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Challenges And Opportunities For Improving Patient Safety Through Human Factors And Systems Engineering

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ABSTRACT Despite progress on patient safety since the publication of the Institute of Medicine's 1999 report, *To Err Is Human*, significant problems remain. Human factors and systems engineering (HF/SE) has been increasingly recognized and advocated for its value in understanding, improving, and redesigning processes for safer care, especially for complex interacting sociotechnical systems. However, broad awareness of HF/SE and its adoption into safety improvement work have been frustratingly slow. We provide an overview of HF/SE, its demonstrated value to a wide range of patient safety problems (in particular, medication safety), and challenges to its broader implementation across health care. We make a variety of recommendations to maximize the spread of HF/SE, including formal and informal education programs, greater adoption of HF/SE by health care organizations, expanded funding to foster more clinician-engineer partnerships, and coordinated national efforts to design and operationalize a system for spreading HF/SE into health care nationally.

With the publication of reports by the National Academies of Sciences, Engineering, and Medicine[1,2] and the President's Council of Advisors on Science and Technology,[3] human factors and systems engineering (HF/SE) has gained recognition as an innovative approach for improving patient safety. A 2005 joint report by the National Academy of Engineering and the Institute of Medicine (IOM) provided a framework for partnerships between systems engineers and health care practitioners to address a range of operational and strategic problems, including patient safety.[2] Subsequent reports by the IOM, the Agency for Healthcare Research and Quality (AHRQ), and others have called for greater involvement of HF/SE. For example, a 2015 report by the National Academies highlights diagnostic errors as a major patient safety issue, with most people likely to experience at least one diagnostic error with possible negative consequences in their lifetime.[4] The conceptual model of that report, adapted from the Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety,[5,6] describes the diagnostic process as a series of activities that engage the patient with health care over time and are embedded in a work system composed of several interacting elements: people (health care professionals, diagnostic team members, patients, and caregivers), tasks, technologies and tools, the physical environment, the organization, and the external environment. Beyond human factors, numerous patient safety issues also manifest from system design and operational issues that systems engineering methods can address.[7] For example, staffing levels can be optimized for safe staff-to-patient ratios, and the management of bed usage can be improved to prevent ED boarding.[8]

While the value of HF/SE in improving patient safety has been demonstrated, the field remains significantly underused and not well understood.[9] In this article we describe HF/SE, its different facets and approaches, and its applications, illustrating its role in patient safety. Because adoption of systems approaches to patient safety remains challenging,[10] we conclude with a discussion of barriers, policy implications, and recommendations about how to more broadly integrate HF/SE into patient safety improvement locally and nationally.

What Is Human Factors And Systems Engineering?

HF/SE encompasses a range of methods and principles to model, improve, optimize, and integrate complex sociotechnical systems (and systems of systems), often with multiple goals and stakeholders, to yield the best overall system performance—including safety. The HF/SE field brings a systems perspective to patient safety that emphasizes multilevel, spatiotemporal analyses of care processes (for example, work system analysis, error propagation and recovery, and patient journey modeling). These approaches are anchored in the broad discipline of industrial and systems engineering[11] and its human factors engineering component (also called ergonomics).[12]

An important principle of HF/SE is to go beyond improving single system elements, such as technology or tasks, and rather to analyze and improve the entire system—that is, both the elements of the system and their interactions.[13] For example, when developing and implementing a patient safety practice, such as preoperative checklists, the entire system needs to be considered where the checklist is viewed as a tool that positively or negatively affects other system elements such as team communication and workflow. As described in online appendix exhibit A1,[14] the core of HF/SE is a systems viewpoint, including system design principles (for example, usability, situation awareness, and system-level alignment), that is implemented through user participation and the use of multiple analytical methods in continuous improvement cycles with learning and feedback loops.

Applications Of Human Factors And Systems Engineering To Patient Safety

HF/SE has been applied to many domains of patient safety[15] and has made significant contributions to the design of processes, technologies, devices, physical environments, and other aspects of work systems. A majority of this work has focused on hospital-based care, most notably on medication safety and health information technology,[16] health care–associated infections,[17] patient falls,[18,19] and patient identification.[20] Another important contribution of HF/SE has been the systematic analysis of safety events, including retrospective and prospective methods such as the Human Factors Analysis Classification System (HFACS),[21,22] failure mode and effects analysis (FMEA),[23] and others.[24] Exhibit 1 summarizes common examples of HF/SE approaches used to address important patient safety issues.

For example, the medication drawer in a code cart used during emergencies was redesigned using HF design principles (for example, grouping, visibility, and organization), which resulted in multiple improvements—reductions in completion time and wasteful actions (such as turning an incorrect vial to find the label) and improvements in perceived visibility, usability and organization, and clinician satisfaction—compared to the usual medication drawer.[25] An analysis of inpatient nursing work, including time studies and the SEIPS model,[5,6] helped optimize medication retrieval and preparation, improve supply management, and reduce interruptions and distractions—resulting in 59 percent fewer requests for missing medications, 30 percent fewer visits to the medication room, and fewer medication errors reported by intensive care nurses.[26] Using a human-centered design process, members of the Surgical Patient Safety Systems (SURPASS) Collaborative Group developed a perioperative checklist,[27] whose use resulted in a 39 percent reduction in surgical patient complications and a 47 percent reduction in in-hospital mortality.[28]

Less patient safety research has been conducted outside of acute care settings, where there is less use of HF/SE. In primary care settings, most HF/SE work focuses on understanding work-system factors that negatively affect safety and the work of primary care professionals.[29,30] In the home environment, some HF/SE safety work has focused on health information technologies,[31] hemodialysis technology,[32] and infusion pumps.[33] Typically the work has addressed usability, the broader system of care,[34] and the patient's work system.[35] HF/SE researchers also have examined safe transitions between hospital and home, highlighting the need to examine safety over longer time periods—especially for older adults.[36,37]

EXHIBIT 1

Examples of human factors and systems engineering (HF/SE) approaches to improving patient safety

Safety issue	HF/SE approach	Examples
Patient safety events and near misses	HF classification frameworks and methods for analyzing system factors that contribute to the events and near misses	Human Factors Analysis and Classification System (HFACS) (note 21)
Medication safety	Human-centered design of medication processes, such as prescription and administration	HF design principles and HF methods for safer design of order-prescribing interfaces (note 16) and code cart medication drawer (note 25)
Health care–associated infections	Analysis of system factors that contribute to the infections	Identification of work-system barriers and facilitators to adherence to contact isolation for patients with suspected or confirmed *Clostridium difficile* infection (note 17)
Patient falls	HF design of work systems for reducing inpatient falls	Human-centered design of fall prevention toolkit (note 19)
Patient identification	Human-centered design of identification armband	HF design of armband for improving patient identification by reducing number of visual scans required (note 20)
Patient safety in primary care	Work system analysis for patient safety	Efforts to counteract the "information chaos" experienced by primary care physicians that can lead to patient safety events (note 30)
Patient safety in home care	HF/SE analysis of medical devices and information technologies used in the home	Analysis of usability and system integration of hemodialysis technology (note 32) and infusion pump (note 33); HF design of consumer health information technologies for home use (note 31)
Patient safety in care transitions	Process analysis of transitions between hospital and home (note 37)	Description of transition process and safety vulnerabilities over multiple phases of care, especially for older adults (note 36)

SOURCE Authors' analysis. **NOTE** Note numbers in parentheses refer to references at the end of the article.

Challenges To Greater Adoption Of Human Factors And Systems Engineering In Patient Safety

Despite many examples of the value of HF/SE,[38] its greater adoption by health care remains challenging.[1–3] Five challenges limit its broader spread: cultural differences between engineers and health care professionals, resource and expertise limitations, the organizational environment, fragmentation of the care process, and policy and market issues.

CULTURAL DIFFERENCES Cultural differences between HF/SE and health care are profoundly important but often unrecognized or underappreciated. Pascale Carayon and Anping Xie[39] identified four HF/SE core values (putting people at the center, systems thinking, continuous improvement, and balancing multiple objectives) and four health care culture core values (scientific inquiry, individual responsibility, autonomy, and excellence), some of which directly conflict with each other. For example, health care cultures often emphasize the work, knowledge, and skills of individuals, which can produce a tendency to blame individuals for patient safety incidents. In contrast, HF/SE seeks to proactively build systems and processes to prevent errors or mitigate their impact. Despite many calls for systems approaches to patient safety, efforts to hold individuals accountable for errors remain,[10] which demonstrates how deeply engrained in health care this mind-set is. HF/SE approaches also tend to follow a different and more time-consuming work style, viewpoint, and pace, compared to rapid improvement approaches—and the two can be at odds.

RESOURCE LIMITATIONS A second barrier is limitations in resources such as technical expertise, time availability, and data infrastructure. Health care professionals often have little time away from clinical work[40] and limited knowledge to apply HF/SE approaches.[1] Although this can be offset through clinician-engineer partnerships, few HF/SE professionals are equipped or trained to work in health care.[2] Moreover, the participatory methods of HF/SE require focused time and involvement from health care professionals[41]—significantly more than is usually available. Additional work, therefore, could adapt and streamline HF/SE methods for the time-constrained environment of health care. For instance, the time-consuming nature of FMEA and other proactive risk-assessment methods[42] in one case led to the development of a faster hybrid risk-assessment method to identify computerized provider order entry vulnerabilities.[43] Data infrastructures also tend not to capture the type of patient safety data needed by HF/SE professionals for system redesign and improvement.[1–3]

THE ORGANIZATIONAL ENVIRONMENT A third barrier to greater HF/SE use is organizational

Health care organizations' hiring or partnering with human factors and systems engineers remains the exception.

environments that are not open to innovation and new ideas. Learning organizations with sufficient resources and decentralized decision-making structures tend to facilitate innovative practices,[41,44] whereas organizations that are hierarchical and respond to failure punitively create obstacles to using HF/SE.[1] Leaders in health care organizations can remove such barriers by committing resources to improvement efforts, raising the visibility of improvements, setting priorities, and managing expectations.[3]

FRAGMENTATION A fourth barrier is fragmented and siloed care processes, which are often designed and managed separately—making the holistic systems approach of HF/SE challenging.[3] Examples include communication and coordination problems across boundaries, separate scheduling systems that result in unsafe staffing levels or patient rooming practices, and clinicians-in-training being educated primarily within their individual disciplines rather than interprofessionally.

POLICY AND MARKET ISSUES Lastly, policy and market considerations can limit HF/SE adoption, especially when there is little incentive to improve health care processes under fee-for-service reimbursement models.[1–3] This situation has improved with the renewed focus on population care accountability under the Affordable Care Act and the movement of the Centers for Medicare and Medicaid Services toward value-based care, which could foster greater adoption of HF/SE. Nonetheless, further work is needed, and resources are needed for hiring HF/SE experts, dedicating clinician time, and improving data infrastructures. Smaller, rural care settings especially may struggle for such resources,[3] which suggests that securing resources for broader HF/SE deployment might need to look beyond individual organizations.

Recommendations For Accelerating The Integration Of Human Factors And Systems Engineering Into Patient Safety

The benefits of HF/SE to patient safety can be more broadly realized through a variety of mechanisms: more widespread adoption and use of HF/SE tools and methods, greater awareness of and training in HF/SE knowledge among health care professionals, and hiring of human factors and systems engineers into health systems.[41] We next propose recommendations for seven groups or areas that are critical to the integration of HF/SE into health care, and we describe the policy implications that address various mechanisms to foster and accelerate greater spread of HF/SE for improving patient safety.

HEALTH CARE PROFESSIONALS Health care professionals, health system leaders, and clinicians-in-training would benefit from greater opportunities to learn and apply basic HF/SE methods. At a minimum, educational programs for physicians, nurses, pharmacists, and others should provide an introduction to HF/SE and its role in patient safety. Fellowships should be created to provide clinicians-in-training with a deeper understanding of HF/SE and skills. Federal funding, such as that available through AHRQ, Health Resources and Services Administration, National Institutes of Health (NIH), and National Science Foundation (NSF) training mechanisms, could support HF/SE health care traineeship programs.

Foundation-managed programs, similar to the W. K. Kellogg Foundation's national fellowship program in the 1970s, also could be initiated to embed HF/SE engineers in health systems and provide systems with education in HF/SE. In addition, individual health systems could support HF/SE fellows or expand existing internal quality and safety programs to include modules on HF/SE topics. Closer relationships between HF/SE academic programs and health sciences schools could be fostered and incentivized.

These recommendations are aligned with those made by the American Medical Association's Accelerating Change in Medical Education Consortium that describe "health systems science" as the third pillar of medical education, in addition to basic science and clinical science.[45] Health systems science includes HF/SE methods for improving patient safety, such as systems approach, the Plan-Do-Study-Act (PDSA) cycle, ensuring the usability of health information technologies, and process analysis. We recommend a partnership between the association and HF/SE professionals and experts to further refine health systems science and implement it in medical education.

HUMAN FACTORS AND SYSTEMS ENGINEERS For more advanced HF/SE work, many more human factors and systems engineers need to be trained in health care applications. This ideally would follow a two-pronged approach to engage both students enrolled in HF/SE programs and faculty members who are teaching and advising these students. Beyond classroom education, experiential curricula should provide HF/SE students with opportunities to work on applied projects or internships embedded in health care organizations. Such opportunities are critical to understanding the organization, environment, and culture of health care delivery.

Similar opportunities are needed for HF/SE faculty members to be exposed to health care's unique challenges, constraints, and opportunities, perhaps through embedded summer or sabbatical fellowships. Such immersion experiences could result in new HF/SE courses in patient safety; improved training of HF/SE students; and identification of HF/SE problems for faculty research, grants, and publications. These changes would further enhance the value of HF/SE to patient safety. Ironically, little systems thinking has been conducted to design bidirectional value-added approaches to partnering health care systems with engineering academic programs, although several approaches could easily be identified and developed.

HEALTH CARE LEADERS AND BOARDS OF HEALTH CARE ORGANIZATIONS Leaders and boards of health care organizations should play important roles in realizing the potential of HF/SE. Ultimately, health systems should hire and engage human factors and systems engineers to help improve patient safety. However, leaders' awareness of and commitment to the value of HF/SE needs to be fostered, perhaps through large-scale projects to demonstrate that value, continued advocacy by national organizations such as the National Academies, and other visibility efforts that develop and disseminate convincing evidence of the value of HF/SE.

Health care organizations also will need to create or identify mechanisms for retaining and promoting human factors and systems engineers, including work opportunities beyond basic applications and joint academic appointments. To maximize the value of HF/SE, more robust data infrastructures (beyond those for providing care) also need to be available for analyzing work systems and care processes, which boards of health systems should support.

Notably, a small number of health care organizations have long legacies of supporting, engaging, and partnering with human factors and systems engineers. Appendix exhibit A2 describes two such organizations, the types of projects typically conducted, and the lessons learned.[14] However, health care organizations' hiring or partnering with human factors and systems engineers remains more the exception than the norm. Many hospitals downsized internal systems engineering groups in the cost-cutting era of the late 1980s and 1990s, and the Society for Health Systems, a professional organization consisting of roughly 1,200 hospital-employed industrial engineers, has not grown much since its formation in 1980.

We recommend a national program charged with developing and implementing a long-term vision for spreading HF/SE throughout health care.

TECHNOLOGY DESIGNERS AND VENDORS Although significant research has shown the value of HF/SE in improving the design of technologies, such as smart infusion pumps, and subsequent improvements in medication safety,[22,46,47] there continue to be patient safety problems related to poor human factors design and technology implementation.[48,49] Significant work remains to more systematically integrate HF/SE (such as usability) in designing health information technologies.[50] For example, vendors,[51] designers, and implementers need to train their staff in human-centered design.[52] Designers and vendors should give more serious consideration to human-centered design and the routine use of multiple HF/SE methods, including understanding of the actual work process, incorporating usability techniques (such as heuristic evaluation) early in the design process, user-testing in simulated environments, and monitoring safety problems of technology in use.[16,53]

REGULATORY AND REIMBURSEMENT AGENCIES Agencies and organizations involved in health care regulation and financing have important roles in the accelerated adoption of HF/SE into patient safety. As three examples, they can support the large-scale demonstration projects

The value of human factors and systems engineering for improving patient safety is clear yet underrealized.

needed to create evidence and broader visibility of the value of HF/SE, provide incentives for health care organizations to integrate HF/SE into patient safety improvement efforts, and create infrastructures to support HF/SE application in small and rural health care organizations that are unlikely to have sufficient internal resources for this effort.

A large majority of health care organizations that are investing in HF/SE are academic medical centers, large nonacademic health systems, or health care systems conveniently colocated with HF/SE university programs. Such organizations represent only a subset of those that would benefit from greater HF/SE use. Federal and state agencies thus should play important roles in developing mechanisms to help rural, smaller, and underresourced health care organizations leverage HF/SE to improve patient safety, reduce disparities, and control costs.

FUNDING ORGANIZATIONS Significant funding increases are needed for HF/SE research in patient safety—in particular, in the areas of diagnostic safety, behavioral health, home care, and care transitions. Home-based patients interact with diverse actors and entities during their care journeys, all of which affect safety through a system of interacting systems that HF/SE can help improve by using analysis, modeling, and design of processes to detect, mitigate, and recover from vulnerabilities and failures.

Funding agencies such as AHRQ, the NIH, and the NSF have recently acted to stimulate the integration of HF/SE and systems science with health services research, including patient safety research. Actions include AHRQ's investment in thirteen Patient Safety Learning Laboratories, several NIH funding announcements for systems engineering modeling in disparities and behavioral health, and a joint NSF-NIH funding program (Smart and Connected Health) to encourage collaboration among health information technology, engineering modeling, and cognitive/behavioral scientists. While these are relatively new programs, the results to date provide further evidence of the value of partnerships between health care and HF/SE researchers.[19,54] However, such opportunities are rare, and greater funding is needed—especially given the size and scope of the health care industry and patient safety issues.

Future research should demonstrate the value of HF/SE to patient safety in primary care and home care. In particular, opportunities exist to demonstrate its value so that devices and health information technologies better support information access, communication, patient self-management, and other essential aspects of home care that are critical to medication safety, the early identification of health problems and their prompt resolution, and the support of patients' safe self-care.

NATIONAL COORDINATED EFFORTS While individual activities along the lines described above should continue and be expanded, more coordinated and widespread efforts will be required to fully realize the potential of HF/SE. As an example, in 2010 the Veterans Health Administration funded the creation of four Veterans Engineering Resource Centers to deploy systems engineering at scale throughout its system. The Center for Medicare and Medicaid Innovation funded a similar effort to test a regional extension center model for health care systems engineering, and the University of Texas health system funded a demonstration project to partner clinicians with engineers across its medical center campus system.

While each initiative achieved partial success, they all faced challenges related to organizational resources, deployment, and scale. We therefore recommend a more coordinated, larger national program charged with developing and implementing a long-term (ten-year) vision for spreading HF/SE throughout health care, similar in spirit to the national effort of the Office of the National Coordinator for Health Information Technology and associated investments in health information technology. A national HF/SE initiative could be led by the federal government, a coalition of foundations, or a coordinated network of large health systems. It might be responsible for operationalizing some of the workforce development, HF/SE value visibility initiatives, fellowship and training programs, large-scale national impact projects, academic partnership mechanisms, curricula unification, and deployment and assistance programs mentioned above.

Conclusion

The value of human factors and systems engineering for improving patient safety is clear yet underrealized. Important and demonstrated application areas include health care–associated infections, medication safety, medical device design and usability, reliability design and fault tolerance, cognition and cognitive burden, workload analysis, clinician burnout, and complexity management. However, several challenges are inherent in broadening the scale, application, and benefit of these methods. An appreciation of systems thinking and systems-of-systems awareness has developed slowly in health care and should be cultivated more broadly. Our recommendations are intended to encourage significantly greater and more impactful HF/SE application, education, and research initiatives in health care to help address the many patient safety challenges that remain. ■

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