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DESIGNING FOR PATIENT SAFETY: A REVIEW OF THE EFFECTIVENESS OF DESIGN IN THE UK HEALTH SERVICE

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1. Introduction

The health service is a highly pressured 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 [Kohn *et al*. 1999] and perhaps as much as a half of these adverse events are judged to be avoidable. In the UK, it has been estimated that 850,000 medical errors occur every year – equating to some 10% of hospital admissions, the cost of which is suffering for patients, families and NHS staff involved and £2billion in additional hospital stays alone [Yeates *et al*. 2001].

Design is a structured process for identifying problems and developing, testing and evaluating user focussed solutions. It has been successfully used to transform products, services systems and even entire organisations. 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 [Bates *et al*. 1997].

The remainder of this paper describes a study commissioned by the Department of Health, in conjunction with the Design Council, the lessons learned and the key findings presented.

2. Scope of the study

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 multiple breakdowns in a system. The study consequently explores the potential for improved design interventions in a whole system context. This is potentially a very broad area of investigation, hence this study focused on medication error and approached the subject 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, including 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.

3. Research methods

The research team employed diverse methods to gather evidence from literature, key stakeholders, and experts from within healthcare and other safety-critical industries. Importantly, it responded to recommendation 120 of the Learning from Bristol report [Kennedy *et al*. 2001] by bringing together managers in the health service, representatives of the pharmaceutical companies and manufacturers of medical equipment, members of the healthcare professions and the public.

The methodology adopted to achieve the objectives of the study comprised three mains parts:

- the development of a baseline of information to inform 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 UK 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. 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 Figure 1.

Objectives \ Methods	1 Systematic literature review, journals and conference papers	2 Literature review, reports and 'grey' literature	3 Information exchange with international experts	4 Prior experience of research team	5 Interviews with healthcare practitioners	6 Input from senior health service and agency personnel	7 Focus groups with healthcare practitioners	8 Workshops with stakeholders from the healthcare sector	9 Workshop with designers	10 Workshop with input from other safety critical sectors
1 Developing baseline information	✓	✓	✓	✓	✓	✓	✓	✓		
2 Investigating special cases	✓	✓			✓		✓	✓		
3a Identifying problems	✓	✓	✓	✓	✓		✓	✓		
3b Identifying best practice	✓	✓		✓	✓	✓	✓	✓		✓

Figure 1. Methods and objectives

3.1 Developing a baseline of information

There is much published material concerning medical error that has emerged from the UK, USA and elsewhere in recent years. Carrying out 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 medication errors due to poor handwriting.

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, 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" [Ingram *et al*. 2000] was used as an illustration of dispensing error. 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.

3.2 Investigation of specific cases

A number of interviews were held with healthcare practitioners/deliverers to set the scene and highlight specific medical issues. These included: general practitioners in both dispensing and non-dispensing practices; practice manager; phlebotomist; head pharmacist in a high street pharmacy; nursing policy manager; consultant in accident and emergency; a chief-executive of a community trust and Social workers. 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, the opportunities for design interventions in each case and their ranking in terms of potential risk and effectiveness.
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 organised a workshop to meet with experts from other safety critical sectors and discuss 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 to suggest where practical system design improvements could be implemented and tested.
A series of workshops was held to facilitate a better understanding of the challenges facing stakeholders across the healthcare industry. The participants of these workshops included:

- representatives from across the primary and secondary care sectors;
- representatives from procurement, licensing, and the equipment and pharmaceutical industries;
- various groups of patients, particularly those with long-term or chronic conditions

The workshops were convened to enable the team to capture the priorities and concerns of the stakeholders, taping into their combined expertise, knowledge and experience. 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.
A further workshop included representatives from the first three workshops, with two additional industry representatives: head of a large design group and a product manager. There were also seven design professionals, ranging from recent graduates to senior designers with experience of design in a medical context and of major design implementation projects. Finally, three focus groups were conducted across the three areas of Midwifery, Accident and Emergency and Cancer/Palliative Care.

3.3 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 was ongoing throughout the research period. After collecting information from all the above sources, the research team discussed how best to the present the findings. Consensus decisions were reached, using a Delphi style consensus meeting, 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.

4. Results

Despite the multiplicity of activities and methodologies employed, what emerged from the research was a very consistent picture. One of a complex system of interactions between diverse stakeholder groups. This convergence pointed to the need to better understand this complex system as the context into which discrete 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.

During the course of the study the research team came across little evidence of understanding within the health service 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 health service 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. The authors do not doubt that this issue is by and large shared by other health services around the World. However, there is also no doubt 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 and error and accidents.

There is much scope for transferring the necessary knowledge and practice from other safety-critical industries, such as nuclear, aviation and defence, 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' (see Figure 2) 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.

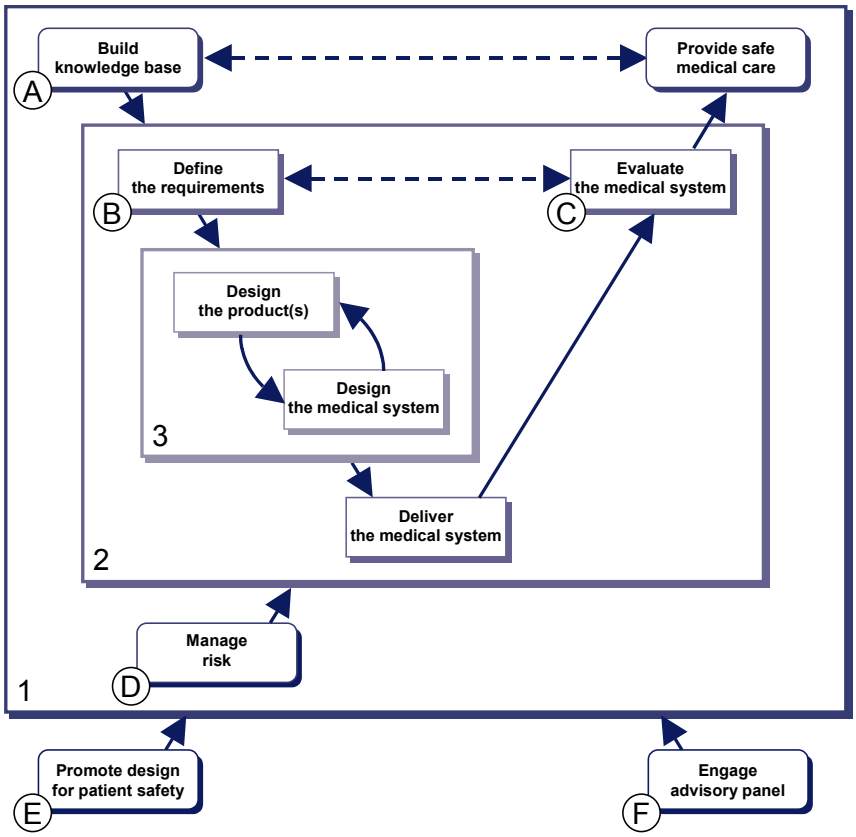

Figure 2. A systems-based user-centred approach to healthcare design

The study 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.

5. Key recommendations

To be successful any design-led 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 (Figure 2). This framework was derived from a review of structured design processes (for example [BS 7000-1 1999]), business processes [Hales 1994], ergonomics models [Moray 2000] and models of verification and validation [Alexander and Clarkson 2000a,b]. The recommendations for change, which align with the boxes of Figure 2, are as follows:

(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 by the NHS of more effective design requirements.
- 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) 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.
(F) Establish an advisory panel to oversee the delivery of the design led approach to patient safety.

The recommendations 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. In summary, 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, there can be no certainty that discrete design solutions will contribute to patient safety.
The results and recommendations of this scoping study were delivered to the Department of Health in the latter part of 2002. The response from the Chief Medical Officer was very positive and the research team were ask to interview the heads of a number of healthcare agencies to ascertain the level of compliance to the systems approach advocated in the report. The response from the agency heads was equally positive. There was some evidence of systems thinking being used, accompanied by a clear desire to improve patient safety through good design practice. The results of the scoping study, along with a plan for action, were launched by the Department of Health in October 2003.

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References

Kohn, L.T., Corrigan, J.M. and Donaldson, M.S. (eds.), "To err is human", National Academy Press, Washington, DC, 1999.

Yeates, M., Jones, I., Kerbel, A., Cox, E., Mapstone, N. and Boyce, J., "A spoonful of sugar – medicines management in NHS hospitals", Department of Health, London, UK, 2001.

Bates, D.W., et al., "The cost of adverse drug events in hospitalised patients", Journal of the American Medical Association, Vol. 277, 1997, pp.307-311.

Kennedy, I., Howard, R., Jarman, B. and Maclean, M., "Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995", Bristol Royal Infirmary Inquiry, CM 5207, 2001.

Ingram, O., Dumbelton, I., Coaker, T., Sheehan, N. and Jewell, T., "Methotrexate Toxicity – An inquiry into the death of a Cambridgeshire patient in April 2000", Cambridgeshire Health Authority, Cambridge, 2000.

BS 7000-1, "Design Management systems - Guide to managing innovation", BSI, London, UK, 1999.

Hales, C., "Managing engineering design", Addison-Wesley, 1994.

Moray, N., "Culture, politics and ergonomics", Ergonomics, Vol. 43, No.7, 2000, pp.858-868.

Alexander, K.L. and Clarkson, P.J., "Good design practice for medical devices and equipment, Part I: A review of current literature", Journal of Medical Engineering and Technology, Vol. 24, No. 1, 2000a, pp.5-13.

Alexander, K.L. and Clarkson, P.J., "Good design practice for medical devices and equipment, Part II: Design for Validation", Journal of Medical Engineering and Technology, Vol. 24, No. 2, 2000b, pp.63-67.

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