

## Patient safety, systems design and ergonomics

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### Abstract

The complexity of the health care environments necessitates an holistic and systematic ergonomics approach to understand the potential for accidents and errors to occur. The health service is also a socio-technical system, and design needs must be met within this context. This paper aims to present the design challenges and emphasises the specialised needs of the health care sector, when dealing with patient safety. It also provides examples of approaches and methods that ergonomists can bring to help inform our knowledge of these systems and the potential towards improving their safety. Mapping workshops provide an example of such methods. Results from these are used to illustrate how the knowledge base required for better design requirements can be generated. The workshops were developed specifically to help improve the design of medication packaging and thereby reduce the probability of medication error. The issues raised are now the subject of further research, design requirements guidance and new design concepts. The paper illustrates the need to engage with the design community and, through the use of robust scientific methods, to generate appropriate design requirements.

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### 1. Introduction

The report ‘An Organisation with a Memory’ (Department of Health, 2000) drew attention to the problem of potentially avoidable events that result in unintended harm to patients. However, the scale of this problem of patient safety is difficult to accurately establish. Published data (e.g. Vincent et al., 2001) suggest widespread and highly prevalent errors leading to adverse incidents, many of which are fatal. The validity of the data is often challenged and under-reporting and reporting bias make interpretation difficult. These problems are not helped by the further confusion surrounding appropriate definitions of terms such as ‘error’ and ‘adverse incident’. Recent attempts to classify adverse drug events and medication errors (e.g. Morimoto et al., 2004) are starting to provide a reliable basis for documenting error in clinical settings and will, hopefully, result in higher quality data being available

to researchers in the future. Indeed, the National Patient Safety Agency’s (NPSA) National Reporting and Learning System (NRLS) now has all 607 National Health Service (NHS) organisations with the capability to report patient safety incidents, with almost all doing so through their chosen route. Despite the limitations of the epidemiological sources and reporting systems (Karsh et al., 2006), there appears to be sufficient consistency in the findings to demonstrate the need for systematic enquiry into the causes of patient safety incidents and the development of interventions to reduce the incidence of error.

The discipline of ergonomics usually advocates a systems approach to the design of work and workplaces. This approach has developed over the past 50 years in order to address the complex interactions that occur between a worker, their tools, their colleagues, and their work organisation. More recently a need to look still further and consider the role of regulations, societal and cultural pressures has been recognised (Moray, 2000).

For the health care sector, this appears to be a daunting, but necessary, challenge. This sector has specific needs given its complexity, scale, and potential impact on its very

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diverse user groups, particularly patients. However, similar complex challenges are being met by a number of other safety-critical industries, including both nuclear and aviation (Buckle et al., 2003). These industries have adopted an ergonomics systems approach precisely because they have realised the dangers of considering only one element of a system in isolation from others. For example, procurement was raised as an issue during a workshop held with representatives from safety critical industries (Cambridge, Surrey, RCA, 2004). Some industries, for example military defence, incorporate an integrated systems approach from the start of the procurement process. Whole lifecycles of products are considered along with other issues, such as available personnel, maintenance costs, attitudes, the competencies of users, training and skill levels needed. All these elements are included in the design costing and a ‘requirements capture’ method has been developed specifically for this purpose. This appears not to be a process that is found in the health care sector. It remains an area requiring urgent research to evaluate the potential benefits for patient safety.

The importance of understanding the causes of errors and the need to undertake a ‘systematic analysis of incidents’ in the health care sector has been stressed elsewhere (Leape et al., 1995; Department of Health, 2001; Audit Commission, 2001). The same argument applies to the need to design within this context and to be aware that the health service is an ever developing socio-technical system.

Systematic ergonomics assessments for understanding accident and error potential are likely to produce the most robust and useful data. When an adverse incident does occur there are likely to be elements within the physical, technological, psychosocial and cultural environments (Nieva and Sorra, 2003; Kho et al., 2005) that are contributing to the event (Health and Safety Executive, 1999). Inevitably, these factors present a significant challenge for those wishing to find ergonomics design solutions to the problems.

This paper:

- presents the design challenges in the health care sector;
- provides examples of approaches and methods that ergonomists can bring to help inform progress towards safer systems;
- illustrates how these approaches might be used to improve the design of medication packaging to reduce the probability of medication error.

## 2. Design challenges in the health care sector

Fig. 1 provides a model of the theoretical process for improving system design in the health sector (Clarkson et al., 2004). It identifies a number of areas that require significant effort if we are to first understand and then

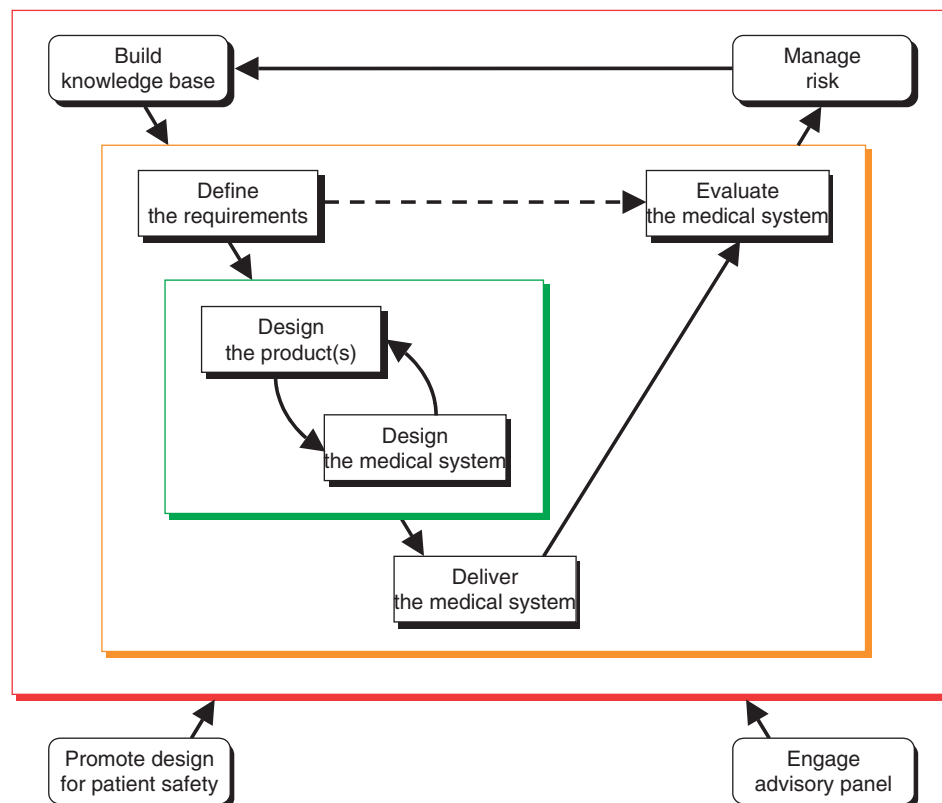


Fig. 1. A systems-based user-centred approach to health care design (Buckle et al., 2003).

improve the safety of health care through system design. This paper will focus on the urgent requirement of building an effective knowledge base that can be used by ergonomists and other system developers to help define design requirements. In fact, ergonomists have a major role to play in both the development of the knowledge base and in developing design requirements. Thus, this paper also deals with a mapping workshop approach that ergonomists/human factors experts might use to meet these requirements. This approach goes some way to meeting the challenge of helping the health care community appreciate the concept of design and its potential for developing safer systems.

### 3. Methods for building a knowledge base for better design

Knowledge is the essential foundation upon which the health service can make evidence based decisions. This knowledge is required so that patient safety hotspots (i.e. risky areas in the health care system) and problems can be successfully and systematically identified, prioritised and acted upon. The first stage of the design process is to develop a good understanding of the problem. Without an effective knowledge base, design briefs and procurement decisions will be flawed and solutions unlikely to be effective (see Fig. 1).

However, our research (Cambridge, Surrey, RCA, 2004) found little evidence of a suitable knowledge base in the health system. What was available was of little help in informing the design process nor could we identify evidence of a body responsible for such a knowledge base. In fact, our results pointed to a complex, poorly understood system where the information that is available is poorly shared across the health care system about what actually happens (e.g. in the home, in the pharmacy, on the ward) or how different conditions impact on the jobs that have to be carried out. Others too (e.g. Ferreira and Hignett, 2005) are recognising the need for an improved systematic knowledge base to inform design requirements. This lack of information is apparent for many tasks, including the challenges of self-administration of medications under differing circumstances, the functioning and use of equipment in different situations, and how information is recorded, transferred, interpreted and understood by users. All of these are further complicated by insufficient information on the differing capabilities of the humans in the system in all the situations in which health care is delivered. The lack of published information about these contexts results in a poor understanding of what is required in order to effectively deliver safe care or on which to build design requirements.

Other safety-critical industries and successful businesses do not have such large knowledge gaps. They understand more thoroughly what happens, when and why, and how individual tasks and elements fit together and interact. They are also aware of the safety implications of these

factors and are engaged in a constant process of review and improvement.

#### 3.1. Mapping workshops

Mapping workshops are one example of a method that ergonomists can use to help generate the knowledge base for better design requirements.

Our recent research (Buckle et al., 2003; Cambridge, Surrey, RCA, 2004) conducted four such workshops. Collectively, the workshops aimed to help deepen understanding of the problems in health care, learn from workers' and patients' experiences (both positive and negative), to identify obstacles and possible areas for improvement, and to prioritise the resulting issues, tease out the design implications and identify opportunities for effective intervention.

Workshops aimed to engage the participants as a group and tap into their combined expertise, knowledge and experience in exploratory and creative ways. A further aim was to prepare the ground for future engagement with the participants in the event of further research being conducted.

To ensure openness from the participants, workshops were conducted under the 'Chatham House Rule', meaning that confidentiality was assured. Discussions were led by a professional facilitator and were recorded on audiotape and through note-taking by several members of the design team. Transcriptions were analysed to produce the results.

Three workshops were held with groups of stakeholders across the health care industry (see Figs. 2 and 3). The data from these sessions were analysed and used to inform and focus a 'creative' workshop. This involved a sub-set of participants from the three health care-related events, working alongside design professionals from the fields of information, product, communication graphics, and packaging design.

The first three workshops took place, in consultation with the following groups from the health care industry.

##### 3.1.1. Primary and secondary health care deliverers workshop

The participants included 20 representatives from across the primary and secondary care sectors. Some of the participants held very senior posts and had a lifetime of experience of health care services, others were more junior and had more day-to-day contact with patients. Their time of service in health care ranged from 8 to 42 years, with an average of 26.9 years.

The specific aims of the workshop were:

- to gain more detailed information of what was thought to be problematic in various care sectors;
- to understand the health care deliverers' experience (both positive and negative factors);



Fig. 2. Mapping workshop.

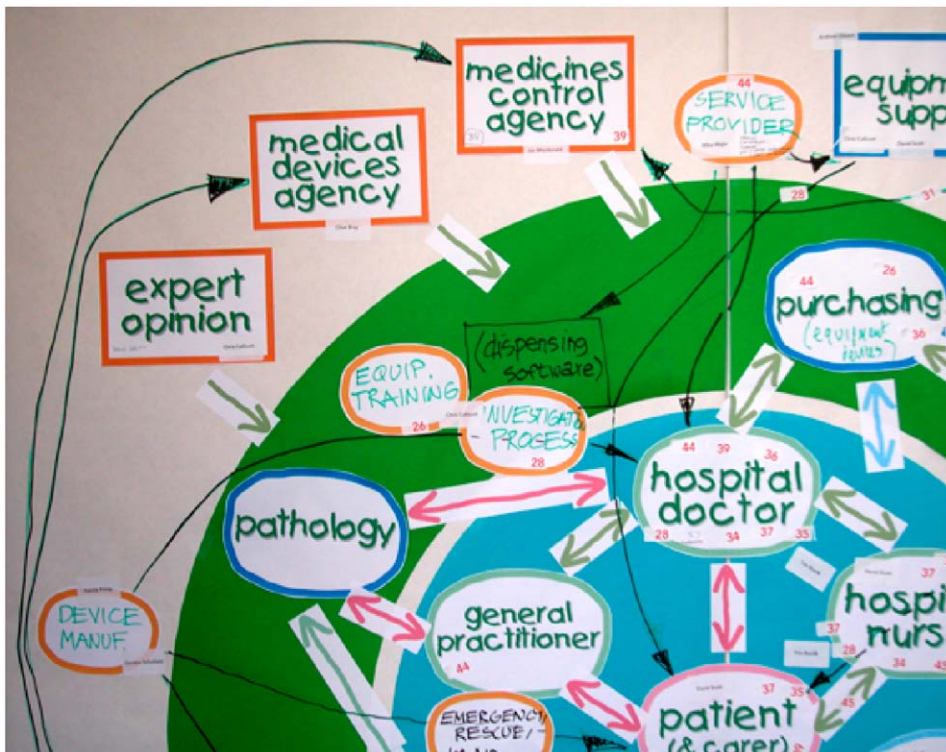


Fig. 3. Mapping workshop detail.

- to prioritise the resulting issues and tease out the design implications; and
- identify opportunities for, and barriers to, effective intervention.

### 3.1.2. Supply chain stakeholders workshop

A key aim of the study was to evaluate how the design process might positively influence the relationship between the designer and manufacturer as well as the supply chain. The participants at this workshop included representatives from procurement, licensing and the equipment and pharmaceutical industries. Professional health care-related experience ranged from 3 to 45 years, with an average of 23.3 years. During this workshop, the issues explored were related to the supply chain (especially medication), existing standards (industry, national and international) and costs and packaging (branding and identity). The information was collected as for the primary/secondary health care deliverers workshop.

### 3.1.3. Patient support groups workshop

This workshop was convened to enable the research team to capture the priorities and concerns of various groups of patients, particularly those with long-term or chronic conditions. It also served to engage the participants as a group and tap into their combined expertise, knowledge and experience. Finally, it prepared the ground for future engagement of the participants, e.g. as part of an institution or sector-based taskforce or cross-sector advisory group. This was a small session, held with four

representatives from patient support groups. The workshop was conducted as a facilitated discussion.

### 3.1.4. Mapping workshop outputs

Major issues identified by the stakeholders ranged from the specific (including examples of prescribing, dispensing, administration and self-administration errors, needle stick injuries and misuse of gases) to the systemic (e.g. a lack of training in the use of medical equipment) (see examples in [Table 1](#) and [Cambridge, Surrey, RCA, 2004](#) for more detail). Various ‘hotspots’ were identified including:

- in the home—around problems associated with packaging, storage, remembering, reading, understanding, etc;
- in transfer/transit—around associated changes in drugs, protocols, people, equipment, records, etc;
- when situations and equipment or medications are new or unfamiliar, and when people are working under pressure and
- in cases of mistaken identity—around look-alike/sound-alike names, branding on packs, changes in packaging, names and terminology, interchangeable connectors for lines and gases, ampoules, equipment calibration and dose delivery.

In addition to simply identifying the problems, workshop participants were asked to highlight contributing factors behind these areas of difficulty. For example, using medical equipment was seen to be a challenge, often due to design-related issues such as: complexity of user interface, variety

Table 1  
Examples of stakeholder priorities from workshops (see [Cambridge, Surrey, RCA, 2004](#) for full details)

	Key problems/errors	Causes
P	Similarity of names and packs	Confusion; lack of differentiating features; working under pressure; the way medications are stored: in pharmacies, on wards, in the home
P	Communication including language and non-verbal	Assumptions; working under pressure; staffing changes; native language and cultural factors; hierarchical culture in NHS; misinformation
P	Information provision is quirky, not systematic	Commercial influence; no central system or single accredited source of information; suppliers; information leaflets protect against litigation rather than provide the right information in appropriate forms for different users
P	Physical access to the contained medications by professionals and users/carers	Pack design; patient ability; conflicts with child and tamper resistance; prompts repackaging of drugs; problems with blister packs
S	Drug identification—difficulty of ensuring use of correct drug	Highlighted by Vincristine, in particular due to child and tamper resistance; prompts repackaging of drugs; problems with blister packs
P & L	Packaging, labelling, presentation, recognition. Differentiation	Size/shape; lack of specification and testing against it; commercial pressure; poor labelling, esp. legibility; incorrect interpretation of instructions
I	Confusion between medications	Delivery systems not differentiated; similar packs/labels; similar names; elderly confused patients
I	Information flow—lack of	Records not with patient—main problem; incorrect modality prescribed; poor handwriting
I	Users override design safety features	Patient plays with device; paramedics in emergency situations; medication separated from pack; cannot understand

P: primary care; S: secondary care; P&L: purchasing and licensing; I = industry.

of makes and models and unclear or missing supporting information including operating instructions. The information provided clues for the participants in the workshop with designers (see below) to assist them in the identification of possible solutions.

### 3.2. Designer workshop

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

The capture method used at the creative workshop proved very effective in eliciting specific and detailed information about how and why problems occur at different locations. To facilitate this process a large drawing of the patient journey/experience was prepared, and used as a trigger for discussion of 'site-specific' issues. Participants were open and very forthcoming, and the atmosphere of the group was one of collective participation and involvement. Several factors influenced this, such as the informality of the venue, the general relaxed nature of the event and the fact that it was 'hands-on' and practical in orientation. Over 90 issues were gathered in little more than an hour of extensive and focused discussion, giving useful detail in relation to: care at home involving GP, community nurse, etc.; the local pharmacy; the surgery and day-care centre; the rescue services; entering hospital; the operating theatre; intensive care; the ward; and patient aftercare.

#### 3.2.1. Design solution teams

More detailed information and mini case studies emerged in the team working sessions which were organised around three simple briefs. Participants were asked to develop three illustrated ideas/scenarios to improve patient safety in relation to: patient records and information; medication/packs and associated information; and drug administration and associated kit and devices. They were then asked to select one idea to present in depth to the whole group. The team leader introduced how the group approached the brief, where it looked for solutions, and the non-preferred ideas, and another person presented the selected idea. As the team leaders were all designers, this ensured that both designers and non-designers presented back to the assembled group.

#### 3.2.2. Solution spaces

Typically, after quite lengthy general discussion to establish a focus and priorities, the teams moved on to discussing very specific and in-depth problems. There was a strong sense of ownership of these by individuals and a very practical desire to reach combined solutions to more

than one problem. In several instances, such detailed information pointed to design solutions, for example,

- Paramedics repack ampoules in a handy (mixed) format using existing larger quantity packs—scope for smaller volume supply or special containers designed for paramedics which give better visibility and identification.
- Information fails to transfer properly from one environment to another, for instance, ambulance drug records are hand written under pressure and using abbreviations/codes and are therefore often mistranscribed—scope for the use of peelable bar-codes in the recording of drug information in many situations including the home. These could be peeled off from medication packaging, or from a sheet and stuck to the patient record, allowing for accurate, swift and keyless transcription to computerised records.
- Patients, paramedics and other carers are often unaware of what medications are for—scope to add this information to prescriptions and labels on dispensed drugs, as an aid to identification and a way of better informing patients, to be pointed out to patients at the pharmacy.

This process led naturally to practical ideas for solutions, which included:

- a patient information system building on patient/doctor interaction and the recording of what their medication was prescribed for, as an aid to communication between, e.g., patients and pharmacists;
- a national patient/drug information system that would give correct information and encourage trust between patient and prescriber/carer;
- simple redesigns of line connectors to eliminate incorrect connections;
- a customised individual drug administration/packaging system to aid medication compliance, particularly for complicated regimes;
- improved pack designs to keep information with medication, both inside and outside the pack, and to facilitate identification of drugs and their use;
- a simplified drug recognition/information system tailored to different users, e.g. patients; community carers and hospital nurses in the ward and in intensive care;
- ways in which peelable barcodes could be used to update patient records both in stressful situations like rescue, and in the ward and the home; and
- ways in which smartcards can be used in hospitals, by paramedics and in the home, to check, monitor and reassure.

Given the nature of the study, and the short space of time allotted to the workshop, none of these solutions has been explored in depth, and the participants themselves rapidly came up with challenges and further issues. The solutions

were not therefore proposed as necessarily viable, but the potential effectiveness of the process has been well demonstrated.

Outcomes from this workshop were captured in the form of design concepts. Confidentiality requirements have limited their presentation in the published literature, although more details can be found in [Cambridge, Surrey, RCA \(2004\)](#).

In summary, from a design perspective, the richness of detail provided was both interesting and valuable. It gave an insight into the complexity of interacting factors contributing to errors, and could help designers better understand the range of factors to be taken into account, and so identify viable solutions.

#### 4. Improving the design

This paper has chosen to focus on medication error for a number of reasons. Firstly, it has been estimated to be one of the major sources of error compromising patient safety ([Audit Commission, 2001](#); [Vincent et al., 2001](#); [Department of Health, 2004](#)). Secondly, it is a challenge well suited to ergonomists as it requires a systematic approach to understanding the system processes, environments, and tasks. Thirdly, the increasing availability of technology suggests opportunities for significant advances and finally, because the wide range of stakeholders engaged in medication production, prescribing, dispensing and consumption requires ergonomics' methods if user needs are to be identified and then met.

Errors may occur at many points in the process of medication use ([Leape et al., 1995](#); [Anderson and Webster, 2001](#); [Ashcroft et al., 2005](#)). They may be due to a multiplicity of interacting factors, many of which have design implications. Completing the mapping process and gathering data on, for example, error type, incidence, consequences and associated costs would allow for targeted action. Important evidence lies with the many stakeholders involved. Such knowledge cannot be acquired without their input, and they can identify design-relevant factors that other research may well fail to capture. In our research, a range of methods was used to explore this issue, from literature review to stakeholder workshops, and hotspots were identified for further investigation (see [Fig. 4](#) and [Cambridge, Surrey, RCA, 2004](#)).

One example of a patient safety issue currently subject to ergonomics investigation is that of medication packaging. This research also demonstrates the complexity of the issues the health service is having to confront ([Department of Health, 2004](#)).

Many interacting factors are involved in such errors—poor handwriting can be misinterpreted; prescriptions do not indicate what the drug is for and hence an additional clue to interpretation is lost; corporate branding enforces visual similarity and detracts attention from key safety information; colour coding schemes tend to focus on brand identity rather than product differentiation; all forms and

strengths of a medication can come in boxes of the same colour and shape, generic names are often less clear than brand names; proprietary and generic names can look and sound very similar; changes of supplier can lead to confusion; as can multiple names for the same drug; alphabetical positioning can place similarly named drugs from the same manufacturer side by side on the pharmacy and working under pressure (or being adversely subjected to any of the many well-established performance shaping factors) can exacerbate any of these issues.

An immediate design response to confusion between drugs in the pharmacy could be that standardisation should be introduced. However, what emerged ([Cambridge, Surrey, RCA, 2004](#)) from consultation with stakeholders working within the NHS is that standardisation is not working effectively because it is driven by conflicting imperatives. As a consequence, industry investment in packaging design and drug identity is not necessarily adding to patient safety.

Even where an individual manufacturer works hard to reduce confusion, its proprietary system/solution will be one of many, and is unlikely to be generalised or become a standard because of competition and brand issues.

An alternative approach is to explore ways to organise pack information so that it guides pharmacy staff through a desirable series of checks, and to make conformity to such a system a purchasing requirement. Other design interventions could focus on introducing additional and differentiating marking or other elements to alert pharmacy staff to potential problems.

The use of creative workshops ([Cambridge, Surrey, RCA, 2004](#)) demonstrated that we currently fail to recognise the full use of cues that pharmacists could use to help them identify medication. For example, senior pharmacists listed many factors that helped them identify and check medications prior to more recent advances in both packaging (e.g. blister packs, etc), boxes and other containers. For example, in the past they could differentiate drugs by their smell, by the feel of them to the fingers, the sound they made when poured out on the counter and the dust they produced.

These and other factors provided near-subliminal information/confirmation as to the identity of the medication. With modern packaging, not only are these subtle clues no longer available to the pharmacist, but the similarity and the proliferation of proprietary and generic medications and forms means that pharmacists are obliged to correctly identify drugs from amongst an increasing number of presentations, which are becoming less easily differentiated. Some recent guidance on the labelling and packaging of medicines (e.g. [MCA, 2003](#)) is emerging but much more systems understanding of the needs and capacities of the end users is still required to ensure appropriate design requirements are specified.

The pharmacy is only one of several situations in which medication errors track back to problems with packaging ([Ashcroft et al., 2005](#)). Indeed, in many instances packaging

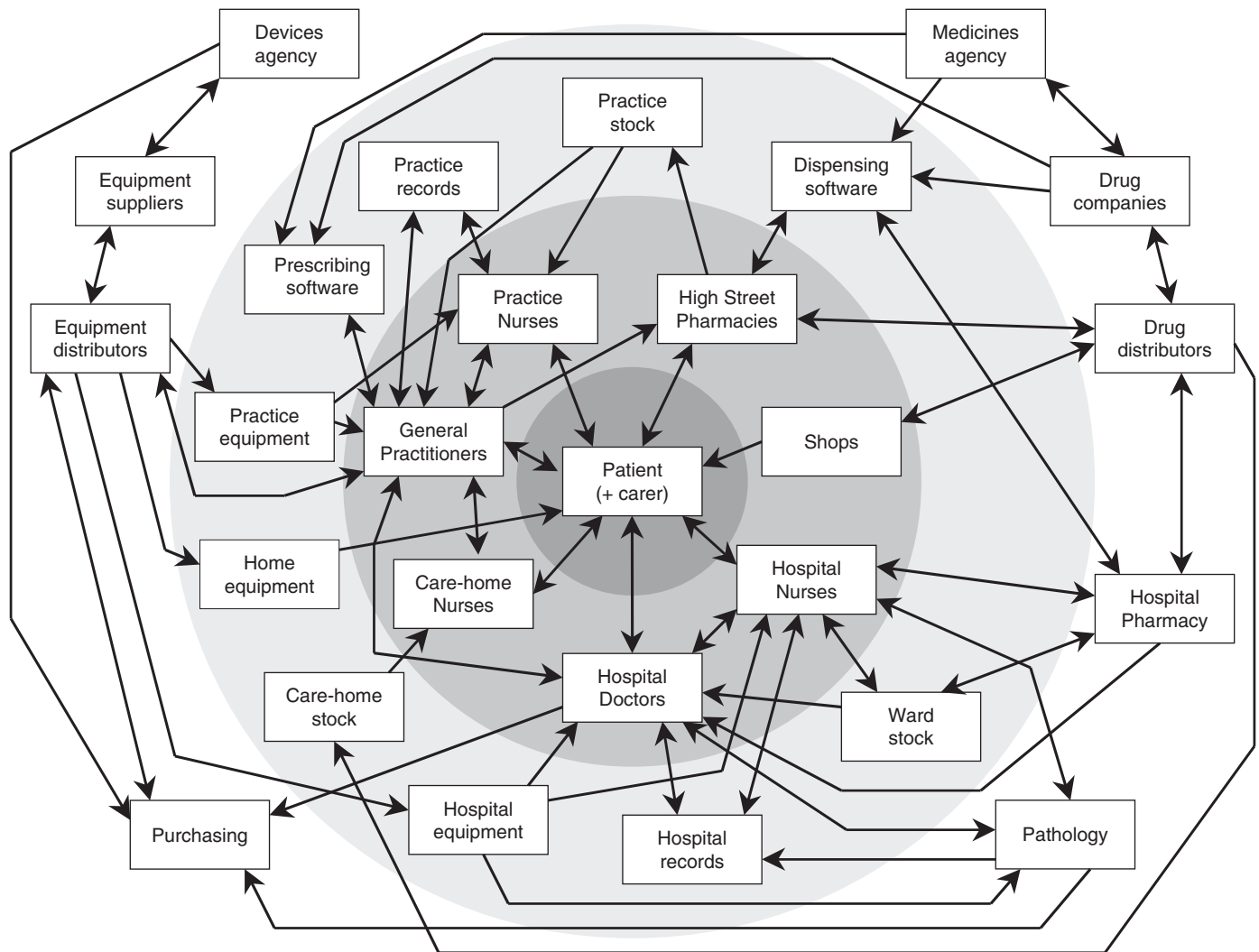


Fig. 4. A patient-centred map of the health care system (Clarkson et al., 2004).

issues should be seen in tandem with information issues. Many medications are used by patients in the home environment. Here too, errors are occurring and packaging and information are important factors. These factors are particularly important in relation to compliance, which is known to be a significant problem affecting a large proportion of medications taken by elderly people (Cramer, 1998; Bernardini et al., 2000, 2001; Moisan et al., 2002).

However, the range of issues faced in the home is significantly different to that faced in the pharmacy (Cambridge, Surrey, RCA, 2004; Ward et al., 2004). For example, in the home, an inability or failure to read or understand the leaflet inside the pack can lead to self-medication errors. This can be ascribed variously to poor eyesight, small font size, the way information is organised and the language used. Other similar problems are associated with legibility and poor durability of printed labels attached at the pharmacy; identifying medications once separated from their original packs; opening blister packs and handling and swallowing tablets, in particular in the case of older and arthritic patients.

The use of a *Patient Support Groups* workshop (Cambridge, Surrey, RCA, 2004) identified other factors that centred on how effectively patients understand and 'own' their own conditions and treatments. This, in turn, impacts on compliance and can interact with the more specific, physical aspects of packaging and information.

## 5. Best practice on designing for patient safety

A recent study Cambridge, Surrey, RCA (2004) showed that there was a significant opportunity to develop a body of best practice case studies and benchmark exemplars. There was also scope for demonstration projects.

While pressure can be put on industry to encourage it to focus on user-centred design practice, industry is unlikely to respond to abstract directives or inducements. What is needed, therefore, is a body of exemplar case studies and demonstration projects that show how such an approach can lead to better and more competitive products.

Under the Research Associates programme of the Helen Hamlyn Research Centre (HHRC), recent graduates of the



Royal College of Art, London, have collaborated with a number of major companies on design-research programmes leading to exemplar inclusive designs, and to new products, services and information campaigns (e.g. Mawle, 2003).

Over the past three years, an important strand of work at the HHRC has been an investigation into packaging and associated information design. The outcomes have been exemplar designs, company-specific tools, and guidance on information design for patient safety published jointly by the HHRC and the NHS National Patient Safety Agency with a foreword from the Chief Medical Officer citing the previous work of the authors of this paper. This publication 'Information Design for Patient Safety' (Swayne, 2005), recommends an inclusive approach to information design for packaging of prescription medicines, based on the consistent application of recognised and well-established graphic and information design principles. This work is seen as a step towards a safer, more cost-effective NHS and it is hoped that it will contribute towards the development of an international context where the health services take a conscientious and proactive approach to the design of health care products.

A parallel design research project investigated preventable medical errors due to pharmaceutical packaging, and sought to establish good pack design practice within GlaxoSmithKline (GSK), the research partner. The project began by exploring GSK's current processes to understand the complexity of the supply chain and innovation processes. The focus was then shifted to immediate and systemic patient safety issues with face-to-face visits, interviews and recorded observations. Findings from this research led to the development of a risk management tool for GSK based on a failure mode and effect analysis. The tool, which has been designed for use within GSK, by pack development and design teams, takes the form of an interactive web application explaining errors due to packaging and recommending best practice. The tool will be accessible to GSK personnel via the company's intranet, and also contains concept packaging solutions designed as a response to the outlined medical errors. Two such concepts were developed to prototype level in order to visualise the design work in three dimensions, and to clearly illustrate the inclusive design approach.

The UK Design Council has been a partner in this process, and leading design consultancies have become involved in developing best practice exemplars.

This work has created commercial opportunities for the companies involved and helped design and industry in the UK to prepare itself for the impact of ageing populations and the Disability Discrimination Act on consumer expectations. Much other material is now available to industry and the design professions on the subject of age-friendly and inclusive design, including a [British Standard \(see BS 7000-part 6, 2005\)](#). There is therefore a significant body of successful practice that can be transferred to the health care system and associated industries.

To inspire change in behaviour within industry and across the NHS it is also important to capture best practice examples of designing for patient safety from around the world. Academic researchers might therefore be encouraged to identify, document and evaluate examples of good industry practice by focusing research funding on the issue.

## 6. Conclusions

The study reported had three main aims. In addressing the first, the research has highlighted the design challenges that exist in the health care sector and the importance of engaging with the design community if patient safety is to be improved. The starting point is to provide a better knowledge base on which design requirements can be based. Currently our documented knowledge of systems, processes, tasks (and their variants) is poor. The second aim was to provide methods to inform safer system requirements. This study has highlighted one method (i.e. mapping workshops) that has been demonstrated as successful in both engaging with stakeholders and in generating a rich knowledge base for the design of medication packaging and the potential for error. The final aim of the study has been met through the workshop outputs. These have identified many issues relating to the design of medication packaging that require attention and some are now the subject of design improvements. However, the scale of the problems and the complexity of the system will require sustained effort if significant advance are to be made and more holistic and systematic ergonomics design solutions are to be found.

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