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Patient Safety (M Coffey, Section Editor)

Simulation Enhances Safety Evaluation in the Design of New Healthcare Facilities

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Abstract

Purpose of review Healthcare is a complex system where dynamic and unpredictable interactions of system components contribute to errors. In the design of a new healthcare facility, there is a need to increase levels of safety evaluation throughout all phases of hospital development as a means to manage risk. Simulation effectively represents the dynamics of care delivery in order to identify and remediate latent conditions in the built environment or work system prior to patient exposure.
Recent findings Emerging literature suggests that the integration of human factor approaches with simulation-based activities has the potential to aid healthcare systems in achieving higher quality care. Simulation-based Hospital Design Testing (SbHDT) and Simulation-Based Clinical Systems Testing (SbCST) are applied in order to proactively identify latent conditions related to the built environment, work system, or care processes; ensure operational readiness; and ease transitioning healthcare systems by promoting preparedness.
Summary Incorporation of simulation into the hospital development process places safety at the forefront of planning. By proactively identifying architectural or system weaknesses, corrective actions can be taken before harm occurs. This review discusses how simulation grounded in safety and architectural design concepts enhance safety evaluation during the development process.

Introduction

In the last decade, there has been a major boom in the rates of hospital construction to create new or replace aging facilities and/or renovate existing ones to support population shifts [1]. Conflicting goals, limited resources, and the pressure to achieve more, faster, in a cost-effective manner challenges systems to consistently deliver high-quality care [2]. Healthcare-related errors are due to flaws in the system, barriers to optimal functioning, and deviations from prescribed work [3•, 4]. These flaws within the system, known as latent conditions [5–9], contribute to adverse events if not corrected [10]. As the relationship between the work environment and safety is becoming clear, it is necessary to increase levels of safety evaluation throughout all phases of hospital development as a means to reduce the risk [1].

Solutions to aid healthcare systems in managing risk involve the integration of human factor approaches with simulation-based activities [4]. While highly variable in approach, simulation is being utilized with increasing frequency in healthcare design, system development, and evaluation in order to proactively evaluate for latent conditions that can be corrected before harm occurs [11, 12•, 13].

The development of a new healthcare facility is a longitudinal endeavor which we describe in two distinct phases. In the early phase of hospital design, Simulation-based Hospital Design Testing (SbHDT) is conducted preconstruction during architectural planning to evaluate the built environment [14•]. In the postconstruction phase of development, Simulation-Based Clinical Systems Testing (SbCST) is conducted in situ in order to evaluate clinical systems and care processes prior to occupancy [15–17, 18•]. SbHDT and SbCST stress the built environment or work system for both routine and high-risk clinical scenarios. Facilitator-directed debriefing is used to conduct a risk analysis and identify latent conditions. Failure mode effect analysis (FMEA) is applied in order to score and prioritize each latent condition identified, thereby focusing efforts on devising solutions that mitigate latent conditions with the highest risk [14•, 15–17, 18•].

This review discusses how simulation is uniquely poised to bring together key safety and architectural design concepts to enhance the safety evaluation of a new healthcare facility (Fig. 1).

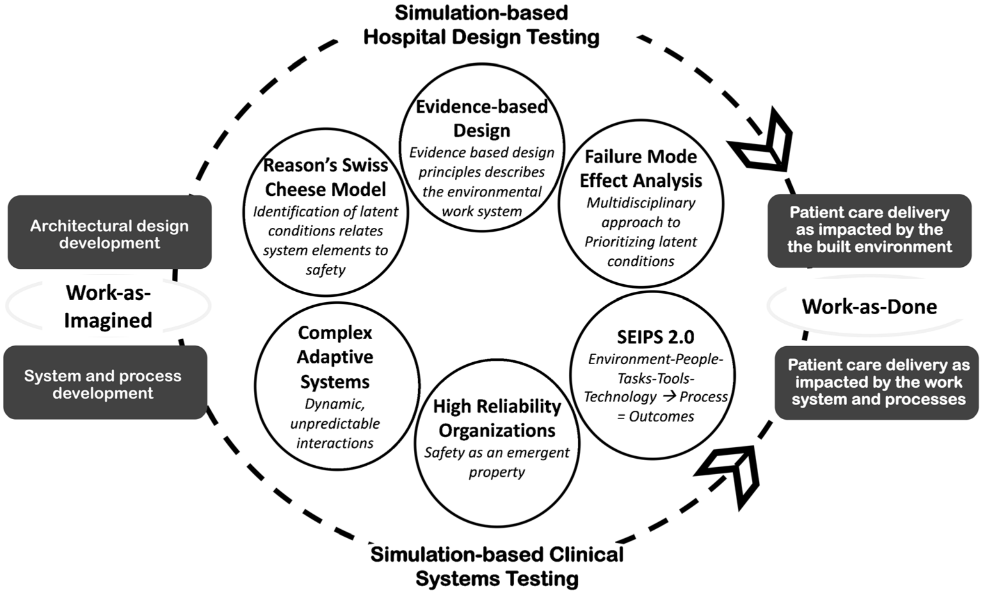

Fig. 1. In the process of healthcare design, simulation grounded in architectural and safety concepts bridges the gap between work-as-imagined and work-as-done.

Safety and architectural concepts

High reliability

High reliability organizations (HROs) are organizations/industries, such as aviation, that operate in complex, high-hazard domains, for extended periods without serious accidents or catastrophic failures [19, 20]. HROs use systems thinking to evaluate and design for safety and are keenly aware that safety is an emergent, rather than a static, property [21]. These organizations maintain safety levels far better than those in healthcare.

Healthcare institutions are increasingly adapting and applying the lessons of HRO science to reach levels of quality and safety of the best high reliability organizations. In designing a new healthcare facility, proactive identification of latent conditions, fostering of safety culture and standardizing the process to reduce variation in care, builds the foundation for a resilient system that allows for challenges and disturbances without leading to system collapse [4].

Simulation integrates HRO concepts and promotes a culture of safety by directly engaging frontline staff and leaders to look at their work system through a lens that is focused on safety [4]. By involving frontline personnel in clinical simulations aimed at stressing systems to find potential threats to patient/provider safety and opportunities for improvement, it applies at least four key principles seen in HROs: (1) preoccupation with failure, (2) reluctance to simplify observations, (3) deference to expertise, and (4) sensitivity to frontline operations. With a focus on the future state, healthcare teams suspend disbelief as they envision future operational models and advancement in care technologies and processes. As a result, they open their minds to inevitable practice change and in comparison, to the current state, are able to identify issues of safety. This shift fosters a bottom-up catalyst to serve as a trigger to transform culture change in the new environment [4].

Healthcare as a complex adaptive system

Healthcare is a complex adaptive system where each component of the system interacts and connects with each other in unpredictable and unplanned ways. In simplistic system modeling, it is assumed if individual system components are understood, then the entire system as a whole is fully realized. In this linear relationship, if each part is made to work better, then the whole system also functions at a higher quality [22]. Due to the complexity of healthcare delivery and the unpredictable ways that system components interact, this simple cause and effect assumption does not apply. In complex system modeling, a single system element is affected by and affects several other elements in a nonlinear interaction, so small changes have large downstream effects [22]. These complex, nonlinear, interactions of system components contribute to errors [23, 24]. The ability to effectively mitigate risk in the design process relies on systems engineering and the study of human factors to better understand the complexities of healthcare delivery [25, 26, 27•]. Simulation effectively demonstrates these dynamic interactions as teams interact and adapt to their environment and work system as they engage in patient care activities.

SEIPS 2.0

The Systems Engineering Initiative for Patient Safety (SEIPS) 2.0 provides a context to characterize these complex system interactions in a clear and concise manner, illustrating the impact that design or process changes have on the work system and patient safety [24]. SEIPS 2.0 describes five components of the work system: person, organization, technologies and tools, tasks, and environment [23, 24]. The work system (structure of an organization) affects how care is provided (process), which in turn impacts how safe care is delivered (outcome) [23, 24]. Feedback loops between system processes to the work system and outcomes to the work system represent opportunities for design and redesign. A failure in any component of the work system has the potential to impact outcomes and when designed well allows systems to function at a higher quality [23, 24]. In SbHDT latent conditions related to the environment are identified, while SbCST evaluates all 5 components of the work system (Table 1) [23, 24].

Evidence-based design

Evidence-based design (EBD) is the study of how the physical environment relates to healthcare outcomes [1, 26]. Rigorous EBD research describing how the built environment impacts patients and staff is applied by architects to influence architectural decisions. EBD encourages designers to create solutions that meet accepted EBD principles in order to reduce healthcare-associated conditions, improve staff job satisfaction, and minimize risk [28].

The Agency for Healthcare Research and Quality (AHRQ) and the Center for Health Design (CHD) describe evidence-based safe design principles (EbSDP) [25, 29]. These well-defined design considerations are known to impact healthcare outcomes and further expand the SEIPS 2.0 definition of the environmental system [23, 24]. SbHDT and SbCST anchored to evidence-based design utilize these principles to ensure that testing objectives are evidence based and

Table 1. Evidence-based design principles applied in SbHDT and SbCST

	Simulation-based Hospital Design Testing	**Simulation-based clinical systems testing**
Timing of testing	Architectural design development preconstruction	System and process development postconstruction, prior to occupancy
Work element evaluated (as described by SEIPS 2.0)	Person, organization, technologies and tools, tasks, environment, and process	Environment
Evidence-based safe design principles	(1) Control and eliminate sources of infection, (2) minimize environmental hazards, (3) optimize adjacencies, (4) support patient/family involvement in care, (5) ensure standardization, (6) reduce communication breakdown, (7) reduce noise, (8) enhance visibility, (9) reduce staff fatigue, (10) automate where possible	(1) minimize environmental hazards, (2) improve visibility, (3) standardization, (4) minimizing staff fatigue based on unit layout and configuration, (5) control/eliminate sources of infection, (6) reduce communication breakdown, (7) protecting privacy, (8) provide safe delivery of care, (9) provide efficient delivery of care, (10) reduce risk of Injury

can detect a wide range of latent conditions and system inefficiencies (Table 1). Scenarios are developed with pre-identified EbSDP objectives in mind, where each task in the scenario is linked to a design principle. Latent conditions related to design elements that do to meet accepted EBD principles are effectively discovered as participants interact with specific design elements in question.

Latent conditions

It is important to further understand how components of the healthcare system as described by SEIPS 2.0 relate to harm. The most recognized framework describing the relationship between system errors and healthcare design can be explained by Reason's Swiss cheese model [6]. This model illustrates how defenses, barriers, and safeguards may be penetrated by an accident.

Latent conditions are flaws that remain hidden until they are revealed retrospectively as a chain of events that contribute to an error [5, 10]. Latent conditions may be error provoking, such as inadequate equipment, or a long-lasting weakness, such as a construction deficiency. An active failure is an error at the level of a frontline provider, where the effect is felt almost immediately [5]. When multiple "holes" align, safeguards may be penetrated, and harm may occur [6]. While unintended, decisions made by architects or system leaders introduce weaknesses into the architectural design or system despite exhaustive planning [5]. For example, lack of a standard location of mounted code blue buttons (long-standing weakness) requires that staff reorient themselves according to each room design (error-provoking condition). If staff cannot find the code blue button during an emergency (active failure), then there may be a delay in care resulting in patient harm (error). During simulation, implementation of care processes in its entirety provides a platform for teams to actively identify latent conditions. The potential impact of those latent conditions is further elucidated and explored during debriefings.

Failure mode and effect analysis

Simulation testing reveals several latent conditions. Ability to categorize and prioritize findings directs teams to focus corrective efforts on addressing latent conditions with the greatest risk of harm. FMEA is an established and widely used proactive risk assessment tool endorsed by AHRQ and Institute for Healthcare Improvement (IHI) [30–32]. It is used by multidisciplinary teams to seek out active and latent weaknesses in systems or processes, analyze causes, assess risk, and devise resolutions to remediate flaws [30, 31, 33].

Methodologically integrating simulation with FMEA allows for a robust description of each latent condition identified, the associated potential active failure, and possible solution. The utilization of an FMEA template ensures that a succinct report of all issues identified during simulation is documented. This makes simulation findings less daunting and provides direction for architects or system leaders who have to tackle the complex task of devising resolutions and alternatives to resolve latent conditions [14•, 18•].

Work-as-imagined versus work-as-done

In the planning of a new healthcare facility and evaluation of the work system, there is a practical need to "imagine" (work-as-imagined, WAI) how work would be conducted as part of the design, administrative, and operational planning [34]. It is impossible however, to precisely predict how work should be done, making work-as-imagined inadequate and even directly misleading [34]. Work-as-done (WAD), on the other hand, reflects actual care delivery and the realities of the work system. Ability to experience work-as-done illuminates how work is shaped by the environment and is necessary in order to identify hazards and make improvements [34].

Work-as-imagined is influenced by variation in perspectives, priorities, backgrounds, and experiences. In healthcare design and system development, work-as-imagined by architects and leadership often does not equate to work as performed by frontline staff. This gap impacts ability to effectively convey design intent, rationale for high-level system decisions, or clinical frontline needs. During architectural design or system planning, ineffective communication may steer decision making down a path that results in ineffective design or care processes that cannot be implemented as intended. By providing a shared experience, simulation bridges this gap in perceptions of varying stakeholders to more precisely illuminate how work is done. Here teams witness a course of events play out instead of having to imagine it or review it in hindsight [34].

Simulation-based Hospital Design Testing

SbHDT, implemented 5–7 years prior to facility opening, heavily focuses on assessing the safety of the physical environment where there is the potential to inform major design modifications that would be cost prohibitive and not feasible in an already built facility [35].

Collaboration between architects and clinical teams must occur early on in the design process to devise a design that meets the needs of all stakeholders. Effective collaboration is challenged by the fact that architects and clinicians see physical space through two distinct lenses. Architects are less familiar with intricacies related to patient care delivery [36•] while clinicians are unfamiliar with the role and impact of the built environment. The ability to effectively convey design intent and elicit useful feedback from clinicians is challenging as clinicians have a difficult time imaging how work would be conducted in a proposed space represented as two-dimensional drawings [27•, 34, 36•]. These traditional design evaluation methods are insufficient to predict the breadth of problems that arise when actually delivering patient care. Unleveled perception between clinical teams and architects can lead to less effective design decisions such as inefficient spatial layout that does not optimally support care activities or safe practices.

Simulations provide clinicians with an immersive opportunity to interact with the proposed architectural design and further evaluate room configurations, spatial requirements, equipment placement and accessibility, visibility, and staff experience [34]. Clinicians are able to provide the architect team with feedback, evaluate the impact of design decisions, test functionality and limitations of the environment, and evaluate design alternatives. For example, a simple mockup of inpatient room size may seem adequate. Yet, during simulations, pinch points and work disruptions are revealed as clinicians maneuver supplies and equipment throughout the room. Creative evidence-based design strategies require major architectural changes to radically alter the physical environment in order to resolve latent conditions and address environmental safety concerns. Changes to unit layout, moving walls, reducing the angle of corners, widening doors, and creation of pass-throughs can be accomplished a level of ease that would be impractical and cost-prohibitive postconstruction. Examples of latent conditions, potential active failures, and solutions identified during SbHDT can be found in Table 2.

Simulation-based clinical systems testing

SbCST conducted in situ, postconstruction, prior to occupancy, is implemented in order to identify latent conditions related to the system, care process, operational models [11], ensure operational readiness [37], and ease transitioning healthcare systems by promoting preparedness [13, 38, 39].

In this phase of planning, a significant amount of administrative and operational planning is centered around developing elements of the work system and efficient, safe care processes. This planning involves the conceptualization of work [26, 38]. However, the ability to predict all of the complexities that could actually occur when taking care of patients is impractical [11, 37, 40]. The potential for unintended consequences exists even when a system is developed with good intentions in mind [11]. Planning by system leaders may not be implemented as intended when performed by frontline staff. Barriers to implementation of processes as intended include time pressure, competing priorities, poor communication, or environmental barriers. These hindrances lead to the development of workarounds by frontline staff. Work-arounds are created to bypass these limitations that fail to comply with best practices or policy results in near misses, mistakes, cognitive failures, or procedural violations.

Simulation narrows the gap between high-level system priorities and the limitations that frontline staff face in achieving those goals. Latent conditions identified during SbCST are related to resources; personnel, medication, and equipment that are missing, malfunctioned, or unable to use, process/workflow; policies or procedures that do not work as anticipated, facility; limitations in the built environment not conducive to efficient and safe care, or clinical performance; gaps in knowledge, technical skills, or institutional processes [17]. Latent conditions with the highest potential to result in harm are opportunities for improvement that requires immediate attention and corrective action before facility opening. Accountability and oversight of change implementation are dependent on administrative, operational, and clinical leadership. Examples of latent conditions, potential active failures, and solutions identified in SbCST can be found in Table 2.

Summary

The ability to achieve seamless care delivery in a highly complex healthcare system is challenging given the diversity of tasks, patient care needs, and infinite combinations of care activities [24]. Human factors are consistently in play in healthcare and the complex ways in which humans interact with the work system make space utilization and process implementation unpredictable [17]. Opportunities for clinical teams to improve safety evaluation during architectural and system development of new healthcare facilities are at hand.

Table 2. Examples of latent conditions, potential active failures, and solutions made to address safety concerns in SbHDT and SbCST

	Examples of latent conditions (evidence-based design principle)	Examples of potential active failures	Examples of solutions and opportunities for improvement
SbHDT	Built-in counters inside of the patient room block sightlines to the head of the bed when sitting in the nursing alcove (improve visibility)	Inability to visualize patient may lead to delay in care if changes in clinical status go unnoticed	Height of alcove adjusted to improve visibility to head of the bed
	The respiratory equipment room and supply room were located far from each other (minimize staff fatigue)	Lack of co-location of these areas led to excessive walking and staff fatigue	The respiratory equipment and supply room was collocated to improve workflow
	The respiratory equipment room was only accessible from one side of the hallway (minimize staff fatigue)	Lack of accessibility led to excessive walking and had the potential to delay patient care	A pass-through was created so that the respiratory equipment room could be accessed from both sides of the hallway
	The collaboration area did not have any private space to hold sensitive conservations regarding patient care (protect privacy)	This had the potential to violate patient privacy	The collaborative area was redesigned to include a private meeting room
	The call room for intensive care providers were located far away from the unit (minimize staff fatigue)	This had the potential to delay patient care and lead to excesses walking and provider fatigue	The call rooms were relocated adjacent to the intensive care units
	The corridors in the emergency department were malaligned creating multiple right-angle turns when maneuvering a patient from an exam room into the trauma bay (minimize environmental hazards)	Multiple sharp right-angle turns created an environmental hazard	The emergency department layout was redesigned to better align corridors easing the transfer of patients from an exam room to the trauma bay
	The trauma operating room (OR) was not easily accessible from the hallway due to the position of the door (minimize environmental hazards)	Multiple sharp angle turns created a hazard when transporting critical patients into the trauma operating room	The trauma OR room was redesigned so that it could be entered directly from the hallway
	The orientation of the doors in the cardiovascular operating room (CVOR) increased traffic in front of the sterile field (control/eliminate source of infection)	This compromised the ability to maintain a sterile field around the operative tables increasing the risk of contaminating sterile equipment	The doors to the CVOR were relocated to minimize traffic in front of the sterile field
SbCST	There was no hand sanitizer mounted outside of the patient room (control/eliminate source of infection)	Lack of accessible hand sanitizer may lead to poor hand hygiene compliance, increasing the risk of transmitting infections	Hand foam was mounted outside each patient room
	The location of the mounted diagnostic set was inaccessible to providers when performing a physical exam (reduce staff fatigue)	Poor ergonomics can lead to staff fatigue	The diagnostic set was repositioned to improve accessibility
	Inability for emergency medical services (EMS) to access the clinic through the back hallways due to security measures (ensure standardization)	Lack of a standard process for EMS entry may create delays in patient care	Process improvement made to ensure that security was notified of patient transfer to escort EMS through badge access only areas
	The door access to the soiled utility room required a keypad code (control/eliminate source of infection)	Key access to the soiled utility room increased the chance of contaminating surfaces when carrying soiled equipment	Access to the soiled utility room was changed from a keypad to badge access
	Poor signage making it difficult for families to navigate through the clinic (support patient and family involvement in care)	Family dissatisfaction and potential to impact workflow and create delays if families were lost in the building	Way finding signage was improved to assist families in navigating through the building

Table 2. (Continued)

Examples of latent conditions (evidence-based design principle)	Examples of potential active failures	Examples of solutions and opportunities for improvement
No clear process for staff to notify additional team members that there was an emergency (automate where possible)	Inability to communicate with team members may delay patient care	A dedicated phone number on all phones was added so that when staff called for help a special ring notified all staff of an emergency
The air temperature in the building increased overnight when the air conditioning automatically turned off, damaging costly lab cartridges and reagents (reduce environmental hazards)	Damage to lab supplies was costly to the organization to replace	A dedicated air unit was installed to maintain cooler temperatures
Staff unclear on how to launch the emergency response team in the case of patient decompensation (reduce communication breakdown)	Lack of a standardized process increases cognitive load of team members and may lead to errors or delay care	A simulation-based training program was initiated to provide the emergency response team with additional education

SbHDT and SbCST recreate the complexities of patient care delivery to evaluate the dynamic interaction of people with their environment helping to level and calibrate perception of patient care from varying perspectives essential to healthcare. SbHDT and SbCST are uniquely poised at the intersection of human factors, high reliability, and safety to be able to integrate these components into hospital development.

Simulation grounded in healthcare safety concepts and evidence-based design principles allows for a better understanding of work system complexity through the categorization of system elements as described by SEIP 2.0. EBD provides a background to better understand the role that the environment plays in impacting healthcare outcomes. EbSDPs expand on the SEIPS 2.0 definition of the environment, providing well-defined design elements that are the focus of pre-identified testing objectives. Anchoring simulations to EbSDP ensures that testing is able to detect a wide range of latent conditions. Theoretically, if elements of design are modified with the EbSDP in mind, there is a higher likelihood that risk will be mitigated prior to occupancy. Reason's model provides the framework to understand how those latent conditions, once identified, can lead to potential harm. For clinical teams, methodologically integrating FMEA with simulation allows for a robust description of simulation findings and prioritization of threats, helping providing direction to address latent conditions with the highest risk.

linear evaluation of the work system by human factors and systems engineering analysis alone are insufficient to evaluate interactions of system components as one cannot fully understand space without using it. Therefore, it is impossible and impractical to assume that design teams, administrative, operational, or clinical planners are able to imagine all of the complexities of care delivery. Despite years and hundreds of hours of preparation and planning, the most obvious and simplest design or process flaws can be missed. Simulation provides an organized platform that more accurately represents work-as-done. Incorporation of simulation into the hospital design planning timeline facilitates countless design or system weaknesses to emerge at a time point that allows for course correction prior to delivering patient care. Continued application of simulation in the evaluation of hospital design has the ability to greatly impact how healthcare facilities are built and tested in the future.

Future directions

The ability to demonstrate the impact of design optimizations made in the preconstructed environment on the system once constructed and occupied with patients is yet to be determined. Research is needed to evaluate the impact of simulation testing on outcomes including cost avoidance associated with design and construction change orders, cost savings from mitigated risks, return on investment, impact on post-occupancy risk reduction, and long-term safety outcomes. Additionally, further research is needed to validate simulation as a methodology to identify and mitigate risk in the hospital design process.

Conclusions

In the design of a healthcare facility, SbHDT and SbCST are applied to proactively identify latent conditions in the physical environment or work system. Simulation narrows the gap between work-as-imagined and work-as-done by facilitating a dialog that breaks down the degrees of separation between perception, intent, and actual clinical care delivery. Most importantly, simulation places safety at the forefront of planning to ensure the development of a facility that will better support productive processes, performance, safety, organizational health, and work satisfaction.

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Author's Contributions

All authors are familiar with submission instructions and are responsible for the content of the manuscript. NC performed background research; conceptualized the manuscript; prepared the article, modified, and revised the tools included in this manuscript; and approved the final version as submitted. KH oversaw the concept and design of this innovation, reviewed, and revised the article, and approved the article as submitted. AD reviewed and revised the article and approved the article as submitted.

Compliance with Ethical Standards

Conflict of Interest

Nora Colman declares that she has no conflict of interest. Ashley Dalpiaz declares that she has no conflict of interest. Kiran B. Hebbar declares that he has no conflict of interest.

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