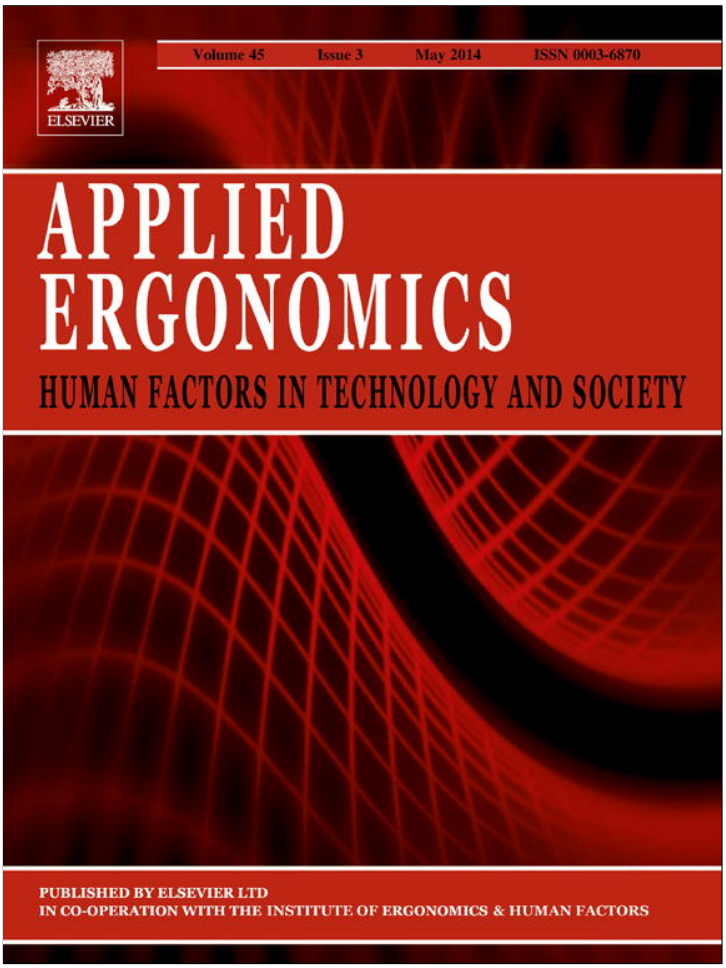

Applied Ergonomics 45 (2014) 629–638

Contents lists available at ScienceDirect

Applied Ergonomics

journal homepage: www.elsevier.com/locate/apergo

Taking ergonomics to the bedside – A multi-disciplinary approach to designing safer healthcare

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ARTICLE INFO

Article history:
Received 26 July 2012
Accepted 2 September 2013

Keywords:
Medical devices
Patient safety
FMEA

ABSTRACT

A multi-disciplinary approach to designing safer healthcare was utilised to investigate risks in the bed-space in elective surgical wards. The Designing Out Medical Error (DOME) project brought together clinicians, designers, psychologists, human factors and business expertise to develop solutions for the highest risk healthcare processes. System mapping and risk assessment techniques identified nearly 200 potential failure modes in hand hygiene, isolation of infection, vital signs monitoring, medication delivery and handover of information. Solutions addressed issues such as the design of equipment, reminders, monitoring, feedback and standardisation. Some of the solutions, such as the CareCentre™, which brings many of the processes and equipment together into one easy to access workstation at the foot of the bed, have been taken forward to clinical trials and manufacture. The project showed the value of the multi-disciplinary and formal human factors approaches to healthcare design for patient safety. In particular, it demonstrates the application of human factors to a complete design cycle and provides a case study for the activities required to reach a safe, marketable product.

1. The opportunity for human factors in healthcare

Human factors/ergonomics is now a constituent part of safety management and systems design in many industries (HSE, 2005; ISO 6385:2004). This is less so in healthcare, where there are still only a few exemplar projects demonstrating either the benefit, or the methods, of a Human Factors (HF) approach. The complexity of healthcare delivery means that there are extensive opportunities for human factors to contribute to improvements. A single patient journey can cross the primary, secondary and tertiary healthcare sectors. Care might be delivered by multi-disciplinary, distributed and virtual teams, often with poor communication between healthcare workers and organisations, entrenched hierarchies and little overview of the overall patient journey. Healthcare staff work in shared work-spaces with complex patients, tasks and equipment, all of which make a formal consideration of human factors necessary. Within this complexity there are clear opportunities to apply HF to common, identifiable components of the system. This paper describes a project that takes a systems approach to a particularly ubiquitous setting, the design of the bed-space and demonstrates the application of human factors to a complete design cycle; from context exploration through to manufactured product. The project used human factors principles and methodology to identify risks, engage healthcare staff and patients, facilitate ideas and develop new designs for the environment, right through to manufacture. Applying HF to a common workspace – the bedside – means that the methods and solutions should be transferable to many other clinical specialties. In particular, it provides an important demonstration of the *process* of applying human factors using a multi-disciplinary team that engages clinicians, designers and human factors professionals. This provides a model that can be applied in other healthcare contexts in the future.

2. The size of the problem

There are around 100,000 reports of patient safety incidents (PSIs) per month to the UK National Patient Safety Agency's (NPSA) Reporting and Learning Service (RLS) from NHS Trusts in England and Wales (NPSA, 2012). Other sources of estimated harm, predominantly using reviews of patient records, place the rate of in-hospital adverse events (unintended injury or complication) at almost 1 in 10 admissions (de Vries et al., 2008).

While these figures are high, they must be considered in perspective of the scale of the NHS (there were 15 million A&E attendances and 85 million outpatient appointments in England

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http://dx.doi.org/10.1016/j.apergo.2013.09.004

during 2010 (NHS IC, 2010)) and that many PSIs are reported as causing no harm (69% in 2010/1 – NPSA, 2012). Yet there is also a recognised under-reporting of patient safety incidents; there are around 300 million GP consultations in England each year but GP reported incidents account for less than 1% of the total reported to the NPSA. Paradoxically, voluntary reporting of incidents is likely to increase as a positive safety culture develops within an organisation (Hutchinson et al., 2009). Each of these conspires to make it difficult to know the extent of unintentional harm in healthcare, and in particular the detail of what goes wrong. Together with the already risky nature of treating seriously ill patients, this has meant there has been a slow acceptance of the high risk nature of healthcare. This is now changing. Landmark reports such as the USA Institute of Medicine's 'To Err is Human' (Kohn et al., 2000) and better incident reporting are helping to establish – as deVries puts it – that 'adverse events *[in healthcare]* are a serious problem'.

3. Establishing human factors in healthcare

Along with the relatively recent recognition of the safety issues in healthcare, human factors is also beginning to gain interest (NPSA, 2010). There are some notable examples of human factors improvements, particularly the standards for medical device design (e.g. AAMI, 2009), the recognition of human factors by groups such as the World Health Organisation (WHO, 2009) and a general promotion of human factors thinking (Reason, 1995; Vincent et al., 2004; Carayon et al., 2006; Norris, 2011; Hollnagel, 2012). The previous understanding of human factors as primarily 'person level' issues (such as teamwork and communication) (NHS III, 2010) is still common, but human factors principles (such as reducing complexity and variability, design for standardisation and standard procedures) and methods (such as co-design, Prospective Hazard Analysis (PHA) techniques or Human Factors Integration) are now developing.

As a result, there are many examples where an absence of human factors or user-centred design is evident. Research on infusion pumps (programmable devices which control the rate of flow of medication through intravenous infusions) found there could be up to thirty different models in use within one organisation, many with differing and/or conflicting interface design (NPSA, 2004a). Colour-coded wristbands have been used to alert staff to a patient's special status (e.g. allergies or risk of falls), yet different colour coding conventions have existed within the same organisation (Sevdalis et al., 2009). Local variation and bespoke procedures are common and even considered necessary, as local circumstances are often considered unique.

However, rather than focussing the human factors argument on examples of poor design, if we are to help establish human factors in healthcare it is more helpful to find positive examples of change and demonstrations of methodology. Reiling (2006) and Ulrich et al. (2008) both give good examples of user-centred approaches to healthcare design. This paper aims to help demonstrate the value of human factors by providing examples of design solutions and demonstrating a methodology to achieve this.

4. Human factors in the design of medical devices and equipment

Physical products are a component of virtually all healthcare processes, from seemingly innocuous equipment such as patient identity wristbands and bedside lockers through to cutting edge medical devices that keeps patients alive. The design of devices, equipment, workspaces, medication (pills, packaging and prescribing systems) and information systems is therefore vital to the safe delivery of care. According to the NPSA's RLS, around 35,000 patient safety incidents are reported each year in England and Wales associated with medical devices and equipment and around 100 of those resulted in death or severe harm (NPSA, 2012). An analysis of these incidents from 2006 to 2007 found the most frequently cited equipment were pumps, catheters/cannula, beds and hoists and resuscitation and surgical equipment. Contributory factors included the design of the equipment ('equipment not operating as intended') or the systems within which they are used ('equipment unavailable') (NPSA, 2008). Designing for safety is a becoming a recognised concept in healthcare (Karsh and Scanlon, 2007) but usability issues are unlikely to be recognised or reported. For instance, research into infusion pumps incidents found that of 25% of devices reported as faulty had no fault (NPSA, 2004b). International standards and regulations do require manufacturers to carry out usability testing (e.g. ISO/IEC 62366:2008; FDA, 2011) but as an 'end user', healthcare appears to be less demanding of good usability than perhaps other industries. This provides little incentive for improvements beyond the minimum required. Other barriers to usability improvements in medical devices (and thereby a reduction in user error) include:

- Financial constraints on healthcare organisations
- Legacy/existing equipment with recognised usability issues that have to remain in service such as pumps or monitors
- Limited usability or human factors support during procurement
- Donated equipment
- A focus on competency and training as a route to safety in healthcare, and a subsequent reticence to blame design ('it's a poor doctor that blames their tools')
- Impetus to fast-track new developments in diagnosis/treatment without consideration of usability
- A poor contextual match between existing work systems and new technology being introduced
- The difficulty in accessing healthcare settings for equipment design research or evaluation.

The DOME project therefore focused on medical devices and equipment with the aim of encouraging the use of a HF in equipment design (as opposed to the design of procedures and processes, although a systems approach would of course consider those working practices and their effect on safety).

5. DOME: designing out medical error

Human factors would endorse a systems approach to ensure the usability and safety of healthcare systems, and the medical equipment and devices that are part of those systems. Designing Out Medical Error (DOME) was a three year project that applied the systems approach to the design of medical devices and equipment. It was a multi-disciplinary project involving designers, clinicians, psychologists, human factors professionals and business experts. The overall aim of the study as described here was to develop a process to design safer medical devices and equipment. The objectives were:

- To develop a multi-disciplinary approach to designing for safety that would provide long term engagement and potential for future design collaborations
- To develop a map, analyse and prioritise the hazards in the surgical wards
- To develop design solutions using a systems approach and co-design methods.

This paper describes the key aspects of the project, such as: disciplines working together to understand risk and co-develop

solutions; the large number of processes – and potential failures in those processes – that take place around the bed-side, just one part of the patient journey; the commonality of causes across multiple failures; and in particular how tackling those causes across a range of processes simultaneously can help to develop effective solutions.

5.1. System boundaries

This study took a systems approach that meant all of the processes within surgical wards were to be considered, similar to the approach developed by Carayon et al. (2006). The study aimed to produce design solutions that could be taken forward for manufacture and widespread implementation. Within the surgical ward setting, a further focus was the hospital bed/treatment space or the bed-side. The investigation focused on patient admission through to discharge in the surgical ward, taking into account but not focussing on, surgery in the operating theatre and any related activities in primary care outside the hospital. This allowed the influence of the entire system of healthcare to be considered whilst providing a manageable and defined area to target.

5.2. Multi-disciplinarity

One of the key objectives of the project was to develop a multi-disciplinary process for developing healthcare solutions. Embedding a human factors approach in healthcare requires clinical staff to be pivotal in the analysis of systems and development of solutions, and for designers to have access to clinical staff and workplaces. Making HFE and design methods accessible and palatable for all users was part of this engagement process. A collaborative approach was adopted that aimed for knowledge and skill transfer between clinicians, designers, psychologists and business experts as well as human factors expertise. Each discipline was vital to the success of the project:

- Clinical and subject matter expertise was required to understand clinical processes, healthcare environments and systems
- Design knowledge and skills were needed to develop creative solutions
- Psychologists and human factors expertise was needed to understand the genesis of human error and the systems approach to safety and design, and to initiate valid methodology approaches
- Business experts enabled the application of risk management approaches and solutions from other industries.

Multi-disciplinary design is difficult to achieve in healthcare as there are very real limits to clinicians' time and to the access to clinical environments. It can be difficult for designers to access clinical areas without the help of a clinician, and clinicians seeking to develop innovations often do not have access to the design and business knowledge needed to see their ideas through to realisation. To ensure true multi-disciplinarity, the research team worked side-by-side on all phases of the project, sharing all research methods. Shared-site working was adopted so that the design staff had regular access to the hospital environment and clinical staff were able to access resources within the design centre.

6. Methodology

Multiple methods were used to analyse processes around the bed-space, identify potential failures and to develop and test appropriate solutions. Observations, semi-structured interviews and shadowing of staff and patients allowed the tasks, equipment, communication, information sources and environment of the bed-space to be recorded in detail. A structured survey and rating scales were used to gather user perspectives on safety and Failure Modes and Effects Analysis (FMEA) was used to analyse and prioritise potential failures. The design phase utilised focus groups, brainstorming and co-design techniques, with simulation and clinical trials being used to evaluate prototypes. See Anderson et al. (2012a) for a detailed description of the methodology.

The first step in a human factors approach to systems design is to understand the healthcare processes in question. Observations and shadowing carried out jointly by the research teams ensured that multi-disciplinary perspectives on the data could be obtained. The inclusion of a clinician in the team was crucial to be able to represent clinical knowledge and to understand tacit skills; likewise, the designers were able to view the processes and environment from a design and safety perspective. It is unlikely that enough understanding of processes and the subsequent hazard analysis would have been possible without this joint perspective. As well as focussing on the ward, data were gathered from the wider parts of the hospital system such as the clinical risk departments, clinical engineering, cleaning, microbiologists, and from the wider NHS landscape such as the procurement chain, innovation hubs and the medical device industry. An interactive map was developed of the overall patient journey, which allowed multiple layers of the system around the bedside to be constructed. This allowed visualisation of the whole patient journey with associated activities, plus annotations embedded at each stage to describe and visualise associated staff, equipment, tasks and workspace.

A work analysis based on 70 h of observation on five general surgery wards at three hospitals during the day, night and weekend (see Anderson et al., 2012a for details) identified fourteen top-level healthcare processes (shown in Table 1).

Given the large number of activities observed within surgical wards, the highest risk processes were prioritised by healthcare workers, patients and visitors (these were hand hygiene, vital signs monitoring, isolation of infection, medication delivery and handover of information) and an HFMEA was used to identify how each of the surgical ward healthcare processes could fail.

Failure Modes and Effects Analysis (FMEA) is an established, prospective risk analysis tool that has been adapted for use in healthcare (Healthcare FMEA or HFMEA) by the US Veterans Association (DeRosier et al., 2002). Since 2002the Joint Commission for Accreditation of Healthcare Organisations has required USA healthcare organisations to complete an FMEA on at least one high risk process per year (Spath, 2003). A scan of the literature would suggest that FMEA is now a popular tool in patient safety having been applied to a wide variety of scenarios [such as the registration of trauma patients (Day et al., 2007); IV medication (Adachi and Lodolce, 2005); medication errors (Crane and Crane, 2006); the management of TB patients (Tellefsen, 2005); and the discharge process (Anthony et al., 2005)]. Anderson et al. (2012a) describe how the HFMEA identified nearly 200 failure modes in the five surgical ward healthcare processes. The causes of the high-risk failure modes in each of the processes were identified using Vincent's classification of system contributory factors (Vincent et al., 1998) and the high-level causes are shown in Table 2.

Table 2 shows that design was cited as a cause of prioritised high-risk failures in all five processes, an issue that might be overlooked by traditional healthcare investigations. A lack of reminders, and poor monitoring of staff performance and feedback were also common, together with poor measurement, a lack of standardisation and simplification, issues with leadership, clear team roles and responsibilities, education, training and testing and patient safety not being a priority.

Table 1
Healthcare processes and associated tasks observed on surgical wards.

Processes	Tasks
Domestic cleaning	• Changing beds • Cleaning floor or bedside equipment • Cleaning of vital signs monitoring equipment • Move bed/furniture • Wet floor safety signs • Looking for equipment/supplies in storage areas
Post-operative mobilisation	• Re-positioning patient in the bed/turning • Sitting up/out • Chest exercises/CoughingTransferring • Use of wheelchair • Standing • Walking on the flat (with or without aid) • Walking on the stairs (off the ward) • Use of bedside controls • Use of bedside rails • Move bed/furniture • Looking for equipment/supplies in storage areas
Use of bedside rails	• Use of bedside rails • Use of bedside controls
Hand hygiene	• Hand hygiene • Alcohol gel • Soap and water
Vital signs monitoring ('Observations')	• Observing patient from nursing station • Cleaning of vital signs monitoring equipment • Vital signs measuring and recording (blood pressure/pulse/respiratory rate/pulse oximetry/ temperature/fluid balance/urine output/ blood sugars) • Use of urinary catheter • Use of NG tube • Use of drains • Move bed/furniture • Looking for equipment/supplies in storage areas
Correct site surgery	• Consent/marking • Pre-operative checklist
Medication delivery	• Dispensing medication • Use of PCA • Management of IV lines and drip stands • Looking for equipment/supplies in storage areas
Ward round	• Ward round • History taking • Examinations • Move bed/furniture • Writing notes/forms • Using the computer • Looking for equipment/supplies in storage areas
Staff hand-over	• Using the telephone • Use of bleeps • Writing notes/forms • Hand-over at shift change (at nurse's station) • Hand-over at shift change (in staff room) • Hand-over at bedside
Isolation of infection	• Hand-washing • Gloves and apron • Changing beds • Cleaning of vital signs monitoring equipment • Looking for equipment/supplies in storage areas • Cleaning floor or bedside equipment
Percutaneous procedures	• Phlebotomy – venepuncture • Cannulation • Sharps disposal • Move bed/furniture • Looking for equipment/supplies in storage areas • Hand-washing • Isolation of infection
Wound care	• Change of dressing • Looking for equipment/supplies in storage areas • Hand-washing • Isolation of infection • Removal of sutures or clips
Activities of daily living	• Resting/Sleeping/Lying down • Eating and drinking • Use bed pan/commode/toilet • Take waste to the sluice • Hygiene – washing/shaving/brushing teeth/ showering/bathing/drying/ • dressing • Entertainment – Patient-line TV/radio/ • phone • Move bed/furniture • Looking for equipment/supplies in storage areas • Call for help – using nurse call button
Other	• Recording an ECG • Taking a mobile Chest X-ray • Building maintenance

6.1. Stage 7: the design phase

The research yielded a rich picture of the most risky processes, where they were most likely to fail, and the causes behind these failures. This information had to be translated into a set of meaningful design briefs for subsequent design work.

These captured the research findings, providing realistic boundaries for design work, and inspired a breadth of ideas. The briefs were based on the on the broad system causes of the failures rather than rooting them in certain, specific failures. For instance, rather than focussing on failures such as 'failure to wear gloves and apron', 'failure to use sterile wipes on equipment' the briefs addressed

Table 2
High level causes of prioritised high-risk failures in the five surgical ward processes (based on Anderson et al., 2012a).

	Hand washing	Vital signs	Isolation of infection	Handover	Medication delivery
Design	X (environment and equipment)	X (vital signs chart)	X (bed-side)	X (handover room and handover sheet)	X (drug chart)
Reminders	X	X	X		X
Monitoring	X	X	X		X
Feedback	X	X	X		X
Lack of patient empowerment	X		X		X
Measurement	X		X		X
Standardisation	X		X	X	
Simplification	X		X	X	
Leadership and clear team roles and responsibilities	X	X	X		
Education, training and testing		X	X	X	
Patient safety not put first		X	X		X
Culture of just getting the job done	X	X			
Lack of facilities			X		
Culture – low status of cleaning			X		
Implementation of new equipment	X				

common causes across all of the five processes, such as equipment being stored away from the bedspace, lack of reminders and lack of accountability. By considering the processes simultaneously, the design work addressed potential failures in the *system* of interlinked processes of care around the bedside rather than a piecemeal approach to specific failures. Five interlinked design briefs were therefore formed around the processes of hand hygiene, isolation of infection, vital signs monitoring, medication delivery and handover of information.

These briefs were validated by a process expert in each case to ensure they captured the findings of the research. A variety of creative techniques were used, from straightforward brainstorming and brain-writing sessions (where participants write/draw ideas before they verbalise them) to more structured lateral thinking exercises (De Bono, 1995). A range of techniques were deliberately employed in order to engage the wide variety of stakeholders in the creative process. This approach combined short term techniques (focus groups) with longer term methods. Front line healthcare workers (nurses, doctors and HCAs) were involved in the creative process through repeated focus groups on three elective surgical wards at each of the three hospital sites for research. An average of seven nurses and three HCAs attended each nursing focus group, five doctors for the doctors group, and patients were approached informally when participating. Participants were presented with a spider diagram of problems and suggested concept areas (without specific designs or illustrated concepts), and were asked to use this as a starting point for their own ideas. Regular co-creation methods of model making, or sketching etc. were abandoned in favour of a more fluid approach (staff often had to leave during the session) where the participants talked through their ideas and the research and design team captured them in words or sketches.

Running in parallel with this, the duration of the DOME project allowed for a longer-term approach to be used. De Bono's techniques were performed both collaboratively among the core research group (two designers, a clinician and a clinical psychologist) during brainstorming sessions, and individually. A working document was created by the designers containing some basic assumptions and De Bono's provocations. For example, one assumption in the task of measuring a patient's temperature is that the nurse is present, places the thermometer in the patient's mouth, waits and notes down the reading. Provocations question these assumptions. What if the nurse is absent? This provokes a range of ideas around the possible remote recording of temperature. What if the patient took the nurse's temperature? This is nonsensical, but could lead to ideas where the patient plays a more active role in the process. What if the reading could be noted down without waiting? This could provoke ideas around a thermometer that stays in the patient, and readings are taken at leisure.

The working document was accessed regularly by the core research group and updated as the provocations were considered. These techniques generated a great breadth of ideas for each brief (some of which are shown in Table 3).

These techniques generated a great breadth of ideas for each brief (some of which are shown in Table 3).

An iterative design process was followed where ideas were continuously presented to healthcare workers and patients for critical input. This was done firstly with text descriptions of designs, later with sketches, and early stage physical prototypes. Over the course of numerous feedback sessions, the breadth of concepts was narrowed down to a few selected designs for each brief. Some were taken forward to paper prototyping and others to 3D prototypes, with feedback at each stage. A suite of design interventions was produced at the end of the project, including the 'CareCentre™' (see Figs. 6 and 7 later), Respiratory Rate Recorder (Fig. 1), a vital signs trolley (Fig. 2), hand hygiene signage (Fig. 3), medication dispenser (Fig. 4) and recommendations for a handover room (Fig. 5). The development of one of these interventions, the 'CareCentre™' is described to illustrate the design process in more detail.

The 'CareCentre™' was developed primarily in response to the isolation of infection brief, though Table 3 shows that it also addresses many of the other briefs, demonstrating the merit of considering multiple processes and design briefs simultaneously. One of the main practical problems to be tackled in this brief was the member of staff neglecting to clean their hands, or to put on disposable gloves and aprons when appropriate. Shadowing nurses trying to obey correct protocols revealed that much time was wasted searching for gloves and aprons (often located far from the bedside). These observations were extended to include the use of typical equipment for common bedside processes. It was found that the medication locker was often inaccessible (located on the wall, often with a patient obstructing), gloves and aprons were situated away from the bedside, no flat surface for reviewing or writing documents, cleaning wipes were not within easy reach (again located on the wall), and the hand gel at the foot of the bed was difficult to access from the bedside.

The concept of rationalising all this equipment into a 'one-stop-shop' met with user approval, and through a series of feedback sessions with front line staff, the list of contents of this all-in-one unit was defined, as well as its position at the bedside.

The first prototype was produced (Fig. 6) and taken to over 120 staff for review. This featured a flat surface for writing documents, a medication locker, hand gel, cleaning wipes, aprons and gloves, and a folder holder to contain the patient's charts. The concept was designed to hook over the end of the bed.

During the subsequent feedback stage, a manufacturing partner was approached, and was involved in the next iteration of the design. The feedback led to the design being free standing, improved durability, and the addition of a clinical waste bin.

This prototype was the subject of more intense assessment, in the form of simulation trials. A fictional scenario was created where a nurse had to perform three common bedside tasks on a patient (actor): measuring vital signs, giving medication and the removal of a cannula. 20 volunteers were filmed performing these tasks in the simulation ward (a bay complete with furniture and equipment to replicate a hospital ward), once with the 'CareCentre™', and once without (order randomised). Analysis of the video outputs (mapping distance walked, and noting times) is on-going. In addition, 6 prototypes were placed on wards throughout St. Mary's hospital, Paddington, for an on-going clinical trial to investigate their impact on staff adherence to infection control protocols (Anderson et al., 2012b).

Further feedback from these sessions informed the subsequent iteration. The design was reduced in size, a no-touch bin was added, and the aesthetics improved to produce the manufactured model (Fig. 7).

7. Discussion

The approach followed in this work will be familiar to ergonomists and human factors professionals. In fact the approach has been formalised in many industries, such as Human Factors Integration Plans (HFIPs) in industries where human factors is most established such as defence (HFIDTC, 2010) and rail (Bourne and Carey, 2011). Yet despite nearly ten years since the publication of Designing for Patient Safety (Buckle et al., 2003) these approaches are still not established in healthcare. Some of the issues that affect the transfer of human factors approaches to healthcare, and particularly those relevant to the DOME project, are discussed below.

Table 3
Design interventions generated for each of the five bedside processes.

Process	Design ideas	Failures	Causes
Isolation of infection	'One stop shop' workstation at end of bed providing easy access to aprons, gloves and wipes	Failure wear gloves, aprons; failure to use sterile wipes on equipment	Gloves, aprons and wipes not easy to access as away from the bedside
	Improved signage to remind users to clean hands		Lack of reminders
	RFID tagging: initiates a reminder when approaching the bedside and records movement to and from the bedside for audit		Lack of reminders; lack of monitoring and accountability
Hand hygiene	'One stop shop' workstation at end of bed providing easy access to hand gel	Failure to use hand gel	Hand gel and gloves not easy to access as stored away from bedside
	RFID tagging: initiates a reminder when entering the bedside and records movement to and from the bedside for audit		Lack of reminders; lack of monitoring and accountability
	Improved signage to remind users to clean hands		Lack of reminders
Vital signs monitoring	Computer on wheels to facilitate automatic transcription of results	Transcription errors	No process to record readings, notes made on pieces of paper and later transcribed into notes
	Improved vital signs trolley to include retractable cables and improve usability	Failure to record observations	Time to record observations due to poorly designed equipment
	Mobile phone application to record respiratory rate	Fail to record respiratory rate	Lack of suitable method or equipment to record rate
		Record respiratory rate incorrectly	Lack of suitable method or equipment to record rate
Handover	A handover toolkit including recommendations for a handover space	Information not handed over or handed over incorrectly	Poor structure of handover, lack of space, noise, no access to IT
	'One stop shop' workstation at end of bed providing writing space and storage for notes at the end of the bed		Poor access to notes at the bedside; lack of writing space
Medicine delivery	'One stop shop' workstation at end of bed providing easy access medication locker	Failure to ensure patient takes medicine	Poor access to medication locker behind bed
	Medication dispensers and holder with drug name, peel-back foil to show if medication has been removed and a reminder if the drug is not available		No feedback mechanism to see if patient taken drug; tablets not marked with name;
	Patient drug chart		Patient doesn't understand medication and so doesn't take it

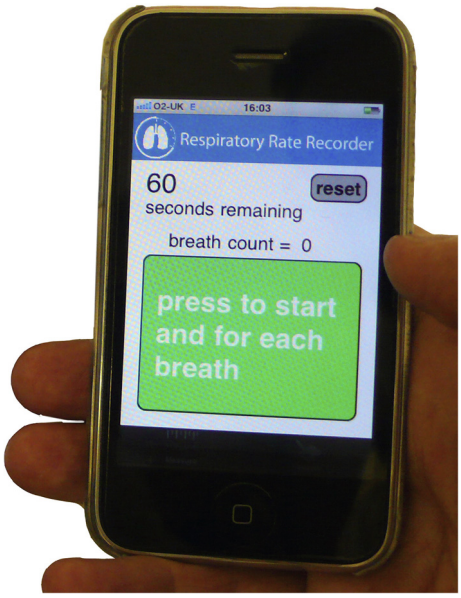

Fig. 1.

7.1. System boundaries

The system under investigation in this project was restricted to a sub-system of a specific clinical speciality (an elective surgical ward). The bedside processes studied are just part of the total care pathway of an elective surgery patient and excluded diagnosis, surgery, discharge and recovery within the community. In turn, elective surgery is only a sub-system of an acute hospital (which could employ over 5000 staff) and in turn of the wider health economy. This gives an idea of the size and complexity of entire healthcare systems and the futility of attempting to understand them fully in the same way as ergonomics/human factors has understood other fields. The selection of a bounded sub-system could therefore be a limitation of this study. However, most safety or improvement interventions will in practice, have to work within boundaries. This makes the systems approach adopted in this study imperative. Using systems analysis tools such as Vincent et al.'s (1998) to identify latent influencing factors (such as organisational culture, training, maintenance, education and staff accountability) ensures that design solutions such as potential RFID tagging and signage would address some of these wider influences.

7.2. Transferability of findings

One of the aims of this study was to demonstrate the value and effectiveness of a systems and multi-disciplinary approach to analysing hazards and developing safety solutions in healthcare.

7.2.1. The designs

The selection of the patient bedside as the domain of interest means that many of the designs might be transferred to other wards and are non-specific to elective surgery. Some design interventions such as the Respiratory Rate Recorder and the hand hygiene signs would also be usable outside of the surgical ward, for instance in out-patient clinics.

7.2.2. The systems approach

The causal analysis demonstrated that for many of the prioritised high-risk failures in the surgical ward there were similar underlying causes, such as availability of equipment, lack of reminders, issues

Fig. 2.

with education and training and design issues. The subsequent design briefs and solutions were developed to address these system level failures; for instance, bringing high frequency use equipment and supplies such as hand gel, sterile wipes and gloves to the bedside reduces travel time and increases likelihood of use. This meant that

Fig. 3.

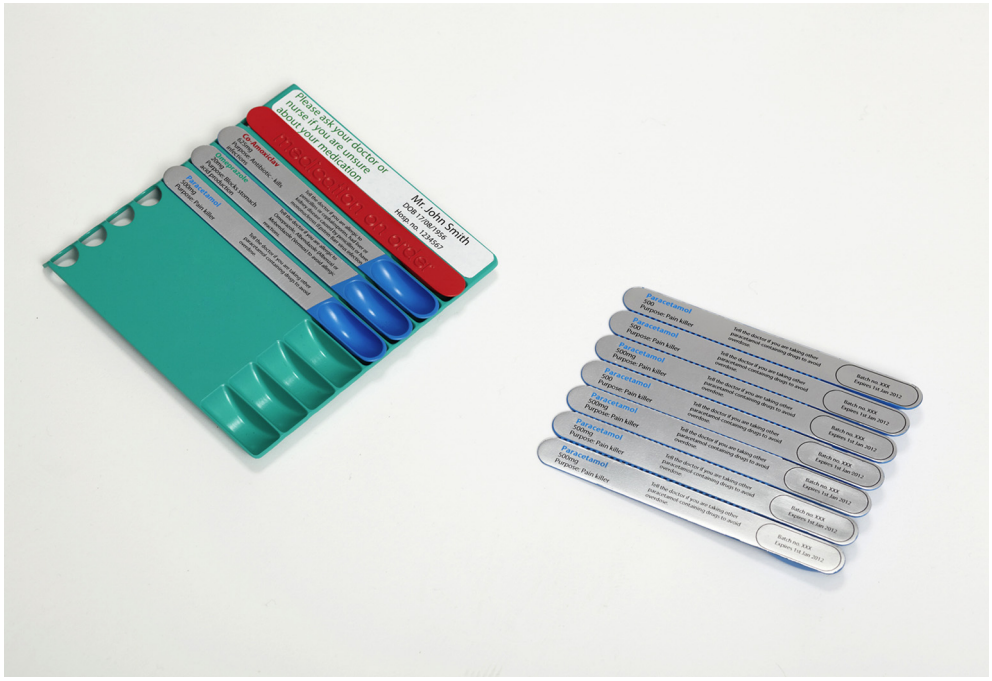

Fig. 4.

one design solution, the CareCentre™, could address multiple failures in many processes e.g. hand hygiene, isolation of infection, handover and medication delivery. This was made possible by applying modified Healthcare Failure Mode and Effects Analysis to multiple healthcare processes in a single healthcare environment.

7.2.3. Sustainability

Common to many of the risks identified in the study were system issues such as lack of accountability, education, procurement and training. Many of these need long term investment and interventions to affect a sustainable change. Whilst the solutions developed in the project will go a small way to influence these, promoting a process that identifies these wider system issues will likely be the most valuable legacy of the project.

7.3. Multi-disciplinary design

Clinicians and designers working alongside each other enabled a shared understanding of key processes and the development of commercially viable, systems-based solutions. In particular,

Fig. 5.

Fig. 6.

clinician involvement provided vital understanding of tacit knowledge and facilitated the engagement of ward staff and subject matter experts in the co-design approach. Observing alongside each other, the designers and clinician were able to share their perspectives. In this project, dedicated clinician time was secured through research funding. However in reality, pressure on clinician time will always be a barrier to developing a workable model of user-centred design in healthcare. However, there are examples of the successful transfer of this multi-disciplinary model into normal healthcare innovation, such as those by the Mayo Clinic in the USA (Mayo, 2009) and the UK NHS Institute (NHS III, 2009). Also, the access to the wards and ward staff that was afforded the design team was unusual, and perhaps can only be achieved when design projects are embedded within the healthcare organisation.

Fig. 7.

8. Conclusions

A number of safety interventions for the surgical ward bedside have been developed through to manufacture (and which are now subject to clinical trials; see Anderson et al., 2012b,c for details of the designs and the testing). Evidence of this sort is vital if the approach promoted in this project is to be adopted more widely in healthcare. The success of the approach can also be indicated by the level of engagement that was achieved with staff on the wards, and the contribution that they made to the co-creation process. Wide and sustained user engagement in safety analysis and design is vital to understand risks, to represent user perspectives and to help implementation. Engagement of this sort also might help to engender a better understanding of system safety amongst users, which might ultimately contribute to a better safety culture. However, finding ways to further promote and implement the collaborative analysis between designers, clinicians and manufacturers that was developed in this project is a future challenge. Encouraging cross-fertilisation and sharing of perspectives during clinician and designer education could help. Financial restrictions in the healthcare sector mean that large scale collaborative design projects such as DOME – involving a large amount of time and resources – are unlikely to become main-stream. Risk assessment methods such as FMEA and causal analysis require training and time, but are vital to understand systems contributions to risk, to avoid a superficial quick-fix and to target efforts where they are most needed. It may be that realistically, shortened or 'light' versions of these methods need to be developed, or resources allocated to specialist help to administer them. Some of the techniques and approaches used in this project are already familiar in healthcare; as stated earlier, the literature contains many healthcare applications of FMEA for instance. 'Systems thinking' has also been widely promoted in the UK through the principles of Lean and the NHS Institute's 'Productive' Series. However, badging these techniques together as a Human Factors approach hopefully will engender a holistic, human-centred view of safety. This project has demonstrated that investing in this approach can yield evidence-based improvements in safety for patients, however the true value will be in transferring this learning into an operational and feasible approach for resource-limited healthcare organisations.

Acknowledgements

The authors would like to thank the EPSRC, Imperial College NHS Trust and in particular all of the staff and patients who contributed to the project.

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