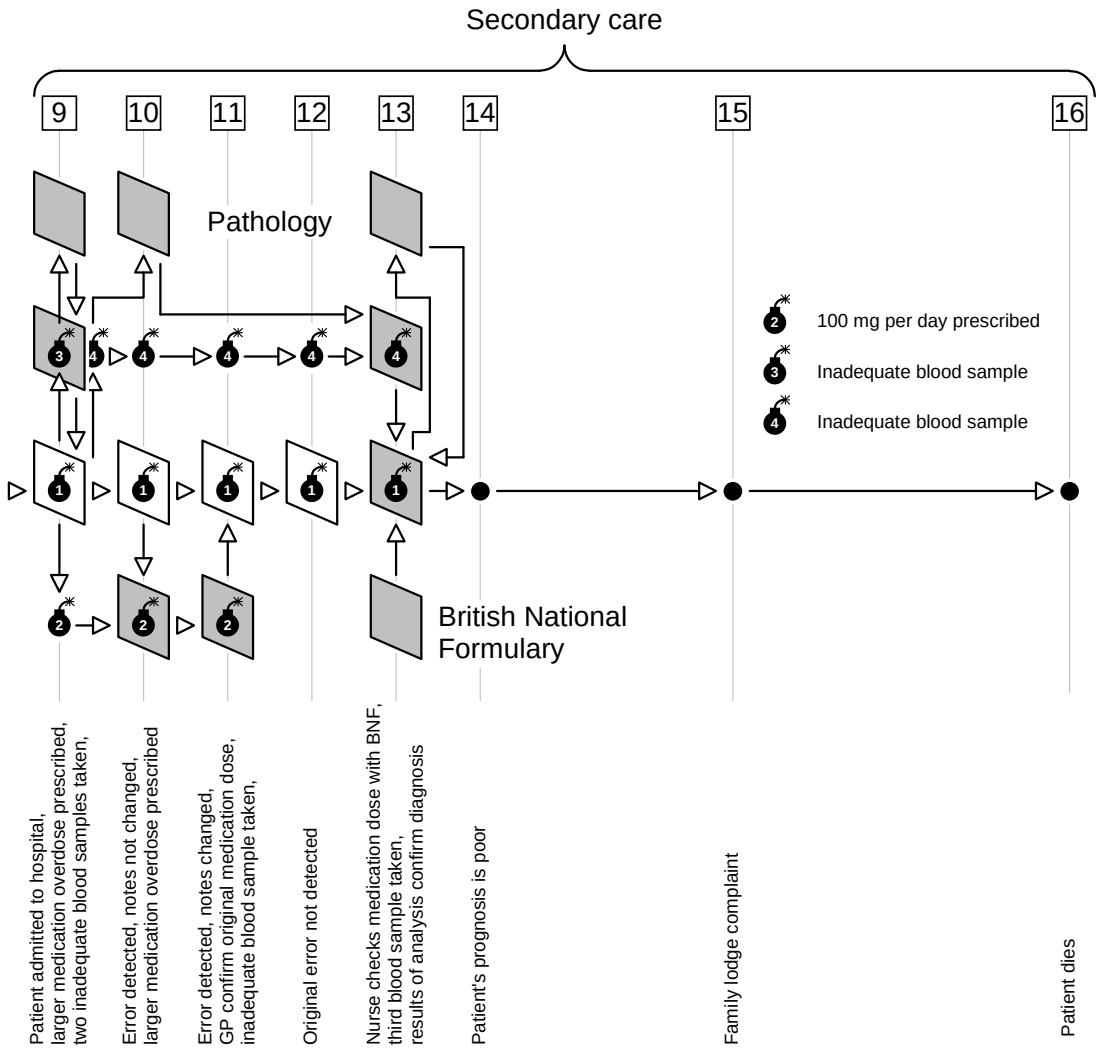


Figure 43: Methotrexate errors in secondary care

It is evident from the diagrams that the initial error could have been discovered much earlier. Reference to the BNF at any stage would have highlighted the problem. Even knowledge of the failure of the second blood test on the day of the test may have saved the patient. The inquiry produced 28 recommendations for change covering a wide range of issues, many of which have their parallels in this report.

This case study serves to illustrate the dangers that can arise when a number of errors or omissions occur together. Ultimately, it was the system as well as the people that contributed to the patient's death. For example, the communication delay between pathology and the ward became a major contributing factor to the late discovery of the error.

Whilst there was no particular product at fault in this case, a number of systems failed through human error and poor design. For example:

- inadequate warnings were available in the prescribing and pharmacy dispensing software;
- there was no immediate mechanism for passing the patient notes from primary to secondary care;
- the use of the British National Formulary (BNF) did not seem to be common place by the

healthcare professionals involved;

- the mechanism for the passing of messages from pathology to the ward was not reliable;
- the 10mg tablets where almost indistinguishable from the 2.5mg tablets; and
- ultimately too much trust was placed in the view that the prescription must be right.

These are all issues of design, system design of elements of healthcare practice, medication design and software design. The study also highlights the importance of the provision of checks and safeguards in the medical profession. Errors will occur. Hence systems must be put in place that create barriers to the propagation of such errors. These barriers must be as diverse as possible to maximise the chances of trapping errors and to minimise the effect of common-cause system failures.

Infusion device review

The following is a short summary of a review undertaken on behalf of the NPSA. This review was carried out concurrently with this scoping study. A summary has been included here as it was felt to be important to the overall breadth of the study.

The aim of this short review of the current literature was to identify and substantiate the presence of solutions to problems (including incidents) associated with the use of infusion devices.

The review, as specified, has considered the following types of infusion devices:

- volumetric infusion devices;
- syringe infusion devices; and
- ambulatory infusion devices.

The research strategy has relied on electronic journal search methods (incl. Ergonomics Abstracts online, Medline, BioMed) for published literature. Unpublished reports and papers have been considered where readily available but their search has not been systematic. The review has been limited because of the very restricted availability of materials in the short time scale allocated to the completion of this report. In some instances the review has been restricted to the abstract of the study reported and not the full paper.

The review has been undertaken with regard to the life-cycle phases of infusion devices, namely: device design and development, manufacturer, marketing, sales and procurement, commissioning, management of devices, routine use, training, maintenance and decommission/removal.

Solutions are rarely “one-off” issues in complex systems such as the provision of healthcare. For example, a sophisticated state-of-the-art electronic monitoring device may be ideal for a clinical research project, but may prove fatal if left on a ward for future use by those unfamiliar with its design and functions.

Solutions are therefore likely to reflect the process required to ensure a safe usable device, as well as appropriate functionality.

It is vital to realise that the infusion device is one element in a complex system of healthcare delivery. The ergonomics work system approach recognises this and has been successfully applied to many complex, safety critical systems. The following model provides a “map” of the system elements that may need to be considered at any stage of the life-cycle of the

infusion device.

It is important to recognise that designers of a control panel will need to consider, for example, the range of potential users, their prior experience or training, their expectations, the operational context, environmental constraints, communication and team needs and management and organisational parameters.

Device design/development

Despite the extensive knowledge in the human factor/ergonomics literature regarding the design of interfaces or equipment and the need to understand the full context of use within a system, there has been surprisingly little published work regarding the design of the interface or other aspects of infusion devices.

Garmer *et al.* (2002) have considered the development of a new user interface for an infusion pump using the human factors/ergonomics approach. Usability analysis was undertaken on existing designs based on observations, interviews, reported incidents and the theoretical basis for memory and human error. A new interface was developed based on a number of ergonomics principles. An evaluation of the reduction in errors was undertaken. The number of errors was reduced but remained significant. The authors suggest that further tests are needed to improve the interface. They have identified, in particular, the need to provide more effective mode operation (e.g. with the use of spring loaded buttons). With regard to the process for finding solutions, the authors emphasise the importance of usability testing with a wide range of methods. They also emphasise the need to study both competent, experienced users and novice or learner users.

Bremer *et al.* (1997) discuss protein delivery with infusion pumps. They consider how micro-electronics have played a role in the miniaturisation of infusion devices. They consider the work of others and conclude that, in the future, we will have cost-effective disposal devices that are programmable and could be adapted to meet each individual therapeutic need. However, it seems likely that these may require a high degree of technical competency to programme.

Another technological advance they suggest is pre-filled and ready-to-use drug cartridges and these could greatly improve infusion applications. They also anticipate that coded, pre-filled cartridges will be automatically recognised by pre-programmed pumps, thus reducing operator error potential.

Currently there appear to be no formal or informal standards available for the design of interfaces for infusion devices (Garmer *et al*., 2002). Thus it is scarcely surprising that a multitude of interfaces exist and that many of these confuse potential operators.

Marketing

Marketing of infusion devices should stress the importance of usability in a way not hitherto observed. Whilst technological advances have enabled the functions on the equipment to become more highly complex and sophisticated, there has been little attention to usability. This has significant implications for the use of devices and therefore their safe application.

Sales and procurement

Procurement of devices by purchasing agencies should be better informed.

Lemburg (1988) has provided recommendations to simplify technical safety assessment and

operating safety with better infusion equipment. The notion of quick checklists to help select infusion devices has also been considered by McConnell (1999), who published twenty questions in order to help a selection committee to pin-point the correct infusion device.

The complexity of the device industry leads to a suggestion that a software package might be developed which would enable improved purchasing decisions to be made. That said, it would also be appropriate for the trials of devices to be far more extensive. Currently it is extremely difficult for purchasers to know whether or not a particular device will be suitable in some of the complex systems in which it may be used.

Commissioning

There appears to be little authoritative literature on the commissioning of infusion devices. However, some general principles apply and these include close liaison with end users throughout the commissioning period, identification of potential problems through appropriate risk assessments, feedback to procurement and manufacturers and the need to adopt appropriate strategies for the implementation of change within the organisation.

Management of devices

The Medical Devices Agencies report on the Management of Infusion Systems (MDADB9504 November 1995) was produced by the Scottish Office Home and Health Department. This report states that the evidence collected on infusion systems revealed a lack of formal management systems and accountability, poor procurement policies, a need for more training, lack of documentation, poor communication of safety warnings and reports for malfunctions and a lack of audit. The recommendations made in this report are clearly essential for any management strategy of infusion pumps.

It is also important that those responsible for the management of the system have a thorough understanding of equipment use within complex works systems. For example, the equipment may work satisfactorily when the user is not under pressure and is only working with one patient. However, the same equipment may prove to be unusable in situations where many patients are being looked after or where the user is under stress or working in complex teams where communication is problematic. This, coupled with training issues, suggests that all Managers should be appraised of the need to consider these aspects.

It is suggested that those responsible for the delivery of the management of infusion devices should be briefed in work systems design, user testing and task workplace analysis. Management of devices might also benefit from the design of audit tools (these could be software based) and systems for obtaining feedback, both good and bad (of use) from all users. Current systems of reporting near miss/adverse incidents, whilst to be commended, do not necessarily reflect the full usability picture.

Routine use

Studying the use of equipment in routine and abnormal situations (atypical) is essential.

A study of incidents involving medical devices used during Anaesthesia and Intensive Care in France in 1998 suggested that user errors, quality control problems during production of the device and design faults were the three main causes. This study by Beydon *et al.* (2001) also pointed to the potential for improving the design of these faulty medical devices and the need for post-marketing vigilance to contribute to such advances.

The trend towards the use of these devices in home care settings requires particular attention. It is suggested that a short survey/audit should be carried out of the use of such devices in home care settings, with specific reference to the problems being experienced by users.

Training

Training will continue to be an essential part of the systems approach to the safe use of infusion devices.

McConnell *et al*. (1996) considered Australian Registered Nurses and their level of knowledge and training with respect to medical device use. They found the most frequently identified reason for incident of patient harm resulting from use of an intravenous infusion pump was user error and inadequate device education. The issues relating to user error included the patient's condition, confusion, equipment malfunction and inadequate knowledge. Solutions based on addressing wider system issues are therefore required. Training in safety critical industries should start from the position of a task analysis. Task analytical training systems have been developed for use in the Aviation industry. These enable a thorough examination of the task to be undertaken which then forms the basis of the development of training needs, the training principles and the training materials. It is also important that any training delivered follows well-recognised concepts in the design of training courses. Walter (2000) describes one such programme for use in the aviation maintenance and inspection industry.

Maintenance and repair

The increasingly widespread use of these devices suggests that a new approach to maintenance and repair might need to be considered. Such an approach will require input from manufacturers and designers as well as those responsible for the use of the equipment. No obvious solutions to this problem are available through the literature but ergonomic "design for maintenance" principles (which are widely available) should be reviewed with respect to equipment. Such information should also be incorporated into any software developed for procurement specification.

Conclusions

This review of solutions (and processes leading to solutions) has found a very limited body of peer reviewed written evidence. This is surprising in view of the extensive use of infusion devices. Even where issues have been addressed there frequently appears to be a lack of basic data on which to build solutions.

The findings of the review support the need for a more systematic approach to finding solutions. The ergonomics work systems approach is seen as being an essential part of that process. Studies that have taken such an approach offer some partial solutions to user interface design for pumps. In general, the failure to adequately research the user needs has led to poor design of devices. This in turn has significant effects on the training needs and costs. Some training programmes exist that appear to be significantly better than those commonly found. Whilst these may be helpful in the short term, solutions to poor design are still required.

The use of better procurement strategies is advised. These may also have the secondary effect of identifying current user problems and, indirectly, encouraging manufacturers to address these shortcomings in design.

Design examples

The following examples show some examples of good and bad design practice.

Bed head rest

To help patients sit up, hospital beds have an adjustable head rest. It is quite heavy and can be difficult and even dangerous to adjust, as illustrated by the photographs below.

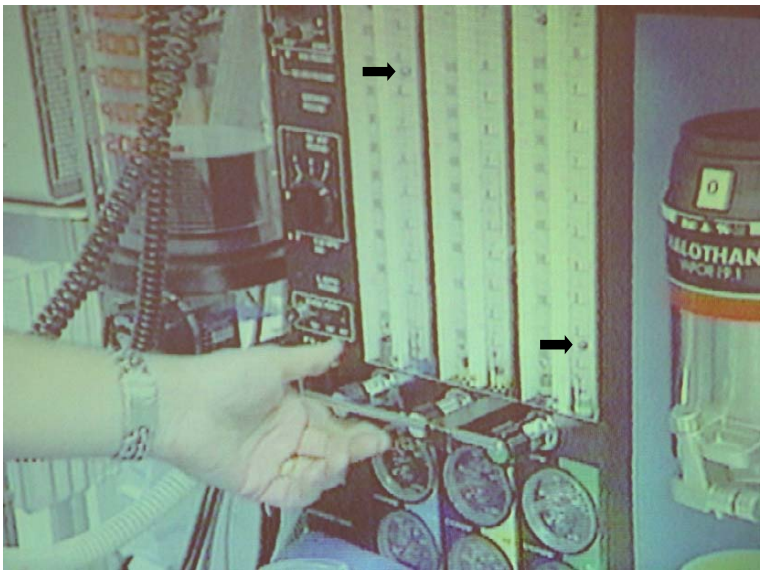

Above left: The starting position, before adjustment. *Above right*: The desired position.

To move the head rest to the desired position (above right), before the bottom bar can clear the mattress, the entire rest must be lifted vertically. Only once the rest has been lifted sufficiently high can it be swung into its desired position. Lifting the head rest invites injury, since it can require a nurse to lift a heavy load at the same time as reaching some distance over a patient or around other medical equipment. Perhaps worse still, if the head rest is lifted only a few centimetres too far, the entire structure can become detached, leaving the clinician suddenly having to support an even greater weight. The result is illustrated in the figure below.

Above: If the head rest is lifted too high, it can disengage from its guiding rails.

Anaesthesia

Anaesthesia has received a lot of attention from the world of design over the last 20 years, so many good design examples exist. The figure below illustrates several good design features on one particular model of anaesthesia equipment.



Above: Part of the control panel of an anaesthesia machine. Notice the three control knobs for adjusting the flow rate of the gases. In front of them is a horizontal bar, which reduces the chance of accidental adjustments to the knobs if the machine is knocked. Each knob is a different shape from the others. This provides some tactile feedback to the anaesthetist as an additional way of letting him or her know that the right (or wrong) gas has been selected.

The black arrows in this picture show the position of balls, which indicate the flow rate of the different gases. One ball is situated at the top of the left-most scale and the other at the bottom of the right-most scale. This illustrates another good design feature – upon increasing the nitrous oxide flow rate, for example, the oxygen flow rate also increases automatically, thus preventing the wrong mix of gas.

Nebuliser

This example illustrates the point that good design can make a considerable difference in treating patients. Good design can be inexpensive and yet improve treatment.

Above: Using a nebuliser can be a frightening experience for paediatric patients. The addition of a friendly face to a nebuliser mouthpiece can make treatment more manageable. In the most extreme cases it can encourage a young child to comply with treatment, rather than refuse it which, in the case of serious breathing disorders, can be very important in terms of safety of the patient.

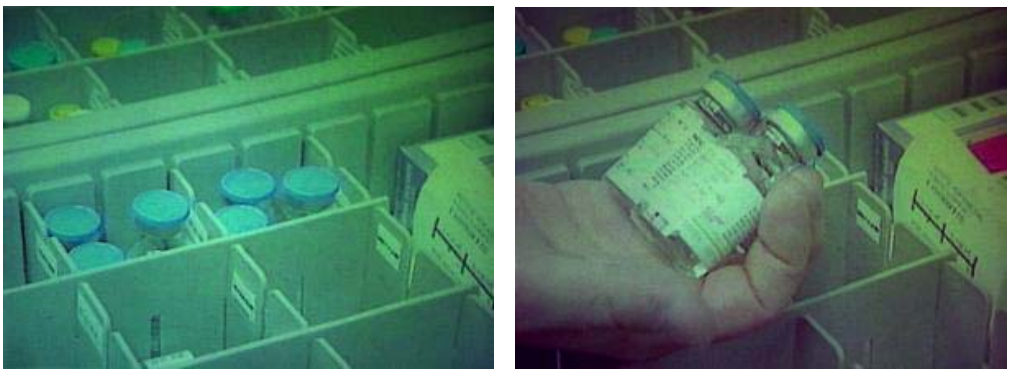
Defibrillator

Treatment of a heart attack requires quick action. Untrained members of the public may panic. If a defibrillator is nearby, there may be little time to spend reading instructions about, for example, where on the body the pads should be placed. The pads in the example below incorporate a diagram which shows the correct positioning. This is an example of a defibrillator for children – the teddy bear shaped connector helps distinguish this set of pads from the adult version.

Above: Printing instructions for use directly onto a medical device.

Labelling

This last example shows the danger of mix-ups between medicines due to poor labelling. The labels are small, with small writing. The tops are an identical colour. Different medicines, with identical tops, are stored next to each other. It is possible to grab the wrong one in a hurry or set the next user up for a mistake by replacing the right medicine bottle in the wrong place.



Above: Similar appearance of medicines containers can lead to mix-ups.

General conclusion

The distinction between good design and bad design lies in the attention to the needs of all the product's end users and the understanding of the system into which the product is released.

Annex 8 – Research team

The Robens Centre for Health Ergonomics

Professor Peter Buckle, *Professor of Health Ergonomics*
Professor Dave Stubbs, *Professor of Ergonomics*
Rhonda Lane, *Research Officer*

The Robens Centre has a long tradition of applying ergonomic approaches to complex work environments in order to optimise the efficiency of the system. The focus of inquiry is often to understand and rectify problems that have arisen, in particular accidents and ill-health of the workforce, damage to plant and product, and errors arising from poor person-equipment interface design. Increasingly the focus has included assessment of wider elements of the socio-technical system in which organisations operate. Thus a consideration of work organisation, safety regulations and economic compliance issues also now form part of the ergonomic approach. The role of litigation and insurance risk in medical error and accident is also well recognised and requires consideration in any ergonomic study of this area. Moray (2000) has provided a model that conveys the complexity of these systems. The research team combined expertise in health ergonomics, industrial design and engineering design. All the partners have an extensive research background relating in some way to healthcare issues.

The Helen Hamlyn Research Centre

Professor Roger Coleman, *Co-Director*
John Bound, *Researcher*

The Royal College of Art has a tradition of engagement with social issues from a design perspective. In the early 1970s it conducted extensive user research which resulted in the design of the standard NHS bed. Since 1980, through its Industrial Design Engineering course, the DesignAge programme launched in 1991, and later the Helen Hamlyn Research Centre, it has developed expertise in user-centred design, population ageing, and more recently, inclusive design and business strategies. The HHRC works with design consultants and design managers in industry on ways in which inclusive design can support business goals, and through its Research Associates Programme on practical design research collaborations with industry and voluntary sector partners. Recent projects have included:

- Instinctive wayfinding in the airport terminal, with BAA plc;
- Making domestic appliances easier to use for older people, with Dyson Appliances;
- Improving visual pack information for older consumers, with Packaging Solutions Advice Group;
- Protective clothing exploiting new materials, with Levi Strauss;
- Improving the environment of disabled teleworkers, with Leonard Cheshire;
- An inclusive pedometer and a campaign to encourage healthy walking, with the British Heart Foundation;
- DIY tools made easier for all, with B&Q;
- Improving packaging for older people, with Waitrose;

- Smart home intelligence to enhance the lives of older people, with Omron Corporation of Japan.

Building on the DesignAge programme, the HHRC maintains a leading international position in the field of design and ageing, through practical projects, research and dissemination, including a Design Council policy paper on population ageing authored by the Centre's Co-Director, Roger Coleman.

Cambridge Engineering Design Centre

Dr P John Clarkson, *Director, Reader in Engineering Design*
Dr Jerome Jarrett, *Senior Research Associate*
Dr James Ward, *Research associate*

Research into medical equipment design has been active in the Cambridge Engineering Design Centre (EDC) since its creation over ten years ago. More recently, Dr Clarkson, in collaboration with Cambridge Consultants Limited, has lead a team of researchers investigating the medical equipment design process with particular emphasis on defining the equipment requirements and the needs for design evaluation. In addition, there is a research focus on design for the older and disabled user. There is some overlap between these areas which are better described by the following:

- *Requirements Capture* – the definition of a systematic method for capturing the requirements for medical equipment and its associated manufacturing and test equipment (Shefelbine *et al.*, 2002; Ward *et al.*, 2003);
- *Design for Verification* – the definition of an approach to integrate risk management with design to improve the efficiency and effectiveness of equipment verification (Ward and Clarkson, 2001; Ward *et al.*, 2002a; Ward 2002b);
- *Design for Validation* – the definition of a framework for Good Design Practice for medical equipment which integrates design, manufacture and validation (Alexander and Clarkson, 2000a; Alexander and Clarkson, 2000b; Alexander *et al.*, 2001);
- *Design for Usability* – the definition of a method to combine a staged design approach with usability heuristics to improve equipment usability (Clarkson and Keates, 2001; Dowland *et al.*, 1999; Harrison *et al.*, 2001; Keates *et al.*, 1998, Keates *et al.*, 1999, Keates and Clarkson, 2001).

The Cambridge team also has close working links with: the Department of Public Health and Primary Care within the Institute of Public Health, Cambridge University Health (CUH) (the health policy and management centre – within the Judge Institute of Management Studies), both at the University of Cambridge; and with the Addenbrooke's NHS Trust.

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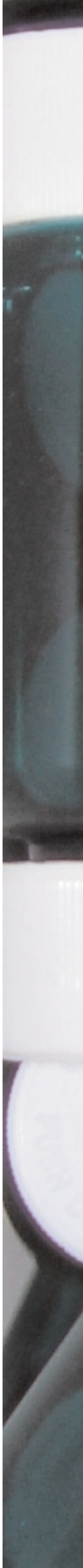

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