Design Council

# DESIGN FOR PATIENT SAFETY

## A SYSTEM-WIDE DESIGN-LED APPROACH TO TACKLING PATIENT SAFETY IN THE NHS

This report sets out a perspective from the world of design – based on a scoping study carried out by a research team from the Universities of Cambridge and Surrey and the Royal College of Art – to identify previously unrecognised opportunities for improved patient safety in the NHS.

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## A SYSTEM-WIDE DESIGN-LED APPROACH TO TACKLING PATIENT SAFETY IN THE NHS

# FOREWORDS

## FOREWORD BY SIR LIAM DONALDSON, CHIEF MEDICAL OFFICER

As part of our drive for high-quality health services, the NHS has been a world leader in introducing a new system for learning from things that go wrong and starting the journey to make health care safer for patients.

The National Patient Safety Agency is already working to improve the safety of NHS patient care – by promoting a culture of reporting and learning from patient safety incidents, by managing the national reporting system to support this function, and by identifying actionable and evidence-based solutions to help prevent avoidable mistakes recurring across the service.

Indeed, the very nature of the NHS gives us the opportunity to implement an integrated, comprehensive approach to patient safety across our national health services – an option not available in many other countries.





### DESIGN FOR PATIENT SAFETY

This report gives a view of the NHS from a fresh standpoint, applying the design approach and experience of other safety-critical industries to deliver a clear message: that the NHS needs to think in broad design and system terms – much more so than it does at present.

Properly addressed, improvements in patient safety will contribute significantly to improving the quality of care for NHS patients. Reduction in errors will also free up resources at present used to cope with the consequences of those errors.

Implementing the thinking set out in this report could go a long way to help achieve that goal. If the NHS can embrace the broad systems approach set out in the following pages, we would undoubtedly save lives.

Improving patient safety is not only a major Government priority but also an international issue. Research from around the developed world suggests that healthcare errors of equal magnitude, and probably with similar causes and similar solutions, are just as likely to occur in fee-for-service and insurance-based systems, as in our own state-funded NHS.

There is already evidence to suggest that well-designed packaging, communications and environments can reduce the incidence of errors within healthcare. But design responses need not be limited to these more obvious areas. We may be able to design-out some of the most

common medical errors and make it, if not always impossible, at least far more difficult for mistakes to trigger specific types of preventable medical accidents.

Echoing the conclusions of my 2000 report *An Organisation with a Memory*, this report concludes that the NHS would gain greatly if it were to adopt modern thinking and practice with regard to designing for safety. It suggests that 'the highest priority should be attached to remedying this without delay'.[1]

The report, jointly commissioned by the Department of Health and the Design Council, builds on our current NHS modernisation agenda, to identify opportunities for improving patient safety through the more effective use of design.

I support the broad findings of the report and look forward to leading a continuing, multi-agency programme to help embed this approach more widely across the NHS.





## FOREWORD BY DAVID KESTER, CHIEF EXECUTIVE, DESIGN COUNCIL

Design is being used to great effect by organisations around the world, developing solutions that meet the needs and desires of people in all walks of life. Norman Foster's Canary Wharf tube station, Harry Beck's London Underground tube map and Jonathan Ive's Apple iMac. What do they have in common? They are all amazingly effective designs. Effective because they have achieved the seemingly impossible: making the complex systems people need in order to get on with their lives into something simple and intuitive that is a delight to use.

The same design thinking can also be used to improve safety. For instance cars are complex machines, driven by error-prone risk-takers, namely humans, and used within a complex environment – the road network. Within the automotive industry, designing for safety has become a key way to differentiate and add value over competitors. For example, Volvo as a brand has become synonymous with safety. Designers, including human factors experts, helped build this reputation by considering the latent needs of road-users. They delivered pioneering innovations such as the safety cage, airbags and ABS brakes, which are industry standards today. The need to prioritise safety, as an essential part of building and managing a business, is shared within the aviation and nuclear industries and in many other sectors – including healthcare.

The Design Council's purpose is to raise awareness about the benefits of using design effectively in business and by public services, and to enable organisations to act on this new-found awareness. We have found the Design for Patient Safety study a very exciting and rewarding initiative to work on.

The researchers' findings, set out in this publication, outline the route towards the goal of a win-win-win for healthcare: safer care for patients, more intuitive and enjoyable working environments for healthcare professionals, and the potential for businesses working within the healthcare industry to add value and differentiate their products through safer designs. The recommendations are an important step towards significantly reducing the risk of medical error across the NHS. I welcome the Government's decision to take this forward as a national initiative.





# EXECUTIVE SUMMARY

## WHY DESIGN FOR PATIENT SAFETY?

Design is a structured process for identifying problems and developing, testing and evaluating user-focused solutions. It has been successfully used to transform products, services, systems and even entire organisations.

**HUMAN BEINGS MAKE MISTAKES BECAUSE THE SYSTEMS, TASKS AND PROCESSES THEY WORK IN ARE POORLY DESIGNED.**

**PROFESSOR LUCIAN LEAPE, HARVARD SCHOOL OF PUBLIC HEALTH**

When applied to healthcare, effective design thinking can deliver 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.

By contrast, 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 either medical staff or the patient – or both.

## ABOUT THIS REPORT

The first part of this report sets out the safety challenge that needs to be addressed and outlines a new design-led approach to reducing the incidence of error and accidents across the NHS.

The second part sets out a series of research-based recommendations and actions, submitted to the Department of Health to help put this approach into practice. This is followed by a response by the Government to the findings of this research.

## THE PATIENT SAFETY CONTEXT

The health service is a highly pressured, complex system where the potential for error and accidents is ever present. International research suggests that ensuring patient safety is becoming one of the most important challenges facing healthcare today, not just in the UK but worldwide.

In 2000, the findings of an expert group on learning from medical accidents in the NHS, chaired by the Chief Medical Officer, were published in the internationally acclaimed report – *An Organisation with a Memory*.[2] The proposed strategy was based around a new national system for reporting, analysing and learning from adverse events involving NHS patients. All of the report's recommendations were accepted by the Government and plans to implement this agenda were announced in *Building a Safer NHS for Patients*.[3] The National Patient Safety Agency was established in 2001 to take forward this strategy.

This new strategy also recognised the key role design can play in delivering safer healthcare products, services, processes and environments. It has recommended 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 STUDY

The *Design for Patient Safety* initiative is a response to this need. It builds on and reinforces the new patient safety approach to move away from a 'blame culture', towards one that encourages learning and recognises medical accidents to be the culmination of failures in the healthcare system.

This publication summarises the key points and recommendations arising from the first phase of this initiative, a scoping study to investigate how the effective use of design could improve patient safety in a whole system context. The study was undertaken by research teams at the Robens Centre for Health Ergonomics at the University of Surrey, the Helen Hamlyn Research Centre at the Royal College of Art and the Engineering Design Centre at the University of Cambridge. The research included widespread consultation with deliverers and practitioners of healthcare; experts from industries where safety is a prime concern; representatives from the pharmaceutical and medical devices industries; patient support groups; and designers. The full research findings were submitted to the Department of Health in the report, *Designing for Patient Safety: A scoping study to identify how the effective use of design could help to reduce medical accidents*.[1]

The main conclusions of the study were that:

- The NHS is seriously out of step with modern thinking and practice with regard to design. A consequence of this has been a significant incidence of avoidable risk and error.

- There is little evidence of design understanding or practice within the NHS equivalent to those which are commonplace in other safety-critical industries and leading commercial organisations.
- There was cause to question not simply the design of medical devices, products, packaging and information, but the way the NHS as a whole uses design in an effective way and its understanding of what design thinking can bring to an organisation.
- 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.
- Such 'big picture' understanding is not present and the highest priority must be attached to remedying this without delay.

The study's recommendations responded to the key issues identified through the research, which were not principally concerned with the design process itself but with developing knowledge, systems and processes that will provide the foundations for effective design decision making across the health service and industry. The recommendations and preliminary projects, summarised in this report provide a framework to achieve a systems-based, user-centred approach to healthcare design for the NHS.

The ideas outlined in the study will need further research to identify their full potential, but they provide the foundations of a much safer NHS in which the opportunity for errors in the healthcare system is 'designed out' *before* accidents occur rather than *afterwards*.





# ACKNOWLEDGEMENTS

The Design Council and the Department of Health would like to thank the Robens Centre for Health Ergonomics at the University of Surrey, the Helen Hamlyn Research Centre at the Royal College of Art, and the Engineering Design Centre at the University of Cambridge, who came together to form the research team that scoped out this new approach to patient safety.

The research team would like to thank the healthcare stakeholders who gave their time for interviews and who participated so enthusiastically in the workshops: the deliverers of primary and secondary healthcare (including the midwives, accident & emergency personnel, cancer and palliative carers who contributed to the focus groups), representatives of various NHS agencies and from the healthcare and pharmaceutical industries, designers and patients groups, and the experts from other safety critical industries who provided considerable insight as to how things could be. The researchers would also like to thank Baker Brown Associates and Working Solutions in Design for facilitating the stakeholder workshops.

The scoping study was jointly funded by the Design Council and the Department of Health. The views expressed in this publication are those of the authors of the scoping study and not necessarily those of either the Design Council or the Department of Health.

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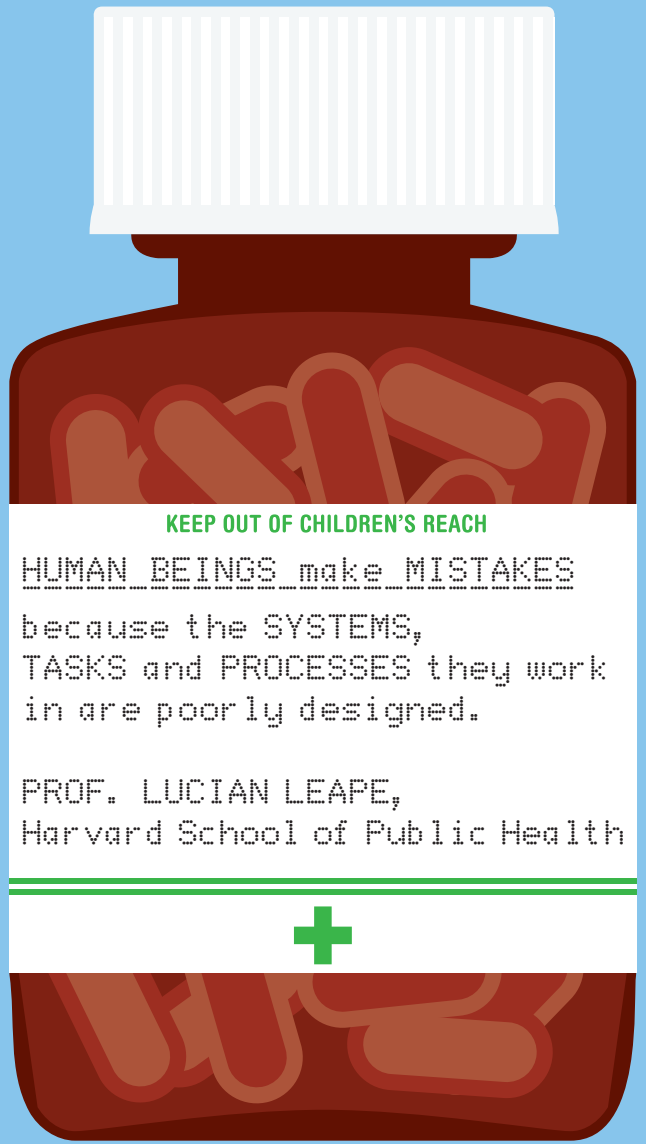





# 1 DEVELOPING A DESIGN-LED APPROACH TO PATIENT SAFETY

## INTRODUCTION

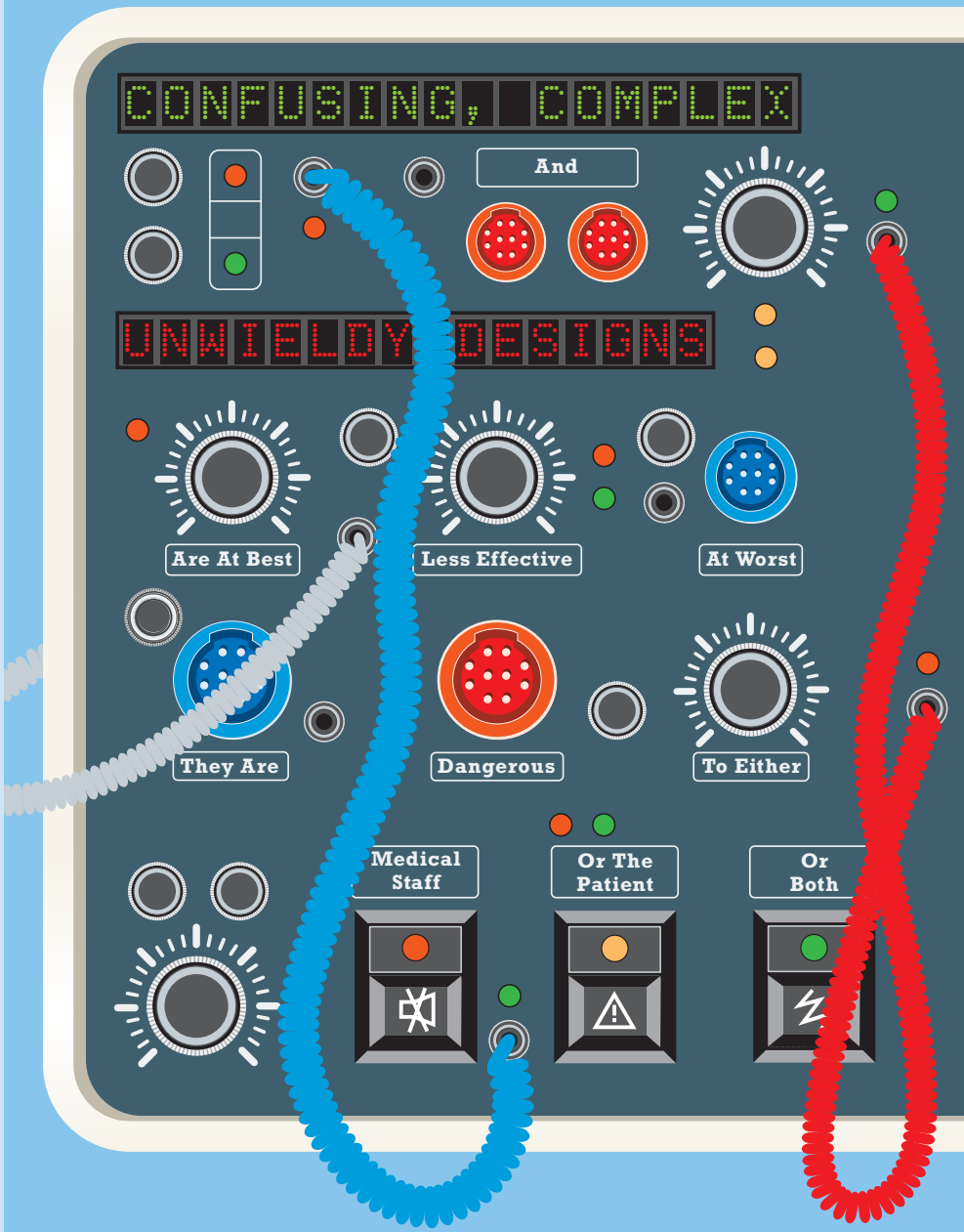
In April 2000, a woman being treated for rheumatoid arthritis in Cambridgeshire died after her prescription for a weekly dose of the drug Methotrexate was inadvertently increased to a high daily dose. The resultant overdosing severely compromised the patient's immune system. The subsequent inquiry found that the incident resulted from multiple failures in the care and treatment of the patient throughout her care pathway, and made 28 recommendations for change covering a wide range of issues in primary and secondary healthcare.[4] The root cause of this turn of events, and of the majority of mistakes taking place in medical environments, is the system itself – a system whose flaws eventually lead to what is called a 'human error'. The *Design for Patient Safety* initiative is a new, proactive approach to patient safety that provides the basis for designing flaws out of the system before they result in such needless tragedies.

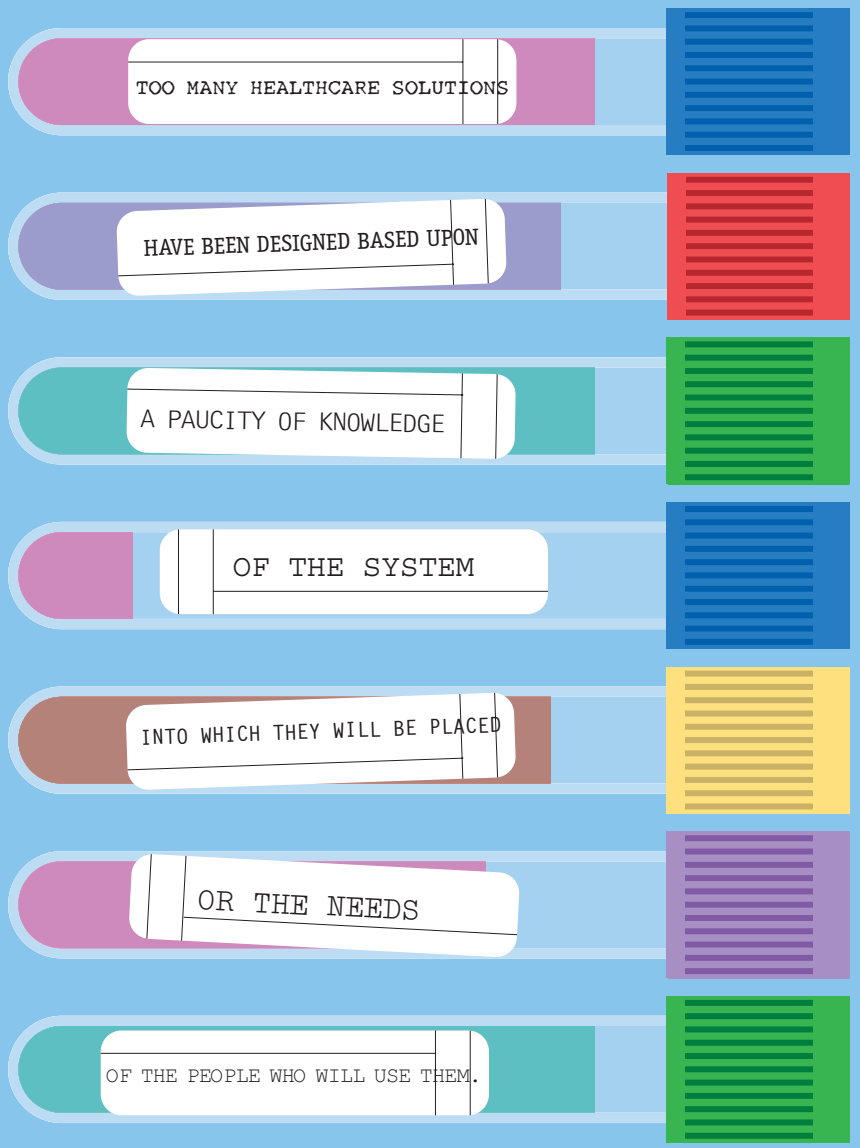
**ACTING WITHOUT UNDERSTANDING WILL NOT GET TO GRIPS WITH THE PROBLEM OF MEDICAL MISTAKES**

In the past, the NHS has not used design in an effective way, nor has it grasped the value and significance of design to patient safety. Too many healthcare products, processes and services have been designed based upon a paucity of knowledge of the system into which they will be placed or the needs of the people who will use them. When this happens, errors in the system can be overlooked or, worse still, are inadvertently designed into the organisation. The new approach to healthcare safety recommended in these pages places the users of medical equipment, services and information at the centre of the issue – so that the *potential* for medical errors and accidents can be reduced through the effective use of design in a whole system context. This requires a fundamental rethink of the way in which the health service deals with risk: first by accepting that the way in which the system works itself often contributes to human errors, then by building an in-depth body of knowledge about the everyday working practices of patients and staff, how they interact with each other and with the many different parts of the NHS. Finally this understanding is used to design a safer system. This is a major task but the benefits should be considerable:

- **For the patient** – it will bring a safer experience of healthcare.
- **For healthcare professionals** – it will result in products, services and processes that are designed to be simple to understand, easy to use and hence less likely to lead to accidents, especially when staff are working under heavy pressure.










- **For the healthcare industry** – it offers the opportunity to add value and differentiate their products through good safety design.
- **For the NHS** – it will result in a better understood, safer and more cost-effective healthcare system, where the burden of medical accidents will be significantly reduced.

This is a proactive solution to the problem of medical errors: the systematic use of design to minimise the potential for mistakes in the NHS. It is an approach taken in the defence, aviation, nuclear and other industries where lives are at stake and safety is a prime concern. They have found that the application of well thought-out design solutions can reduce risks to an acceptable level and the NHS must now adopt this method if it is to achieve a standard of patient safety that society expects from a 21st century public service.

This new patient safety perspective has been developed through an initial study, jointly commissioned by the Department of Health and the Design Council, to deliver ideas and recommendations for a design approach to reduce the risk of medical error and improve patient safety across the NHS. This study was undertaken over a relatively short period during 2002, and explored the potential for improved design interventions in a whole-system context focusing on medication error.

The research team employed diverse methods to gather evidence from literature, key stakeholders, and experts from within healthcare and other safety-critical industries. Despite the multiplicity of activities and methodologies employed,[5] what emerged from the research was a very consistent picture. It showed a system of interactions 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.

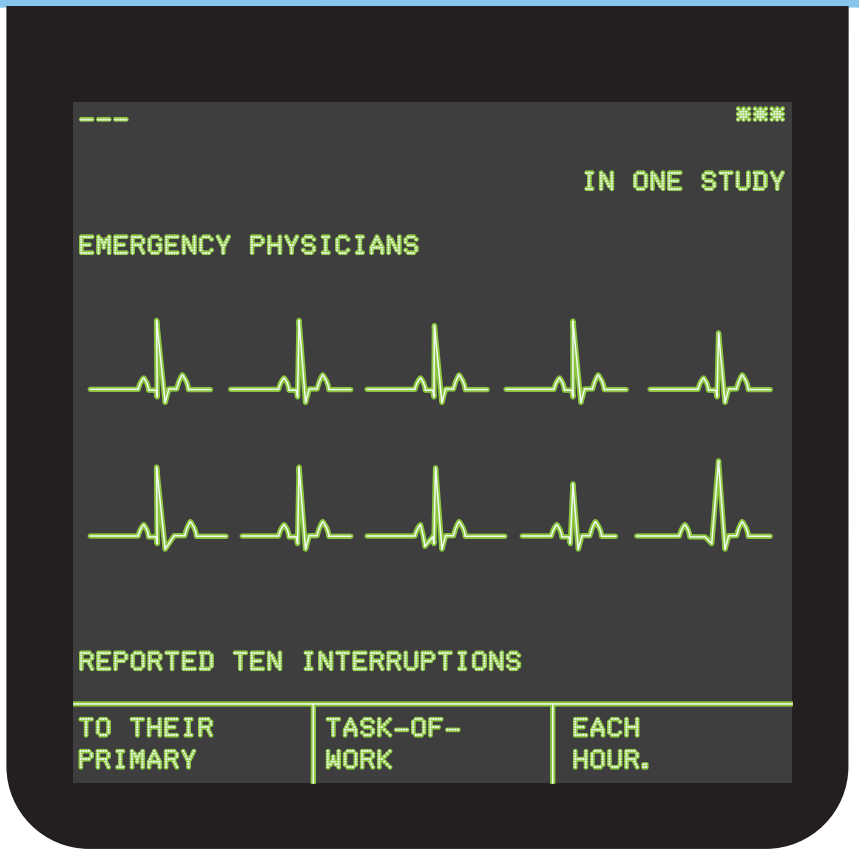
This convergence pointed to the need to better understand this complex system as the context into which specific design solutions must be delivered. Without that broader understanding there can be no certainty that any single design will contribute to reducing medical error and its consequential cost.

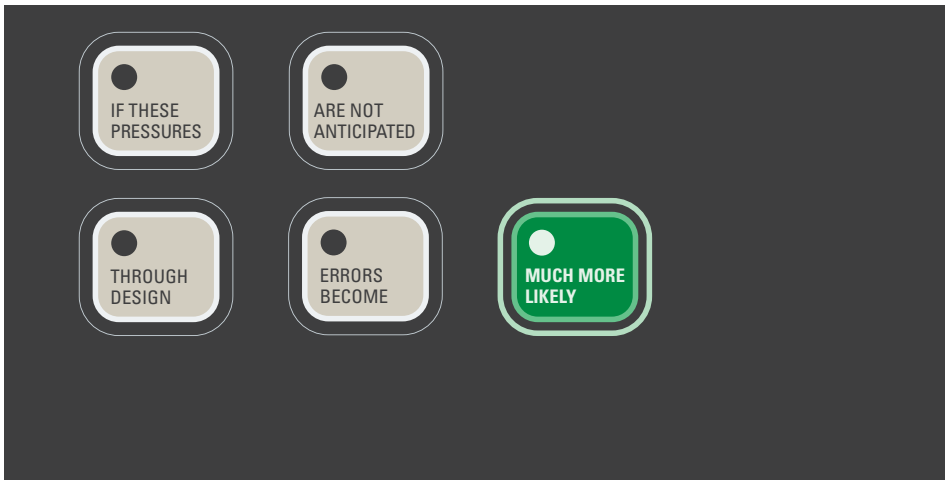
This report summarises the findings of the initial study. The study threw up key issues and often challenging messages for the NHS, which along with its conclusions and recommendations, are based on the research findings interpreted in light of the extensive experience of the research team.

Britain is not, of course, alone in facing the problem of medical errors. But the national remit of the NHS places it in a strong position to offer solutions that could have lessons for healthcare providers around the world. This can only happen by investigating the way in which the health system itself operates, inadvertently contributing to accidents – and then using this knowledge to design out the potential for mistakes.

The Government has demonstrated its commitment to reducing medical errors. The ten key recommendations in the internationally acclaimed report – *An Organisation with a Memory* – were accepted by the Government. In the process, patient safety became a key component








of *The NHS Plan*[6] and a major strand of the NHS quality and clinical governance agendas. *Building a Safer NHS for Patients* set out the Government's plans to implement this agenda, based around a new national system for reporting, analysing and learning from adverse events involving NHS patients – now being taken forward by The National Patient Safety Agency.

The Government is now equally committed to building the knowledge needed to go beyond quick fixes to deliver long-lasting, consistent improvements in patient safety. Acting without this understanding will not get to grips with the problem of medical mistakes. Acting with it could make the NHS a pioneer in the field of medical safety.

**IF WE TRULY WANT SAFER CARE**
**WE WILL HAVE TO DESIGN SAFER CARE SYSTEMS.**

DR DAVID BATES, CHIEF, DIVISION OF INTERNAL MEDICINE,
BRIGHAM & WOMEN'S HOSPITAL

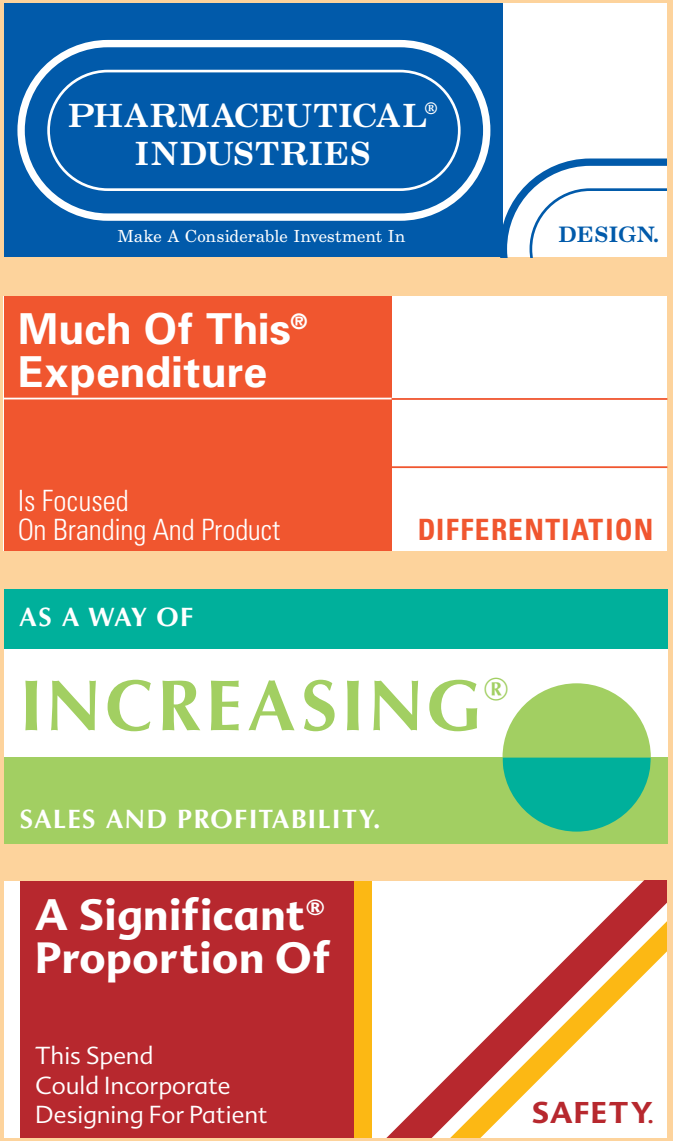
## THE SAFETY CHALLENGE

Ensuring the safety of people who come into contact with health services is one of the most important challenges facing healthcare today. While no country in the world can give an accurate figure on the numbers of people affected by healthcare errors, there are some UK and international academic studies available. Findings from the UK, US, Australia, New Zealand and Denmark all suggest that about 10% of patients admitted to hospital may suffer some kind of adverse outcome. In the USA it is estimated that at least 44,000, and perhaps as many as 98,000 die in hospitals each year as a result of medical errors.[7] Even using the lower estimate these deaths exceed those attributed to breast cancer, AIDS and motor vehicle accidents. And perhaps as many as half of these adverse events are judged to be avoidable. Reducing this disturbing toll of human lives requires a rethink of our approach towards medical safety.

**THE TASK IS TO ANTICIPATE AND REDUCE MEDICAL ACCIDENTS BY GAINING A MUCH BETTER UNDERSTANDING OF THE HEALTH SERVICE AND ITS USERS, AND THEN USE THAT KNOWLEDGE TO DESIGN SAFER SOLUTIONS.**

It is inevitable that a medical system as highly pressured as the NHS will have a great potential for errors. The task is to anticipate and prevent accidents – by gaining a much better understanding of the complex interactions within the health system that govern the use of medications and equipment, and then using that knowledge to design








safer solutions. Every day in the NHS there are many interactions within and between different medical teams, the environments they work in, the care they deliver, the equipment they use and the information they need to keep track of patients and their treatments. So when mistakes do occur, the causes – in all but the most obvious of cases – are likely to be just as complex, originating in the physical, the technological and the psychosocial environments.

When an elderly person fails to take a prescribed medicine, for example, is this due to a single cause such as poor communication in the pharmacy? Or is it the result of an unreadable leaflet on a medicine bottle? Has poor vision or mental confusion contributed to the problem? Or is it the result of a complex chain of interrelated factors? The underlying causes of medical errors must be clearly understood before effective design solutions to these problems can be offered – but, until now, there has been little comprehension of this wider context within the NHS.

Patient safety cannot be improved by simply adjusting the design of medical devices, packaging and information because, at present, there is little in-depth understanding about how staff and patients use – and sometimes misuse – these items. This knowledge is required so that patient-safety 'hotspots' in the system (risky situations, risky moments, risky items and risky users) can be systematically identified and acted upon. This is the first, critical, stage of the design process: without this understanding, design briefs and procurement decisions will be flawed and solutions unlikely to be effective.

In short, there is a widespread lack of knowledge about the complex systems of interactions between the many stakeholders and the equipment, medications, environments and other associated products and services that constitute the health service. This is symptomatic of the NHS's past failure to understand how the design of the system itself can contribute to medical mistakes and errors. There has also been a widespread assumption that human error is an inevitable cause of mistakes – but little awareness of the extent to which factors such as poor information, cluttered labelling, confusing and unwieldy designs or the similarity of names and packages can burden already pressured workloads and make 'human error' more likely to occur. It may well be that this 'blame culture' with its emphasis on human error has been distracting attention from underlying design flaws that can be corrected.

This worrying situation can be changed if more is learnt about what is really required to safely deliver healthcare. The challenge facing the health service is to find a new way of approaching the design of safety-critical products, services and processes that will:

- reduce the chance of errors occurring
- increase the chances of discovering errors when they do happen
- reduce the harmful effects of errors that do occur.

This report advocates a design approach whose starting point is a proper understanding of user needs, in this case healthcare providers and patients, by understanding what they do and how they act, as well as the systems context they are interacting in. The following pages outline such an approach – one that has the potential to significantly reduce the annual toll of deaths and injuries caused by medical mistakes in the NHS.

**WITHOUT A SYSTEMS UNDERSTANDING THERE CAN BE NO CERTAINTY THAT ANY SINGLE DESIGN WILL CONTRIBUTE TO REDUCING MEDICAL ERROR.**





## LEARNING FROM OTHERS

Other safety-critical industries do not have the knowledge gaps identified in relation to our healthcare system. They understand very precisely what happens in their businesses and how individuals interact with the various parts of their organisation. They are also engaged in a constant process of review and improvement of the safety implications of these factors.

There is now a growing body of evidence that healthcare professionals are not solely responsible for medical mistakes. Rather, the fault lies in the systems that have been put in place to support NHS staff in the delivery of safe, quality healthcare. This understanding of the role that the healthcare system plays in patient safety, is motivating a new NHS strategy – *Building a Safer NHS for Patients* – to rectify system failures that have, in the past, led to errors and accidents. It is a strategy that has been acknowledged and adopted by many high-risk businesses, such as the nuclear and aviation industries. They have done so because they realise the dangers of considering elements of a system in isolation from each other. The most forward-looking companies now work to develop quality relationships with their staff and customers, to develop specifications based on their needs and aspirations and then to use them as a basis on which to commission the design of new equipment and technology. They invest significant sums of money to design safer systems and see no conflict between such goals and cost efficiency – because the success of their products and services, and ultimately of the company itself, depends on such a proactive approach.




There is a need for a quantum shift in practice within the NHS. Patient safety could be significantly improved by the introduction of similar user-centred systems-based approaches within the healthcare service. In particular, the following approaches should be investigated:

### PURCHASING EQUIPMENT

High-risk industries have adopted an integrated 'system design' approach towards the way they identify equipment specifications. The defence industry, for example, does this from the very start of its procurement process and bases its designs on information drawn from a variety of areas: the lifecycle of a product is taken into account along with maintenance costs and the attitudes, training and skill levels of likely users. The process has been standardised by the use of a 'requirements capture' method developed specifically for this purpose.

The need to be critical of healthcare design requirements and to take a more user-focused systems-design approach has been underlined by US Food and Drug Administration guidance:

> 'Product developers make incorrect assumptions about user needs, and marketing personnel make incorrect assumptions about the needs of product designers. Incorrect assumptions can have serious consequences that may not be detected until late in the development process. Therefore, both product developers and those representing the user must take responsibility for critically examining proposed requirements, exploring stated and implied assumptions, and uncovering problems.'[8]

## TASK ANALYSIS

Safety-critical industries recognise the importance of task analysis in the development of equipment that is safe and easy to use – and many analytical techniques have been developed. Task analysis – comparing the aim of an activity with the tasks actually undertaken to achieve the objective – is a critical component in the design of products that minimise the chance of human error. Using this technique, designers can pinpoint where vital actions are being omitted, where dangerous shortcuts are being taken or where false assumptions are being made about the state of the system itself.

Such analysis enables goals to be defined, the steps used to achieve these goals to be accurately assessed, and interactions between the person and the system to be identified. There are hardly any examples of task analyses drawn from medical settings and so there can be no systematic understanding of what is actually going on in healthcare situations. Without this knowledge it is not possible to effectively evaluate the safety of designs for medical products or services.



One simple example of a task analysis in healthcare is for a hand-held blood glucose meter which includes the tasks listed below – noting that the tasks are performed by the 'user', by the 'device' or by a combination of the two:

1 **Patient's finger is lanced with automatic lancing device (device and user).**
2 **Blood sample is placed on test strip (user).**
3 **Test strip is placed in device (user).**
4 **The sample is allowed to react with reagents in the test strip for a specific time (device and user).**
5 **Blood glucose level in the sample is measured (device).**
6 **The resulting value is displayed (device).**
7 **The displayed value is read, interpreted and acted upon (user).**

Having identified the functions and tasks as above, they can be analysed to determine where human factors could have an impact. For example, the second task of placing a sample of blood on a test strip can raise some fundamental questions:

- **Are any use-related hazard scenarios possible?**
- **How might they occur?**
- **How likely are they?**
- **What are the possible consequences?**
- **How might they be prevented?**





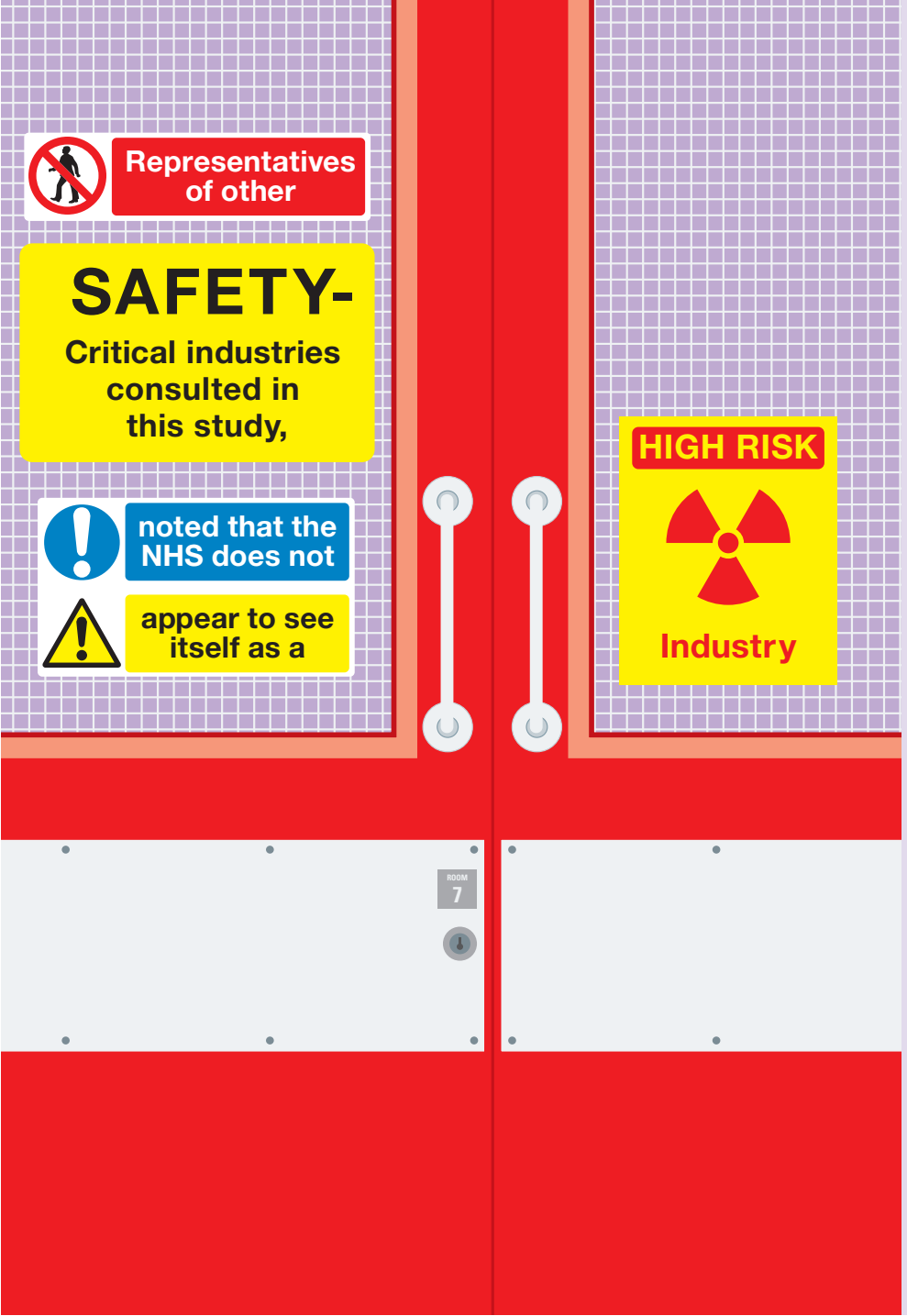
And in order to address these questions, the analyst should try to focus on the key issues, such as:

- **How difficult is it for users to use the device components and accessories to do this task correctly?**
- **Is the proper use of test strips evident to the user?**
- **What characteristics of the user population might cause some users to have difficulty with this task?**

In early glucose monitors, the user had to perform the fourth task manually. The users had difficulty in doing this task competently, which in turn affected the accuracy of the results. In newer models this task was done automatically by the device. Therefore by considering the human factors issues and improving on the design of the device, this particular challenge and potential hazard was removed.[9]

### EQUIPMENT-RELATED INFORMATION

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. And in many safety-conscious industries, equipment performance and usage are 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 tracking of particular part numbers in the case of suspected design errors.






### TRAINING

Training in safety-critical industries such as the health service should also be developed by task analysis. The aviation industry, for example, obtains a thorough understanding of all the tasks involved in a particular job before developing a training manual for the task.

### INCIDENT REPORTING

The health service is moving towards an improved system of reporting and learning from adverse incidents and near misses through the National Patient Safety Agency, established in 2001, but the researchers noted that the defence and nuclear industries have gone beyond this by insisting on the reporting of *potential* incidents. Such a proactive approach generally provides more detailed information than does reactive reporting. And although the confidential reporting systems used in the NHS 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.

### REGULATION

High-risk industries in the commercial world are answerable to a powerful independent regulatory body that oversees their systems, audit trails and training. The NHS, by comparison, is a highly fragmented organisation largely lacking in unified standards, procedures and protocols.

The NHS as a whole must now follow this lead by directing investment towards patient safety in a similarly effective way. The solutions that are put in place must go beyond short-term, quick fixes, to deliver consistent and sustainable gains in patient safety in ways that are well established in other high-risk industries.





## A SYSTEMS-BASED, USER-CENTRED APPROACH TO HEALTHCARE DESIGN

The opportunity for medical errors cannot be removed entirely, but errors can be minimised by accurately predicting the form that they are likely to take. The success of this strategy depends on a thorough understanding of the healthcare system and of how healthcare users and patients really behave within it, which can be very different to how they are expected to behave. It also involves knowing how such users interact with the multiplicity of equipment, medications, environments and information that they come across in the health service.

Designers of medical equipment, for example, must allow for the range of potential users, their experience, training and expectations, the context in which the equipment is to be used, and the requirements of the medical team, as well as important management, communication and organisational issues. Medical products, services and environments can then be designed to:

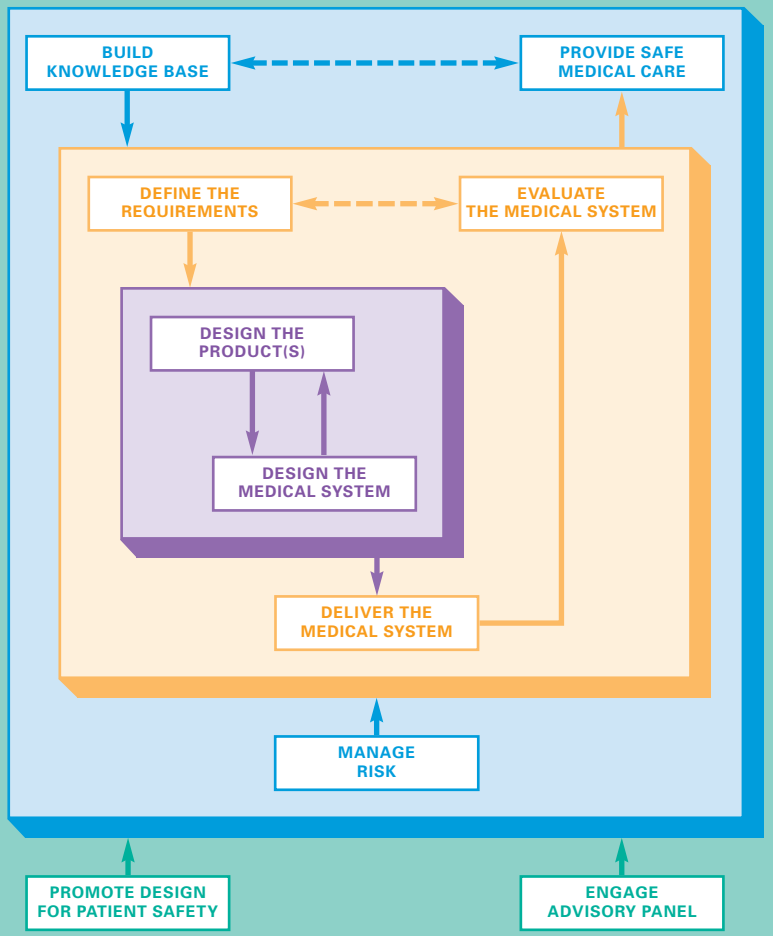
- **Prevent user error from occurring** – by encouraging simple-to-use and intuitive device operation. Anaesthesia machines, for example, may have knobs of different shapes and colours to control the flow of oxygen and nitrous oxide gases being delivered. This provides tactile as well as visual feedback, which helps prevent errors in selecting the wrong control knob. 'Forcing functions' may also help ensure that users are less able to make mistakes when performing certain device

operations. For example, by providing shrouding around connector pins, such good design ensures that 'male' pins cannot be fitted into incorrect 'female' sockets such as wall-mounted power supplies.

- **Alert users to possible dangers** – by providing warning messages. Anaesthesia machines, for example, may sound a warning alarm if excess gas pressure occurs.
- **Reduce the effect of use errors** – such as through the use of fail-safe systems or backup safety systems, should an error occur. Anaesthesia machines, for example, have pressure release valves to reduce pressure and protect patients' lungs.

The diagram opposite represents a model of the systems-based, user-centred approach to healthcare design developed by the research team from established system design theory, and advocated as the core of the Design for Patient Safety Initiative.[10]

Successful product or service development, resulting in the provision of safe medical care (shown in the blue box), cannot be achieved in isolation of the system or environment into which it will be introduced. The system needs to be understood, as well as the needs of people that work within it, illustrated in the model by the 'build knowledge base' element. This improved understanding will support a number of activities (shown in the orange box). It will lead to the setting of more effective design requirements by the NHS, which provides a strong foundation for successfully designing the product and the system it is to fit into (purple box). Effective design requirements are also a prerequisite to improvements in procurement and innovation practice.



The design of the product and the system is linked, as knowledge about the system should affect the product, and vice versa. The product and system designs are then delivered and their effectiveness and outcomes must be evaluated. This process will be unique to a particular product or service and be actively managed to minimise technical and commercial risk. Only from this basis can safe medical care be provided.

The whole of this approach would be informed and assisted by an advisory panel made up of industry, academic and healthcare experts and require proactive promotion to all stakeholders.

Another way to see this model is in terms of the building blocks of a stable and enduring process, leading to enhanced patient safety:

**1 Build a knowledge base, a sound understanding of the reality of the medical system; and use this to**

**2 Develop and define effective design, purchasing and usability requirements; leading to**

**3 The innovations in product and system design and in procurement practice; that will**

**4 Deliver high-quality user-centred designs solutions that can be evaluated and proven within the medical system; and thereby**

**5 Provide safer and more effective medical care.**

With this understanding of the medical system and its users, design can significantly enhance the safety of staff and patients by proactively minimising the potential for mistakes. Without it, there is the very real possibility that a solution to one error may in fact create more safety problems than it solves.





The *Design for Patient Safety* research points very clearly to there being no simple answer to the problem of medical accidents. Rather, there is a series of complex, interrelated issues that need to be addressed as a whole and that are not sufficiently well understood to be amenable to rapid solutions. Because of this, the recommendations on the following pages are not principally concerned with the design process itself. Instead they offer a strategy that will develop the knowledge, systems and processes to provide the foundations for more informed and safer design decision making across the NHS and industry. Six key areas are addressed through the recommendations in order to achieve this systems-based user-centred approach to healthcare design:

**1 Building an effective NHS knowledge base**

**2 Defining effective design requirements**

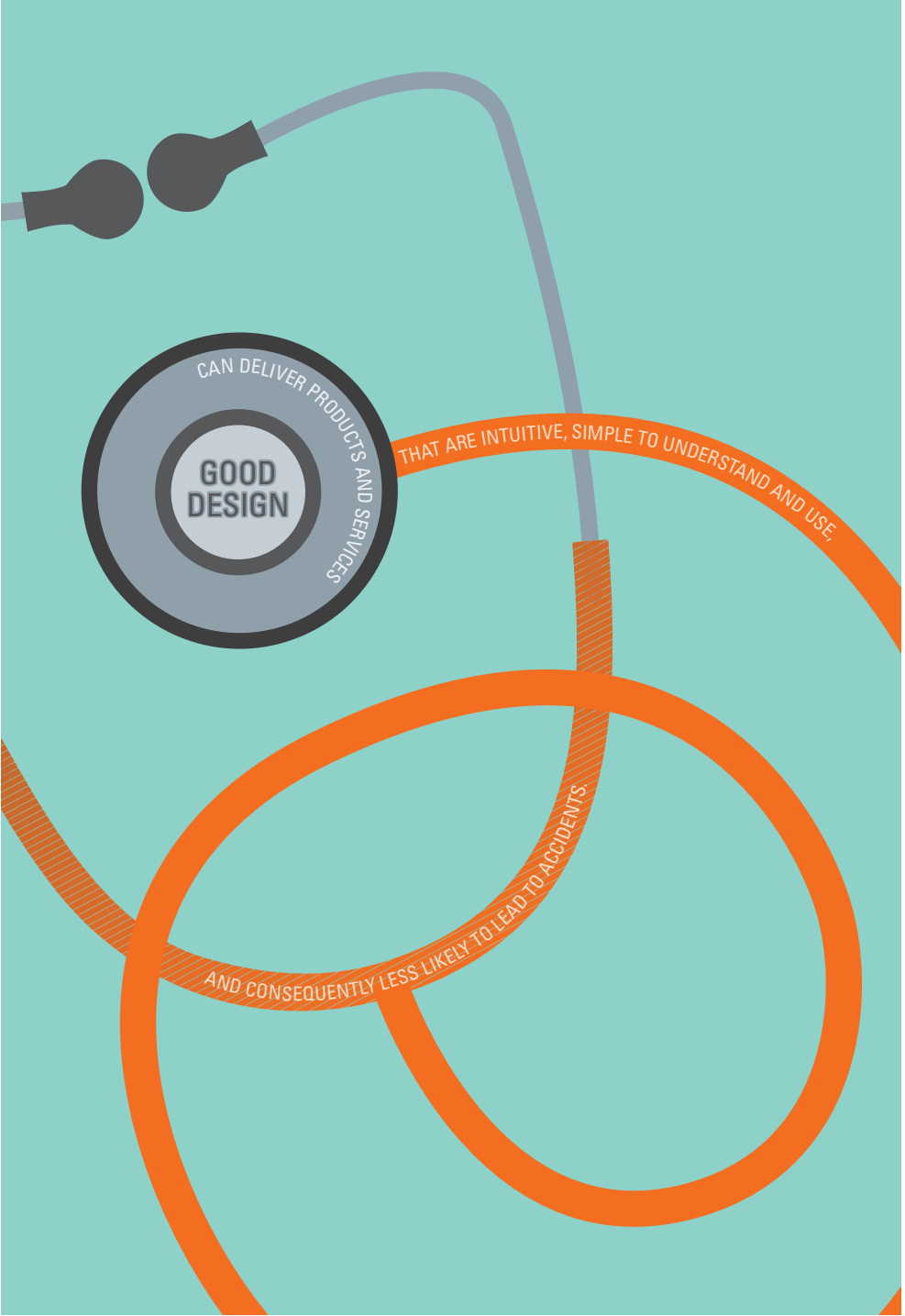
**3 Evaluating for safety and ease of use**

**4 Managing risk**

**5 Communicating the importance of design for patient safety**

**6 Establishing a strategic advisory panel to oversee a design-led approach to patient safety.**

The recommendations have been drawn from the disciplines of systems engineering, healthcare ergonomics and user-centred design. They are followed by a detailed plan of action and a selection of preliminary projects that will give substance to the ideas outlined in this report.






# 2 RECOMMENDATIONS

The recommendations that follow are a summary of those provided to the Department of Health by the initial scoping study undertaken by research teams at the Robens Centre for Health Ergonomics at the University of Surrey, the Helen Hamlyn Research Centre at the Royal College of Art and the Engineering Design Centre at the University of Cambridge. Please see the full scoping study report for more extensive discussion around each of the 13 recommendations and 45 action points provided therein.[1]

## 1 BUILDING AN EFFECTIVE NHS KNOWLEDGE BASE TO UNDERPIN BETTER DESIGN DECISION-MAKING

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

The health service must emulate the approach taken by other high-risk industries: informing the design process by learning precisely how the different parts of the organisation function and interact with each other

and by engaging in a constant process of review and improvement. To achieve this, the NHS should obtain the necessary knowledge from the following areas:

### WHEREVER THE HEALTHCARE SYSTEM INTERACTS WITH PATIENTS

This entails gaining a thorough understanding of the healthcare environments that exist in hospital wards, ambulances, the home, pharmacies, GP surgeries and so on. Because this is a very large undertaking, the initial research work should first address priority areas of concern such as obstetrics and gynaecology, and medication.

### THE CONNECTIONS BETWEEN THE DIFFERENT PARTS OF THE HEALTH SERVICE

Communication and the flow of information between the many different parts of the health service are vital to patient safety. The same can be said about different working practices and cultural issues. So an in-depth knowledge of these issues is required to ensure the effectiveness of any design solutions offered to prevent medical mistakes. This entails mapping out staff roles and responsibilities – and the flow of people, products and information within the system – to ensure a comprehensive understanding of the way in which the component parts of the NHS fit together. Consultation with healthcare professionals is essential to the success of this process. It is also vital to identify organisational conflicts and barriers to change that affect patient safety and understand how other industries have succeeded in removing them.





### HEALTHCARE TASKS IN HIGH-RISK SITUATIONS

In their dealings with patients, healthcare professionals regularly undertake tasks that have risk attached to them. These tasks might appear straightforward – for example, ensuring that a patient is provided with the correct drug in the right quantity – but checking and careful attention to detail are required to ensure this happens without error. When staff members are also caring for many other patients at the same time, the possibilities for errors and mistakes increase. This is also the situation where the same piece of equipment, packaging or information is used in a hospital ward, in a patient's home, on the roadside at night, or under pressure in emergencies. To pinpoint the risks, it is essential that more knowledge is gained about tasks undertaken around accident hot-spots in the home, around the hospital bed, during patient transfers, when paramedics are using shorthand in critical situations and when patient records are being transcribed.

### THE REQUIREMENTS OF BOTH PATIENTS AND HEALTHCARE STAFF

The variety of situations in which equipment and information have to function in the NHS, together with the range of potential users, increases the need for accurate data on health service staff and patients. This can be achieved by encouraging designers to work closely with appropriate groups of stakeholders and patients, especially with those 'critical groups' whose responsibilities and working environments present the highest risks (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 environments, and patient groups). For example: older people and those for whom English is a second language and who are likely therefore to have problems reading and understanding medication packaging and information leaflets; paramedics and accident and emergency clinicians who may experience similar problems under stressful working conditions. An in-depth understanding of these needs and capabilities will help to produce safer designs for all users of the NHS.

## DEVELOPING A BODY OF BEST PRACTICE ON DESIGNING FOR PATIENT SAFETY

A series of case studies and projects should be developed that demonstrate how user-centred design practice can lead to better, safer – and therefore more desirable and competitive – products. These examples can be used to raise awareness across the healthcare industry of the commercial benefits of considering patient safety from a systems perspective when designing products.

## IMPROVING THE DESIGN AND MANAGEMENT OF HEALTHCARE INFORMATION

The design of information is a key component of a safer healthcare system. The structure and content of information and the means by which it is captured, stored and accessed are particularly important if it is to effectively meet the needs of its users and make the most of the technology available. There are three key requirements in the healthcare sector:





### 1 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.

But access to the complete medical history of a patient is not always possible: separate notes are kept for primary and secondary care, and different sets of notes are sometimes held in different parts of a hospital. Patients are also often responsible for providing the hospital with their medication history – which may not be accurate or complete. Safe and effective knowledge management is the result of careful design and the following approaches are recommended to deliver effective patient related information:

- **Standardisation –** Patient notes need to minimise the time taken to record accurate and complete information and maximise the information available to others in a coherent form. Standardising forms and reporting syntax aids this process – by improving accurate analysis and diagnosis and by lessening the chance of mistakes caused by the use of different descriptions for the same condition.
- **Evidence trails –** The treatment rationale must be visible in the notes – in other words, there must be a clear trail of evidence from patient symptoms to treatment protocol.
- **Access –** Healthcare staff must have 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 to patient notes if they are to check medication regimes.

**2 Effective monitoring and maintenance of medical equipment**

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

**3 Effective information sharing**

There is also an urgent need to find an effective means of disseminating critical information to healthcare professionals and of keeping this information up to date. Consultants have to know the latest innovations in their field, GPs the latest drugs and drug reactions, pharmacists the source of the cheapest drugs – to name but a few. This raises the question as to how design could best be used to disseminate such information to busy professionals.

## 2 DEFINING EFFECTIVE DESIGN REQUIREMENTS FOR PATIENT SAFETY

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 an early stage of product development, patient safety may well be compromised. The NHS should encourage better design decision making by:





### SETTING MORE EFFECTIVE DESIGN REQUIREMENTS

Effective design solutions to healthcare systems 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. These design requirements must be understood and incorporated into product specifications and regulatory requirements if safer designs are to be commissioned, procured and more widely used across the NHS. Consequently, the quality of purchasing criteria, standards, guidelines and effective design briefs are both at the heart of the problem and an important part of the solution.

A clearer understanding is also required of how the many and diverse purchasing policies of the NHS impact on the design and promotional strategies adopted by manufacturers, so that the NHS can more favourably influence the design of products with regard to patient safety. NHS purchasing decisions, for example, must take into account the needs of users and the ease of use of products, not just price. They must also be based on the life-cycle costs.

### INVOLVING HEALTHCARE USERS, PURCHASERS, DESIGNERS AND MANUFACTURERS AT ALL STAGES OF THE DESIGN PROCESS

These stakeholders should be involved at all levels of the process of identifying, understanding and addressing risk within the healthcare system. There should be closer liaison between manufacturers and end users throughout the design commissioning period and end-users should also be more effectively consulted in procurement decisions.

### INVOLVING THE APPROPRIATE AGENCIES IN DESIGN AND RISK MANAGEMENT

There is a significant opportunity to involve NHS agencies, along with the new National Patient Safety Agency, more effectively 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 a potentially significant impact on patient safety.

Learning from and integrating the appropriate agencies at each stage of the process (from capturing and identifying problems and design requirements to conducting post-implementation evaluation) should 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 and services.

## 3 EVALUATING FOR SAFETY AND EASE OF USE

To ensure patient safety, a standard guide needs to be developed that shows how to evaluate the effectiveness of new designs for individual services and products and their interactions with other elements within the system. There is also a need to introduce effective procedures to monitor the performance of existing designs. Such assessment is





particularly important when systems are changed – by the adoption of new working practices, for example, or the introduction of a new monitoring device. The effect of such a change must be evaluated to determine whether the new system meets its safety and operational requirements. There is also a particular need to establish a common language for preparing incident evaluation reports – much success in this area has been achieved in the USA.

## 4 IDENTIFYING, CONTROLLING AND MANAGING RISK IN THE NHS

Successful businesses, whose products or methods of operation raise safety concerns for their staff or customers, minimise the possibility of errors by being proactive. This means avoiding risk wherever possible, evaluating the risks that cannot be avoided, combating 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. The NHS needs, therefore, to implement consistent and effective risk management strategies at all levels of the organisation, by building on examples of 'best practice' in other industries and in healthcare services internationally. Such a strategy will prevent significant opportunities to identify risk from being lost – risky situations, risky moments and risky items of equipment – which could in turn be addressed by design.

## 5 COMMUNICATING THE IMPORTANCE OF 'DESIGN FOR PATIENT SAFETY' ACROSS THE HEALTHCARE INDUSTRY

The NHS should demand safer products from manufacturers, including ones which are easy and intuitive to use. Manufacturers respond to what the NHS demands – least-cost design solutions – but are not specifically motivated to advance patient safety as there is no incentive for them to do so. When buying in bulk, the health service has sufficient leverage to influence the market and this should be exploited to encourage 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 health service needs to develop an understanding of what drives industry and where that differs from the needs of patients and healthcare services, and then look at ways in which these conflicts can be resolved to increase patient safety.





## 6 ESTABLISHING A STRATEGIC ADVISORY PANEL TO OVERSEE A DESIGN-LED APPROACH TO PATIENT SAFETY

Many obstacles will need to be overcome before a system-wide design-led approach will have an impact on patient safety. There are many stakeholders involved in the design decision-making process in healthcare, and influencing their behaviour in a systematic way will need to be driven from the centre. An authoritative advisory body is needed to drive the necessary changes through the health service and oversee the new approach to preventing medical mistakes. It will be composed of individuals working in the stakeholder and design communities – and its brief will be to assist those responsible for following through on the recommendations of this report (which are discussed in more detail in the following section). The members of such an independent body would co-operate with the National Patient Safety Agency. They should also be properly resourced to ensure they have sufficient status within both the design and healthcare communities to work effectively.

# 3 A PLAN OF ACTION

The scoping study's recommendations provide the foundations of a design-led approach to improving patient safety in the NHS. To facilitate this new method, and to ensure the effectiveness of the recommendations of this report, a practical course of action is proposed that will begin to address the design issues that affect incidence of error and accidents in the health service.

## 1 BUILDING AN EFFECTIVE NHS KNOWLEDGE BASE TO UNDERPIN BETTER DESIGN DECISION-MAKING

Achieving this recommendation would result in the availability of a useful, accessible and centrally available knowledge base to inform the design process. To deliver this, the following areas must be addressed:

### A WHEREVER THE HEALTHCARE SYSTEM INTERACTS WITH PATIENTS

#### A1 Primary care

Knowledge of these areas could be gained through specific research initiatives in the shorter term and a focused collaboration with the research councils over a longer period. Information capture would be both systematic – through structured observations, recording and reporting – and anecdotal, by tapping into the practical experience of relevant health professionals.





#### A2 Home care

A thorough understanding of research initiatives in this area is essential if the key issues such as the high levels of medication non-compliance are to be understood. Knowledge of the contexts in which patients are failing to take their medicines as prescribed is essential if future work is to be efficiently and effectively targeted to improve patient safety in the home. Only then can design solutions be developed against the background of well-understood contexts in which they will function. It will also make it easier to evaluate the effectiveness of new designs as to whether they really are improving patient safety and supporting care-givers in carrying out their work.

#### A3 Secondary care

This should be a simpler task given the greater availability of research studies in this area. As well as using the research methods outlined in the last section, the research should also include a review of relevant literature.

#### A4 Mapping 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. This work must involve the many stakeholders and care-givers involved in the system as they can identify design-relevant factors that other research may well fail to capture.

## B HEALTHCARE TASKS IN HIGH-RISK SITUATIONS

### High-risk activities – risky situations, risky moments and risky items of equipment

These must be identified and prioritised. Information about the prevalence of particular errors is available in published literature and through discussion with stakeholders. Mapping out patient pathways through the healthcare system can also help to identify potential 'hotspots' and activities that might contribute to a higher possibility of errors. A patient pathway is the connection between patients, healthcare professionals, artifacts for treatment (eg medication) and organisations, through which information and medication flow. A task analysis should then be undertaken for each identified high-risk activity, which in turn can be fed back into the system and used to underpin its redesign to improve safety. For example, task analysis could have an impact on the design of machine interfaces, health protocols, personnel selection, training requirements and on job and team design.

## C DEVELOPING A BODY OF BEST PRACTICE ON DESIGNING FOR PATIENT SAFETY

Exemplars of effective patient safety designs should be captured in case studies and through practical demonstration projects. With research funding, academics can be encouraged to identify and evaluate examples of good industry practice. Design journals can then be actively encouraged to seek papers on the subject and design magazines to publicise articles on 'best practice'. There should also be design industry competitions, sponsored by the Department of Health and others, partnerships between medical colleges, pharmaceutical companies and UK design schools as well as collaborations between healthcare professionals and appropriate research institutions. In addition, examples of international 'best practice' could be researched and publicised.





## D IMPROVING THE DESIGN MANAGEMENT OF HEALTHCARE INFORMATION

### D1 Introduce a unique ID for every patient in the UK

Before other issues of information access can be addressed, it is vital to know that whatever medical notes are under discussion actually refer to the right patient. The introduction of a unique patient ID across the UK would make such identification much more reliable – this concept is currently being assessed in Scotland.

### D2 Defining user needs and best practice for:

#### D2i The design and use of patient information

An analysis of the information needs of all professionals involved in patient care must be undertaken, coupled with a survey of current systems and approaches. Protocols for data management can then be defined and trialled with the help of those intending to use the system.

#### D2ii Prescribing and administering critical medicines

Immediate progress may be made in this area. For example – the integration of medication protocols with patients' medication charts can reduce errors and, at the same time, provide evidence of the dosing rationale for a particular patient. Although this happens to some extent at the moment, it does so only on a highly ad-hoc basis.

#### D2iii The design and use of equipment information

Much can be learnt from the experience of other industries in which such information management systems are commonplace. In addition, a study should be undertaken to define the requirements of an equipment information system for healthcare.

#### D3 Identify and remove barriers to information sharing

Undertake a survey to uncover existing barriers and suggest alternative ways of disseminating information to busy professionals.

#### D4 Learn about effective information networks

Effective delivery of critical information requires a balance between the amount of information and its visibility. So design solutions to this problem must package information in a form that recipients can assimilate in the time they have available for this task. Much can be learnt from other industries that face similar issues – and from those in the healthcare profession, such as hospital pharmacists, who already run effective information networking activities.

## 2 DELIVERING EFFECTIVE DESIGN REQUIREMENTS FOR PATIENT SAFETY

This will be facilitated by:

### A DEVELOPING 'USABILITY' CRITERIA

One way to ensure common industry and NHS objectives for the development and procurement of safer designs is to develop clear criteria for the 'usability' of its products and services. These criteria





should be applied across the board – covering equipment, packaging, information and the form of medication itself – and be as effective for patient care in the home and the community as in secondary care. Competition between manufacturers would then be redirected to meet the criteria in cost-effective ways, while the improvements in usability they introduce would reduce errors and lighten the load on hard-pressed staff. There have been cases where patients have been seriously injured when a nurse has misread the number seven for one, and has over-infused as a result. Because the flow read-out was hidden in the display panel, the top of the seven was obscured from view. This small design flaw can result in a serious problem. By considering human factors and creating usability criteria for particular devices, this should decrease the risk of such adverse consequences.

### B DRAWING UP SPECIFICATIONS FOR SAFER EQUIPMENT

Evidence gained from safety assessments and in-use monitoring of performance can be used to help devise equipment design specifications. Similar to the development of usability criteria, using such assessments as the basis for design specifications would further encourage manufacturers to deliver measurable improvements in patient safety. They would also make NHS purchasing choices, which currently are driven by lowest-cost comparisons and the subjectivity of senior health professionals, more realistic and rational. This could offer an alternative to standardisation, which may not always deliver the required improvements in patient safety. This is illustrated by a case in which a physician treating a patient with oxygen set the control knob to between one and two litres per minute, not aware that the

numbers represented a discrete rather than continuous setting. No oxygen was flowing through, yet the knob rotated smoothly, giving the suggestion that the intermediate setting of the machine was possible. The patient became hypoxic before the error was discovered. A design solution would have been a rotary control that snaps into a discrete setting along with some indication of flow.

### C CREATING 'LIFE-CYCLE COSTING' GUIDANCE

Current purchasing criteria for products and services are based on cost rather than patient safety. A more rational approach would be to consider life-cycle costs. Although the initial purchase price of a particular piece of equipment may be lower than that offered by a competitor, once durability and reliability are taken into account, the picture may change. Many other factors impact on the life-cycle 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 applied to whole-life costs would offer a more rational basis for purchasing decisions. By introducing such guidelines, product requirements could be more accurately stated and industry would compete to deliver value for money against those requirements. Life-cycle analysis is already being used to assess the environmental impact and sustainability of some products – and the knowledge gained in these areas should now be applied to patient safety.





### D DEVELOPING ADEQUATE PATIENT SAFETY GUIDELINES FOR PACKAGING DESIGN

This should help to remove the repeated confusions that arise from similarities of name, brand identity, colour, box size, shelf position, and inconsistent or confusing packaging of medication.

### E GENERATING A BETTER UNDERSTANDING WITHIN THE INDUSTRY ABOUT THE IMPORTANCE OF A SYSTEMS VIEW OF DESIGN AND SAFETY

Safe products and services can only be successfully introduced into the NHS by clearly understanding the environment into which they will be introduced. Safety depends on taking a systems perspective to design and this must be properly understood by the healthcare industry. An example of good design and systems thinking in manufacturing is the 1.5hp – 3hp range of Hydrovane compressors. Faced with a declining market share the company redesigned its models, reducing direct manufacturing costs by 50%. The key was repackaging all elements of the units except the heart of the well-proven compressor. Assembly, test, servicing, manufacturing methods and production lead-times were all defined right from the initial concept stage, resulting in a concentric stackable design configured to allow fast and easy assembly. By taking into account the total system of manufacture, the business cut overall production lead times from weeks to days.

### F DEVELOPING GUIDANCE FOR ENGAGING STAKEHOLDERS IN THE DESIGN PROCESS

Guidance is needed on how to do this successfully. The scoping study[1] used a number of methods for understanding and recording the experiences of healthcare users, purchasers, designers and manufacturers. These helped identify problems and possible sources of errors and also increased the participants' understanding of real patient issues. The methods used here have been recorded and could form the basis of future studies.

### G IMPROVING COMMUNICATION BETWEEN STAKEHOLDERS

Close liaison between healthcare users, purchasers, designers and manufacturers, particularly throughout the commissioning and development period, ensures that potential problems are quickly identified. It also enables the effective evaluation of equipment and the adoption of appropriate strategies for the implementation of change within the NHS.

### H RESOLVING CONFLICTS OF INTEREST BETWEEN STAKEHOLDERS

Workshops led by a professional facilitator are a practical means of achieving this objective. More than 90% of those invited to the workshops organised for the scoping study, did in fact attend, providing strong evidence of stakeholders' commitment to resolving the challenge of medical error. Once around the table, with a shared goal in mind, conflicts can be broached and ameliorated.





### I REVIEWING AND REFINING THE REMIT OF RELEVANT AGENCIES

This review will place the agencies' responsibilities in the context of patient safety to provide a clearer picture of the extent of current guidance and controls. Mapping NHS agency responsibilities against patient safety issues will enable a clearer understanding of their respective roles, useful both for stakeholders within and beyond the health service. Where gaps or omissions are evident, it will be important to clearly define a change of remit and responsibility of the appropriate agencies to meet patient safety design requirements.

## 3 EVALUATING FOR SAFETY AND EASE OF USE

The groundwork for developing an effective system for evaluating safety within healthcare should be undertaken by:

### A DEVELOPING GUIDELINES TO EVALUATE THE EFFECTIVENESS OF CHANGE

New guidelines are needed to evaluate changes in the healthcare system (eg as a result of new equipment or revised operating protocols). Before new equipment or revised operating protocols are introduced into the NHS, thinking about the evaluation should begin by defining the specification of a new system. Such thinking continues throughout the whole life of the system, until it is removed from use. It is important that any such assessment is consistent with other major healthcare systems.

### B ENSURING A COMMON UNDERSTANDING OF THE DEFINITIONS OF MEDICAL ERRORS

Common definitions of medical errors must be agreed across the healthcare system. Evaluation often requires reference to historical data and information relating to similar systems – and a study of the way in which other industries approach this issue would help with the preparation of such definitions. In practice, however, it is important that agreed definitions of medical errors are derived from the risks inherent in the particular system under investigation. The US has undertaken some initial work in this area – and this now needs to be further developed.

### C ENCOURAGING IN-USE AUDITING AND VALIDATION OF THE DESIGNS OF EXISTING PRODUCTS

Validation establishes that designs do what they are required to do. In other words – have we built the right thing? How effectively have we done this? And what scope is there for improvement? Validation during design development and later in post-production, is essential if task analysis and user-research (which help this process) are to prove effective in reducing risk and error.

### D COMPILING A DATABASE OF EVALUATION METHODS

This would prove useful for industry and the NHS. It would help bring about a common understanding of what evaluation can achieve and the best methods that should be used in any particular case. Such a database might also include information to assist the assessment of comparable products – such as advanced simulation methods and the results of past evaluations.





## 4 IDENTIFYING, CONTROLLING AND MANAGING RISK IN THE NHS

Three initial steps should be taken to achieve this recommendation:

### A TRAIN PRIMARY AND SECONDARY CARE STAFF IN RISK ASSESSMENT

Nurses, doctors, pharmacists and paramedics are trained to recognise and respond to various patient conditions. But their professional training does not equip them to assess 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.

### B ENCOURAGE CONTINUOUS RISK MANAGEMENT

Some activities are obvious sources of potential injury – such as staff using complex equipment for which they have not been trained. Some risks are less apparent – for instance, when a doctor writes a prescription for a patient who he/she does not know. Effective evaluation of such risks requires efficient feedback between stakeholders. Once risks have been identified and steps taken to protect patients from injury, continuous management is required to prevent a resurgence of accidents.

### C APPLY THE RISK MANAGEMENT PROCESS TO SAFETY HOT-SPOTS IDENTIFIED THROUGH ANALYSIS OF THE PATIENT PATHWAYS

Once risks have been identified, strategies for minimising them should be applied to the hot-spots in patient pathways throughout the healthcare

system, and in particular to the processes involved in medication and equipment procurement. By working with the stakeholder groups that were established for the purpose of this study, it is possible to make an early start on the process of identifying and controlling such risks.

## 5 COMMUNICATING THE IMPORTANCE OF 'DESIGN FOR PATIENT SAFETY'

To ensure a wide appreciation of the need to use a systems-based, user-centred approach to design in healthcare, the following approaches should be put into practice:

### A RESEARCH THE BEST COMMUNICATION METHODS FOR INTERFACING WITH INDUSTRY

Once these are clearly understood, the new approach to design for medical safety should be disseminated to designers and decision makers in industry.

### B QUANTIFY HOW MUCH THE PHARMACEUTICAL AND MEDICAL DEVICE INDUSTRIES SPEND ON DESIGN

These industries make a considerable investment in design. Much of this expenditure is focused on branding and product differentiation as a way of increasing sales and profitability. A significant proportion of this spend could incorporate or be redirected towards designing for patient safety. Understanding how much is spent, why, and towards what ends could identify opportunities for design improvements and also tap into significant funds at a relatively low cost to the NHS.





### C ENCOURAGE MANUFACTURERS TO IMPROVE THE SAFETY OF PRODUCTS AND SERVICES

Basing NHS purchasing decisions on well-founded criteria for usability and patient safety should stimulate innovation and competition among commercial producers. Manufacturers who meet the criteria will see this as a means of making their products stand out from the crowd – not just in marketing to the NHS, but to other healthcare markets as well.

### D ENCOURAGE THE NHS TO USE ITS 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.

### E MAKE THE NHS MORE ACCESSIBLE TO DESIGNERS

Currently, design students and professionals have to negotiate too many bureaucratic hurdles before they can gain access to healthcare staff and environments to carry out research. This does not encourage practical work in the field – and special arrangements should be introduced allowing designers more ready access to the health service. Steps should also be taken to ensure that healthcare and medication design issues are incorporated into design curricula at all levels, and that these can be disseminated to a wider audience, including industry.

## 6 ESTABLISHING A STRATEGIC ADVISORY PANEL TO OVERSEE A DESIGN-LED APPROACH TO PATIENT SAFETY

This should begin by defining the scope and operation of an advisory panel, which would work closely with the National Patient Safety Agency. The supporting research for the initial study contains considerable work on these areas, and should act as a starting point for any such initiative. The exact workings of the panel are beyond the scope of this report, but it should be an active working group which assists those responsible for following through on the recommendations, to ensure that:

- Research areas are clearly defined and funding is encouraged for research aimed at understanding the design implications of medical errors.
- Significant sources of error and adverse events are explored from a design perspective.
- Relevant design information is fed back to industry and the NHS so as to focus future investment on patient safety.
- Future design decisions are made on the basis of sufficient relevant 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.
- Purchasing decisions are made on the basis of sound evidence of value for money when the costs resulting from adverse events are taken into account.





# PRELIMINARY PROJECTS

A number of initial projects are also being put forward to improve safety in parts of the health service. They are examples of the kind of work that needs to be undertaken to begin to get to grips with the problem of medical errors in the NHS. They are not an alternative to the recommendations and action plan outlined above, but should rather be seen as complementary to – and building upon – the system design approach.

## PROJECT 1

Tackle the issue of non-compliance in the community – in collaboration with a major pharmacy chain

**The aims:** to improve treatment efficacy especially for those on complex drug regimes; to minimise mistakes and adverse incidents and to develop an integrated system that unites users, carers and manufacturers.

## PROJECT 2

Develop a standardised design for a personalised medication dispenser

**The aims:** to improve the reliability of dispensing medicine; to reduce the potential for errors and to place the patient at the centre of an integrated health service safety culture.

## PROJECT 3

Introduce a system for a single patient ID for the NHS

**The aims:** to reduce the potential for mistakes.

## PROJECT 4

Develop usability criteria for the purchase of medical devices

**The aims:** to provide information on key equipment requirements and characteristics to help smart purchasing.

## PROJECT 5

Develop and design pharmaceutical packaging and labelling that reflect the needs of all users in the NHS

**The aims:** to reduce the possibility of errors and to develop a culture in which the health service takes a lead in the design of healthcare products.





## PROJECT 6

Undertake a risk assessment of patient safety in defined care pathways to prioritise safety design improvements

**The aims:** to develop a culture of risk assessment, surveillance and prevention.

## PROJECT 7

Identify and publicise the best international examples of medical safety designs

**The aims:** to foster a new climate of co-operation between designers, manufacturers and healthcare providers.

## PROJECT 8

Work with the United States and other systems worldwide

**The aims:** to identify and learn from global best practice.

# 4 THE WAY FORWARD: THE GOVERNMENT'S RESPONSE

Improving the quality and safety of care is at the heart of the Government's strategy for moving towards a more patient-centred and responsive National Health Service.

The preceding pages give a new perspective on the NHS, setting out the need to think in broad design and system terms, much more so than we do at present – not just in terms of the design of specific pieces of equipment or buildings, but in all aspects of the services we deliver for NHS patients.

For example, before reorganising healthcare services, in introducing new solutions to improve care, when commissioning or purchasing healthcare products, there is a need to always consider the wider issues of safety and usability, the needs of those who will or could potentially be involved, how changes will operate in real situations and how they will impact on the broader healthcare system.

This broader systems-design approach can already be found in many areas of the NHS, and there are some excellent examples of work which begin to meet many of this report's recommendations.

- Our National Service Framework and Cancer Plan programmes demonstrate examples of taking a more 'whole systems' approach to improve the delivery of care in key areas of NHS services.





- The National Patient Safety Agency is already beginning to improve the safety of NHS patient care and is spreading a culture of reporting and learning from when things go wrong across all areas of the NHS.
- The National Programme for Information Technology (NPfit) is already addressing at least two key areas highlighted in this report: the NHS Information Authority has previously mapped an extensive range of NHS healthcare processes – providing a knowledge-base for the NHS to draw upon – and the National Programme is working to deliver an Integrated Care Record Service and, through its National Design Authority, an NHS-wide Enterprise Architecture.
- A group drawn from the Medicines and Healthcare products Regulatory Agency, National Patient Safety Agency working with manufacturers, healthcare professionals, patients and others has developed best practice guidance on safer labelling and packaging of medicines, for immediate implementation and with the support of the pharmaceutical industry.
- Work is also ongoing to improve the quality of the information provided to patients with their medicines and to further develop and extend the use of child-resistant packaging.

However, there is no doubt we can do more to systematically instil this thinking.

## THE WAY FORWARD

The Government's Chief Medical Officer will lead a multi-agency programme board of stakeholders and expert advisers to consider how best to implement the recommendations and actions suggested in this report, to identify key projects that already demonstrate the benefits of the systems-design approach to safety which can be used to spread this thinking more widely, and to consider any gaps or overlaps in the current structures. The National Patient Safety Agency will take a major role within this programme.

The programme board will aim to encourage existing project teams to work in partnership to maximise benefits and will seek to draw on advice and expertise from networks of experts in this field to support specific projects or the overall programme.

The healthcare industry will be crucial to the success of this programme. The *Design for Patient Safety* initiative brings an opportunity for us to work in partnership with industry to help ensure that the design of healthcare products increasingly focuses on delivering safer patient care.

The early stages of the *Design for Patient Safety* programme are unlikely to have major resource or cost implications, as initial work will involve a great deal of drawing together of existing projects. However, there may be costs and resources as well as benefits involved in implementing aspects of this ongoing programme. We will carefully consider the cost implications of the proposals, piloting projects as necessary and assessing risks and resource implications as would be





the case for any similar work. We will also work with industry and key stakeholders across the NHS to get best value for money from the proposals.

This is not a 'quick fix' approach, quite the reverse. This programme is about safety of care and 'whole systems' design – for many of us in the NHS and in Government this will require a different way of thinking, one which will take time to bed in.

However, implementing the approach set out in this report will allow the NHS to design safety into its systems and processes, as well as its products and services – into all aspects of the way we deliver care for NHS patients.

Consequently, the Government welcomes the *Design for Patient Safety* report. The study provides us with a framework to help achieve a health service where all those who have an influence in delivering care have the safety of patients at the front of their minds, and where decisions increasingly take into account the wider implications for patient safety.

We believe this challenging and exciting initiative has the potential to bring huge benefits to the NHS.

# 5 CONCLUSION

In the past we have assumed that good intentions and hard work have protected the safety of patients. The statistics appear to tell a very different story, with research from other countries confirming just how common medical errors really are. They also demonstrate that there is a huge potential to reduce suffering and avoidable death, if we pay greater attention to safety and quality in design, understand the needs of healthcare providers and patients and anticipate mistakes. To achieve this we need to learn from other industries – such as airlines and nuclear power – where safety is 'mission critical' and a systems approach has been taken to designing out the opportunity for error.

As health services around the world are suffering similar problems of equal magnitude, these can reasonably be expected to have similar causes and similar solutions. This represents a significant opportunity both for the NHS and the UK healthcare industry to respond to this challenge. The nature of the NHS gives us the opportunity to implement an integrated, comprehensive design-led approach to patient safety. The UK healthcare industry can benefit from this new-found awareness in its sizable domestic market, enabling its companies to add value, innovate and differentiate their products through safer design thinking.

However, the UK will only reap these dividends if the healthcare sector embarks upon an extensive knowledge-gaining programme





to understand how a poorly designed healthcare system regularly contributes to medical accidents and, crucially, applies systems- and user-centred thinking. The complexity of this task should not be underestimated. It is a major undertaking that will require significant changes in the way in which medical accidents are perceived and managed. But it is an essential one if the safety of both patients and staff in the NHS is to be significantly improved.

The Government is now putting in place a programme of work to take forward the strategy outlined in this report. This is just the first step of many required to address the safety issues that exist in the health service through design. A much wider plan of work is now needed to implement this design-led approach to patient safety so that it can become embedded into everyday working practices of the health service.

The safety of patients in our National Health Service is a major Government priority. By introducing the changes suggested here, the NHS will begin to make real inroads into a problem that afflicts healthcare systems all over the world. In doing this, the health service will forge a path that other care providers will, in time, come to emulate.

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