Part 2b. Practices Designed To Improve Overall System/Multiple Targets

Chapter 31. Human Factors and Ergonomics

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How Important Is the Problem?

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 sociotechnical systems. For instance, a systems analysis of medication errors\(^1\) identified a range of proximal causes of medication errors, such as rule violations, memory slips and lapses, poor communication with other services, and incorrect pump programming caused by poor design of the pump interface. Lack of attention to HFE in areas such as technology design can contribute to medication errors and preventable adverse drug events.

The Institute of Medicine (IOM) report on Medication Errors\(^2\) emphasizes the need for addressing HFE issues, such as the design of medication labels and packages, and the design of medication administration technologies (e.g., infusion pump). A study by Han et al.\(^3\) in a pediatric hospital showed an increase in mortality rates after the implementation of Computerized Provider Order Entry (CPOE); many factors that contributed to the increase were related to HFE. For instance, the design of the CPOE interface required about 10 clicks per order, thus significantly increasing time needed to enter orders. The poor usability of the CPOE system and its lack of integration with clinician workflow contributed to delays in patient care that were a major factor in the increased mortality rate after CPOE implementation.

The recent IOM report on Health IT and Patient Safety\(^4\) clearly indicates the need for HFE in the design, implementation and use of health IT. The report proposes a sociotechnical approach that emphasizes the need for health IT to support clinical workflows. Increased cognitive workload associated with the implementation and use of health IT and lack of usability of health IT are two HFE issues associated with patient safety incidents highlighted in the report.

A systematic review showed how environmental hazards can contribute to patient safety incidents such as patient falls.\(^5\) For instance, the use of bedrails can contribute to patient falls by contributing to entrapment injuries.

These studies provide evidence for the importance of HFE in patient safety; they highlight the range of physical, cognitive and organizational HFE issues that can contribute to patient safety incidents. There are many other examples of how lack of attention to HFE contributes to patient safety incidents. For instance, a fatal medication error occurred on July 5, 2006 at St. Mary’s hospital in Madison, WI: An epidural penicillin solution instead of an intravenous (IV) penicillin retain was administered to a 16-year old pregnant patient’s IV line, causing her immediate death. A root cause analysis identified several HFE issues that contributed to the fatal error.\(^6\) The IV and epidural bags had similar designs, and both medication bags could be connected to IV and epidural tubing. A barcoded medication administration (BCMA) technology had been recently introduced in the hospital, but the nurse did not use it. Because of the technology’s poor usability and lack of training (i.e., HFE issues), many nurses did not use the technology and thus could not take advantage of its safety features.

Vincent et al.\(^7\) describe three groups of factors for explaining adverse surgical outcomes:
1. patient risk factors (e.g., increased body mass index, presence of comorbidity)
2. surgical skills (e.g., technical skills), and
3. operation profile (or system factors).

The operation profile includes a range of HFE-related system factors, such as operative environment, team performance and communication, and decisionmaking processes. System characteristics are factors that, in addition to patient characteristics and the skills of the surgery team, can contribute to complications and adverse events. A range of system factors can influence the safety of surgery and can be addressed by using concepts, models, theories and methods from HFE. Vincent’s approach can be extended to patient safety incidents in other care settings besides surgery. Patient characteristics and clinician skills and knowledge are important for patient safety; but poor system design can also contribute to patient safety incidents. HFE helps to identify system design deficiencies and hazards that affect patient safety and provides the concepts and methods to improve system design and, therefore, patient safety.

What Is the Patient Safety Practice?

According to the International Ergonomics Association (IEA), “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 optimize human well-being and overall system performance.”

Key Characteristics of Human Factors and Ergonomics

“Human Factors” and “Ergonomics” are synonymous names for the discipline; the discipline is often referred to as Human Factors and Ergonomics or HFE. HFE covers a wide range of physical, cognitive, and organizational issues involved in system design. Physical HFE issues include physical dimensions of tools that do not fit physical characteristics of users (e.g., too small font size on computer screen), inappropriately designed physical environments (e.g., lighting too bright and creating glare, noisy and distracting environment) and physical layout that does not support clinician work (e.g., monitoring patients from the central nursing station). Cognitive HFE issues include interactions between people and the rest of the system such as perception, memory, attention, mental workload, and support for decisionmaking. At the organizational level, HFE focuses on communication and coordination, teamwork, job design, sociotechnical system, and system design, and change (e.g., participatory ergonomics). Other examples of physical, cognitive and organizational (macroergonomic or sociotechnical) HFE issues of relevance to patient safety can be found in textbooks and papers.

Rather than attempting to fit the person to the system, HFE works to fit the system to the person. Systems should be designed to accommodate the range of characteristics, needs, and limitations of people. In this context, people means single individuals, teams, or larger organizational units. According to the IEA definition, the objective of HFE-based system design is to improve both human well-being and overall system performance. Patient safety can be considered one aspect of ‘overall system performance.’ From an HFE viewpoint, patient safety activities should not only reduce medical errors and improve patient safety, but also improve human well-being, such as job satisfaction, motivation and acceptance of technology. For instance, patient safety programs that increase the workload of already busy clinicians would not
be considered well designed from the HFE perspective. See Table 1 for a summary of the key characteristics of HFE.

Table 1, Chapter 31. Key characteristics of HFE and its application to patient safety

<table>
<thead>
<tr>
<th>Definition of HFE by the International Ergonomics Association (<a href="http://www.iea.cc">www.iea.cc</a>)</th>
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<tbody>
<tr>
<td>Name of the discipline</td>
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<tr>
<td>Range of HFE issues</td>
<td>Physical, cognitive and organizational (macroergonomic or sociotechnical) issues of HFE are all relevant to patient safety.</td>
</tr>
<tr>
<td>Goal of HFE</td>
<td>The goal of HFE is to fit the system to the people instead of fitting people to the system.</td>
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<tr>
<td>Objectives of HFE</td>
<td>The objective of HFE-based system design is to improve both well-being and system performance. Patient safety is one component of system performance.</td>
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**Human Factors and Ergonomics Applications to Patient Safety**

HFE contributes to five domains of patient safety: (1) usability of medical devices and health information technology, (2) focus on human error and its role in patient safety, (3) role of health care worker performance in patient safety, (4) system resilience and its role in patient safety, and (5) HFE systems approaches to patient safety.

**Usability of Medical Devices and Health IT**

A significant focus of HFE in health care and patient safety has been the design of usable medical devices and health IT. For instance, to improve medication management in medical emergencies, HFE principles were used to redesign the code cart medication drawer. User testing was conducted to compare the medication retrieval time and number of wasteful actions associated with the existing and prototype drawers. Compared with the existing drawer, the prototype drawer resulted in shorter medication retrieval time and fewer wasteful actions. The prototype drawer also received higher ratings for visibility, organization, and general usability. A detailed example of the application of usability methods for improving safety of radiotherapy treatment delivery is provided in the section on “What are the beneficial effects of the Patient Safety Practice?”

Health IT can contribute to patient safety by eliminating hazards. However, it may also create new hazards. Usability is one HFE design characteristic that can influence health IT’s patient safety benefits, or lack thereof. HFE methods have been used to improve the usability of CPOE order sets to design the user interface of a software application that was developed to extract and present data relevant to the treatment of critically ill patients to providers, and to improve the design of medication alerts. The second example in the section on “What are the beneficial effects of the Patient Safety Practice?” provides information on the usability evaluation of CPOE technology.

**Human Error and Patient Safety**

Another major focus of HFE in patient safety has been understanding the nature of human error and identifying the mechanism of human error involved in patient safety. This probably represents the largest contribution of HFE to patient safety. The Swiss Cheese model of Reason describes the alignment of hazards (or ‘holes’) that can lead to an accident—(e.g., a patient safety event) and distinguishes between latent failures and active failures. Latent failures
result from decisions made by system designers and organizational decision-makers that lead to unsafe conditions. Active failures are errors made by the operators of the system.

Vincent and colleagues have adapted Reason’s Swiss Cheese model to patient safety. They describe 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 (i.e., errors and violations), which may then produce an incident if the defenses and barriers are not appropriate. Reason’s Swiss Cheese model and its patient safety version by Vincent and colleagues include both errors and violations as active failures. Recent HFE research has broadened the focus on human error and developed knowledge about the contribution of violations to patient safety.

Bogner has proposed another HFE model of human error and patient safety: the Artichoke model defines layers of system factors that influence provider-patient interactions, such as legal-regulatory-reimbursement, national culture, organization, physical environment, social environment, and ambient environment. The frameworks proposed by Vincent and colleagues and Bogner can be used by health care organizations to investigate specific patient safety incidents.

Health Care Worker Performance

Performance obstacles may endanger patients by making it difficult for clinicians to perform tasks and procedures safely. A range of physical (e.g., lifting, injecting, charting), cognitive (e.g., perceiving, attention, communicating, awareness) and social/behavioral (e.g., motivation, decision-making) performance processes can influence patient safety. When obstacles are present in the work environment, physical, cognitive and social/behavioral performance of clinicians may be challenged and accidents may occur. Performance obstacles have been identified for ICU nurses, staff in outpatient surgery centers, and hospital nurses. Information on performance obstacles can be used to improve working conditions of health care professionals; these changes may produce patient safety benefits. When faced with performance obstacles, clinicians have to improvise ways of getting their work done. HFE research has characterized such work-arounds and their patient safety implications in nursing medication administration, especially in the context of BCMA use. HFE has proposed a range of approaches, including work teams and team training, to enhance health care worker performance, and improve communication, coordination, and information flow.

System Resilience

Recently, HFE research in patient safety has focused on system resilience. Resilience has been defined as “the ability of systems to anticipate and adapt to the potential for surprise and failure.” 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. The WHO model of patient safety incorporates the concepts of error detection and mitigation. Strategies for error detection and recovery have been explored among nurses, in particular critical care nurses, and among pharmacists. This line of HFE research can produce information about mechanisms for achieving resilience, such as cross-checking. Resilience engineering builds on and extends the work done by High Reliability Organization (HRO) researchers. A key characteristic of HROs is mindfulness, i.e., the ability to prepare for the unexpected and to be vigilant about hazards, and one aspect of mindfulness is organizational commitment to resilience.
Four factors contribute to resilience\textsuperscript{59}:
1. knowing how to respond to disruptions and disturbances
2. monitoring events, in particular those likely to lead to an accident
3. anticipating developments, threats and opportunities
4. learning from patient safety incidents.

Further research is necessary to understand how these factors contribute to resilient performance; this research should focus on understanding the role of distributed cognition (i.e., the distribution of knowledge across the social and physical environments as well as across time) and situation awareness in demanding situations and the ways that clinicians react and deal with surprising, demanding situations and other vulnerabilities or hazards.\textsuperscript{60}

**Human Factors and Ergonomics Systems Approaches to Patient Safety**

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. These systems approaches address the following: (1) a broad range of system variables that can affect patient safety, (2) interactions between system elements, and (3) interacting system levels.\textsuperscript{28,61} These approaches include the systems approach proposed by Vincent and colleagues\textsuperscript{8,62} and the SEIPS (Systems Engineering Initiative for Patient Safety) model of work system and patient safety proposed by Carayon and colleagues.\textsuperscript{63}

Vincent and colleagues\textsuperscript{8} defined seven types of system factors that can influence clinical practice and lead to patient safety incidents:
1. patient factors
2. task and technology factors
3. individual (staff) factors
4. team factors
5. work environmental factors
6. organizational and management factors
7. institutional context factors.

This framework can be used to identify factors that contribute to patient safety incidents. The SEIPS model of work system and patient safety\textsuperscript{63} (Figure 1) identifies a slightly different set of system factors: (1) individual factors (which include characteristics of the staff and patient), (2) tasks, (3) tools and technologies, (4) environment, and (5) organizational factors (which include team factors). In addition to defining the system and emphasizing system interactions,\textsuperscript{64} the SEIPS model describes how system design can influence care processes and other connected processes (e.g., delivery of supplies, housekeeping, purchasing of medical equipment). Based on the Structure-Process-Outcome framework of Donabedian,\textsuperscript{65} the SEIPS model proposes that system design can contribute to deficiencies in care processes and thus to patient safety incidents. Because the SEIPS model is anchored in HFE, employee and organizational outcomes are addressed along with patient safety, reflecting the fact that patient safety and worker safety and well-being are positively correlated and have common system contributing factors.\textsuperscript{66}
With recent emphasis on the role of health IT in patient safety, sociotechnical systems approaches have been proposed, for instance, by the IOM report on Health IT and Patient Safety. The work system of the SEIPS framework is a representation of a sociotechnical system (the technology is part of a larger system and interacts with various system elements). The sociotechnical system model proposed by the IOM includes all elements of the work system model, except for the physical environment.

**Human Factors and Ergonomics as a Patient Safety Practice**

HFE as a patient safety practice can take three different forms:

1. using HFE tools and methods,
2. increasing HFE knowledge, and
3. recruiting HFE engineers.

HFE tools and methods for patient safety include usability evaluation of technologies or devices, work system assessment for performance obstacles and hazards, and risk assessment of care processes. Other examples of HFE tools and methods are described in the section on the beneficial impacts of HFE as a patient safety practice.

Increasing HFE knowledge may involve training and educating a range of health care professionals and workers, including patient safety officers, quality improvement specialists, and
health IT staff, as well as leaders of health care organizations, policymakers, and vendors and manufacturers of medical devices and health IT applications.

Health care organizations may hire HFE engineers in order to accelerate adoption and dissemination of HFE. Integration of HFE engineers in health care organizations may enhance the impact of HFE in a wide range of relevant departments and functions of health care organizations, such as patient safety, risk management, quality improvement, employee health, and health IT implementation and optimization.

Why Should This Patient Safety Practice Work?

Theories and models underlying the HFE approach to improving patient safety target the design of work systems and care processes and aim to promote and facilitate performance of all individuals involved. HFE focuses on how to design work systems and processes for supporting safe behaviors and activities in both system design and operation. According to the SEIPS model of work system and patient safety, HFE deficiencies in the design of work systems can negatively influence the safe delivery of care processes, and therefore, lead to patient safety incidents (see Figure 1).

HFE for patient safety is based on four mechanisms that connect system variables to patient safety (see Table 2).

Table 2, Chapter 31. HFE mechanisms between system design and patient safety

<table>
<thead>
<tr>
<th>HFE Mechanisms</th>
<th>Objectives of System Design</th>
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<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 3 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>The objective of HFE system redesign is to identify and remove performance obstacles. 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 (i.e. Balance Theory of Job Design).</td>
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<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, such as allowing problem or variance control at the source.</td>
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<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.</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 optimized or balanced.</td>
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Human Factors and Ergonomics Design Principles

A range of HFE design principles have been proposed for optimizing specific elements or aspects of the work system. These principles can be used to design work systems to eliminate hazards and performance obstacles. For instance, The Handbook of Human Factors in Medical Device Design 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; these usability heuristics include consistency, a match between technology and the user’s mental model, minimizing memory load, and users in control. The physical design
of the work system should minimize perception time, decision time, manipulation time, and the need for excessive physical exertion, and optimize opportunities for physical movement.69,82,83

From an organizational 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 (e.g., support from co-workers in case of emergency) within the work environment.84,85 Table 3 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.86

Table 3, Chapter 31. Examples of HFE design principles

<table>
<thead>
<tr>
<th>Focus of HFE</th>
<th>Examples of HFE Design Principles</th>
</tr>
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<tbody>
<tr>
<td>Physical HFE</td>
<td>Minimizing perception time, decision time, and manipulation time</td>
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<td></td>
<td>Reducing or mitigating need for excessive physical exertion</td>
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<td></td>
<td>Optimizing opportunities for physical movement</td>
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<tr>
<td>Cognitive HFE</td>
<td>Consistency of interface design</td>
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<td></td>
<td>Match between technology and the user's mental model</td>
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<tr>
<td></td>
<td>Minimizing cognitive load</td>
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<td></td>
<td>Allowing for error detection and recovery</td>
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<td></td>
<td>Feedback to users</td>
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<td>Organizational HFE</td>
<td>Worker opportunities to learn and develop new skills</td>
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<td></td>
<td>Worker control over work system</td>
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<td></td>
<td>Worker access to social support</td>
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<td>Participation in system design</td>
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</table>

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 aligned75 and that system interactions be optimized.64 For example, when a new BCMA system is introduced, it is important to ensure that the technology is designed according to HFE principles (e.g., 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 organization), then BCMA may contribute to diminished rather than improved clinician performance and patient safety.

The goal of HFE-informed design is work system that supports the work of individual and teams.75,81 This is the essence of the user-centered design approach.87

**HFE Implementation Principles**

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 realizing the patient safety potential of health IT.88,89 These implementation principles are essential and applicable to the implementation of all kinds of work system design. A key HFE system implementation principle is user participation. Participatory ergonomics programs can be implemented in health care and lead to substantial improvements in occupational health and safety90,91 and potentially in patient safety. However, it may be difficult to use participatory ergonomics in a high-stress, high-pressure environment, such as an ICU, where patient needs are critical and patients require immediate or continuous attention.90,91 Further research is needed to
refine and develop HFE implementation principles and methods for facilitating user participation in designing work systems for patient safety.

**What Are the Beneficial Effects of the Patient Safety Practice?**

The 2005 report by the U.S. Institute of Medicine and the National Academy of Engineering stressed the importance of using HFE as a key systems engineering tool to design health care systems and to improve quality of care and patient safety.92 Numerous studies use HFE tools and methods to identify system factors that contribute to medical errors; based on these data, researchers or other system designers devise recommendations for improving health care 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 health care technologies, concomitant design of health care technologies and work system, and design of health care processes. 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 both patient safety and employee outcomes). In general, this evidence is provided through the use of multiple quantitative and qualitative methods.

HFE-based interventions involve changes in work systems and processes and, like any change, may produce unanticipated effects. However, a core principle of HFE is to ensure that work systems and processes are designed to produce patient safety benefits. The purpose of an HFE approach is (1) to anticipate potential negative patient safety consequences (e.g., conducting a work system or process analysis, or a proactive risk assessment), and (2) to learn about potential negative effects on patient safety during the implementation process and fix problems as quickly as possible (e.g., system resilience).

This review 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 four 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: Human Factors and Ergonomics 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.93,94

**Step 1: Human Factors and Ergonomics Analysis**

The researchers first evaluated the existing radiotherapy treatment delivery process. Over a 3-month period, an HFE engineer conducted 30 hours 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 treatment-delivery system. Since the two HFE experts were not authorized 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, 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 (i.e. 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: Human Factors and Ergonomics in the Design and Implementation of Health IT

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

Beuscart-Zéphir and colleagues developed an HFE framework for health care technology and work system design, along with a set of structured methods to optimize the work system. The HFE framework includes 4 stages: (1) analysis of the sociotechnical system and the demands of stakeholders, (2) cooperative design of the health care technology and the work system with the institution, designers and developers, (3) iterative evaluation and redesign, and (4) 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 CPOE.100

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 characterize physician–nurse and nurse–nurse communication about medications, and to assess nurses’ interactions with paper patient records. Then more than 7,000 paper medication order sheets issued 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 (e.g., interactions between nurses and the technology when administering medications), collective (e.g., verbal communications supporting cooperation during the medication management process) and organizational (e.g., distribution of tasks across different health care 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 (e.g., 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.101 A total of 35 issues related to workload, compatibility, control, homogeneity, guidance, and error prevention was identified and rated on a four-point scale for severity.

In laboratory user testing, 8 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 Human Factors and Ergonomics 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 health care 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
modeling of the work systems. The HFE framework of Beuscart-Zéphir and colleagues is now routinely integrated into the IT project management of the Centre Hospitalier Universitaire of Lille, France.

Example 3: Human Factors and Ergonomics in the Physical Design of Operating Rooms

In the third example, HFE is used to address infection-control problems in the operating room (OR). To minimize infection risk, surgical devices were suggested to be positioned within the clean airflow in the OR according to well-known 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: Human Factors and Ergonomics 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 2 of 4 ORs in February 2009,
2. temporary marking was implemented in all four ORs by June 2009, and
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 2 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 positionings of surgical devices in the clean airflow. In addition, post-implementation interviews with 3 ophthalmic surgeons, 3 surgical and anesthesia nurses, and 2 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 4: Human Factors and Ergonomics in the Design of Care Processes

HFE can also help to improve the design of care processes. 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 health care and provide input for health care process design. The fourth study we review describes an FMEA of the IV medication
Step 1: Formation and Training of FMEA Team

A multidisciplinary team consisting of representatives from anesthesiology, biomedical engineering, central supply, human factors engineering, internal medicine, nursing, pharmacy, and quality improvement performed a health care failure mode and effects analysis (HFMEA) to evaluate the intravenous (IV) medication administration process using both current IV pump and a Smart IV pump technology. The team members were trained for 1 to 2 hours in the VA’s HFMEA method.

Step 2: FMEA Analysis Process

The FMEA process consisted of 46 hours of meetings over 4.5 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 IV medication administration process map. Two HFE experts conducted a total of 52 observations of nurses administering medications with the current IV pump. Medication administration and IV 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 IV pump and then repeated the mapping process with the Smart IV pump. In the process map with the current IV pump, the team identified 10 steps for retrieving the medication and tubing, and 24 steps for pump programming were identified. For the Smart IV pump, the team identified 14 unique pump programming steps and new tubing setup and insertion steps.

Following process mapping, the team analyzed failure modes potentially associated with IV 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 prioritized failure modes were proposed and categorized into the five elements of the work system (see Figure 1): (1) policies and procedures, (2) training or education, (3) physical environment, (4) people, and (5) technology software or hardware change. The evaluation of the impact of the FMEA on patient safety was based on: (1) audits of programming of pumps for errors, (2) monitoring of end-user training for time to achieve competency, and (3) monitoring and recording of IV medication administration event reports and informal and formal complaints about pump functioning. Post-implementation results suggested that the goal of mitigating risk to patients from potential or known failure modes was achieved.
How Has the Patient Safety Practice Been Implemented, and in What Contexts?

HFE can contribute to patient safety in a range of care settings. Table 4 describes selected HFE issues in various care settings. The issues are categorized as physical, cognitive, or organizational HFE issues, and are related to the various work system elements (see Figure 1). These issues interact as part of the larger work system and produce the vulnerabilities that can lead to patient safety incidents.
<table>
<thead>
<tr>
<th>Care Settings</th>
<th>HFE Issues</th>
<th>Physical (P), Cognitive (C) or Organizational (O) HFE</th>
<th>Elements of the Work System [I, T, T/T, E, O]*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia</td>
<td>Impact of fatigue and sleep deprivation on psychomotor performance and mood of anesthesiology residents&lt;sup&gt;113&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
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<td></td>
<td>Workload, production pressure and burnout of anesthesiologists&lt;sup&gt;114,116&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
<td></td>
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<tr>
<td></td>
<td>Poor display and control design of medical devices: auditory and visual alarms affect vigilance and situation awareness of anesthesiologists&lt;sup&gt;117,118&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
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<td></td>
<td>Working in a multidisciplinary team: anesthesiologists working with a new surgeon or nurse may need extra effort to communicate effectively, in particular during stressful conditions&lt;sup&gt;113&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
<td></td>
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<tr>
<td>ED</td>
<td>Limited availability of information: patient history and other information are often not easily accessible by ED clinicians who had no prior contact with patient&lt;sup&gt;117&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
<td></td>
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<tr>
<td></td>
<td>Design of ED physical environment: overcrowding, noise&lt;sup&gt;119,120&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
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<td></td>
<td>Usability and workflow issues of ED status boards&lt;sup&gt;119,121&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
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<td></td>
<td>Impact of shift work on cognitive and work performance of ED clinicians in particular during routine work&lt;sup&gt;119,121&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
<td></td>
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<tr>
<td></td>
<td>Limited opportunity for ED clinicians to maintain their skill level for risky and difficult, but infrequent, procedures&lt;sup&gt;119,121&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
<td></td>
</tr>
<tr>
<td>Home Care</td>
<td>Usability and acceptance of computer-based self-management tools for elderly patients with disability and functional decline: usability of interface, functional and physical accessibility&lt;sup&gt;122&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
<td></td>
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<td></td>
<td>Design problems of telemedicine applications: poor usability, e.g., extensive amount of text on screen&lt;sup&gt;123&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
<td></td>
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<tr>
<td></td>
<td>Informal care giving: fatigue, musculoskeletal injuries during personal care&lt;sup&gt;123&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
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<tr>
<td>ICUs</td>
<td>Varied, dynamic, rapidly-changing condition of patients that require rapid clinician responses&lt;sup&gt;113&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
<td></td>
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<td></td>
<td>Design and implementation of guidelines and best practices, e.g., for infection control&lt;sup&gt;114&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
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<td></td>
<td>Workload, stress and burnout of ICU physicians and nurses&lt;sup&gt;7,115,116&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
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<tr>
<td></td>
<td>Information flow and decisionmaking in handoffs of patients: across units, across services; patients discharged; shift changes&lt;sup&gt;113&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
<td></td>
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<td></td>
<td>Design of alerts/alarms in medical devices and health IT&lt;sup&gt;120,117&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
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<td></td>
<td>Design and implementation technology for remote monitoring of ICU patients&lt;sup&gt;117&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
<td></td>
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<tr>
<td></td>
<td>Design of ICU patient rooms: open versus closed&lt;sup&gt;113,119&lt;/sup&gt;</td>
<td>P C O I T T/T E O</td>
<td></td>
</tr>
<tr>
<td>Care Settings</td>
<td>HFE Issues</td>
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<td>Elements of the Work System [I, T, T/T, E, O]*</td>
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<tr>
<td><strong>Long-Term Care</strong></td>
<td>Poor working conditions and job stressors: understaffing, training, feeling unable to meet resident needs, overtime, heavy workload, mostly standing and walking, risk of back injuries due to moving patients (^{124})</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Physical environment: doors cannot accommodate a wheelchair, layout of facility does not allow nursing station in a convenient place (^{124})</td>
<td>X</td>
<td></td>
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<tr>
<td><strong>Pediatrics</strong></td>
<td>Cognitive, communication, and speech limitations of children and their dependency on adults result in communication challenges, and risk of delayed diagnosis or misdiagnosis (^{125,126})</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Equipment not designed for children: CT scan with adjustable exposure for children, cribs with adjustable height (^{125,126})</td>
<td>X</td>
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<td></td>
<td>Design problems of CPOE technology: weight-based dosing, age-dependent lab normal values (^{125})</td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td>Design problems of BCMA technology: barcodes with different sizes, packaging of pediatric medications (^{125})</td>
<td>X</td>
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<tr>
<td><strong>Primary Care</strong></td>
<td>Reliance on memory: missing diagnostic testing results, lack of tracking system; physician needs to remember ordered tests (^{127,128})</td>
<td>X</td>
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<td></td>
<td>Multi-modal communication between patient and clinicians: retrieving and recording information, information loss (^{127})</td>
<td>X</td>
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<td></td>
<td>Memory and information processing: patients with multiple problems, incomplete patient charts (^{127})</td>
<td>X</td>
<td></td>
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<td></td>
<td>Workload and time pressure of clinicians: addressing several patient problems in limited time (^{127})</td>
<td>X</td>
<td></td>
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<tr>
<td><strong>Surgery</strong></td>
<td>Operating room environment: clutter, noise, lighting, temperature, motion/vibration; impact on surgical performance (^{129})</td>
<td>X</td>
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<td></td>
<td>Teamwork: miscommunication, lack of coordination, and lack of team familiarity and stability contribute to errors during surgery (^{129,130})</td>
<td>X</td>
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<tr>
<td></td>
<td>Poor design and implementation of technology affect acceptance and use: e.g., integration of information across displays, unreliable audible alarms, shape of input controls, and lack of proper training for surgeons (^{129,130})</td>
<td>X</td>
<td></td>
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<td></td>
<td>Impact of physical and mental workload on performance: task duration, strength requirement, mental demands, and time pressure increase stress and fatigue, and may affect cognitive processing (^{129})</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Design and implementation of surgery checklist (^{131})</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Poor safety culture: lack of a culture to take responsibility for patient safety, report errors, learn from mistakes, and adapt individual and organizational behavior based on lessons learned from mistakes (^{129})</td>
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</tbody>
</table>

* NOTE: Elements of the work system include the individual (I), his/her tasks (T), tools and technologies (T/T), the physical environment (E) and the organization (O) (see Figure 1).
Are There Any Data About Costs of the Patient Safety Practice?

The integration of HFE in health care and patient safety requires leadership and commitment as well as resources (i.e., money, time, effort, knowledge, expertise, skills, methods and structures). Health care organizations that invest in HFE typically engage in one or several of the following activities: using HFE tools and methods, increasing HFE knowledge among their staff, and recruiting human factors engineers. However, there is no information available about the costs of these different HFE approaches.

It is important to recognize the key role of HFE in the early phase of system design. When HFE is used early in the design process, system issues can be identified and solved more efficiently and effectively, and with less risk that the fix to the system design will itself create other hazards. This implies that designers, manufacturers, and vendors of health IT applications, medical devices and other technologies must have in-house HFE expertise.

A case study of a medical device manufacturer demonstrates the challenges of implementing HFE. Patient Controlled Analgesia (PCA) pumps that were introduced in 1988 were intended to allow patients to administer small and frequent dosages of analgesia, and reduce nurse workload. However, the poor HFE design of the device increased the likelihood of dosage programming errors, which in some cases led to death. It took 6 years between the first reported incident of patient death related to PCA pump programming error and the hiring of a HFE engineer by the device manufacturer in 2001. Significant efforts may be required to speed up the dissemination of HFE to improve patient safety across the health care industry.

Fostering communication and collaboration between HFE and the health sciences and professions is critical achieving significant improvements in patient safety. Clinicians and HFE engineers need to learn to understand each other’s perspectives. Because the HFE knowledge domain is broad and deep (see description above of the physical, cognitive and organizational aspects of HFE), learning HFE can be a significant investment. It is not sufficient to have physicians or nurses who have read a book or taken a seminar on HFE; this will not make them HFE experts. On the other hand, HFE engineers need to understand health care before they can have a significant impact on patient safety. The training of ‘biculturals’ in both medicine (or nursing or pharmacy or other health science) and HFE can accelerate the application of HFE to improve patient safety. Because biculturals have deep knowledge of and training in both HFE and a health science, they can help to ‘translate’ and disseminate HFE knowledge and tools.

Are There Any Data About the Effect of Context on Effectiveness?

Despite the critical role of HFE in improving patient safety, the application of HFE to health care may not be straightforward or spontaneous. More work is needed to understand the challenges faced by health care organizations in adopting, implementing and institutionalizing HFE in their operations. In the context of health care organizations, HFE can be conceptualized as an innovation whose adoption, diffusion, and maintenance are associated with challenges. As described earlier, HFE patient safety practices include: using HFE tools and methods, increasing HFE knowledge, and recruiting HFE engineers. A range of contextual factors can affect the effectiveness of these HFE-based interventions or innovations, such as structural characteristics of health care organizations (e.g., size, level of functional differentiation, and level of centralization of decisionmaking), cultural characteristics of health care organizations (e.g., leadership, strategic vision, approach to experimentation and risk, and learning style),
management and implementation tools (e.g., top management commitment, human resource issues, funding, and communications), and wider environmental factors (e.g., legal and regulatory requirements, efforts by national and international HFE organizations, and collaboration between health care organizations). Cultural conflicts between the HFE systems approach and health care can also impede the adoption and dissemination of HFE in health care organizations (e.g., physician autonomy may hinder the team collaboration and communication stressed by HFE).

The case study described by Vicente shows that HFE is more likely to be integrated in the organization of a medical device manufacturer if the manufacturer (1) has leaders who support adoption of HFE, (2) experiences a profound performance crisis related to poor HFE performances, and (3) operates in an environment in which advocacy for HFE can be found at all levels of the complex sociotechnical system. Further research is needed to identify the key contextual factors that can facilitate adoption and dissemination of HFE. Specifically, studies are recommended for developing a theoretical framework to describe and evaluate contextual elements and generating empirical evidence on how different contextual elements can influence the success of HFE interventions.

Conclusions and Comment

A study conducted by an HFE leader, Al Chapanis, and his colleague in the early 1960s provided information on medication administration errors and the system factors that contributed to these errors. Since then, awareness of the importance of HFE in medication safety and other patient safety domains has significantly increased. Patient safety leaders call for increasing involvement of HFE in helping not only to characterize system factors that contribute to patient safety, but also to inform system design interventions. This chapter has described the range of patient safety issues and care settings that HFE can be applied to. Further research is needed to continue developing the evidence for the value of HFE-based interventions for patient safety.

Numerous chapters in this report describe how patient safety practices can benefit from HFE. For instance, chapter 6 reviews the evidence for the patient safety impact of Smart IV pump. HFE problems in the design of the pump interface and alerts have limited the patient safety impact of Smart IV pumps. HFE can provide the design principles and methods to improve Smart IV pump technology (e.g., usability of pump interface design) and enhance its impact on patient safety. Chapter 34 describes the strong empirical evidence for the impact of nurse-patient ratio on patient safety. One potential mechanism for this impact is related to nursing workload. HFE principles and methods can be used in the design of work systems to reduce or mitigate nursing workload, and therefore, improve patient safety. Chapter 16 highlights some of the HFE challenges that can be addressed with integrated information displays in the OR, especially if these displays are designed to support team situation awareness and coordination.

These examples show that many patient safety practices can benefit from HFE. 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. HFE is a core element of patient safety improvement; therefore, every effort should be made to support HFE applications in patient safety. A summary table is following (Table 5).
Table 5, Chapter 31. Summary table

<table>
<thead>
<tr>
<th>Scope of the Problem Targeted by the PSP (Frequency/Severity)</th>
<th>Strength of Evidence for Effectiveness of the PSPs</th>
<th>Evidence or Potential for Harmful Unintended Consequences</th>
<th>Estimate of Cost</th>
<th>Implementation Issues: How Much do We Know?/How Hard Is it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potentially applicable to all patient safety problems</td>
<td>Not assessed systematically but Moderate- to High evidence for some specific applications</td>
<td>Negligible</td>
<td>Moderate</td>
<td>A lot/Moderate</td>
</tr>
</tbody>
</table>

References


