ABSTRACT

Background Human factors and ergonomics (HFE) approaches to patient safety have addressed five different domains: usability of technology; human error and its role in patient safety; the role of healthcare worker performance in patient safety; system resilience; and HFE systems approaches to patient safety.

Methods A review of various HFE approaches to patient safety and studies on HFE interventions was conducted.

Results This paper describes specific examples of HFE-based interventions for patient safety. Studies show that HFE can be used in a variety of domains.

Conclusions HFE is a core element of patient safety improvement. Therefore, every effort should be made to support HFE applications in patient safety.

INTRODUCTION

Many patient safety incidents are related to lack of attention to human factors and ergonomics (HFE) in the design and implementation of technologies, processes, workflows, jobs, teams and socio-technical systems. HFE is now recognised as a key discipline to help reduce or mitigate medical errors,12 to improve the design and implementation of health IT,3 and to eliminate hazards that contribute to patient falls.4 According to the International Ergonomics Association,5 ‘ergonomics (or human factors)’ is the scientific discipline concerned with the understanding of the interactions among humans and other elements of a system, and the profession that applies theoretical principles, data and methods to design in order to optimise human well-being and overall system performance.’ The objective of HFE-based system design is to improve wellbeing (eg, clinician and patient satisfaction) and overall system performance that includes patient safety.6 From an HFE viewpoint, patient safety activities should not only reduce and mitigate medical errors and improve patient safety, but also improve human wellbeing, such as job satisfaction, motivation and technology acceptance. For instance, patient safety programmes that increase the workload of already busy clinicians would not be considered well designed from the HFE perspective. In this paper we described various HFE approaches and contributions to patient safety, and then provide details on a few illustrative examples of HFE applications in patient safety.

HFE APPROACHES AND CONTRIBUTIONS TO PATIENT SAFETY

In this section, we describe a few selected contributions of HFE to various patient safety domains. Other contributions of HFE to patient safety such as teamwork training are reviewed in other papers of this special issue7 and the Agency for Healthcare Research and Quality report on patient safety strategies.8 We also highlight mechanisms that link HFE to patient safety.

Various HFE approaches to patient safety

A significant focus of HFE in healthcare and patient safety has been the design of usable and safe medical devices and health IT,9 such as the redesign of code cart medication drawer.10 Health IT can contribute to patient safety by eliminating hazards,11 but can also create new hazards.12 Usability is one HFE design characteristic that can influence health IT’s patient safety benefits, or lack thereof.3

Another major focus of HFE in patient safety has been understanding the nature
of human error and identifying the mechanisms of human error involved in patient safety.\textsuperscript{13, 14} The Swiss Cheese model of Reason\textsuperscript{15} describes the alignment of hazards (or ‘holes’) that can lead to an accident (eg, a patient safety event) and distinguishes between latent failures and active failures. Vincent and colleagues\textsuperscript{14} adapted Reason’s Swiss Cheese model to patient safety, and described management decisions and latent failures that can influence error and create conditions that produce safety violations. In turn, these conditions create problems for care delivery and may lead to unsafe acts (ie, errors and violations), which may then produce an incident if the defences and barriers are not appropriate. The frameworks of Vincent and colleagues\textsuperscript{14} and Bogner\textsuperscript{16} can be used by healthcare organisations to investigate patient safety incidents.

Performance obstacles may endanger patients by making it difficult for clinicians to perform tasks and procedures safely.\textsuperscript{17} A range of physical (eg, lifting, injecting, charting), cognitive (eg, perceiving, attention, communicating, awareness) and social/behavioural (eg, motivation, decision-making) performance processes can influence patient safety.\textsuperscript{18} Performance obstacles have been identified for intensive care unit nurses,\textsuperscript{19, 20} staff in outpatient surgery centers,\textsuperscript{21} and hospital nurses.\textsuperscript{22}

Recently, HFE research in patient safety has focused on system resilience,\textsuperscript{23} or ‘the ability of systems to anticipate and adapt to the potential for surprise and failure’.\textsuperscript{24} Because not all errors may be prevented, HFE researchers have developed models to understand how errors can be detected, corrected, mitigated, and dealt with by operators.\textsuperscript{25} Strategies for error detection and recovery have been explored among nurses,\textsuperscript{26} in particular critical care nurses,\textsuperscript{27} and among pharmacists.\textsuperscript{28, 29} Resilience engineering builds on and extends the work done by high-reliability organisation (HRO) researchers, in particular the HRO concept of mindfulness, that is, the ability to prepare for the unexpected and to be vigilant about hazards.\textsuperscript{30}

The first four HFE approaches focus on specific aspects of HFE and patient safety: usability of technology, human error, clinician performance and resilience. A number of HFE approaches have been proposed to describe more comprehensive systems of patient care, such as the systems approach proposed by Vincent and colleagues\textsuperscript{14, 31} and the SEIPS (Systems Engineering Initiative for Patient Safety) model of work system and patient safety proposed by Carayon and colleagues.\textsuperscript{32} Vincent and colleagues\textsuperscript{14} defined seven types of system factors that can influence clinical practice and lead to patient safety incidents, such as patient factors, task and technology factors, and organisational and management factors. The SEIPS model of work system and patient safety\textsuperscript{32} identifies a slightly different set of system factors: individual factors (which include characteristics of the staff and patient), tasks, tools and technologies, environment, and organisational factors (which include team factors). In addition to defining the system and emphasising system interactions,\textsuperscript{33} the SEIPS model describes how system design can influence care processes and other connected processes (eg, delivery of supplies, housekeeping, purchasing of medical equipment). Because the SEIPS model is anchored in HFE, employee and organisational outcomes are addressed along with patient safety, reflecting the fact that patient safety and worker safety and wellbeing are positively correlated and have common system contributing factors.\textsuperscript{34}

### Table 1  HFE mechanisms between system design and patient safety

<table>
<thead>
<tr>
<th>HFE mechanisms</th>
<th>Objectives of system design</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A work system that is not designed according to HFE design principles can create opportunities for errors and hazards (see table 2 for examples of design principles)</td>
<td>The objective of HFE-informed system design is to identify and remove system hazards from the design through maintenance phases.</td>
</tr>
<tr>
<td>2. Performance obstacles that exist in the work system can hinder clinicians’ ability to perform their work and deliver safe care</td>
<td>If some obstacles cannot be removed, for instance, because they are intrinsic to the job, then strategies should be designed to mitigate the impact of performance obstacles by enhancing other system elements (ie, balance theory of job design)\textsuperscript{31, 42}</td>
</tr>
<tr>
<td>3. A work system that does not support resilience can produce circumstances where system operators may not be able to detect, adapt to, and/or recover from errors, hazards, disruptions and disturbances</td>
<td>Work systems should be designed to enhance resilience and support adaptability and flexibility in human work,\textsuperscript{43} such as allowing problem or variance control at the source\textsuperscript{44}</td>
</tr>
<tr>
<td>4. Because system components interact to influence care processes and patient safety, HFE system design cannot focus on one element of work in isolation,\textsuperscript{32, 33}</td>
<td>Whenever there is a change in the work system, one needs to consider how the change will affect the entire work system, and the entire system needs to be optimised or balanced\textsuperscript{41, 42}</td>
</tr>
</tbody>
</table>

HFE, human factors and ergonomics.
performance obstacles. For instance, the *Handbook of Human Factors in Medical Device Design*\(^\text{36}\) provides a comprehensive set of principles for medical device design. Usability heuristics or rules of thumb for user interface design have been developed for health IT and medical devices.\(^\text{37}\) The physical design of the work system should minimise perception time, decision time, manipulation time, and the need for excessive physical exertion, and optimise opportunities for physical movement.\(^\text{35} 38\) From an organisational HFE viewpoint, work systems should be designed so that tasks are reasonably demanding physically and cognitively. Workers should have opportunities to learn, adaptive levels of control over their work system, and access to social and instrumental support (eg, support from coworkers in case of emergency) within the work environment.\(^\text{39}\) Table 2 provides some examples of HFE design principles; additional information on HFE design for specific work system elements can be found in the *Handbook of Human Factors and Ergonomics*.\(^\text{40}\)

Given the systems focus of HFE, it is important not only that each component of the system be designed appropriately, but also that system components be aligned\(^\text{44}\) and that system interactions be optimised.\(^\text{33}\) For example, when a new barcoding medication administration (BCMA) system is introduced, it is important to ensure that the technology is designed according to HFE principles (eg, usability heuristics). However, it is also important that the technology fits with the rest of the work system. If there is not sufficient space in which to use the BCMA (interaction between the technology and the physical environment) or if users are not provided with adequate training (interaction between the technology and the organisation), then BCMA may contribute to diminished rather than improved clinician performance and patient safety.

### Table 2 Examples of HFE design principles

<table>
<thead>
<tr>
<th>Focus of HFE</th>
<th>Examples of HFE design principles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical HFE</td>
<td>To minimise perception time, decision time, and manipulation time</td>
</tr>
<tr>
<td></td>
<td>To reduce or mitigate need for excessive physical exertion</td>
</tr>
<tr>
<td></td>
<td>To optimise opportunities for physical movement</td>
</tr>
<tr>
<td>Cognitive HFE</td>
<td>To ensure consistency of interface design</td>
</tr>
<tr>
<td></td>
<td>To match between technology and the user’s mental model</td>
</tr>
<tr>
<td></td>
<td>To minimise cognitive load</td>
</tr>
<tr>
<td></td>
<td>To allow for error detection and recovery</td>
</tr>
<tr>
<td></td>
<td>To provide feedback to users</td>
</tr>
<tr>
<td>Organisational HFE</td>
<td>To provide opportunities to workers to learn and develop new skills</td>
</tr>
<tr>
<td></td>
<td>To allow worker control over work system</td>
</tr>
<tr>
<td></td>
<td>To support worker access to social support</td>
</tr>
<tr>
<td></td>
<td>To involve users in system design</td>
</tr>
</tbody>
</table>

HFE, human factors and ergonomics.

In addition to principles for designing work systems and processes, HFE has developed principles for changing work systems. For instance, in the context of health IT, HFE implementation principles, such as participation, communication and feedback, learning and training, top management commitment and project management are critical to realising the patient safety potential of health IT.\(^{45} 46\) These implementation principles are essential and applicable to the implementation of all kinds of work system design.

### HFE-BASED INTERVENTIONS FOR PATIENT SAFETY

Studies have used HFE tools and methods to identify system factors that contribute to medical errors; based on these data, researchers or system designers devise recommendations for improving healthcare work systems and processes. These studies are useful for highlighting the importance of HFE to patient safety; however, they do not provide empirical evidence for the value of HFE in improving patient safety.

Empirical studies of how HFE-based interventions affect patient safety are few, those that are available have addressed usability of healthcare technologies, concomitant design of healthcare technologies and work system, and design of healthcare processes. This paper is not intended to be a systematic review of HFE-based interventions for patient safety, especially given the broadly different clinical topics and the small number of studies in each clinical topic. Rather, our objective is to highlight the variety of HFE applications and to describe the details of a small number of HFE applications that produced patient safety improvements. Thus we review only six studies to demonstrate various HFE applications. These examples also show that HFE applications for patient safety do not have to wait for accidents to occur; HFE is primarily a proactive system design approach.

#### Example 1: HFE in the design of radiotherapy treatment delivery system

In the first example, HFE methods were used in the design of a radiotherapy treatment delivery system.\(^{47} 48\)

**Step 1: HFE analysis**

The researchers first evaluated the existing radiotherapy treatment delivery process. Over a 3-month period, an HFE engineer conducted 30 h of field observations of radiation therapists performing their regular tasks. Workflows of radiation therapists, in particular their interactions with the treatment-delivery system, were recorded. Based on these observations, the researchers compiled a list of tasks regularly performed by radiation therapists during treatment delivery.
Step 2: heuristic usability evaluation

One experienced therapist and two HFE engineers performed a heuristic evaluation of the usability of a treatment-delivery system. Since the two HFE experts were not authorised to operate the system, the therapist performed the tasks and explained the workflow to the engineers. The two HFE experts independently identified HFE issues based on 14 usability heuristics,37 and evaluated the severity of each usability issue; they then compared their ratings and reached consensus on a final list of usability issues and their severity. A total of 75 usability issues were identified; of these, 18 were classified as having a high potential impact on patient safety (ie, high severity), 20 were classified as medium severity and 37 were classified as low severity. For instance, when the therapist entered notes into a patient’s file, the notes could be deleted without warning if the therapist selected another patient’s file before saving the notes. This usability issue violated the heuristics of feedback, error recovery and ability to undo, and was rated with high severity. The recommendation for technology redesign was to warn therapists that their notes might be deleted if they have not saved them.

Step 3: system redesign and evaluation

The existing treatment delivery system was redesigned based on HFE design principles. Two focus groups with experienced radiation therapists provided feedback on the redesigned treatment delivery system, and the system was further refined. Finally, user testing with 16 radiation therapy students was conducted to compare the current and redesigned treatment delivery systems. Using each of the two systems, students went through four scenarios related to typical treatment-delivery tasks. Three of the four scenarios were designed with a high potential for certain use errors to occur (overlooking an important note, shifting the treatment couch incorrectly, and overlooking a change of approval dates). The error rates and overall time to complete each scenario were measured. At the end of the testing, participants were asked to fill out a questionnaire to compare various attributes of the two systems. Results showed that error rates for overlooking an important note and for overlooking changes in approval dates decreased significantly with the redesigned treatment-delivery system (from 73% to 33% and from 56% to 0% respectively). The redesigned treatment delivery system led to efficiency gains (the mean task completion time was reduced by 5.5%) and improvement in user satisfaction.

Example 2: HFE in the design of ED telemetry system

In the second example, a phased HFE approach with significant end user participation is combined with in situ simulation to assess an existing emergency department (ED) telemetry system and redesign it to improve performance of cardiac arrhythmia detection.49

Step 1: HFE system analysis

The researchers used multiple methods to assess the existing telemetry system and its design deficiencies. Several hardware problems were identified by conducting a hardware inventory and function diagnostic. Field observations and web-based surveys revealed several HFE problems related to the use of the telemetry system, such as limited accessibility, poor usability and utility and alarm fatigue. Informal discussions with clinical staff (eg, physicians, nurses, ED technicians) held during shift change and impromptu on-shift meetings provided additional information on all work-system elements related to the telemetry system (see figure 1). The researchers also gathered input from ED clinical practice and administrative leadership councils and patient safety and simulation workgroups.

Step 2: HFE system design and implementation

Based on the initial analysis phase, work system constraints and HFE specifications for redesigning the telemetry system were determined by researchers and stakeholders (eg, institutional biomedical engineers, the device manufacturer, clinical staff). Through an iterative process, a multifarious intervention was developed to address the three categories of HFE issues: physical HFE issues—hardware repair and repositioning to enhance alarm audibility and visibility, replacement of traditional keyboard and mouse with touchpad input devices to compensate limited workspace; cognitive HFE issues—adjustment of alarm parameter to reduce false alarms; integration of the telemetry system into nurse charting informational workflow to improve general utility; and organisational HFE issues—coordination of institutional infrastructure for routine maintenance, announcement of study conduct and intervention at ED personnel meetings to increase user awareness, group in-servicing and on-shift in-servicing of ED personnel to tackle knowledge deficit of system operation. The intervention was implemented incrementally over a period of 17 months.

Step 3: evaluation of telemetry system redesign

Twenty pre-intervention, 10 interim and 20 post-intervention arrhythmia simulation sessions were conducted over three separate 2-week periods to evaluate the initial telemetry system and compare it with the redesigned telemetry system. Performance data (eg, time between initiation and detection of simulated arrhythmia, detection method, role of the first responder) were collected in each period. The overall arrhythmia detection rate was 5% at baseline, 40% during the interim period and 55% with the fully redesigned telemetry system. Results of post-intervention user surveys indicated that the redesigned...
telemetry system empowered clinical providers during patient care duties and had the potential to improve patient care. However, a review of alarm log record showed frequent false-positive alarms with the redesigned telemetry system; this indicates the need for further system redesign efforts to continue to support and improve clinicians’ ability to detect cardiac arrhythmia.

**Example 3: HFE in the design and implementation of health IT**

Various work system factors can affect the acceptance and effective use of healthcare technologies. Inadequate planning for implementation and lack of integration of healthcare technologies in existing work systems are associated with work-arounds and technologies falling short of achieving their patient safety goal. HFE approaches, which emphasise simultaneous design of the healthcare technology and the work system, are recommended for achieving a balanced work system and fulfilling the full potential of healthcare technology in improving patient safety.

Beuscart-Zéphir and colleagues developed an HFE framework for healthcare technology and work system design, along with a set of structured methods to optimise the work system. The HFE framework includes four stages: analysis of the sociotechnical system and the demands of stakeholders; cooperative design of the healthcare technology and the work system with the institution, designers and developers; iterative evaluation and redesign; and assessment of the new work system and its impact on patient safety and overall performance of the sociotechnical system. The HFE framework was used to improve the design and implementation of computerized physician order entry (CPOE).

---

**Step 1: analysis of medication use process and recommendations for system redesign**

Researchers conducted a systematic qualitative analysis of the medication ordering–dispensing–administration process. Field observations and semi-structured interviews were performed with nurses to identify nursing tasks in the medication administration process, to characterise physician–nurse and nurse–nurse communication about medications, and to assess nurses’ interactions with paper patient records. Then more than 7000 paper medication orders written by physicians and the corresponding paper medication-administration records from nurses were reviewed.

**Step 2: cooperative system design**

The results of observations, interviews and document review were presented to nurses for feedback; software engineering models (e.g., UML and Petri Nets) were created to model the distribution of tasks observed. Factors contributing to the safety of medication process were identified at three levels: individual

---

Figure 1 Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety. Reproduced from Carayon et al with permission from BMJ Publishing Group Ltd.

---

(A work system can be balanced through either compensatory balance when positive work system elements compensate for negative work system elements, or overall system balance when the combination of positive and negative work system elements produces benefits with regard to outcomes.)

---

(eg, interactions between nurses and the technology when administering medications), collective (eg, verbal communications supporting cooperation during the medication management process) and organisational (eg, distribution of tasks across different healthcare professionals). Recommendations for work system redesign were proposed, such as the need to provide nurses with specific information at each step of the preparation and administration of medications, and the need for regular physician–nurse communications about patient treatment and changes to the plan of care (eg, daily briefing either before or after medical rounds).

Step 3: usability evaluation of CPOE technology
The researchers also evaluated the usability of the proposed CPOE technology. Five independent HFE experts evaluated the user interface of the software application, using a set of HFE criteria. A total of 35 issues related to workload, compatibility, control, homogeneity, guidance and error prevention were identified and rated on a four-point scale for severity.

In a laboratory user testing, eight nurses used the think-aloud method in a simulation of the preparation of medication dispensers and the validation and documentation of medication administration. The laboratory test was designed to reproduce the nurses' typical work environment. Scenarios were created based on the results of the initial work system analysis. Nurse participants identified a total of 28 usability issues during the test.

Step 4: iterative HFE redesign
In the next phase of CPOE technology redesign, possible solutions for each of the identified usability issues were proposed and evaluated with respect to costs and benefits. Mock-ups and prototypes were developed for those solutions. Iterative usability evaluations and technology redesigns were done until all critical usability issues were addressed. To evaluate the impact of the HFE-based design of healthcare work system on patient safety, the researchers proposed to link the system redesign to the actual identification of adverse events.

In a recent project, the researchers used statistical data mining methods to semi-automatically identify adverse drug events and to link the identified adverse drug events to the analysis and modelling of the work systems. The HFE framework of Beuscart-Zéphir and colleagues is now routinely integrated in IT project management of the Centre Hospitalier Universitaire de Lille, France.

Example 4: HFE in the physical design of operating rooms
In the fourth example, HFE is used to address infection-control problems in the operating room (OR). To minimise infection risk, surgical devices were suggested to be positioned within the clean airflow in the OR according to HFE design principles.

Step 1: benchmarking of system
A multidisciplinary team of hospital surgical staff learned from the experience of runway operators at an international airport regarding marking, position of materials, traffic flows, safety rules and regulations, and incident management. They applied this knowledge to OR traffic flows, position of surgical tables and materials, safety management and the process of incident reporting.

Step 2: HFE system design
The multidisciplinary team designed and implemented floor marking to support consistently correct positioning of surgical devices. The implementation was carried out in three steps:
1. temporary marking was implemented in two of four ORs in February 2009;
2. temporary marking was implemented in all four ORs by June 2009;
3. permanent floor marking was implemented in all ORs in December 2009.

Step 3: evaluation of system redesign
Compliance with positioning of surgical devices within the clean airflow was evaluated by observing a total of 182 surgeries before implementation of the floor marking. One month after the implementation of the temporary floor marking in two ORs, compliance data were collected by observing 195 surgeries in ORs with floor markings and 86 surgeries in ORs without floor markings. Four months after implementation of the temporary floor markings in all four ORs, 167 surgeries were observed to collect compliance data. Finally, 199 surgeries were observed 1 month after the implementation of permanent floor markings. Floor marking resulted in significantly increased compliance with recommended positioning of surgical devices in the clean airflow. In addition, post-implementation interviews with three ophthalmic surgeons, three surgical and anaesthesia nurses, and two managers showed enhanced safety awareness among surgical staff. Although the researchers did not use the term ‘HFE’ to describe their study, their approach used a systematic work system analysis and led to a solution firmly rooted in the HFE systems approach.

Example 5: HFE to identify patient safety hazards in surgery
In the fifth example, an HFE approach was used to identify and categorise patient safety hazards in cardiovascular ORs.

Step 1: identification of work system hazards in cardiovascular ORs
A multidisciplinary team of researchers from clinical medicine, health services research, human factors engineering, industrial psychology and organisational...
sociology identified patient safety hazards in five hospitals through observations, contextual inquiries and pictures of the environment and tools and technologies in cardiovascular ORs. Four team members (a health services researcher, a cardiac anaesthesiologist, a nurse and a human factors engineer) conducted the observations; two of them were present for each surgery. A total of 20 cardiac surgeries were observed over about 160 h, and 84 contextual inquiries were recorded. The four team members reviewed all of the data, including observation notes, contextual inquiries and the pictures, and identified patient safety hazards.

Step 2: categorising the work system hazards
The researchers used deductive and inductive approaches to analyse the qualitative data and categorised the work system hazards in cardiovascular surgeries. The SEIPS model\(^\text{132}\) (see figure 1) was used in a deductive manner to create high-level categories of patient safety hazards, which were further developed in subcategories based on emerging themes from the data (inductive process). A total of 59 patient safety hazard categories were identified:

1. care provider: variations in performing procedures, inappropriate professional conduct;
2. task: increased workload, interruptions in the workflow;
3. tools and technologies: usability issues, tools and technologies not available in a timely manner;
4. physical environment: limited physical space in the ORs, poor arrangement of equipment;
5. organisation: lack of a culture to report patient safety incidents, poor communication;
6. processes: evidence-based practices not followed, poor supply chain management.

Step 3: proposing solutions for system redesign
Based on the patient safety hazards identified in the study, the researchers propose solutions for system redesign, such as standardisation of care across an organisation, teamwork training for care providers, further analysis with methods such as proactive risk assessment (see next example), use of simulation to evaluate the physical layout of ORs before building them, and use of recommended communication practices such as repeat back.

Example 6: HFE in the design of care processes
HFE can help to improve the design of care processes.\(^\text{61}\) Proactive risk assessment methods, such as failure mode and effects analysis (FMEA), are HFE methods that can be used to evaluate high-risk processes in healthcare and provide input for healthcare process design.\(^\text{62,63}\) A number of publications provide guidance for conducting proactive risk assessment such as FMEA\(^\text{62,64}\) and discuss challenges in performing such analysis.\(^\text{65,66}\) The sixth study describes an FMEA of the intravenous medication administration process conducted to assess the potential HFE and safety issues of a new intravenous pump.\(^\text{67}\)

Step 1: formation and training of FMEA team
A multidisciplinary team consisting of representatives from anaesthesiology, biomedical engineering central supply, human factors engineering, internal medicine, nursing, pharmacy and quality improvement performed a healthcare Failure Modes and Effects Analysis (HFMEA)\(^\text{68}\) to evaluate the intravenous medication administration process using current intravenous pump and Smart intravenous pump technology. The team members were trained for 1–2 h in the Veteran Affairs’ HFMEA method.\(^\text{68}\)

Step 2: FMEA analysis process
The FMEA process consisted of 46 h of meetings over 4½ months and unfolded in three steps:

1. process identification and mapping;
2. failure mode identification and scoring;
3. determination of interventions and outcome measures.

Multiple data sources were used to develop the intravenous medication administration process map. Two HFE experts conducted a total of 52 observations of nurses administering medications with the current intravenous pump.\(^\text{69}\) Medication administration and intravenous pump events reported with the current pump were retrieved from the hospital’s event reporting system. The FMEA team mapped the medication administration process with the current intravenous pump and then repeated the mapping process with the Smart intravenous pump. In the process map with the current intravenous pump, the team identified 10 steps for retrieving the medication and tubing, and 24 steps for pump programming were identified. For the Smart intravenous pump, the team identified 14 unique pump programming steps and new tubing setup and insertion steps.

Following process mapping, the team analysed failure modes potentially associated with intravenous pump use. About 200 failure modes were identified and scored with respect to severity and probability of occurrence. A hazard score was calculated by using the product of the severity and probability of occurrence ratings. Failure modes with low or low–moderate hazard scores were assessed for detectability, and only non-detectable failure modes were considered for further action. All failure modes with moderate to high hazard scores were considered further.

Step 3: recommendations for process redesign
Recommendations for prioritised failure modes were proposed and categorised into the five elements of the work system\(^\text{1,2}\) (see figure 1): policies and procedures; training or education; physical environment; people; and technology software or hardware change. The evaluation of the impact of the FMEA on patient safety was based on: audits of programming of pumps for errors; monitoring of end-user training for time to achieve competency; and monitoring and recording of intravenous medication administration event reports and informal and formal complaints about pump issues.
functioning. Post-implementation results suggested that the goal of mitigating risk to patients from potential or known failure modes was achieved.

CONCLUSIONS

A study conducted by an HFE leader, Al Chapanus, and his colleague in the early 1960s provided information on medication administration errors and the system factors that contributed to these errors.\(^{70–72}\) Since then, awareness of the importance of HFE in medication safety and other patient safety domains has significantly increased. Patient safety leaders have called for increasing involvement of HFE in helping to characterise system factors that contribute to patient safety and to inform system design interventions.\(^{3, 73, 74}\) This paper has described examples of HFE contributions to specific patient safety problems.

Further research is necessary to document and demonstrate the value of HFE-based interventions and their impact on patient safety. Evidence for the effectiveness of HFE-based interventions should include data on changes in the work system, changes in the process and changes in outcomes (including patient safety and employee outcomes). In general, this evidence is provided through the use of multiple quantitative and qualitative methods.

Numerous patient safety practices can benefit from HFE input. Patient safety practices target some aspect of the work system (see figure 1) and should be designed and implemented according to HFE principles to produce patient safety benefits. For instance, checklists have been shown to improve patient safety.\(^{75, 76}\) Checklists can be considered as a tool in the work system (see figure 1), and their patient safety benefits are enhanced when they are designed and implemented to fit the rest of the work system.\(^{77}\) An intervention study at the VA included teamwork training, ongoing coaching, and tools such as a checklist that supported teamwork.\(^{78}\) The checklist acted as a tool to trigger OR communication rather than as a simple memory aid. The checklist is a tool that requires changes in other elements of the work system (see figure 1).

HFE is a core element of patient safety strategies.\(^{8}\) Therefore, every effort should be made to support HFE applications in patient safety. Healthcare leaders, executives, administrators and vendors should ensure that HFE is included in any patient safety improvement. This can be accomplished through the use of HFE tools and methods (eg, usability evaluation of health IT), HFE training in healthcare organisations and vendors, or hiring of HFE engineers.\(^{79}\)

Acknowledgements Partial funding was provided by AHRQ through a contract to RAND (HHSA-290-2007-100621) and by the Clinical and Translational Science Award (CTSA) programme, previously through the National Center for Research Resources (NCRR) grant 1UL1RR025011, and now by the National Center for Advancing Translational Sciences (NCATS), grant 9U54TR000021. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

Contributors PC: major contribution in the conception and design of the paper, major contribution in drafting and revising the paper, major contribution in final approval of the version to be published. AX and SK: some contribution in the conception and design of the paper, some contribution in drafting and revising the paper, some contribution in final approval of the version to be published.

Funding Partial funding was provided by AHRQ through a contract to RAND (HHSA-290-2007-100621) and by the Clinical and Translational Science Award (CTSA) programme, previously through the National Center for Research Resources (NCRR) grant 1UL1RR025011, and now by the National Center for Advancing Translational Sciences (NCATS), grant 9U54TR000021. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

Competing interests None.

Provenance and peer review Not commissioned; externally peer reviewed.

Open Access This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 3.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/3.0/

REFERENCES

Systematic review

55 de Korne DF, van Wijngaarden JDH, van Rooij J, et al. Safety by design: effects of operating room floor marking on the


