

Human factors systems approach to healthcare quality and patient safety



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ABSTRACT

Human factors systems approaches are critical for improving healthcare quality and patient safety. The SEIPS (Systems Engineering Initiative for Patient Safety) model of work system and patient safety is a human factors systems approach that has been successfully applied in healthcare research and practice. Several research and practical applications of the SEIPS model are described. Important implications of the SEIPS model for healthcare system and process redesign are highlighted. Principles for redesigning healthcare systems using the SEIPS model are described. Balancing the work system and encouraging the active and adaptive role of workers are key principles for improving healthcare quality and patient safety.

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1. Introduction

In the early 1960's Chapanis and Safren¹ (Chapanis and Safrin, 1960; Safren and Chapanis, 1960a,b) conducted one of the first human factors and ergonomics (HFE) studies on medication safety. The researchers used the critical incident technique to examine medication errors. They identified a total of 178 medication administration errors over a period of seven months: (1) wrong patient, (2) wrong dose of medication, (3) extra unordered medication, (4) medication not administered, (5) wrong drug, (6) wrong timing of medication administration, and (7) incorrect medication route. A range of work system factors contributed to medication

errors, such as failure to follow required checking procedures, and verbal or written communication problems. This study highlighted the importance of work system issues in medication safety. However, it was not until the publication of the US Institute of Medicine report "To Err is Human: Building a Safer Health System" in 1999 (Kohn et al., 1999) that HFE and its systems approach were recognized as critical for patient safety across all healthcare domains.²

Healthcare professionals, leaders and organizations understand the importance of HFE as a scientific discipline that can produce knowledge to redesign healthcare systems and processes and improve patient safety and quality of care (Carayon et al., 2013; Gurses et al., 2012b; Institute of Medicine, 2012; Leape et al., 2002; Pronovost and Goeschel, 2011; Pronovost and Weisfeldt, 2012). For instance, the World Health Organization curriculum on patient safety includes 11 topics, among which two are core to HFE: (a)

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¹ In the published papers on this research, the name of Chapanis' co-author was spelled in two different ways: Safren and Safrin.

² An exception is the anesthesia discipline that recognized the value of HFE in the early 1980's and applied HFE tools and methods to the design of monitors and devices as well as simulation as an educational method (Spath, 2000).

topic 2: What is human factors engineering, and why is it important to patient safety?, and (b) topic 3: Understanding systems and the impact of complexity on patient care (Walton et al., 2010). The US Agency for Healthcare Research and Quality (AHRQ) promotes an HFE approach to the design of health information technology (IT) (NRC Committee on the Role of Human Factors in Home Health Care, 2010, 2011) and has published a variety of guidance documents on using HFE systems models to analyze patient safety events in healthcare delivery (Henriksen et al., 2008, 2009). Various IOM reports have called for the incorporation of HFE, and of systems approaches generally, into health and healthcare research, design, and policy (Grossman et al., 2011; Institute of Medicine, 2001, 2004, 2006, 2012; Reid et al., 2005).

Given the complexity of healthcare (Carayon, 2006), HFE interventions that do not consider issues across the whole system, including organizational factors, are unlikely to have significant, sustainable impact on patient safety and quality of care. For instance, improving the physical design of a medical device or the cognitive interface of health IT is important; but without understanding the organizational context in which these technologies are used, workers may develop work-arounds, the tools may not be used safely, and health IT may be usable but not useful. Therefore, an HFE systems approach to healthcare quality and patient safety should include organizational HFE or macroergonomic considerations.

We have proposed an HFE systems approach to address patient safety and other quality of care problems (see Fig. 1). The SEIPS (Systems Engineering Initiative for Patient Safety) model of work system and patient safety (Carayon et al., 2006b) is based on the macroergonomic work system model developed by Smith and Carayon (Carayon, 2009; Carayon and Smith, 2000; Smith and Carayon-Sainfort, 1989; Smith and Carayon, 2001), and incorporates the Structure-Process-Outcome (SPO) model of healthcare quality

(Donabedian, 1978). The SPO model of Donabedian (1978) is the most well-known model of healthcare quality. The integration of the work system model with this prominent model of healthcare quality increases the acceptability of the SEIPS model by the healthcare community. In this paper, we first describe the SEIPS model of work system and patient safety and its research and practical applications. We then emphasize the principle of ‘balance’ and focus on system interactions that need to be considered in order to make significant progress in healthcare quality and patient safety.

2. SEIPS model of work system and patient safety

Key characteristics of the SEIPS model include: (1) description of the work system and its interacting elements, (2) incorporation of the well-known quality of care model developed by Donabedian (1978), (3) identification of care processes being influenced by the work system and contributing to outcomes, (4) integration of patient outcomes and organizational/employee outcomes, and (5) feedback loops between the processes and outcomes, and the work system (see Fig. 1).

2.1. Work system model of healthcare

Table 1 describes the elements of the work system and provides examples for each element of various work systems. Even if the elements are described separately, it is important to emphasize interactions between the work system elements (see further discussion on system interactions in the section on “Balancing the work system for patient safety”). The SEIPS model is a dynamic model: any change in the work system produces changes in the rest of the work system.

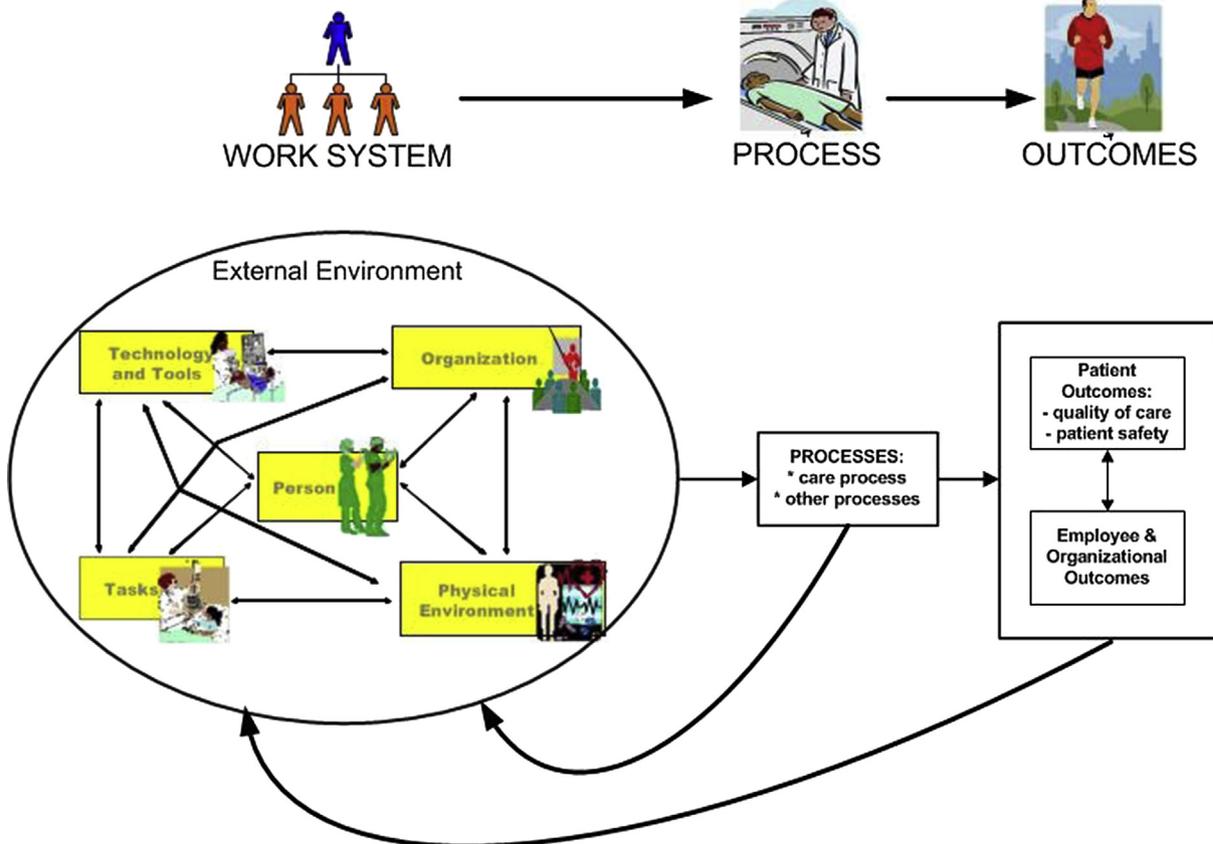


Fig. 1. The SEIPS model of work system and patient safety (Carayon et al., 2006b).

Table 1
Work system model and healthcare examples.

	Person	Tasks	Tools and technologies	Physical environment	Organization
Definitions	The individual at the center of the system can be a single individual (e.g., physician, nurse, patient) or can be a group of individuals (e.g., team, organizational unit). Individual characteristics include: - physical characteristics: strength, height, weight - cognitive characteristics: expertise, experience - psychosocial characteristics: motivation, need for social support	Description and characteristics of tasks: variety, content, physical and psychological demands	Health information technologies Medical devices Other tools and technologies	Physical layout Workstation design Noise Lighting Temperature and humidity Air quality	Formal and informal organization Organizational culture and climate Rules and procedures Organizational structure and management
Example: ICU nurse	Physical, cognitive and psychosocial characteristics	Direct patient care Care coordination Indirect patient care Non-patient care (Douglas et al., 2012)	Electronic or paper record Medical devices and monitors Equipment Supplies	Physical layout of the unit Physical characteristics of patient room	Interaction with nursing manager ICU safety culture Teamwork (e.g., interdisciplinary rounds)
Example: Patient-centered medical home team	Members of the team and their characteristics	Communication Care coordination Sense making	Health information technologies such as EHR to communicate and share patient-related information	Physical layout of the physician practice	Organizational support for teamwork
Example: Patient	Patient knowledge, alertness and present symptoms	Timing and number of medications to take	Pillbox Blood glucose meter	Lighting conditions and distractions in the home	Meal schedule Access to medications

We have clearly distinguished between the physical environment of the work system and the external environment that can influence all work system elements. In the initial description of the SEIPS model (Carayon et al., 2006b), the external environment was not explicitly stated. Given the major role of regulatory, professional and consumer/patient groups in healthcare delivery, we have added the 'external environment' to the original version of the SEIPS model (see Fig. 1). This is in line with other HFE systems approaches that describe the impact of the external environment on the work system and actors in the system (Kleiner, 2006; Moray, 2000; Rasmussen, 2000). The external environment is comprised of extra-organizational rules, standards, legislation, and enforcement, as well as characteristics of the healthcare industry in general and the healthcare workforce (Karsh et al., 2006; Kleiner, 2006, 2008).

In healthcare, the work system model can be used to describe the work of clinicians, other healthcare professionals, and care teams as well as patients and their caregivers (see Table 1). Clarifying the 'person' at the center of the work system has been another conceptual evolution of the SEIPS model. In the initial publication (Carayon et al., 2006b), the focus was on the healthcare professional at the center of the work system; other ways of conceptualizing the person were briefly described, such as the person as a team or the person as a patient. Over the years the SEIPS model has been further expanded to include these other 'persons' at the center of the work system. Several examples of clinicians' work systems are described in the section on "Work system performance obstacles and facilitators" (see below). Examples of the SEIPS model for team-based care and patient 'work' are provided below.

The person at the center of the work system can be a group of people such as healthcare teams. Similar to trends in other industries, increasingly teams are proposed as a way to organize healthcare work and manage care processes to enhance healthcare quality and patient safety. For instance, AHRQ, collaborating with the US Department of Defense Patient Safety Program, has invested significant resources in developing and implementing the Team-STEPPS program (Agency for Healthcare Research and Quality, 2008). Another example of teamwork in healthcare is the patient-centered medical home model whose aim is to improve quality in primary care (Stange et al., 2010; Vest et al., 2010). The work system of the patient-centered medical home can be characterized as follows (Wetterneck et al., 2012):

- person: Members of the team include physicians, nurses, and other staff at the primary care clinic. The implementation of patient-centered medical home often relies on the hiring of nurse case managers whose primary responsibility is care coordination (Steele et al., 2010). Patients and families are also part of the medical home team.
- tasks: Major tasks of the patient-centered medical home team include communication and care coordination.
- tools and technologies: The team uses various health information technologies such as electronic health record and health information exchange systems to communicate and share patient information. Information technologies such as secure email messaging and web portals are often used by patients to communicate with healthcare professionals, i.e. physicians and nurses.

- physical environment: The physical layout of the physician practice needs to allow for team meetings and huddles.
- organization: Organizational issues are critical for effective patient-centered medical home teams. Research by Nutting et al. (2012) on the patient-centered medical home describes how a new ‘mental model’ of physician practice organization is necessary for successful implementation of patient-centered medical home. In particular, they recommend a ‘meaningful care team approach’ in which roles and contributions to the team are clearly outlined.

The primary person in the center of the work system can also be the engaged patient, e.g., a patient self-managing a chronic illness such as heart failure or diabetes and related health needs (e.g., diet, exercise). The patient is typically not the only person in the work system and often interacts with others such as family members and informal (lay) caregivers and healthcare professionals such as physicians, home care nurses, or case managers, to carry out their “health work” (Zayas-Caban and Brennan, 2007). One of many health work processes in this system is medication-taking in the home, where person factors could include patient knowledge, alertness, and present symptoms; task factors include the number of medications and their dosages; tools and technologies might be pillboxes and blood glucose monitors; organization factors include meal schedule and access to medications; and environment factors include lighting conditions and any distractions in the home. Relevant outcomes include health or disease outcomes such as disease progression as well as personal satisfaction, quality of life, and financial solvency.

2.2. SEIPS model as an extension of the structure-process-model (SPO) of healthcare quality

The SEIPS model builds on the well-known SPO model (Donabedian, 1978) that includes structural, process and outcome measures of healthcare quality. Donabedian’s (1988) description of healthcare structure is rather limited with a focus on material resources (e.g., facilities, equipment), human resources (e.g., number and qualifications of staff) and organizational structure (e.g., organization of medical staff, methods of reimbursement). We extended the SPO model and replaced the ‘Structure’ by the work system. This improvement produces a more systematic approach to analysis and improvement of healthcare quality and patient safety. The consideration of all work system elements allows for a deeper and broader understanding of the factors that can contribute to healthcare quality and patient safety. Therefore, the range of possible solutions for improving healthcare quality and patient safety is wider.

2.3. Influence of the work system on care processes

The inclusion of care processes in the SEIPS model fits with modern organizational concerns for quality improvement such as Total Quality Management and lean thinking. There has been a recent push for introducing lean thinking in healthcare (Toussaint, 2009). However, such approaches need to consider HFE and sociotechnical system aspects (Holden, 2011b; Joosten et al., 2009). According to Holden (2011b), lean thinking can be considered as an organizational change that produces (positive and/or negative) changes in work system design, which in turn affect healthcare quality as well as employee and organizational outcomes. Therefore, he recommends that lean applications in healthcare such as emergency departments would benefit from an HFE approach by recognizing the contributions of people (e.g., workers, patients) in the change process and considering people’s needs (e.g., worker need for control). The SEIPS model can, therefore, be a framework to ensure that process analysis and quality improvement efforts in healthcare integrate HFE issues.

Several examples of SEIPS studies of care processes are described below. These examples demonstrate how the work system can be used to describe care processes (Carayon et al., 2004): a care process can be considered as a series of tasks performed by individuals using various tools and technologies in a specific environment. The organizational conditions of the work system are represented in the care process through transitions between different individuals and their tasks, coordination and communication across the process, and other temporal aspects of the process (e.g., scheduling of tasks). An important aspect of care processes is to understand how all of the work system elements interact and are organized over time; this goes beyond the mere (static) description of the work system. The temporal nature of care processes is important as healthcare tasks have all kinds of patterns; they may occur simultaneously, in parallel, or sequentially at different time scales (e.g., minutes, hours, days) (Carayon et al., 2012b).

2.4. Patient outcomes and employee/organizational outcomes

In line with HFE and its double objective of worker well-being and system performance (Dul et al., 2012; International Ergonomics Association (IEA), 2000), the SEIPS model includes patient outcomes such as patient safety and other dimensions of healthcare quality as well as outcomes associated with healthcare workers and organizations. According to the SEIPS model, the objective is to design work systems that benefit both patients and healthcare workers and organizations. Any healthcare system redesign should therefore achieve both types of benefits.

Many HFE applications in healthcare focus on the occupational safety and health of workers (Carayon, 2012), such as methods for reducing work-related musculoskeletal disorders of nurses (Nelson et al., 2006). This research is important, but needs to be extended to include impact on patient outcomes. Research by Trinkoff et al. (2011a, 2011b) shows that characteristics of nurses’ work system such as high psychological and physical demands are related to adverse patient outcomes such as pneumonia deaths. This research is important as it demonstrates that well-known HFE work system variables (e.g., job demands) are related to adverse patient outcomes; therefore, improving healthcare work systems using HFE principles should produce benefits for both patients and healthcare professionals.

2.5. Feedback loops between the process and outcomes, and the work system

Data on care processes, patient outcomes and/or employee and organizational outcomes can be used to identify problems and opportunities for redesigning the work system; this is a key feature of the feedback loops in the SEIPS model. These feedback loops indicate that changes in the work system can occur as healthcare organizations collect, analyze, and use process and outcome data. The impact of work system redesign can then be evaluated by examining their effect on care processes and outcomes. This represents cycles of healthcare system design, implementation, and continuous improvement (Carayon, 2006; Carayon et al., 2011a).

The SEIPS model is a dynamic model where work systems may adapt in response to different care processes and outcomes. The ‘workers’ in the system, i.e. healthcare professionals and patients/families, develop strategies to perform their tasks, sometimes in response to work systems that are not appropriately designed. For instance, in studies of bar coding medication administration (BCMA) technology implementation in pediatric hospitals, Holden et al. (2012, 2013, 2011b) found that, consistent with the feedback loops in the SEIPS model, staff nurses, as well as nursing leaders (Novak et al., 2013), altered the BCMA technology and the broader work system in order to achieve desired process and outcome changes.

Strategies developed by healthcare workers when faced with work system obstacles include work-arounds and safety violations (Alper et al., 2012; Alper and Karsh, 2009; Halbesleben et al., 2010; Koppel et al., 2008). A systematic review of safety violations across all industries identified the following categories of variables as predictors of violations (Alper and Karsh, 2009): (1) individual characteristics (e.g., attitude toward compliance), (2) information or training (e.g., lack of knowledge of safety rules), (3) design to support worker needs (e.g., inadequate tools, low staffing level), (4) safety climate (e.g., management ignoring violations), (5) competing goals (e.g., time pressure), and (6) problems with rules (e.g., outdated or impossible to follow rules). All of these variables in the work system are relevant in healthcare as described in a study of work-arounds in medication administration (Koppel et al., 2008). Understanding work-arounds and safety violations can provide important information on aspects of the work system that need to be redesigned to promote safe behaviors and enhance patient safety.

Table 2 summarizes the various aspects of the SEIPS model that are of value to healthcare.

3. Research applications of the SEIPS model of work system and patient safety

The SEIPS model has been used by numerous healthcare researchers, professionals, and educators. Researchers have used the SEIPS model to study timeliness of follow-up of abnormal test results in outpatient settings (Singh et al., 2009), to examine the safety of EHR (Electronic Health Record) technology (Sittig and Singh, 2009), to evaluate ways of improving electronic communication and alerts (Hysong et al., 2009), to assess work system barriers and facilitators to the provision of outpatient pharmacy services (Chui et al., 2012), to improve patient safety for radiotherapy (Rivera and Karsh, 2008), and to characterize patient safety hazards in cardiac surgery (Gurses et al., 2012a). The SEIPS model has been adopted by patient safety leaders, such as Peter Pronovost from Johns Hopkins University (Pronovost et al., 2009). It also serves as the basis for the “human factors paradigm for patient safety” developed by Karsh et al. (2006) that has itself been adopted by others (DeBourgh and Prion, 2012; Holden, 2011a, 2011b; Holden et al., 2011a).

We have used the SEIPS model in our research to examine patient safety in multiple care settings (e.g., Intensive Care Unit or ICU, pediatrics, primary care, outpatient surgery, cardiac surgery, transitions of care) and to study the implementation of various forms of health IT (e.g., EHR, CPOE or Computerized Provider Order Entry,

health information exchange technology, BCMA, smart infusion pump, tele-ICU).

3.1. Work system performance obstacles and facilitators

The design flaws in or incompatibilities between work system components cause clinicians to experience ‘performance obstacles’ (anything that hinders clinicians from performing their job). In a mixed methods research study with interviews of 15 ICU nurses (Gurses and Carayon, 2009) and a survey of 272 nurses in 17 ICUs (Gurses et al., 2009; Gurses and Carayon, 2007), we identified 13 categories of performance obstacles that hinder ICU nurses from completing their tasks; the obstacles were related to one or more elements of the work system:

- task: e.g., dealing with many family issues
- tools/technologies: e.g., unavailability of necessary equipment in a timely manner
- physical environment: e.g., insufficient and poorly designed workspace
- organization: e.g., delay in getting medications from pharmacy.

We then used the SEIPS model to test the impact of performance obstacles on nursing workload, quality of working life, and quality of care using a structural equation modeling approach (Gurses et al., 2009). The survey data analysis shows that obstacles related to the physical environment, family-related issues, supply chain management (e.g., access to supplies, stock in patient rooms, access to patient chart, delay in getting medications), and equipment-related issues affect ICU nurses’ perceptions of quality and safety of care either directly or indirectly via their influence on workload (Gurses et al., 2009). These results are important as they provide information about the ICU nurses’ work system factors that need to be addressed in order to improve their quality of working life as well as the quality and safety of care they provide to patients. Achieving this dual objective is key to HFE as described by Dul et al. (2012). Another recent study proposes that work system obstacles are actually the result of ‘misfit’ between two or more work system elements (Holden et al., 2013).

Similarly, we applied the SEIPS model in an outpatient surgery study to identify performance obstacles and facilitators (Carayon et al., 2006a, 2005b, 2005c). We distributed surveys containing open-ended questions to all clinical staff at five surgery centers and asked them to identify performance obstacles and facilitators related to various stages of the outpatient surgery process (before,

Table 2
Value of SEIPS model to healthcare.

Characteristics of SEIPS model	Value to healthcare
Integration of SPO model in SEIPS model	Healthcare professionals’ familiarity with SPO model translating to adopting SEIPS model
Work system model	Broad focus, not just individual focus; support to develop wide set of solutions for redesigning system
Patient outcomes and employee/organizational outcomes	Benefits for both patients and healthcare workers
Generic model	Applicability to any healthcare domain and healthcare quality or patient safety problem
Person at the center of work system can be healthcare professional, patient, or team	Flexibility in applying model to various work systems and various people
Feedback loops from processes and outcomes, to work system	Emphasis on the need for healthcare organizations to monitor, consider, and take advantage of ongoing feedback
Process influenced by work system	Expanded view of process that integrates all work system elements Importance of care processes as well as connected processes (e.g., housekeeping)
System interactions	Emphasis on systemic impact of organizational and sociotechnical changes

during, and after surgery). The performance obstacles and facilitators reported by the outpatient surgery staff covered all work system elements: communication with patients and healthcare providers [task and organization elements], coordination [organization element], time-related issues such as time pressure [task and organization elements], quality and availability of equipment and supplies [tools and technologies element], and noise [physical environment element] (Carayon et al., 2005b). Obstacles associated with the flow and coordination of patients' pre-operative clinical information posed the greatest concern to patient safety and were the target of the follow-up intervention (Schultz et al., 2007).

In a recent study, we examined performance obstacles and facilitators experienced by nurse care managers who coordinate care for patients after surgery and patients with chronic diseases during transitions from the hospital (Alyousef et al., 2012; Carayon et al., 2012a). This study focused on care coordinators' use of multiple health IT applications and identified performance obstacles in all of the work system elements:

- person: health IT training and knowledge issues
- task: issues with patient-related information processing and management (e.g., need for duplicate data entry in multiple health IT applications)
- tools and technologies: technology design problems such as slow response times
- physical environment: limited physical access to computers
- organization: organizational obstacles to the effective use of health IT such as delay in access to patient-related information.

An interdisciplinary group of researchers, including human factors and systems engineers, conducted a prospective, descriptive study to identify hazards to patient safety in the cardiac surgery perioperative period (Catchpole and Wiegmann, 2012; Gurses et al., 2012a; Pennathur et al., 2013). Based on the data obtained from 20 cardiac surgeries, a total of 58 categories of hazards were identified in all elements of the work system:

- people: lack of professionalism
- tasks: high workload
- tools and technologies: poor usability
- physical environment: cluttered workspace
- organization: hierarchical culture and non-compliance with guidelines.

These studies point to the value of a systems approach to identify all aspects of the work system that can potentially affect patient safety. A deeper and broader HFE system analysis produces a wide range of system redesign solutions to improve healthcare quality and patient safety (Catchpole and Wiegmann, 2012).

3.2. Work system impact on care processes

A key element of the SEIPS model is the focus on care processes that may be affected by the work system. The literature on healthcare quality focuses on care processes and patient outcomes, but has not paid sufficient attention to the structural factors (work system) that can influence these processes and patient outcomes as well as employee and organizational outcomes. Therefore, our research can provide useful information on how to redesign work systems in order to improve care processes and subsequently, patient outcomes. Because processes mediate the impact of the work system on outcomes in the SEIPS model (see Fig. 1), we have studied perceived process change as an indicator of success or failure of an intervention on the work system. This includes studies

of nurses' perceptions of the medication administration process before and after the introduction of BCMA technology (Holden et al., 2011a) and attending physicians' perceptions of how their cognition changed with a newly implemented CPOE/EHR (Holden, 2010). Our research has also examined the following care processes: ICU nursing medication management (Faye et al., 2010), the bedside rounding process in a pediatric hospital (Carayon et al., 2011d), and compliance with patient care guidelines in the ICU (Gurses et al., 2010, 2008).

A proactive risk assessment (PRA) of the medication management process³ was conducted with nurses from an adult cardiovascular ICU (Faye et al., 2010). The PRA consisted of two 2-h focus groups with nurses. In the first focus group, nurses were asked to 1) review and add to a list of failure modes that the research team had gathered from their observations of the medication management process and interviews with nurses from the same unit, and 2) identify contributing factors of those failure modes (using the work system model). In the second focus group, nurses were asked to specify activities they complete to (1) recover from the failures and their contributing factors and (2) increase the quality and safety of their patients. The SEIPS model was displayed and explained to nurses during both focus groups to discourage them from blaming themselves or other healthcare professionals for failures. We also emphasized that system factors and interactions that are poorly designed may cause and contribute to failures during the medication management process.

Recently patient- and family-centered care has emerged as a key principle for quality and patient safety, in particular for vulnerable patients such as children (Institute of Medicine, 2001). Hospitalized children are more likely to be exposed to potentially harmful medication errors than adult patients (Kaushal et al., 2001). Family-centered rounds are proposed as a process for engaging parents and children and for identifying errors and other hazards that can harm children. During family-centered rounds, the interdisciplinary team of physicians, nurses, and other relevant healthcare professionals meet at the patient bedside to discuss the patient's care and involve the active participation of the patient and family (Sisterhen et al., 2007). Implementation of family-centered rounds involves numerous changes in the work system. Using the SEIPS model, we identified work system obstacles and facilitators to family engagement in the rounding process (Carayon et al., 2011d). For instance, computer use can enhance family engagement by allowing parents to review data on the computer screen. On the other hand, the placement of the computer may create a barrier between the physician describing the child's clinical status and the parents. Other work system factors such as communication style of the physician, involvement of nurses, and position of the team members were identified as facilitators to family engagement. Obstacles included size of the team present in the child's room and use of medical jargon by the healthcare team. These data on work system obstacles and facilitators were then used to develop strategies for improving family engagement in family-centered rounds (Kelly et al., 2013).

Research using the SEIPS model has also examined the process of compliance with patient care guidelines in the ICU (Gurses et al., 2010, 2008). A range of work system factors can contribute to increased ambiguity regarding the implementation and use of evidence-based guidelines, and therefore, affect compliance with

³ The ICU nursing medication management process is comprised of seven steps: (1) assessing patient, (2) obtaining a medication, (3) administering a medication, (4) monitoring/reevaluating patient, (5) educating patient and/or family during the ICU stay, (6) educating patient and/or family in preparation for discharge, and (7) conducting nurse-to-nurse handoff.

the guidelines. For instance, ambiguity in the task element may be manifested in the lack of clarity of who is completing which guideline tasks and when. Ambiguity in the organizational element relates to role definition, authority, and accountability for the performance of the guideline.

These studies show the importance of identifying the multiple work system elements that contribute to effective, efficient, and safe care processes. Health services research produces information on the relationship between care processes and outcomes; however, this is not sufficient to identify what needs to be changed or redesigned to improve outcomes (Berwick, 2005). Health services research studies can, therefore, benefit from complementary research using the SEIPS model.

3.3. Impact of health IT on work system, care process and patient safety

In many countries, health IT is seen as a significant means of improving healthcare quality and patient safety (Bates, 2000; Bates and Gawande, 2003). However, the evidence for the quality and safety benefits of health IT is limited (Chaudhry et al., 2006; Institute of Medicine, 2012). The lack of attention to HFE in the design, implementation, and use of health IT contributes to limited success of health IT, the failures to implement and sustain health IT, and safety problems linked to health IT (Karsh et al., 2010). Our research has examined the impact of health IT on work system and patient safety in a variety of domains: BCMA technology in hospital settings (Carayon et al., 2007b; Koppel et al., 2008), smart infusion pump technology in a hospital (Carayon et al., 2010; Schroeder et al., 2006; Wetterneck et al., 2006), and CPOE/EHR in ICUs (Carayon et al., 2011c; Hoonakker et al., 2010, 2011; Wetterneck et al., 2011). We have also used the SEIPS model to classify self-reported facilitators and barriers to physicians' use of implemented CPOE/EHR (Holden, 2011c) and to improve the design of a clinical decision support for primary care physicians (Hoonakker et al., 2012). Some of this research is described here.

According to the SEIPS model, when new health IT is implemented, it transforms the work system structure, thus altering care processes and then influencing outcomes such as patient safety (Holden, 2011a). We therefore studied how nurses in pediatric hospitals perceived three medication management processes before and after BCMA implementation (Holden et al., 2011a). Nurses' perceptions of the accuracy, usefulness, consistency, time efficiency, ease of performance, and safety of medication processes were significantly different following BCMA implementation compared to perceptions prior to BCMA. BCMA's incorporation into the work system had varying effects: some processes were perceived to improve whereas others were perceived to worsen. Another study of BCMA use by hospital nurses showed that, even a few years after implementation, a range of work system factors affected the safe use of the BCMA technology (Carayon et al., 2007b). For instance, interruptions by patients, families, and physicians often occurred while nurses were administering medications using the BCMA technology; this can produce distractions and medication administration errors. Nurses also identified various work system factors that promoted the safe use of BCMA technology such as need for verifying patient identity and medication.

In a study of the implementation of CPOE/EHR in four ICUs of a large hospital, we assessed the impact of the technology on the work system, the medication use process and errors, and various patient and employee outcomes. Results of our study show that ICU physicians tended to be less satisfied and accepting of the CPOE/EHR technology as compared to ICU nurses (Carayon et al., 2011b, 2011c; Hoonakker et al., 2010). Furthermore, satisfaction with CPOE/EHR did not change over time for ICU physicians, but

improved significantly for ICU nurses (Hoonakker et al., 2013a). While the CPOE/EHR technology seemed to negatively impact nurses' and to a lesser extent, physician and mid-level provider perceptions of certain aspects of communication (e.g., timeliness) 3 months after implementation as compared to 6 months before implementation, by one year after implementation these perceptions returned to the same level or higher level as before technology implementation. These results demonstrate that an HFE systems approach needs to examine the impact of a change such as a new technology for all user groups or stakeholders. In addition, it is important to assess the temporal and dynamic aspects of system changes as indicated by our longitudinal analysis of the quality of communication (Hoonakker et al., 2013a). In this analysis, communication timeliness deteriorated 3 months after implementation of the technology, but then improved and was found to be significantly higher 12 months after implementation. We also found an increase in certain medication error types after implementation, namely duplicate medication order errors (Wetterneck et al., 2011). The SEIPS model was used to analyze causes of the increased errors and we found issues with team communication as well as suboptimal EHR interface and clinical decision support alert design.

Holden (2011c) used categories of the work system to describe factors that facilitated or impeded physicians' use of CPOE and EHR for inpatient and outpatient care. Facilitators and barriers spanned six categories of user attributes including knowledge about CPOE/EHR and motivation, four technology attributes such as speed and usability, five organizational/support factors such as technical support and time allowance, and four environment factors such as physical space and wireless connectivity. In other analyses, Holden (2010; 2011a) assessed physician perceptions about technology-related changes in processes and outcomes that might influence their use and non-use of CPOE/EHR.

SEIPS research on health IT confirms the systemic and temporal consequences of the introduction of technology on the entire work system and care processes. Assessing the impact of technology on the work systems of various users is critical for understanding the systemic consequences of the technology. This can help to clarify the benefits and challenges associated with the technology for different groups of users. Some user groups may benefit more from the technology than others; this information is important for managing the sociotechnical change process and anticipating any acceptance problems. In addition, SEIPS research has confirmed the need to look at the short- and long-term consequences of technology. For instance, short-term negative consequences of technology implementation may disappear over time as the technology design and integration improved. The impact of health IT on the work system is not a linear process that unfolds over time; it is more like a journey in which the work system changes and adapts, and the person adapts to the work system as well (see section below on "Balancing the work system for patient safety").

4. Practical applications of the SEIPS model of work system and patient safety

The SEIPS model can be used by HFE researchers and practitioners to introduce HFE to healthcare leaders and clinicians. The model, highlighting the social and technical system elements and their interactions that can influence processes and outcomes, helps expand healthcare professionals' thinking. Instead of taking a micro-level approach focusing on the individual, healthcare professionals now have a tool to help them take a macro-level systems approach to solving problems and enhancing healthcare quality and patient safety.

The SEIPS model of work system and patient safety represents a major tool to introduce and promote HFE in healthcare; it has been used by numerous healthcare researchers, professionals and educators. Because the SEIPS model is based on the work system model, it allows the various domains of HFE (cognitive, physical and organizational ergonomics) to be integrated and combined. This systems approach is necessary to understand complex patient safety issues (Carayon, 2006).

The SEIPS model is the conceptual framework for a range of HFE tools and methods used to evaluate healthcare work systems and processes and their impact on healthcare quality and patient safety, such as survey questionnaire (Carayon et al., 2005a; Hoonakker et al., 2010, 2011), observation methodology (Carayon et al., 2005d; Carayon et al., 2007b), interviews (Carayon et al., 2006a; Gurses and Carayon, 2009), and proactive risk assessment of healthcare processes (Carayon et al., 2011e; Hundt et al., 2013; Wetterneck et al., 2009, 2006).

Additionally, the SEIPS model can be used to make sense of data during data analysis, even if it was not used as a framework while collecting the data. For example, when analyzing incident data from an error reporting system, the SEIPS model can be used to group the incidents into different processes (e.g., direct patient care vs. indirect patient care processes) or outcome types (e.g., patient-vs. employee-related). It can also be used to categorize the contributing factors of the incidents into the five work system elements. This helps healthcare organizations take a systems approach to identifying the root causes of errors rather than only blaming the person who committed the error.

The SEIPS model can be used by healthcare organizations to (1) analyze patient safety events (e.g., root cause analysis), (2) analyze high-risk care processes, (3) anticipate the potential safety consequences of sociotechnical changes such as the introduction of a new medical device or EHR technology, and (4) enhance health sciences curricula.

Root cause analyses (RCA) are conducted to investigate safety events. RCA teams can use the work system model to systematically consider all possible work system factors that could have contributed to the sentinel event and discover that a 'root cause' is unlikely to be discovered. The work system model can be a guide when asking questions about the event:

- who was involved [Person]
- what were they doing [Tasks]
- what tools/technologies were they using [Tools/technologies]
- where did the event take place [Environment]
- what organizational conditions contributed to the event? [Organization]

Once all of the system factors that are related to the event have been identified, the sequence of events can be mapped in the form of a process that integrates the various system factors. We have conducted this type of analysis for a fictitious case of wrong site surgery (Carayon et al., 2004). In the fictitious case, we created a process map that described the various steps of the process (from surgical site identification to the surgical process) while also considering all work system elements. Using the HFE systems approach advocated by the SEIPS model, one can identify a range of work system factors that contribute to wrong site surgery: information conveyance and ultimate (mis)documentation (*task*), delayed and inaccurate documentation (*task*) by the surgeon's nurse in the patient's record (*tool/technology*), and communication with the patient and other providers in a noisy *environment* at an *organization* where residents were involved in surgery, not solely the surgeon "familiar" with the case. All of these issues negatively affected and were affected by *people* – both the patients and clinicians.

Some care processes may be identified as high-risk processes that need to be redesigned. The SEIPS model can be used to conduct a process risk analysis to ensure that all factors contributing to the vulnerabilities or failures in the process are systematically considered and assessed. We have conducted proactive risk assessments of intravenous (IV) medication administration (Wetterneck et al., 2006), ICU nursing medication management (Faye et al., 2010), and patient transfer from surgery to the ICU (Hundt et al., 2013). Proactive risk assessment methods can be used to evaluate risks in current processes as well as to anticipate risks that (could) occur with modifications in care processes associated with sociotechnical changes (Carayon et al., 2011e).

The SEIPS model has also been used in educational and training activities related to HFE and patient safety. For instance, a graduate-level certificate in patient safety was developed at the University of Wisconsin-Madison and organized to teach HFE and the SEIPS model to students in various disciplines, including industrial and systems engineering, population health sciences, medical physics, nursing, and pharmacy (Karsh et al., 2005). The SEIPS model is also the core of the curriculum for the short course on HFE and patient safety that has been taught annually at the University of Wisconsin-Madison since 2004. The week-long short courses have been attended by more than 400 healthcare professionals and manufacturers/vendors engineers to learn about the basics of HFE and HFE applications to patient safety and health IT. Finally, the SEIPS model is used to teach third-year medical students about systems-based practice and analyzing errors and undesirable patient outcomes from a systems perspective as part of the patient safety curriculum at the University of Wisconsin.

5. Balancing the work system for patient safety

Understanding how the design and implementation of the work system can improve patient safety requires not only an assessment of specific aspects of the work system, but more importantly a deep understanding of work system interactions (Waterson, 2009; Wilson, 2000). According to Wilson (2000), the goal of HFE is "to understand the interactions themselves in order to design the more diffuse, complex, and multi-faceted interacting system" (page 563). The SEIPS model proposes an HFE systems approach to healthcare quality and patient safety; therefore, we need to understand interactions between work system elements and their influence on care processes, patient outcomes, and employee/organizational outcomes. These system interactions are at the core of the Balance Theory of Smith and Carayon (Smith and Carayon-Sainfort, 1989; Carayon and Smith, 2000).

5.1. Redesigning healthcare systems through balancing

The Balance Theory proposes that the individual elements of the work system be designed according to well-known HFE principles (Carayon et al., 2007a). The first step is to eliminate obstacles in the numerous work system elements. As described above, research has clearly shown that many different work system elements are performance obstacles and affect patient safety, employee safety, and healthcare quality in a range of healthcare settings, workplaces and situations. Eliminating obstacles is critical; but this approach is not sufficient, and in some cases, not feasible. For instance, our research on ICU nurses shows that patient characteristics are key performance obstacles; ICU patients are very sick and complex and create multiple demands for ICU nurses. Eliminating this obstacle is not feasible; other elements in the work system need to be addressed to mitigate the negative impact of this obstacle. Therefore, a complementary approach examines balance in the work system.

Two approaches to balancing the work system have been proposed: (1) compensatory balance and (2) overall system balance (Carayon and Smith, 2000; Smith and Carayon-Sainfort, 1989). Compensatory balance in the work system is achieved when one positive element ‘compensates’ for negative elements in the work system. Overall system balance is achieved if the overall combination of positive and negative elements produces more benefits than problems for system outcomes (e.g., patient safety and worker well-being).

Using the SEIPS model, we examined sources of motivation and satisfaction of tele-ICU nurses (Hoonakker et al., 2013b). Tele-ICU nurses use different health IT applications to each monitor up to 50 patients located in different remote ICUs. Data from interviews with 50 tele-ICU nurses in 5 tele-ICUs showed that their work motivation and satisfaction were related to all elements of the work system. The nurses derived most motivation and satisfaction from the challenging aspects of their tasks, the physical working conditions, and the organization, in particular the teamwork in the tele-ICU. However, elements of the work system also reflected sources of dissatisfaction such as lack of physical activity (environment) and lack of acceptance by some ICUs (organization). Overall, each element of tele-ICU nurses’ work system contained both positive and negative characteristics. For example, with regard to their tasks, tele-ICU nurses described the low job content of some tele-ICU tasks such as documentation and data collection, but also often talked about the interesting task challenges in their job. This is an example of compensatory balance as described by the Balance Theory (Smith and Carayon-Sainfort, 1989). Tele-ICU nurses mentioned positive work system characteristics more frequently than negative characteristics. This may be an indication that their work system is overall well-balanced with more sources of satisfaction than sources of dissatisfaction.

5.2. Active and adaptive role of workers

The individual at the center of the work system is influenced by the work system, but also influences the rest of the work system. When we examine the work system, we tend to focus on identifying system factors that either facilitate or hinder performance (performance facilitators and obstacles) and system factors that increase stress (job stressors) or increase satisfaction and motivation. See section above on “Work system performance obstacles and facilitators”. Workers are influenced by work system elements, and therefore react and adapt to the work system (e.g., changing their work methods to adapt to the new technology). As described above, one example of adaptive behavior is the work-arounds created by workers to achieve their job despite performance obstacles and poorly designed work systems (Halbesleben et al., 2008; Holden et al., 2013; Koppel et al., 2008).

It is also important to recognize that workers adapt their work system; they can play an active role in their work system. For instance, Weir et al. (2011) showed how physicians and nurses began to use a computerized patient documentation system as a communication tool. This is an example of how workers adapt a tool (i.e. computerized patient documentation) to perform tasks (i.e. communication) not considered in the functional design of the tool. This example of the active role of workers in using technology is in line with the structurational model of technology by Orlikowski (1992). The active role of workers in their work system is also a key element of the resilience engineering approach (Woods and Hollnagel, 2006). Workers develop strategies to adapt or respond to demands of the current situation (Paries, 2011); resilience is, therefore, characterized by four capabilities: (1) knowing what to do, (2) knowing what to look for, (3) knowing what to expect, and (4) knowing what has happened (Hollnagel, 2011).

The two roles of the person at the center of the work system, i.e. person influenced by the work system and person influencing the work system, are not separate. They can, for instance, be integrated through the concept of job control or autonomy. Worker adaptation can be fostered by a work system that allows workers to exercise control and be autonomous. In turn, a work system that allows for worker control and autonomy produces positive employee and organizational outcomes, such as reduced stress and improved satisfaction and motivation (Carayon, 1993; Frese, 1989). For example, interruptions in healthcare can have a negative impact on the persons being interrupted, such as loss of attention (Grundgeiger and Sanderson, 2009) and stress (Baethge and Rigotti, 2013), but work systems that support job control may facilitate the ability of workers to decide how to respond to interruptions (Rivera-Rodriguez and Karsh, 2010).

5.3. HFE systems approach to redesign

A range of technological, organizational, and structural interventions is being implemented to improve healthcare quality and patient safety. For instance, as described above, there has been a major push to implement health IT to improve the efficiency, effectiveness, and safety of patient care. These sociotechnical and structural changes can benefit from the SEIPS model as any change in one element of the work system (e.g., implementation of a new technology) will affect the other elements of the work system. This can be accomplished, for example, through a proactive risk assessment as described in the section above. It is important to recognize that we cannot anticipate all possible work system changes that occur after the implementation of a new technology (e.g., BCMA or EHR) or a new work organization (e.g., patient-centered medical home). The feedback loops in the SEIPS model are important in this regard as they highlight the need for regular assessment of the work system and its impact on processes and outcomes. As described above, the feedback loops are also important for continuous improvement.

An HFE systems approach to healthcare redesign as suggested by the SEIPS model addresses the multiple work systems of importance for the specific healthcare quality or patient safety problem to be addressed. Oftentimes the focus is on the work system of a single individual; optimizing the work system for one individual may have negative consequences for the work system of other individuals. An example of the problem with this narrow approach is the issue of resident duty hours. Long hours for medical residents affect patients (e.g., errors related to resident fatigue) as well as the residents themselves (e.g., burnout) (Ulmer et al., 2008). Improving the work system of residents, such as their work schedule, can reduce serious medical errors (Landrigan et al., 2004) and enhance resident well-being. However, this work system redesign may have negative effects on the work system of attending physicians who supervise the medical residents. Attending physicians may have to work longer hours to compensate for the shorter hours of residents; they may then experience fatigue and stress that can lead to errors. Therefore, it is important to define the right level and scope of the system in order to address healthcare quality and patient and employee safety.

6. Conclusion

The SEIPS model has been used successfully to introduce and promote HFE to healthcare researchers, professionals, and educators. Knowledge of specific HFE topics (e.g., teamwork, usability, coordination, physical stressors, resilience) is necessary to study healthcare quality and patient safety issues. We advocate that this specialized HFE knowledge focusing on specific aspects of the work

system can have significant impact if it takes into account the entire work system. If the broad work system is not clearly considered, this specialized HFE knowledge is at risk of either examining the wrong problem or using the wrong approach to solve the problem. We encourage HFE researchers and practitioners to embrace the proposed HFE systems approach to increase the relevance and significance of their effort targeted at improving healthcare quality and patient safety.

Future research on the SEIPS model should explore work system interactions and their impact on healthcare quality and patient safety (Waterson, 2009). This research should help answer the question of how to redesign healthcare systems and processes to achieve benefits for both patients and healthcare workers. We also need to develop methodologies and measures for assessing balanced work systems that can produce benefits for all stakeholders.

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