COMMENTARY

Translating Evidence into Practice Using a Systems Engineering Framework for Infection Prevention

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THE CURRENT STATE OF INFECTION PREVENTION

The current infection prevention era is defined by the rise of healthcare-associated infections (HAIs) and multidrug-resistant organisms (MDROs). Efforts to combat these and other emerging pathogens have resulted in rapid and ongoing evolution of the contemporary infection prevention environment. Currently, HAIs impose a significant burden on the US healthcare system. Recent analysis of National Healthcare Safety Network data from the early 2000s suggests that at least 1.7 million HAIs occur yearly in US hospitals, associated with at least 99,000 deaths.[1] These numbers have likely increased over the past decade and suggest that HAIs are among the leading causes of death in the United States.[2]

Beyond their impact on mortality, HAIs also exert a substantial financial burden. Data from the Centers for Disease Control and Prevention show that direct inpatient hospital costs of HAIs range from $36 billion to $45 billion. This is higher than the estimated annual costs for coronary artery disease ($17.5 billion), acute coronary syndromes ($11.8 billion), and congestive heart failure ($11.2 billion), the 3 diagnoses associated with the highest inpatient hospital costs.[3]

In recent years, HAIs have come under greater scrutiny by patients, providers, healthcare institutions, and regulatory agencies at the forefront of the patient safety movement, leading to increased momentum in research in this important area. Recent large efficacy studies have provided insight into prevention of HAIs,[4,5] and while much in infection prevention remains fertile ground for discovery and efficacy research, there is now an accumulating body of well-designed studies of interventions to mitigate the largely preventable burden of HAIs. As science moves from evidence generation to translation into practice, an effective framework to promote, facilitate, and evaluate the implementation of evidence-based strategies in infection prevention is needed. For any approach to be successful, however, it must take into account the complexity and ambiguity of the healthcare system.

HEALTHCARE SYSTEM COMPLEXITY AND AMBIGUITY

With an ever-growing array of medical knowledge, procedures, and technology, increasing complexity has become the rule throughout the modern healthcare system. This high-complexity environment can impede consistent implementation of evidence-based interventions and far exceeds the cognitive limits of any individual care provider.[6] Monitoring an average intensive care unit (ICU) patient's vital signs generates 240 data points and requires approximately 200 clinical interventions on a daily basis.[7,8] Even in the outpatient clinic, a modern primary care provider manages on average nearly 600 unique diagnoses, 300 unique medications, and more than 100 unique laboratory tests. Although there is repetition in outpatient medical care, the 25 most common diagnoses account for only 40% of all primary diagnoses, suggesting significant variety and substantial primary care provider management of complex diagnoses and medications.[9]

In addition to the complexity of health care described above, recent work also suggests that ambiguity is another factor to take into account when considering implementation of interventions in health care. Ambiguity is defined as "uncertainty or vagueness that may prevent the system from achieving its purpose."[10(p353)] For example, as described by Gurses et al[10] in their study of ICU work systems, there may be uncertainty about goals of care (task ambiguity), how to conduct a task (method ambiguity), and when to change processes for special populations (exception ambiguity). For successful implementation, quality improvement initiatives that aim to improve adherence to HAI prevention guidelines should identify, take into account, and address the ambiguity of underlying systems as an important first step. For example, explicitly defining the roles and responsibilities of team mem-

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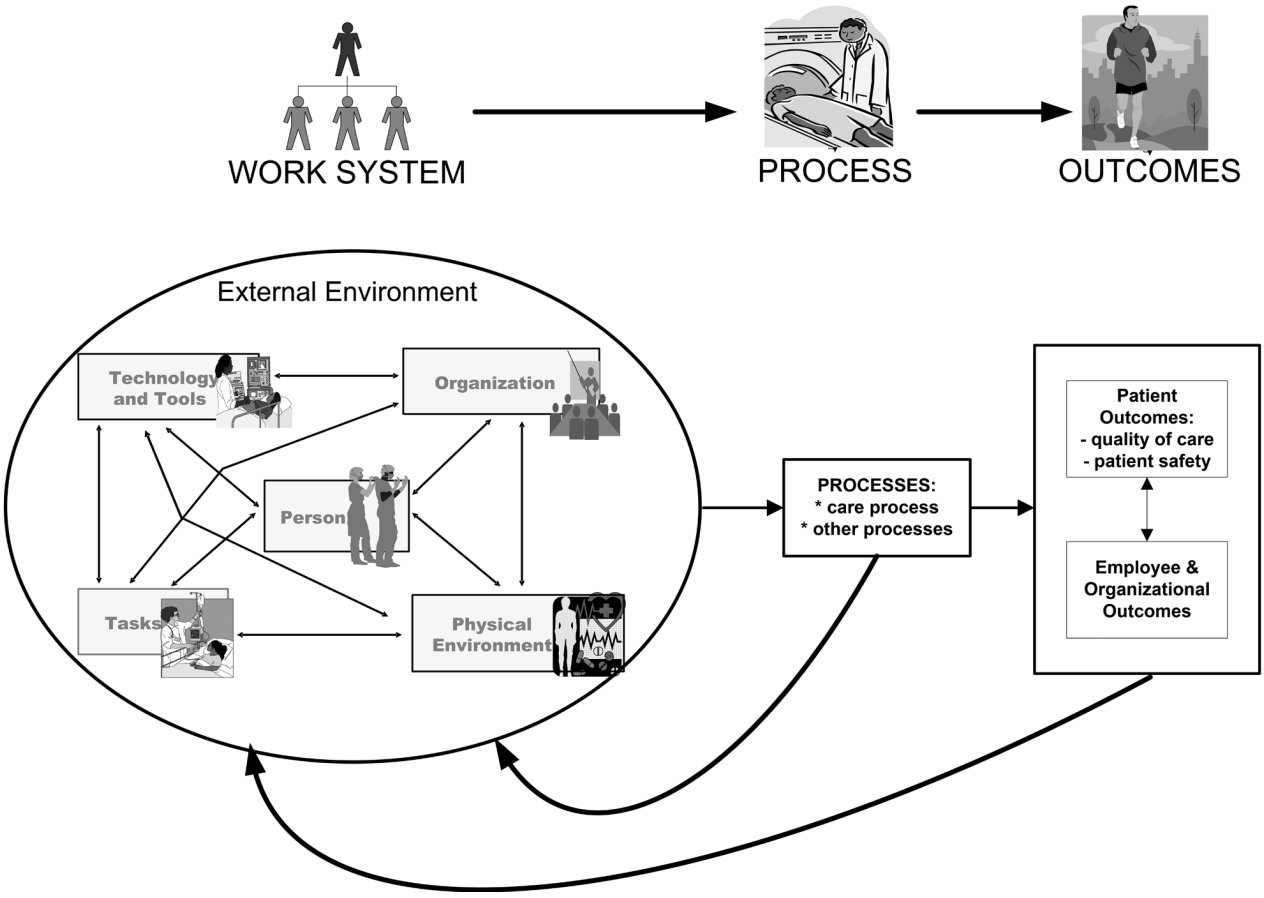


FIGURE 1. Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety. A color version of this figure is available online.

bers with regard to the work system may help reduce ambiguity.

As healthcare systems evolve and adopt new models of care, such as ambulatory surgery centers and long-term acute care hospitals, this complexity and ambiguity will become even more pervasive. Other contributing factors include an environment of increasingly limited work hours, increasing patient care handoffs, and a greater presence of multidisciplinary teams. This confluence of complexity, ambiguity, and a continuous evolution of healthcare delivery underscores the need for a structured systems-based approach that can serve as a framework for implementation of infection prevention practices.

HUMAN FACTORS ENGINEERING AND INFECTION PREVENTION

Systems engineering approaches represent an important advance in our understanding of process improvement because these approaches recognize that the product of any process is the result of multiple system elements as well as multiple interactions among those elements. Systems engineering further suggests that accurate understanding of the independent and interdependent relationships among system elements is crucial to effective process improvement. This is particularly relevant to health care because improving health care itself does not automatically lead to improvement in overall health, and improving individual healthcare system components does not necessarily improve the healthcare system as a whole.

Such systems-based improvement approaches have been prominently implemented in the automotive industry. Perhaps most well known, the Toyota production system divides large, complex processes into distinct steps with explicitly defined procedures and responsibilities.[11] Beyond efficient and high-quality manufacturing, a systems approach has also yielded dramatic safety improvements in the field of commercial aviation. Increased mechanical reliability partially contributed to improved aviation safety, but systematically addressing human factors was equally important. For example, crew resource management (CRM), originally developed by NASA in the 1970s, trained flight crews to address inadequate communication, leadership, and decision-making skills.[12] Because CRM acknowledges that flight crews are prone to human error, it teaches methods for recognition and mitigation of the cognitive errors inevitable in a high-stress,

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TABLE 1. Key Features of Human Factors and Ergonomics (HFE) Systems Approaches Developed for Patient Safety

Patient safety HFE model	Key features
Swiss cheese model	Focus on etiology and contributing factors to patient harm
Healthcare professional performance paradigm	Emphasis on enhancing clinician performance and eliminating performance obstacles
System resilience	Analysis of a system's ability to cope with and recover from errors and failure
Structure-process-outcome model	Defined relationships and linkage among system structure, process, and outcome
Systems Engineering Initiative for Patient Safety model	Broad, interconnected work system that influences processes and outcomes

SOURCE. Adapted from Carayon et al.[25]

high-risk environment. Despite the connection with the frequently high-stress, high-risk environment of modern health care, these systems approaches with significant potential for quality improvement are largely underutilized in health care.[13]

Human factors engineering (HFE) is the scientific discipline concerned with understanding the interactions among humans and other elements of a system in order to improve system performance and well-being.[14] The term "system" is intentionally general, as it can represent a multitude of human interactions with physical objects, ideas, other humans, and institutions. Concordantly, the field of HFE is divided into the domains of physical, cognitive, and organizational ergonomics. Physical HFE design reduces the need for excessive physical exertion, optimizes physical movement, and decreases physical constraints and workload. Cognitive HFE design improves consistency among interfaces, matches technology and human mental models, and decreases cognitive load. Organizational HFE design provides opportunities for workers to develop new skills, fosters worker input and participation in work system design, and enhances worker access to social support.[15] Beyond the study of humans and their systems, the practice of HFE in health care directs system design appropriate for healthcare worker characteristics and limitations as well as emphasizing patient well-being.

Early adoption of general HFE principles has demonstrated success in health care, particularly in HAI infection prevention. A seminal study in this regard, the Keystone ICU study,[16] demonstrated dramatic reduction in central line–associated bloodstream infections with a bundled systems-based approach including clinician education, use of a central line cart with necessary supplies, checklist implementation, discussion of daily goals (including catheter removal), and monthly feedback on rates of catheter-related bloodstream infections.

These interventions addressed several well-described infection control challenges as they relate to HFE. Monthly feedback of infection rates addressed the challenge of delayed feedback—that is, subsequent infection from missed infection prevention tasks may not become evident until later, possibly in a different environment with different healthcare providers. Checklist use addressed the high cognitive workload of recalling the complex, multistep process of central line insertion. Additional checklist benefits included standardizing best evidence-based practices.[17]

PATIENT SAFETY HFE APPROACHES

Conceived by the British psychologist James Reason, the well-known Swiss cheese model employs "holes" to represent an alignment of hazards that may culminate in untoward outcomes.[18] It also distinguishes between latent failures (system design) and active failures (operator error). Originally applied to the analysis of industrial accidents, Reason's Swiss cheese model was further refined and adapted to patient safety by the work of Vincent et al.[19] With regard to medical care, latent failures were defined as "fallible decisions" typically made by management personnel not directly involved in patient care (ie, the blunt end). Conversely, active failures included unsafe acts or omissions committed by operators with immediate patient impact (ie, the sharp end). The Swiss cheese and derivative models are particularly well suited for patient safety event investigation, as they focus on the etiology of and contributing factors to patient harm.

An alternative HFE paradigm for patient safety conceptualized by Karsh et al[20] acknowledges the role of reducing errors and patient harm but emphasizes the importance of enhancing clinician performance. Physical, cognitive, and social/behavioral performance processes are defined with the goal of eliminating as many performance obstacles as possible. More recent patient safety HFE approaches have also addressed health system resilience—that is, "the ability of systems to anticipate and adapt to the potential for surprise and failure."[21(p4)] Much of this work is modeled after high-reliability organizations and resilience engineering.[22,23]

In contrast to the comparatively restricted scope of the above-described approaches, the need for a more comprehensive HFE approach to patient safety has been recognized for several decades. Developed in 1966, Donabedian's structure-process-outcome (SPO) model was among the first to connect healthcare services with healthcare outcomes.[24] Structure refers to the context of healthcare delivery, both physical and organizational; process embodies the entirety of patient care activities; and outcome represents the results of these patient care activities. Even today, Donabedian's SPO model remains a key framework for healthcare quality analysis. More recently, however, even more comprehensive patient safety HFE approaches have been proposed.

First described in Carayon et al[25] in 2006, the Systems

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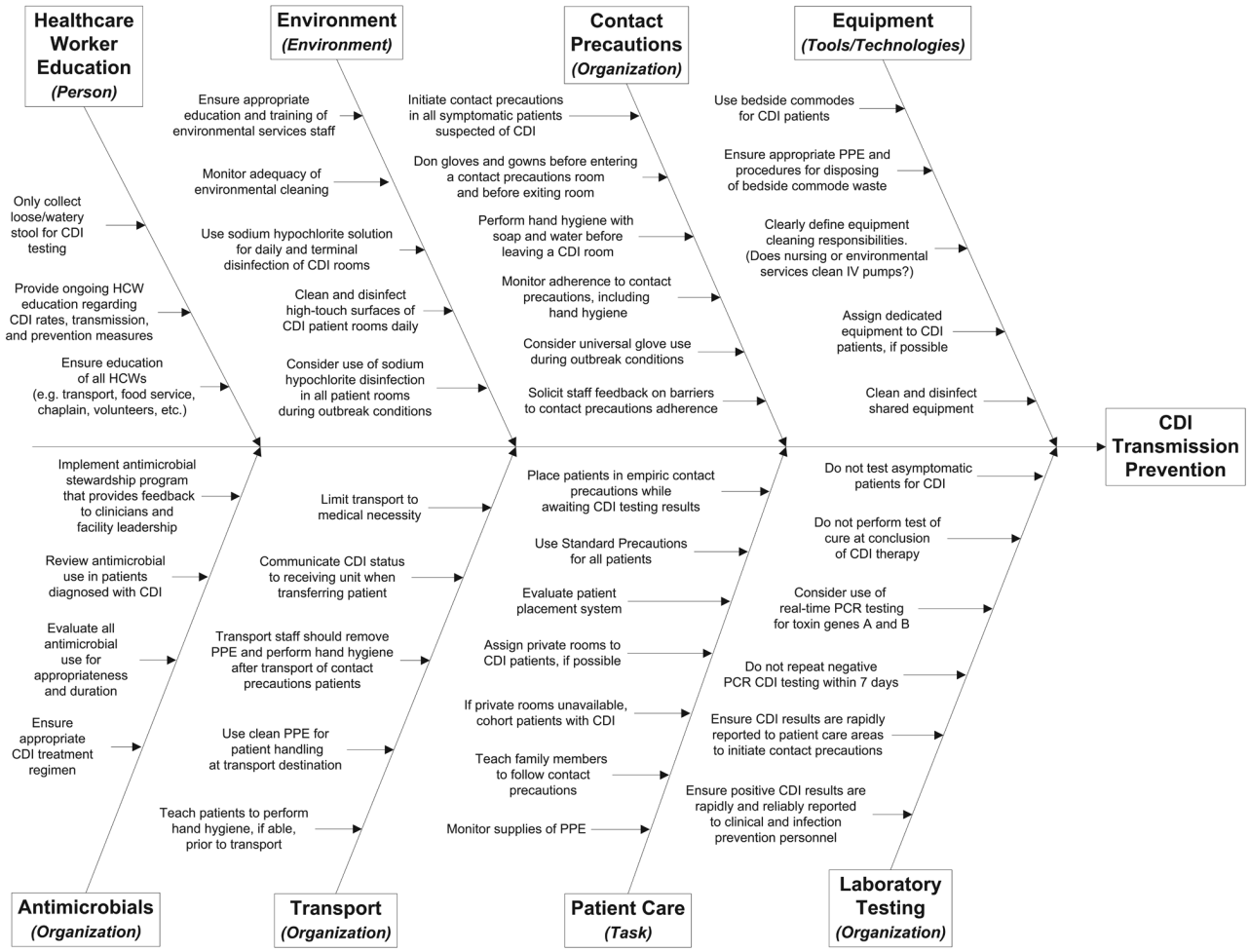


FIGURE 2. Fishbone (Ishikawa) diagram of prevention of *Clostridium difficile* transmission. Text in parentheses and italics represents the relevant Systems Engineering Initiative for Patient Safety work system component for each category of *C. difficile* transmission prevention. CDI, *C. difficile* infection; HCW, healthcare worker; IV, intravenous; PPE, personal protective equipment; PCR, polymerase chain reaction. Adapted from Carrico.[41]

Engineering Initiative for Patient Safety (SEIPS) model is an innovative approach to patient safety with roots in the industrial engineering field of HFE. The SEIPS model defines system elements that both contribute to and mitigate medical errors. At the core of the SEIPS model is the work system, which consists of a person, tasks, tools and technologies, the physical environment, and organizational conditions (Figure 1). The descriptive framework and broad focus of the SEIPS model provides significant flexibility and generalizability. Table 1 summarizes key features of HFE systems approaches developed for patient safety.

The SEIPS model supports multiple "persons" at the center of the work system (eg, patient, family members, nurse, and physician). The 5 work system components influence multiple processes (eg, work, clinic, or care), which in turn affect multiple outcomes (eg, patient, employee, or organization). The SEIPS model also includes feedback loops from processes and outcomes back to the work system. These feedback loops represent information obtained from analysis of care processes and outcomes then used to redesign the work system.

The SEIPS model has been utilized in diverse healthcare settings to guide quality improvement and enhance patient safety. It has been used to evaluate the timely follow-up of abnormal outpatient imaging results with an advanced, integrated electronic medical record (Veterans Health Administration's Computerized Patient Record System).[26] Qualitatively, the SEIPS model has been employed to assess barriers to providing cognitive pharmaceutical services at community pharmacies.[27] The SEIPS model has been used to improve patient safety in a variety of healthcare environments, including outpatient surgery centers, inpatient cardiac operating rooms, and radiotherapy clinics.[28] Our group also has firsthand experience using the SEIPS model to optimize management of ventilator-associated pneumonia.[29] We now examine the potential for using SEIPS in the prevention of a major HAI, *Clostridium difficile* infection (CDI).

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TABLE 2. Application of the Systems Engineering Initiative for Patient Safety Model to Evaluation of a *Clostridium difficile* Prevention Bundle

Component	Elements (examples)
Work system	
Person	Physicians, nurses, nursing assistants Environmental services Patients
Organization	Relationship between research and clinical teams Patient safety/infection control culture Current *C. difficile* prevention policies Organizational management style
Tools and technologies	*C. difficile* bundle Electronic medical record Computerized physician order entry
Tasks	Suspecting *C. difficile* diagnosis Initiating empiric isolation Ordering *C. difficile* testing Continuing isolation if positive test Hand hygiene Environmental cleaning and disinfection
Environment	Medical-surgical units: • Physical layout • Noise • Lighting • Temperature, humidity, air quality • Availability and location of sinks
Process	
Care processes	Adherence to *C. difficile* bundle
Other processes	Assessment of facilitators and barriers to *C. difficile* bundle adherence *C. difficile* bundle improvement processes
Outcomes	
Patient outcomes	Rate of *C. difficile* infection
Employee/organizational outcomes	Healthcare worker satisfaction with *C. difficile* bundle Institutional financial burden of *C. difficile* infection

C. DIFFICILE INFECTION AND PREVENTION

C. difficile is a reemerging pathogen that has become a challenge to control. In some places, it has surpassed methicillin-resistant *Staphylococcus aureus* as the major HAI pathogen. Currently, it represents the primary infectious cause of nosocomial diarrhea, with an estimated yearly financial burden approaching $2 billion in the United States.[30] While CDI is considered largely preventable with consistent implementation of infection control guidelines published by the Infectious Diseases Society of America, for a number of reasons elucidated below, CDI is a very complex HAI. First, *C. difficile* has spore-forming capabilities, which allow persistence on hard surfaces for months, and it is difficult to decontaminate the environment. Hospital acquisition rates of *C. difficile* are 1%–13% in patients hospitalized for less than 1 week and 50% in patients hospitalized for more than 4 weeks.[31,32] Second, pathogenesis and modes of transmission have not been fully defined, and the optimal diagnostic test and testing strategy remains unknown.[33] Third, antimicrobial stewardship and infection control practices may play equally important roles in control. Fourth, recurrent CDI is a significant problem, and large CDI reservoirs exist in asymptomatic patients and possibly healthcare workers.

Furthermore, all patient contact represents a potential source of new CDI infection or transmission, which includes multiple healthcare workers (eg, physicians, residents, nurses, nursing assistants, students, physical/occupational therapists, food service workers, environmental service workers, spiritual service workers, and volunteers) as well as patient family members. Finally, CDI is increasing in hospitalized popula-

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tions previously considered to be at low risk, including pediatric patients and peripartum women,[34,35] and community-acquired CDI is also increasing among patients with no apparent conventional CDI risk factors.[36] The multiple stakeholders involved and complexity of CDI transmission prevention are summarized in the fishbone (Ishikawa) format in Figure 2. Although traditionally used to identify causes of and contributing factors to adverse events, this application of the fishbone diagram to describe causes of and contributing factors to favorable or desired outcomes is consistent with recently suggested modifications to this tool.[37]

SEIPS MODEL APPLIED TO CDI PREVENTION

The complexity and associated challenges of CDI prevention mandate a new, innovative approach. The broad focus, flexibility, and generalizability of the SEIPS model make it particularly well suited to the task of CDI prevention. Table 2 shows a conceptual application of how the SEIPS model may inform implementation of CDI prevention strategies as they relate to a generic *C. difficile* bundle frequently utilized by healthcare institutions. Also shown in Figure 2 are the relevant SEIPS work system components for each category of *C. difficile* transmission prevention.

To demonstrate the applicability of the SEIPS work system in CDI prevention, we apply the SEIPS model to the following hypothetical example of a missed infection prevention opportunity: A physician (person) suspects a patient may have CDI and orders *C. difficile* testing (task and tool/technology). However, the physician (person) is unaware of a recent requirement to order empiric contact isolation (task) for all patients undergoing *C. difficile* testing (tool/technology) as part of the hospital's (organization) most recent update to its *C. difficile* bundle (tool/technology). The patient's nurse is aware of the recent policy change (organization), but the physician is unable to find the nurse at a noisy, congested nurses' station (environment) to discuss the plan for testing (task). Consequently, initiation of contact precautions (task) is delayed, adherence to the *C. difficile* bundle (care process) is compromised, and the hospital's rate of CDI may increase (patient outcome).

While the above-described scenario centers on the physician as the "person" in the SEIPS work system, multiple persons are clearly involved (eg, the patient, patient's nurse), each with their respective work system, processes, and outcomes relevant to the goal of CDI prevention. Although relatively simple, this example highlights the utility of mapping elements to the SEIPS work system to thoroughly evaluate *C. difficile* prevention bundle barriers and facilitators. Of note, the multiple persons in the SEIPS work system encompass the patient as well as the patient's family and caregivers. This is particularly appropriate as patient behavior and engagement is crucial to effective infection prevention in both the healthcare system and the community. We agree with previous authors that patient and family collaboration in implementing HFE at all levels of healthcare system engagement can only strengthen HFE and infection prevention integration.[38]

In conclusion, HFE represents an important discipline for addressing the growing complexity and ambiguity of our healthcare system as well as for effective translation of evidence into practice. HFE is highly relevant to the field of infection prevention, especially as it relates to the growing burden of HAIs and MDROs. Recognizing underutilization of HFE principles, others have argued for stronger HFE engagement and connection with the field of infection prevention,[39,40] and we join them in calling for additional research on the application of HFE to infection prevention. Last, given its comprehensive nature and demonstrated success in health care and infection prevention, we believe the SEIPS model to be particularly suited to integration with infection prevention practices.

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