



DESIGNING FOR PATIENT SAFETY: DEVELOPING METHODS TO INTEGRATE PATIENT SAFETY CONCERNS IN THE DESIGN PROCESS

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ABSTRACT

Purpose

The project aimed to develop consensus around important patient safety issues to be considered during various stages in the healthcare design process and to identify key activities, methodologies, and tools for improving facility design in terms of patient safety.

Scope

There is an urgent need for a strong methodology to identify and eliminate built environment latent conditions that impact patient safety during the planning, design, and construction of healthcare facilities. The project focused on developing the processes, tools, and approaches by which safe design features could be incorporated into building designs.

Methods

Resources and background materials for the seminar were developed by (1) reviewing literature for design tools/approaches and a framework for tool evaluation, (2) compiling opinion papers by industry and academic experts, and (3) developing a safe design roadmap for healthcare administrators. About 70 individuals with diverse backgrounds attended the 2-day seminar, which involved presentations and discussions in different formats—presentations, panel discussions, tours, and workgroups. After the seminar, the notes were analyzed and synthesized, and a survey was conducted to gain attendees' feedback.

Results

One of the key findings from the seminar was that it is critical to focus on patient safety issues during the predesign phase of a healthcare facility building project. This affects all key decisions made downstream in the project. Seminar attendees identified high-priority design activities for patient safety: articulation of project mission/vision, operational/future state planning, simulation, process-led design, measurable goals/metrics, ongoing check-ins, post-occupancy evaluation, and safety reviews. Highly rated design tools included simulation, process analysis, link

analysis, balanced scorecard, failure modes and effects analysis, and others. Most attendees viewed the seminar as highly valuable and effective.

Keywords

Healthcare design process, patient safety, safe design tool, design activity.

EXECUTIVE SUMMARY

Purpose

The project aimed to develop a strong foundation for integrating patient safety considerations into the facility design process by organizing a national seminar attended by multidisciplinary stakeholders. Specific goals included: to develop consensus around important patient safety issues or concerns to be considered during various stages in the healthcare facility design process, including issues that need to be considered in a patient safety risk assessment (PSRA) in the *2014 Facility Guidelines Institute (FGI) Guidelines for Design and Construction of Healthcare Facilities*; and to identify key activities, methodologies, and tools for improving the facility design process in terms of patient safety.

Scope

The physical environment constitutes a key latent condition in healthcare settings that impacts patient safety. However, even though research evidence has clearly indicated the significant impacts of building design on patient safety outcomes, safety considerations are addressed inadequately and not integrated into the physical environment during the design process.

There is an urgent need for a strong methodology to identify and eliminate built environment latent conditions that adversely impact patient safety during the planning, design, and construction of healthcare facilities. The project focused on organizing a national seminar to develop consensus around the processes, tools, and approaches by which safe design features could be incorporated into building designs. The project also focused on developing a framework for a PSRA tool and to make changes to the text in *FGI Guidelines* around PSRA.

Methods

The project was conducted in several steps: (1) development of resources and background materials for the seminar, (2) seminar planning and logistics, and (3) postseminar survey and data analysis. Resources and background materials for the seminar were developed by (1) reviewing literature to select seven design tools/

approaches from relevant fields and a framework for tool evaluation, (2) compiling opinion papers by industry and academic experts, and (3) developing a safe design roadmap for healthcare administrators. About 70 individuals with diverse backgrounds attended the 2-day seminar on October 11–12, 2011. Invitations were delivered by emails and phone calls with follow-ups. The seminar venue was located in a state-of-the-art meeting facility at the newly opened Virtua Voorhees Hospital, the design of which involved a process-driven design approach to improve patient safety and healthcare efficiency. The seminar agenda was developed to best meet the project goals and enable participants to fully understand and engage with the topic discussions. It involved presentations and discussions in different formats—presentations, panel discussions, tours, and workgroups. After the seminar, the seminar notes were analyzed and synthesized, and a survey was conducted to gain attendees' feedback.

Results

One of the key findings from the seminar was that it is critical to focus on patient safety issues during the predesign phase (strategic planning, master planning, operational planning, and programming) of a healthcare facility building project. This affects all key decisions made downstream in the project. It was also noted that the design process should not be linear but happening iteratively in small cycles. Seminar attendees identified high-priority design activities for patient safety: articulation of project mission/vision; operational/future state planning; simulation; process-led design; measurable goals/metrics in the predesign stages; and simulation/mock-ups, ongoing check-ins, post-occupancy evaluation, and safety reviews in the design/construction stages. The design team needed to be formed as early as possible and include individuals with multiple backgrounds.

Almost all of the seven design tools (link analysis, root cause analysis, failure mode and effects analysis, simulation, work sampling, balanced scorecard, and process analysis) were considered relevant and applicable to the healthcare design process. Design tools highly rated on feasibility included balanced scorecard and process analysis. The most generalizable tools included balanced scorecard, link analysis, and process analysis.

The safe design roadmap for healthcare administrators was perceived as a comprehensive tool providing an overarching structure that facilitated

multidisciplinary communication and decision making. Workgroup participants suggested that: The format should be revised and customized to fit the needs of administrators as well as other team members; supporting materials such as glossary terms, tools, and examples should be provided; the goals and roles of team members should be clearly stated at the beginning.

Participant Feedback

Most attendees viewed the seminar to be highly valuable and effective. The seminar was perceived to serve as a “model for improving design approach and tools” for performance improvement in general. However, respondents thought the 2-day timeframe was too short to cover many important issues in great depth. Many respondents expressed willingness of supporting further development of the safe design tools and approaches.

Lessons Learned

The seminar was only the beginning to achieve consensus in the development of strong design tools and methods of designing for patient safety. It would be desirable that similar meetings focusing on patient safety should be conducted in the near future to carry on the momentum of continuous development. Adjustments should be made in future meeting agendas to allow thorough discussion on topics that are perceived by participants as critical in designing for patient safety.

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PURPOSE

The basic premise of the project was that the built environment is a critical component of the healthcare system that impacts patient safety. Identifying and eliminating built environment latent conditions are critical to improving patient safety outcomes in healthcare. The seminar aimed to develop a strong foundation for integrating patient safety concerns during the facility design process by bringing together a multidisciplinary panel of experts using a 2-day conference format. The conference focused on understanding the issues that needed to be considered in the development of a patient safety risk assessment (PSRA) to be included in the *2014 Facility Guidelines Institute (FGI) Guidelines for Design and Construction of Healthcare Facilities*. Specific goals of the project included to

- identify how safety concerns are identified and addressed during the planning and design process in other fields,
- identify key methodologies and tools from other fields that can be adapted for use during the design of healthcare facilities,
- develop consensus around key patient safety issues that need to be considered at different stages in the healthcare facility design process, and
- develop a set of questions/issues for the design team to address at each stage of the healthcare facility design process.

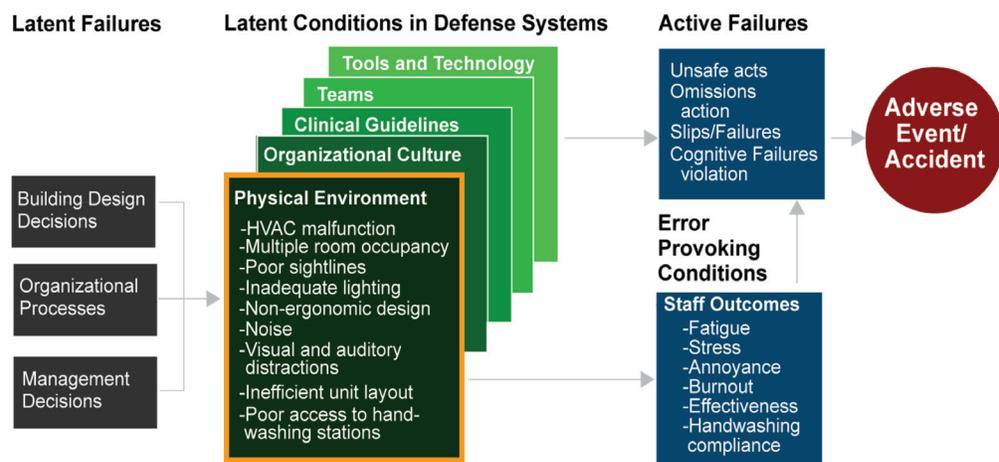
SCOPE

Background

Since the release of the Institution of Medicine report *To Err Is Human* (Kohn, Corrigan, & Donaldson, 1999), patient safety improvements have remained elusive, in spite of a host of interventions (Watcher, 2010). Recent studies have demonstrated no significant improvement for a number of healthcare-associated conditions including the failure to reduce postoperative, blood stream, and catheter-associated urinary tract infections (Agency for Health Research and Quality, 2010). Landrigan and colleagues' (2010) study of 10 North Carolina hospitals over 10 years found 25.1 harms per 100 admissions. Levinson's (2010) Department of Health and Human Services' Office of the Inspector General's report found that 13.5% of hospitalized Medicare patients experienced adverse events and another 13.5% experienced temporary harms. All of these harms significantly impact the nation's healthcare bill, with 1.5 million errors estimated to contribute an additional \$19.5 billion annually as found in a medical claims study by the Society of Actuaries (2010). Perhaps these results reflect an incomplete understanding of the puzzle that quality healthcare represents.

It has become increasingly clear that the problem of patient safety does not lie solely in the hands of clinicians or frontline healthcare staff. The healthcare system has many inherent latent conditions (holes and weaknesses) that interact in complex ways that result in adverse events (Reason, 2000). A growing body of research shows that features in the built environment such as light, noise, air quality, room layout, and others contribute to adverse patient safety outcomes like healthcare-associated infections, medication errors, and falls in healthcare settings (Joseph & Rashid, 2007; Ulrich et al., 2008).

FIGURE 1
Conceptual Model of Physical Environment Elements as Latent Conditions in Patient Safety



Conceptual model based on Reason's model showing the role of the environment as a latent condition or barrier to adverse events in healthcare settings. From "Designing for Patient Safety: Developing a Patient Safety Risk Assessment" by Joseph, A., & Taylor, E., 2010, Presentation at the 2010 Guidelines for Design and Construction of Health Care Facilities Workshops, Chicago.

The conceptual model in Figure 1, based on Vincent, Taylor-Adams, and Stanhope's (1998) work and Reason's (2000) work, shows the role of the physical environment elements as the latent conditions that contribute to patient safety. Often, these latent conditions that adversely impact patient safety are built into the physical environment during the planning, design, and construction of healthcare facilities. For example, the location of emergency departments and intensive care units might necessitate the transport of critically ill patients over long distances, potentially causing patient complications. Handwashing sinks located in inconvenient or inaccessible locations might result in poor handwashing compliance among physicians and nurses.

Given the massive investment anticipated in healthcare facility construction in the next 10 years, there is an urgent need for a well-defined and standard methodology to identify and eliminate built environment latent conditions that impact patient safety during the planning, design, and construction of healthcare facilities. Design teams themselves are often unfamiliar with the possible built environment impact on patient safety and even less familiar with ways to incorporate these concerns into the design process. While fields such as aviation and other high-risk industries have been able to harness human factors, engineering, and cognitive science that result in the preferred human response and, consequently, improved safety, no similar method currently exists for the design of new healthcare facilities or major renovation projects.

Brief introductory language around a patient safety risk assessment (PSRA) was included in the appendix of the 2010 *Guidelines for Design and Construction of Health Care Facilities* from the Facility Guidelines Institute. The Joint Commission, many federal agencies, and authorities in 42 states use the *Guidelines* either as a code or a reference standard when reviewing, approving, and financing healthcare construction projects; surveying, licensing, certifying, or accrediting newly constructed facilities; or developing their own codes. Currently, the PSRA is very loosely defined, and the 2010 *Guidelines* do not provide any information on how such an assessment could be conducted. There is an excellent opportunity to draft a well-defined facility lifecycle risk assessment approach and evaluate existing safety tools to provide an evidence based foundation for further development of the PSRA in the 2014 edition of the *Guidelines*.

The Designing for Patient Safety seminar sponsored by the Agency for Healthcare Research and Quality (AHRQ) and the Facilities Guidelines Institute (FGI) provided the opportunity to bring together interdisciplinary experts who have developed proven effective methods for addressing safety issues during the design process. Virtua Health was a key partner and host for the seminar. The new Virtua Voorhees facility that opened in May 2011 was designed using a process-driven approach from the start and served as a case study and tour site. The 2-day meeting served as a catalyst for developing consensus around the key issues to consider in the PSRA as well as the methods that will be most effective across the different phases of the facility lifecycle. The information resources developed as part of this seminar, as well as the consensus findings from the seminar, provide the foundation for the PSRA. Additional white papers and specific tools that comprise the PSRA will be developed over the next 3 years so that concrete information will be available to guide design teams as they embark on a patient safety risk assessment during the facility design process.

Scope

The focus of this project was on tools and approaches used in different fields to enable design teams to focus on safety issues in the design process. Another highly significant and related area of research focuses on how built environment features (e.g., location of handwashing sinks) impact safety outcomes (e.g., handwashing compliance). A brief summary (patient safety design framework) was developed on this related topic to provide context to seminar participants, but the seminar did not

specifically focus on the impact of design on safety outcomes, rather on the processes by which safe design features were incorporated into building designs.

Since a key focus of this seminar was on developing a framework for a PSRA that would eventually be fully incorporated into the *Guidelines*, the project also focused on understanding the structure of other similar risk assessments in the *Guidelines* (such as the infection control risk assessment or ICRA) and their potential relationship with the proposed PSRA. As such, several members from the health guidelines revision committee (HGRC) were invited as seminar participants so they could provide their feedback and also help in developing consensus that could be carried back to the larger meeting of the HGRC.

METHODS

The project focused on two key areas: development of resources and background material for the seminar and seminar planning and logistics. Some key resources were developed in order to meet the goals of the project. These included (1) a literature review of design tools for patient safety and a framework for tool evaluation, (2) a compilation of opinion papers written by industry and academic experts, and (3) the development of a safe design roadmap for healthcare administrators. The team also focused on developing an agenda for the seminar that would best meet the goals for the project. The Center for Health Design (CHD) project team conducted regular conference calls throughout the process with an advisory committee of five experts who provided guidance, suggestions, and comments.

Literature Review and Tool Evaluation

The literature review focused on the tools and approaches that were potentially useful for incorporating patient safety in the design process. The goal was to generate a set of tools or methods used to enhance patient safety in the design process that could be discussed and evaluated in the national seminar. The literature review involved several steps. First, a scan of design tools and approaches for patient safety was conducted in the fields of human factors, architecture, engineering, business management, and so on. The search was conducted in PubMed, EBSCO, and Internet search engines. Relevant articles, books, or other publications were reviewed. In addition, two compendiums around patient safety published by AHRQ in recent years were examined closely to identify relevant design tools (Henriksen, Battles, Marks, & Lewin, 2005; Henriksen, Battles, Keyes, & Grady, 2008). Additional tools were recommended by the advisory committee and other experts in the field. The result of this step is a list of 14 design tools and approaches, including

- link analysis
- root cause analysis
- failure mode and effects analysis

- simulation
- work sampling
- balanced scorecard
- process analysis
- participatory ergonomics
- lean
- six sigma
- patient safety rounds
- work design process
- systems engineering initiative for patient safety
- socio-technical probabilistic risk assessment

Next, further literature search and reviews were conducted focused on the tools/ approaches identified in the first step. Relevant information including the definition, the history, and the examples of use in healthcare settings; typical process of implementation; limitations; and additional resources was extracted from the literature for each tool/approach. The information for each tool/approach was synthesized into a brief summary that was about 1.5 to 3 pages long.

In the final step, the project team reviewed the 14 tool summaries and selected seven design tools (the first seven in the above list) for workgroup discussion on the national seminar (see Appendix III for summaries of the seven design tools). The selection of tools was based on a set of criteria including the relevance to the facility design process, the scope of use, and the documented effectiveness and validity of tools. It was also decided to focus only on actual design tools and exclude high-level design approaches or philosophies (e.g., lean). Each workgroup was asked to evaluate one of these tools and the safe design roadmap. The tool summary, as well as relevant research articles, was provided to seminar participants 2 weeks prior to the meeting. A tool evaluation form was provided and participants were asked to rate each tool on a scale of 1-5 on a set of criteria. Participants were asked to reflect on the following questions to support their rating.

Usability

- Is the tool easy to understand and use by a multidisciplinary group?
- Is the tool already a requirement as part of any accreditation or government reporting systems?
- Do hospital teams commonly use this tool?

Relevance

- Has the tool been used in the healthcare facility design process?
- Can the tool be easily modified to use in this context?

Feasibility

- Would this tool be too time consuming to use for a facility design project?
- Would it require significant resources (people, equipment, space) to use this tool?
- Does the use of the tool require special expertise or software?

Generalizability

- Can this tool be used in many different types of healthcare settings, project scopes, and organizations?

Additional questions that were provided for discussion included:

- Is the tool reliant on information from other processes or phases? If so, does it build on a prior step in the process? What types of information are needed from previous steps?
- At what phase in the facility lifecycle do you think this tool will be most applicable?
- Please provide any recommendations for modifying this tool to make it applicable for healthcare facility design.
- Are there any other aspects of this tool that you would like to share with the group?

Opinion Paper Compilation

Around 20 industry experts were invited to provide their perspectives on designing for patient safety—how patient safety can be addressed by design and how safety considerations can be integrated into the design process. A total of 17 experts completed and submitted sixteen 1- to 2-page opinion papers. The 17 authors represent diverse professional backgrounds including architecture, interior design, human factors, engineering, medicine, nursing, infection prevention, and hospital administration. The opinion papers were copyedited and compiled into a document called *Perspectives on Designing for Patient Safety*. The document was provided to all participants ahead of the seminar to serve as the context for the discussions during the meeting (see Appendix II).

Development of a Safe Design Roadmap/CEO Checklist

Recognizing that healthcare administrators are the final decision makers and the ultimate drivers of designing for patient safety, the project team placed high priority on developing a safe design roadmap or checklist for healthcare administrators to facilitate communication and the optimization of safe design principles. The project team worked with the advisory committee members who had healthcare administration experience to develop the questions that healthcare administrators should ask during the different design stages in a typical healthcare facility project from strategic planning to occupancy in order to improve patient safety. The purpose of the safe design roadmap is to provide CEOs and their leadership team with a facility project management tool that captures the opportunities to use physical environmental features to help improve patient safety outcomes. The tool is divided into sections that correspond to the facility lifecycle phases; each phase includes key questions and variables that shape facility planning and project decision-making. Based on current research, the checklist variables guide senior leaders through the facility project management process, helping them to integrate facility design into patient safety programs, specify patient safety goals, and identify corresponding facility features to incorporate in the design. Necessary supporting care process and organizational culture transition activities are noted as well.

In addition, a design framework and considerations for safe design were developed based on previous work by CHD (Joseph & Rashid, 2007) and Reiling, Hughes,

and Murphy (2008). The conceptual framework and 10 design considerations for patient safety provided essential background material about the relationship between the design of the physical environment and patient safety outcomes. This information was provided to participants before the seminar to facilitate and stimulate discussion.

Seminar Development

Participants

In order to meet the goals of the projects—specifically as they related to understanding approaches from different fields—the CHD project team reached out to individuals with diverse backgrounds: architects, interior designers, planners, clinicians, hospital administrators, researchers, human factors experts, industrial engineers, guidelines experts, and facility managers. A list of invitees was compiled to include known experts on the topic as well as individuals who expressed strong interest in the topic. The invitations were delivered by emails and phone calls with follow-ups. About 70 individuals attended the seminar. The participants were assigned to seven workgroups. Each workgroup consisted of 9 to 10 participants from different backgrounds (see Table 1) including one six sigma black-belt facilitator (part of Virtua staff).

Also, given the strong focus on developing content for the *Guidelines*, each group included at least one person from the Healthcare Guidelines Revision Committee (HGRC) of the Facilities Guidelines Institute. A Basecamp website was developed for the purpose of the seminar, and secure accounts were created for all participants. All background materials were shared via the Basecamp website. Participants were also encouraged to communicate with each other prior to the seminar through the Basecamp site as well as through conference calls. Each workgroup was assigned different tools to evaluate. Summaries on those tools as well as relevant research papers were provided to workgroup members. They were asked to fill in their tool evaluation on forms provided prior to the seminar.

Occupation \ Workgroup	#1	#2	#3	#4	#5	#6	#7	Total
Architect/designer/planner	3	4	2	2	1	2	1	15
Clinician/hospital administrator	3	4	5	3	4	4	4	27
Researcher	2	2	1	2	2	2	4	15
Human factors/patient safety expert	1		1	3	1	1	1	8
Facility management	1				1			2
Total	10	10	9	10	9	9	10	67

Settings

The seminar was conducted at Virtua Health’s Center for Learning, a meeting facility located on the first floor of the new replacement hospital, Virtua Voorhees. Virtua Health, a comprehensive healthcare system headquartered in Marlton, NJ, is one of CHD’s Alumni Pebble Partners. Virtua Voorhees Hospital is a new 364-bed, state-of-the-art digital hospital and outpatient center. Virtua utilized a process-driven design approach to improve patient safety and healthcare efficiency in its new facility. As such, Virtua Voorhees served as an excellent case study for seminar participants. The Center for Learning includes five classrooms, a simulation lab, and four think tanks. All rooms were equipped with audio and visual capabilities, plus a wireless internet connection. Virtua Health also provided the staff and resources to videotape seminar sessions. The majority of the seminar took place in the meeting rooms at the Center for Learning. The seminar also included a facility tour of the new Virtua Voorhees hospital led by Virtua staff.

Seminar Agenda

The seminar was conducted on October 11-12, 2011. The 2-day seminar was organized to enable the participants to fully understand and engage with the topic at hand. Table 2 shows the final agenda for the seminar. The first day involved presentations and discussions in different formats —presentations, panel discussions, and tours. The content of the presentations was developed to expose this multidisciplinary group to a range of topics that would be critical to understand in order to participate in workgroups on Day 2. Thus, Day 1 included presentations about the *Guidelines* as well as different tools, approaches, and case studies that looked at the issue of incorporating patient safety concerns in the design process. Day 1 also included facility tours of Virtua Voorhees and discussions with Virtua team members about their experience during the design process.

Day 2 was designed to enable participants to dive deeper into two main areas.

1. The potential framework of the PSRA and the types of activities that might be included in a PSRA. Participants were asked to identify key activities that would be important from the perspective of incorporating patient safety in various stages of the design process—broadly divided into predesign and design/construction (what), team composition and responsibilities (who), the time and procedure of conducted the activities (when and how), the tools, and the required documentation.
2. Evaluation of tools that might be most relevant for incorporating safety concerns in the facility design process. Participants were asked to rate the usability, relevance, feasibility, and generalizability of each tool and provide suggestions on how to modify and use the tool for safe design. Participants were also asked to provide comments and suggestions regarding the safe design roadmap, including its strengths, weaknesses, and aspects that needed to be improved.

Workgroup members presented their key findings to the entire group after each workgroup discussion. The PSRA workgroup session was followed by a consensus workshop to identify high-priority activities that could be included in the PSRA. Seminar participants ranked the PSRA activities identified by the group in predesign and design/construction phase as high priority, medium priority, or low priority. This information was then tabulated to identify the top 5 high-priority activities in predesign and design/construction phases. Participants performed a similar ranking exercise for the types of documentation that may be required as part of a PSRA.

Each workgroup presented its evaluation of its assigned tool and the safe design roadmap. This was followed by a short discussion.

Table 2 The Seminar Agenda	
Time	Agenda Item
Day 1	
8:30–8:45	<i>Welcome to Virtua</i> — Richard P. Miller, Virtua Health
8:45–9:00	<i>Welcome to the seminar</i> — Debra Levin and Anjali Joseph, The Center for Health Design
9:00–9:30	<i>Designing for safety: Challenges and opportunities</i> — Kerm Henriksen, AHRQ
9:30–10:00	<i>Performance driven design at Virtua</i> —Tejas Gandhi, Ninfa Saunders, Michael S. Kotzen, Virtua Health
10:15–11:00	<i>Virtua breakout discussions: NICU, inpatient unit, & ED design</i> —Virtua Health
11:00–12:15	<i>Tour of Virtua Voorhees Hospital</i> —Virtua Health
1:15–2:00	<i>Incorporating patient safety in the guidelines</i> — Linda Dickey, Skip Gregory, Ellen Taylor, FGI Health Guidelines Revision Committee
2:00–4:00	<i>Panel discussions</i> —John Reiling, Rob Tannen, Jonas Shultz, Tejas Gandhi, Bill Rostenberg
4:30–5:30	<i>Mistake proofing built environments and processes</i> —Keynote by John R. Grout, Berry College
Day 2	
8:54–12:00	<i>Workgroups – Session 1: Patient safety risk assessment (PSRA) processes</i> —All participants
12:45–2:00	<i>Workgroups - Session 2: Safe design tools and roadmap</i> —All participants
3:00–3:30	<i>Wrap-up & next steps</i> —Eileen Malone, Jim Lussier, Anjali Joseph

Seminar Follow-up

After the seminar, the easel notes taken at the seminar were transferred to an electronic transcript in Microsoft Word. The notes were then analyzed and synthesized. The information was compiled into three tables: (1) safe design activities in the predesign and design/construction stages as well as required PSRA documentation, (2) comments and suggestions about the safe design roadmap, and (3) the evaluation of safe design tools. In addition, an online survey questionnaire was sent to all the participants to gather their comments about the conference and suggestions for improvement. The questionnaire also included a question asking whether the respondents were willing to participate in the future development of the materials presented in the seminar.

RESULTS

Key Activities by Design Phases (PSRA)

The discussions throughout the seminar, specifically from the seven workgroups, produced rich insights into the activities around designing for patient safety. There was extreme consensus that time and effort needed to be dedicated to focusing on patient safety issues during the predesign phase (strategic planning, master planning, operational planning, and programming) of the healthcare facility design project. The decisions made during predesign significantly impact the design parameters going forward and outcomes of the project from a safety perspective.

Attendees also noted that the design process should not be linear. Instead, the design activities should happen iteratively in small cycles. The design efforts should be an important part of the overall continuous improvement of patient and staff safety in any healthcare organization. Attendees identified the importance of assessing different design and operational solutions using tools such as a priority matrix or d-FMEA. Some workgroups also suggested that business planning was as important as other phases and should be considered as a stand-alone design phase by itself.

The workgroups identified a range of activities that should be undertaken during predesign and design/construction phases to improve patient safety outcomes. Table 3 (on the next page) shows the top high-priority activities identified by most of the attendees.

Table 3 High-Priority Activities in Designing for Patient Safety

Design Phase	High-Priority Activities
Pre-design	<ol style="list-style-type: none"> 1. Articulation of project mission/vision around patient safety. The majority of the attendees felt that the articulation of a clear statement around patient safety at the start of the healthcare facility design project was of paramount importance as it sets the tone for the activities of the team through the course of the project. The project mission/vision statement should come directly from the organization’s strategic planning and gap analysis, which should be a continuous iterative process. 2. Operational/future state planning. Attendees identified the importance of clearly defining future states and planning processes that would help in achieving those states prior to even embarking on the actual design of the building. 3. Simulation/mock-ups. Attendees identified the importance of using simulation and mock-ups very early in the design process to help visualize key concepts and identify possible built environment latent conditions. 4. Process-led design. Attendees highlighted the importance of designing the care processes in parallel to the building design. The importance of flexibility in design to accommodate changing processes was also discussed. 5. Define measurable goals/metrics. Attendees discussed the importance of collecting baseline data around key patient safety outcomes such as falls, healthcare-associated infections, and medical errors; conducting a patient safety survey; and developing goals for improving these outcomes.
Design and construction	<ol style="list-style-type: none"> 1. Simulations/mock-ups. Simulations and mock-ups were considered the most important activity during the design and construction phases from the perspective of identifying built environment latent conditions. 2. Ongoing team check-ins at every phase. Attendees felt that safety priorities needed to be institutionalized, and the teams needed to have regular check-ins during all phases of the project to ensure that safe design features were being implemented as envisioned. 3. Post-occupancy evaluations. Post-occupancy evaluations were identified as a key activity to be undertaken once the building is completed and occupied to ensure that the building was effective in providing safe care and supporting the staff in conducting their work in a safe and efficient manner. 4. Safety reviews. Similar to the check-in, the attendees felt the safety reviews would enable the team to review plans and construction documents using a patient safety lens.

The seminar participants felt that the design team needed to be multidisciplinary to ensure that patient safety issues were effectively addressed and should include clinicians, administrators, facility managers, architects, consultants, human factors specialists, and researchers. The multidisciplinary team should be formed as early as possible. Various team members may lead the team effort in different stages, for example, administrators leading in the strategic planning stage and designers leading at the design stage. Many different tools were identified for use at different facility design phases including design failure modes and effects analysis (FMEA), process mapping, spaghetti diagrams, link analysis, Pareto analysis, safety culture surveys,

quality function deployment, and more. Table 4 lists tools and documentation identified by attendees. The participants felt that conducting a patient safety risk assessment (PSRA, as currently referenced in the *FGI Guidelines* appendix) might involve healthcare design teams documenting their findings from using these tools as well as the documentation from other risk assessments such as the infection control risk assessment (ICRA). Participants also identified an operational plan that documents key processes in the new facility as another potential requirement for a PSRA. It was also noted that caregiver safety should be addressed simultaneously with patient safety.

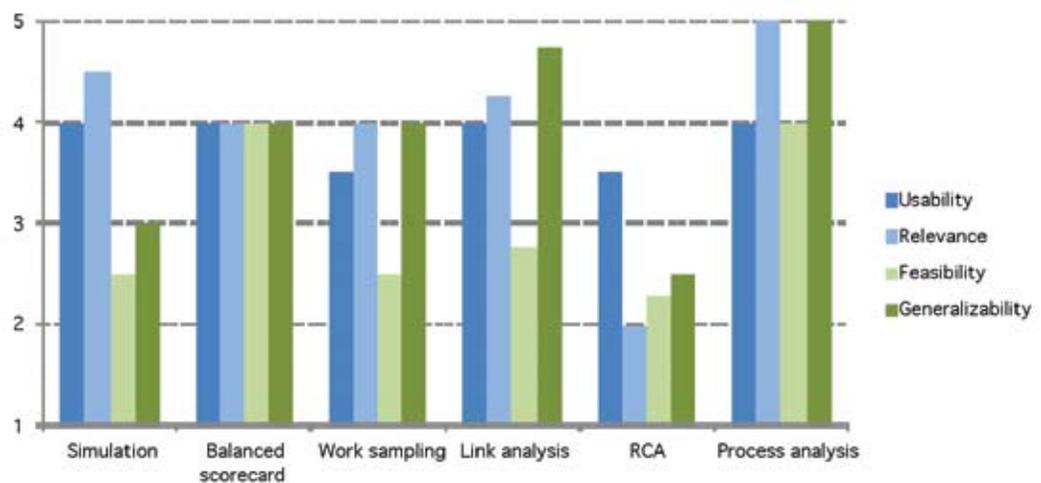
Table 4 Tools and Documentation Recommended by Seminar Attendees

Design Phase	Tools	Documentation
Pre-design	<ul style="list-style-type: none"> • Balanced scorecard • Benchmarking • Brainstorming • Case studies • Communication plan • Critical pathway analysis • Failure modes and effects analysis • Focus groups • Lean and six sigma • Link analysis • Pareto analysis • Photo journal • Process mapping/analysis • Safety of culture assessment • Simulations/mock-ups • Spaghetti diagram • Statistics gathering • Task analysis • Time motion study 	<ul style="list-style-type: none"> • Business case (line-item budget for safety) • Documentation of current safety issues and safety opportunities (data + root cause analysis [RCA]) • Measurable goals defined/metrics • Operational plan (flow diagram, narrative) • Patient safety risk assessment (PSRA) • Repetitive room design • Risk management matrix • Strategic plan • Vision/mission statement
Design and construction	<ul style="list-style-type: none"> • Bump analysis • Flow assessment • Failure modes and effects analysis • Link analysis • Operational safety risk assessment • Post-occupancy evaluation • Priority matrix in patient safety issues • Safety plan during construction • Safety-related punch list • Safety review • Simulation 	<ul style="list-style-type: none"> • Documentation of evidence-based design and safety design elements • Construction documents • Risk matrix • Safety plan • Post-occupancy evaluation documentation • Punch list

Tool Evaluation

Each workgroup evaluated one of the seven design tools (see Methods section). Most of these tools were considered relevant and applicable to the healthcare facility design process. Balanced scorecard, process analysis (process mapping), and link analysis were ranked high on all key criteria. Simulation and FMEA were also ranked high, and workgroups felt that these methods were already being used in the facility design process and could be modified to make it feasible for projects of different scopes. Teams felt that these methods could readily support the design teams in making key decisions that impacted patient safety. The balanced scorecard was suggested as helping with continuous monitoring for patient safety. Other tools such as process analysis and root cause analysis (RCA), (aggregated data from RCAs being most beneficial) would be critical during predesign and planning phases. FMEA, simulations, and link analysis could be effectively used at different design phases and could support decision making at varying levels of design detail.

FIGURE 2
Ratings of Design Tools



Note: Ratings on a scale of 1-5; 1 represents the lowest rating, 5 represents the highest rating.

As shown in Figure 2, almost all tools were rated high in terms of usability (ratings ≥ 4 for simulation, balanced scorecard, link analysis, and process analysis) and relevance (ratings ≥ 4 for all except RCA). The most feasible tools included balanced scorecard and process analysis. The most generalizable tools included link analysis, process analysis, balanced scorecard, and work sampling.

Safe Design Roadmap/CEO Checklist

The safe design roadmap was perceived to be a comprehensive tool including a lot of good content to facilitate multidisciplinary discussions and stimulate creative thinking around patient safety. It was also noted that the roadmap provided an overarching structure or framework under which many specific design tools can be used to support different design phases. In addition, the attendees felt that the roadmap was a much-needed work in the field.

However, attendees also thought that the roadmap in its current format was less than desirable and made suggestions for improvement.

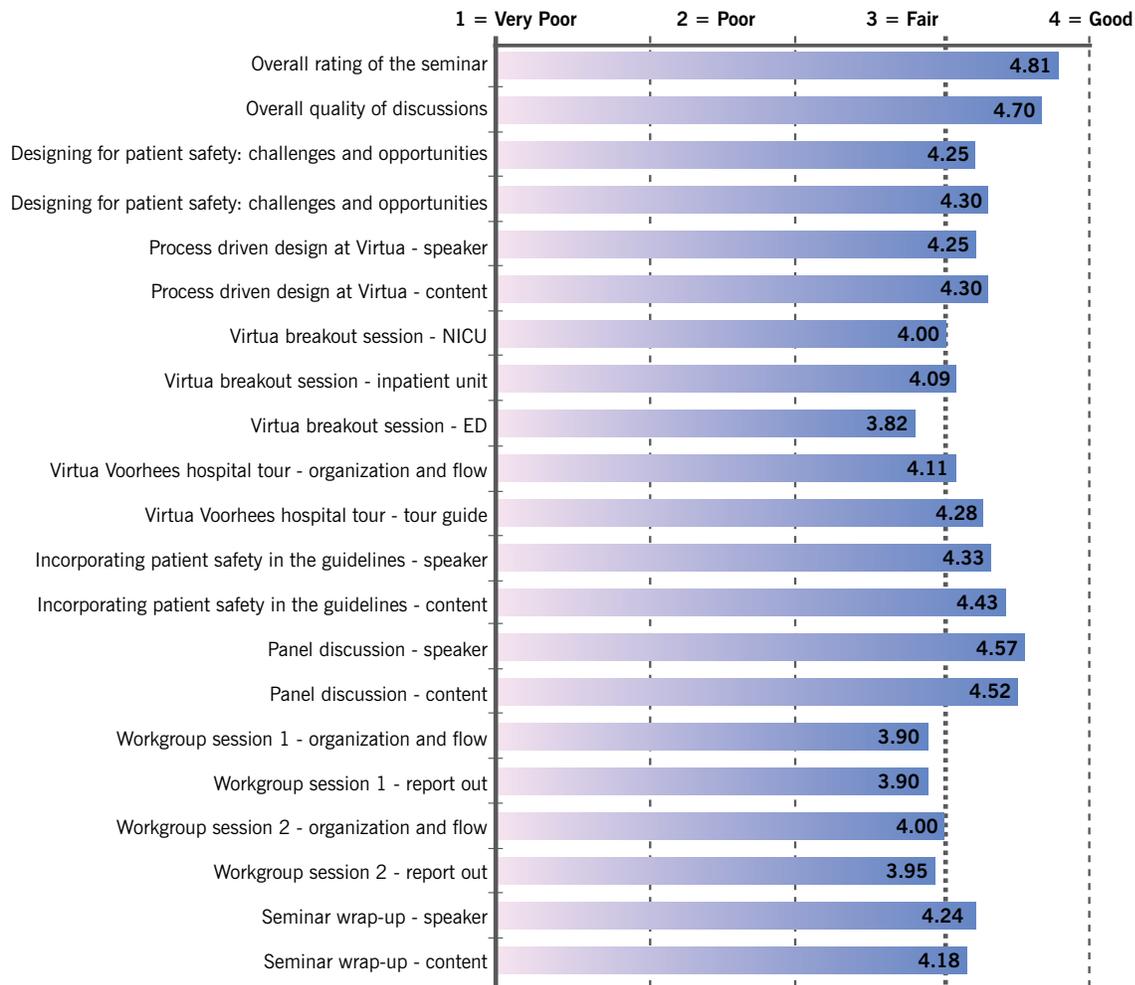
- First, as a tool specifically designed for CEOs or other administrators, it appeared to be too long and complex to be easily comprehensible and useful. One suggestion was to make the list of questions or checklist items shorter and more concise, supplemented by elaborated explanations and additional information related to the questions in appendix or in sidebars or pop-ups. Another suggestion was to design different checklists for different team members (disciplines) such as administrators and designers so that the CEO tool only included those questions/items pertinent to his or her decision making. It was also suggested to call the tool a roadmap or other similar name (e.g., guiding questions) to prevent users from expecting a short checklist of critical items.
- Second, attendees suggested providing supplementary information including glossary terms, references, and tools that could be used to address specific questions or topics; a reading list; and vivid examples such as Pebble Partners or other facilities, as well as succinct instructions for use.
- Third, more specific aims of enhancing patient safety should be articulated clearly upfront. Similarly, the definition of safety and the roles or responsibilities of team members should be clarified at the beginning.
- Fourth, attendees also suggested that the roadmap should be made customizable to serve the needs of various facilities.

Participant Feedback About the Seminar

A total of 21 participants responded to the post-seminar survey. Most of the seminar components were rated as good to very good by the respondents. Among them, the panel discussion in the afternoon of Day 1 received the highest ratings. Figure 3 (on the next page) shows the average ratings of the sessions and the overall seminar. All respondents felt that sufficient information was provided, the seminar agenda was effective, and the discussions were helpful in providing structure to the PSRA in the *Guidelines*. Eleven respondents expressed willingness to contribute to the future development of the various components, including tools, opinion papers, safe design roadmap, and PSRA.

In the answers to open-ended questions, respondents reported that both the formal sessions and the informal interactions were highly valuable and met the needs of the industry. Several respondents noted that the seminar could serve as a model for improving the design approach and tools for “performance improvement” in general. However, respondents also felt that the 2-day timeframe was too short, and that there was not enough time to cover all the important issues in great depth. Probably because of the time limitation, some respondents thought that the facility tour did not provide enough exposure to the potentially interesting design features implemented through lean process improvement at Virtua.

FIGURE 3
Participant Ratings of the Seminar Components



LIST OF PUBLICATIONS AND PRODUCTS

1. *Design for Patient Safety Tool Summaries*

- Failure modes and effects analysis
- Balanced scorecard
- Work sampling
- Link analysis
- Process analysis
- Simulation
- Root cause analysis

2. *Safe Design Roadmap*

3. *Opinion Papers*

- Design Flexibility in, Design Errors out, by John Grout
- Designing for Safety: A Systems Perspective, by Kerm Henriksen
- Collective Accountability: Primum Non Nocere (First Do no Harm),
by Eileen Malone
- Leading a Horse to Water: A Proverbial Dilemma for Patient Safety, by Skip Gregory
- Designing a Healthcare Setting With Infection Prevention in Mind, by Linda
Dickey and Judene Bartley
- Perspectives on Designing for Patient Safety, by James Lussier
- Perspectives on Designing for Patient Safety, by John Reiling
- Design for Healthcare Is not Special, by Rob Tannen
- Using Patient Simulation Within Mockups to Evaluate Room Design,
by Jonas Shultz
- Desperately Seeking Safety in the Surgery and Imaging Environments, by Bill
Rostenberg

- Patient Safe Healthcare Facilities by Design, by Rosalyn Cama
 - The Interior Designer as Safety Expert and Risk Manager, by Jain Malkin
 - Designing the Hospital to Reduce Harm and Enhance Staff and Patient Well-Being, by Paul Barach
 - Patient Safety Issues: The Critical Link Between Patient Safety and Staff Safety and the Inclusion of Human Factors Expertise in Healthcare Design, by Mary Matz
 - Human Factors Systems Approach to Healthcare Facility Design, by Pascale Carayon
 - Design for Patient Safety—Thinking at the Intersection, by Ron Smith
4. Video clips from Day 1 presentations (to be edited and available from the CHD website)
 5. Webinar presentation at HCD Virtual Symposium—Dec 7: Joseph, A., & Taylor, E. (2011). Designing for Patient Safety, Findings from a National Seminar. Healthcare Design Conference Virtual Symposium.
 6. Ellen Taylor (2012). Designing for Patient Safety—Considering a Patient Safety Risk Assessment. Paper accepted for presentation at the 2nd International Conference on Human Factors and Ergonomics in Healthcare, a subset of the 4th International Conference on Applied Human Factors and Ergonomics 2012 (AHFE 2012), San Francisco, California, July 21–25, 2012.
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APPENDIX II: OPINION PAPERS

Designing for patient safety is a complex, multidisciplinary undertaking and involves participation from a diverse set of stakeholders. This compilation of papers reflects the views of industry experts representing many diverse fields including architecture, interior design, medicine, nursing, healthcare epidemiology, human factors, industrial design, and hospital administration. Based on their personal experiences and expertise, these experts provide their perspective on how patient safety issues can be considered and integrated into facility design and suggest approaches for addressing patient safety during the facility design process.

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Design Flexibility in, Design Errors out

John R. Grout, PhD

The halving of medical errors called for in the 1999 Institute of Medicine report, *To Err Is Human*, has not occurred: not after the five years specified in report's goals; not even after 12 years. Worse, no overall industry-wide improvement can be documented. Yet there is a growing set of outliers where dramatic improvements have occurred. Among these are Thedacare and Virginia Mason and many other organizations that have used lean thinking to improve their processes. These organizations have made dramatic gains in patient safety, along with improvements in length of stay, patient satisfaction, and cost reduction. Each of these organizations has focused on the improvement of processes and the elimination of process waste.

These lean organizations have learned that processes should be in two contradictory states at the same time: Processes should be standardized and processes should be constantly improved. These are two hallmarks of lean thinking. The dilemma is that if the process is to be standardized and at the same time a moving target consistent with continuous improvement, how can designers and architects facilitate these processes? My opinion is that it is all about designing in flexibility. A hallmark of lean thinking is flexibility and quick changeovers. While in manufacturing, this means quick changeovers from one product to another on machines, in the case of facilities, it means the ease and speed of changing layouts within the facility to accommodate changes in the process. This has been demonstrated within factories, where elite teams of technicians design and build small flexible equipment, all on wheels, all easily reconfigured.

In addition to flexibility, lean thinking focuses on several more concepts. These include value, flow, pull, and perfection. The concept of value explores what the process beneficiary (patient) would prefer in a perfect world, and then backs away from the perfect world just enough to find a feasible solution. The resulting process is often a very different process than currently exists. Flow creates processes where steps occur rapidly and immediately after each other. Pull means not working according to a predetermined schedule, but rather planning work so that demand can be responded to easily and instantaneously. Organizations that are successful at focusing on value, flow, and pull find that the results are significant performance improvement and an expansive vista of additional problems and opportunities

that can be fruitfully pursued. This ongoing pursuit of opportunities and problem solutions results in repeated steps approaching perfection. Each step will involve design changes. Precisely predicting the nature of these changes is impossible. If there is good news to be had in this scenario, it is that generally less space will be needed to house processes, not more.

Within this lean thinking framework, my interests lie in the quality improvement techniques most notably linked to lean thinking: *poka-yoke*. This term is Japanese slang meaning *mistake proofing*. In this context, mistake proofing is the use of process design features to prevent human errors. Donald Berwick called for human errors “to be made irrelevant to outcome, continually found and skillfully mitigated.” He claimed that the answer is in “systems of work...the answer is in design.”

In order for Berwick’s ideas to come to fruition, designers will need to become even more effective at eliciting, shaping, and sometimes even constraining behavior. Designers of all kinds need to be provided with an enhanced vocabulary of approaches for creating safer designs. This vocabulary should include approaches to design that provide barriers to error and those that enable precise, correct action. These methods should include a broad portfolio of approaches to design that prevent errors before they occur, detect errors almost instantaneously, prevent the influence of errors when they do occur, and reduce ambiguity and confusion in the work environment.

This vocabulary will need to be developed by each of us along with many others. It will need to be profoundly collaborative. It will need to be interdisciplinary. It will require the sharing and utilizing of the best ideas from psychology, engineering, architecture, construction, quality management, production and operations management, and healthcare. I’m optimistic that patients can be made much safer as designers, engineers, and healthcare professionals join forces to continually improve processes.

Designing for Safety: A Systems Perspective

Kerm Henriksen, PhD

Are we designing healthcare facilities based on the activities and care processes that take place within them? Are we listening to the right sources for guidance—the providers who use the facility as a workplace, the patients who expect to be treated

and recover without undue risk, and family members who come to visit and provide support? Are we using appropriate techniques and tools for learning about the activities that take place? The professionally correct response to these somewhat biased and loaded questions would be to answer in the affirmative. In a more truthful and reflective moment, however, we might find ourselves saying, “Well, I’m not sure” or “How do we go about it?”

The Design Challenge

Safety by design represents a different way of thinking about patient safety and quality-of-care challenges. Rather than relying solely on traditional quality improvement efforts after the hospital or clinic has been built (when operating budgets are typically limited), a more proactive approach is to take safety and quality considerations into account during the earliest stages of facilities design. Safety is actually an emergent property of systems; it does not reside in a physical structure, device, work process, or person, but comes from the intricate interactions among a system’s components.

Weick (2002) referred to safety as a “dynamic non-event.” It takes a lot of attention to operations for nothing bad to happen in complex environments. Far too often, the dynamic interdependencies among physical spaces, technologies, personnel, and clinical processes are not well-aligned, resulting in cumbersome work environments for providers and substandard care for patients. To promote safety and overall system performance, design efforts need to integrate as seamlessly as possible the interdependencies among physical spaces, technologies, work processes, and people (Henriksen, Isaacson, Sadler, & Zimring, 2007). A necessary first step, however, is an assessment process that enables designers to gain a good understanding of the nature of clinical work involving patients and providers.

Understanding the Care Processes Involving Patients and Providers

As noted by Wallen (2007), the traditional design process typically starts with a functional space allocation program, preliminary construction budget, and project schedule. Somehow it is assumed that care processes involving patients and providers can be retrofitted into the designated spaces. For Wallen and other safety-by-design advocates, it makes greater sense to start the design process with a sound understanding of the care processes and risks associated with the activities and interactions among patients, providers, technology, and specialized medical

equipment and supplies, and then design the spaces to accommodate the unique activity. Safety and quality of care aren't something that solely happen after the facility is built, they happen upstream from the very start of the design process. The challenge for providers and their design colleagues is to work out the clinical processes as they should occur—not as performed now or as constrained by preconceived space allocation notions—and then design the building around the processes. During the present dynamic period of healthcare reform and change, there has never been a better time to innovate.

Using Appropriate Techniques and Tools

Other hazardous industries have made impressive strides in reducing risks to people and harm to the environment by using various front-end analysis and risk-assessment techniques. There is a need for planners and designers of healthcare facilities to become more familiar with these techniques and tools (Joseph & Taylor, 2010). Such a need can be satisfied, in part, by developing an inventory or repository of techniques and tools that already have been used in facilities recognized for their safety and quality-of-care features or those techniques and tools used in other industries that have good potential for application to facilities design. Function and task analysis, failure mode and effects analysis, process mapping, fault tree analysis, operation sequence diagrams, spaghetti maps, mock-ups, simulations, modeling, usability testing, and operational tryouts are a few that come easily to mind. By making the techniques available and put into use, the strengths and limitations of each become more apparent, as well as how they may need to be modified to enhance their effectiveness.

The Research Funding Outlook

The need to evaluate the feasibility of new safety-by-design approaches frequently gives rise to questions about funding opportunities. Given current political sentiment regarding government spending, one could easily assume that prospects for funding facilities design initiatives are less than promising. Yet under the Patient Protection and Affordable Care Act of 2010, the Center for Medicare and Medicaid Innovation (CMMI) came into existence, and, with a \$10 billion budget across a 10-year period, is soliciting new payment and service delivery models for Centers for Medicare and Medicaid Services (CMS) beneficiaries that can be tested and, ultimately, spread nationally. An essential question for conference participants is, “What are the design implications for the objectives that CMMI is trying to achieve?”

Funding sources may not include the words *facilities design* in the titles of their requests for applications, but this does not mean there are no opportunities for improving safety and quality of care through design-driven efforts. Flexible, multidimensional, and system-oriented strategies are likely to serve the researcher well. Not all research requires vast amounts of external funding. It might be possible to address some research gaps with relatively modest levels of external funding, while recognizing that other gaps require more moderate levels. Yet other gaps are likely to require more programmatic and substantial funding efforts. By diversifying strategies, the researcher increases his or her chances of always having an approach in play appropriate for the temper of the times.

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Collective Accountability: Primum Non Nocere (First Do no Harm)

Eileen B. Malone, RN, MSN, MS, EDAC

This Is Personal

During the past decade, my family has had plenty of personal experience with unintended patient harm. In 2001, my then energetic and youthful 70-year old mother was diagnosed with a blood disorder that began her journey toward leukemia. With this diagnosis, she joined other vulnerable individuals at risk for what we used to call

untoward events. Over a 4-year course, the disease progressed to a chronic leukemic condition, which resulted in multiple hospitalizations for infections that her body could not fight alone. It was during one of her last hospitalizations that she contracted a healthcare-associated infection that fueled the leukemia into an acute form, ultimately killing her. My mother was receiving care in one of our nation's top-10 hospitals, by a caring team—a group of one of the world's leukemia experts, with me as her healthcare advocate—and none of this was enough to prevent her premature death.

Three-years later, my brother-in-law underwent groundbreaking robotic surgery—again in one of our most prestigious hospitals by a skilled surgeon—for a tumor at the base of his tongue. The procedure required multiple intubations, but he weathered them well, and the surgeon got all of the cancer. We were thrilled that he had escaped the disfiguring and quality-of-life-altering standard surgery and that he was now cancer-free. However, on the morning of his discharge, he went into respiratory arrest, was intubated, and spent another week in the intensive care unit for a presumed ventilator-acquired pneumonia.

Almost 2 years ago, my father was hospitalized for 10 days, during which I developed a case of sciatica after sitting for long periods in his patient chair prompting me to investigate, with an interior design colleague, the relationship between furniture features and healthcare outcomes (Malone & Dellinger, 2011). And this summer, my elderly mother-in-law, who has Alzheimer's, slipped off the bed she has used for 20 years, gashing her head and breaking her wrist, 3 days after moving into an assisted-living memory-care facility, significantly complicating her transition. I suspect that most of you have at least one tragic tale to tell given the alarming statistics emerging about unintended harm.

A Professional Epiphany: Unintended Harm Is Pervasive and the Costs Are Enormous

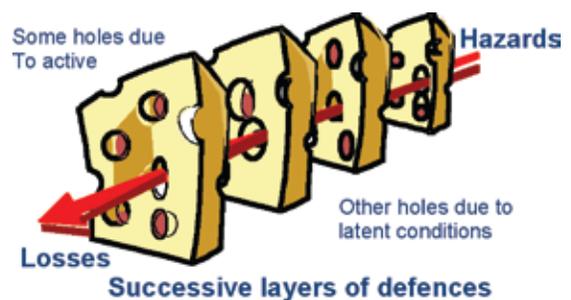
As a former quality assurance nurse, I was well-aware of the iatrogenic or nosocomial or adverse or sentinel events that can complicate a patient's hospitalization. Each discovered event was absolutely regretted and analyzed for improvement opportunities. But there was a certain level of acceptance in the healthcare community that these events were expected care complications. My acceptance changed dramatically when in 2000 I read the Institute of Medicine's seminal examination of patient safety in *To Err Is Human* (1999) with its mind-boggling statistics, including one study that estimated that 98,000 Americans die each year

from adverse events. Healthcare-associated infections (HAI) alone account for 1.7 million incidents (Malone & Dellinger, 2011) with costs estimated to be between \$35.7 billion to \$45 billion annually (Scott, 2009). Patient falls and their associated injuries represent the No. 1 adverse event, accounting for 6.4% of reported sentinel events (The Joint Commission, 2005, 2009). More recent studies suggest that these estimates are low and not just confined to the inpatient setting.

One recent study analyzed medical claims data and used mathematical models to assess the risk of harm and project costs to the entire population, estimating that the annual cost of measurable medical errors that harm patients was \$17.1 billion in 2008 (Van Den Bos, Rustagi, Gray, Halford, Ziemkiewicz, & Shreve, 2011). Erber and colleagues examined 600,000 cases and found 2.3 million hospital days accounting for \$8.1 billion in healthcare costs and 48,000 preventable deaths that could be attributed to HAI sepsis and pneumonia alone (Eber, Laxminarayan, Perencevich, & Malani, 2010). Landrigan and his team found 63.1% of the 25.1 harms per 100 admissions in 10 North Carolina hospitals were preventable (Landrigan, Gareth, Bones, Hackbarth, Goldmann, & Sharek, 2010). The Department of Health and Human Services' inspector general discovered that 13.5% of hospitalized Medicare patients experienced adverse events, and another 13.5% experienced temporary harm, 44% of which was thought by physician reviewers to be preventable (Levinson, 2010). A recent study revealed that, in 2009, the number of paid malpractice claims reported to the National Practitioner Data Bank for adverse events in the outpatient arena were similar to those in the inpatient setting (Bishop, Ryan, & Casalino, 2011). Amazingly, all of this harm has occurred in spite of an array of patient safety improvement initiatives during the past decade (Wachter, 2010). What are we missing?

Eliminating Environmental Latent Conditions by Enabling High Reliability

Anyone in healthcare can tell you that analyzed episodes of harm almost always reveal that more than one safeguard failed. James Reason provides us with a helpful framework to understand how this harm happens (Reason, 2000). His Swiss cheese model suggests that each defensive layer is more like a slice of Swiss cheese—filled with holes that are constantly moving and closing, which when combined with active



failures on the part of caregivers and latent conditions like the environment, set the perfect trajectory for harm and loss (Figure 1). Although a culture of safety, leadership, and robust improvement processes remain essential in high-reliability organizations (Chassin & Loeb, 2011), we are beginning to appreciate that *healthcare environmental features represent latent conditions that can be designed to help eliminate harm*. Other high-risk industries, like commercial aviation and nuclear power, understand the important role the environment plays in shaping preferred human responses and supporting a collective mindfulness as the dominant culture that highly reliable organizations share.

Collective Accountability

We are all accountable for achieving safe care. At this seminar, we have a wonderful opportunity to validate a blueprint that can help with the creation of safer healthcare facilities—a challenging task given the thousands of decisions inherent in each project. Since, as Atul Gawande reminds us—“We are built for novelty and excitement, not attention to detail” (Gawande, 2009)—we will consider a draft safety design checklist to focus our mind on all of the key project steps and examine other tools that can provide a framework to guide the design, construction, and lifecycle activities for healthcare facilities.

We have many incentives to do so, beyond the immediate financial ones being driven by the 2010 Patient Protection and Affordable Care Act, which ties hospital reimbursement to a demonstrated reduction in patient harm. Each one of us only has to consider those we care most about to appreciate the importance and value of this work. Given the current scrutiny of patient safety and unintended harm, we have an opportunity to ensure that environmental variables are included in a truly comprehensive patient safety approach. And as we do so, let us remember the Hippocratic oath: “As to diseases, make a habit of two things—to help, or at least to do no harm.”

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Leading a Horse to Water: A Proverbial Dilemma for Patient Safety

Skip Gregory, NCARB

(One of the oldest English language proverbs describes leading a horse to water but being unable to make it drink. The following are thoughts on this proverb as it regards patient safety from a past authority having jurisdiction.)

Sometime in the late 1980s, it occurred to some of us who were conducting inspections in Florida of renovations in occupied hospitals and nursing homes that, generally speaking, there was little thought being given to the impact of this construction activity on the patients and residents occupying these facilities. The standard building process was being implemented in which the owner contracts with a design professional to design the renovation, the design professional provides the contractor with a set documents describing the renovation, and the contractor provides the subcontractors with this information to build the renovation.

What we saw when we visited these facilities was construction activities taking place in and around patients and residents without any particular effort being given to how this was impacting them. Air distribution systems were being interrupted for long periods of time, major demolition was taking place in patient-occupied areas without physical separation, sprinkler and fire alarm protections were being removed with no thought of the impact on fire safety, and so forth. It was as if all this work was being done inside an unoccupied building, instead of one that was occupied by at-risk patients and residents.

And although we did not have convincing and controlled data to suggest the patients and residents were being affected adversely by these conditions, we began to understand there was a risk in ignoring the simple fact these were actual living, breathing persons and not just furniture pieces that could be moved around to make way for new construction.

In 1993 we begin talking to the design architects regarding how these renovations could be phased so there would be less impact on the patients/residents in the areas of construction. Because we were reviewing the plans and specifications for these projects, we were able to require more detail about how the patient/resident areas were to be safeguarded and separated during construction and how the utility systems, exits, and fire alarms systems were to be maintained.

Unfortunately, the architects and engineers had little experience with this and told us their liability insurance would not permit them to provide this type of information on the construction documents because it was ways and means and was the purview of the contractor. The contractor told us he had no idea what to do because he was not a clinician and could not make the judgments required. He could only develop plans that would facilitate the early and successful completion of the project to meet contractual obligations. And the owner/provider told us he was not the expert in building processes and simply hired professionals to do the work.

As we learned more about the risks involved and how to properly mitigate them, we had difficulty convincing the persons who were responsible for this work there was a significant problem because there were few requirements in the codes that were directly related to this issue.

So we worked to develop some new language for the *Guidelines for Design and Construction of Health Care Facilities* that would describe what should be done and how to do it. We invited practitioners in the areas of infection control to come to Florida and lecture on this topic. And for the next 15 years, we gave lectures on infection control during construction at venues for infection preventionists, owners/providers, healthcare contractors, architects, and engineers.

But even now I am often met with blank stares when I talk about the Infection Control Risk Assessment (ICRA), as if this was the first time the subject had come up. It is unfortunate, but what is written in the *Guidelines* is not always incorporated into the design process. And because the ICRA was developed by and for hospitals, it has even less impact on nursing home owners and providers who still believe it does not apply to them. Many still do not know what the letters I C R A stand for much less know or care very much about how to properly develop one. They often see this process as only another bureaucratic nuisance that needs to be dealt with, not a serious risk to health and safety.

This became such a problem in Florida that construction documents are no longer approved unless they are accompanied with a complete ICRA and a reasonable and well-thought-out phasing plan that is described in detail and incorporated into the construction documents. Because the authorities having jurisdiction cannot be present at the job site of every job, this is the only way to assure the building concepts of the ICRA involving systems, separation, and phasing are actually thought out and developed prior to any work being started in the facility. When a detailed plan and design of these temporary measures are incorporated into the construction documents and when the additional budget requirements necessary to implement this plan and design are provided, there is a much better chance for the building concepts of the ICRA to actually become part of the project.

Concepts written into a design guideline are of little use until they are converted into actions that incorporate the intent and not just the letter of those concepts. It is important to remember, as new and more detailed ideas for patient and resident safety are developed, that until these concepts are actually required and enforced as part of the design and construction process, there will be little change. It is unfortunate but true that even when overwhelming facts are presented, we do not always do the things that we know are best.

So, as we go forward and develop more overarching patient safety risk assessments and refine the concepts that are known to be best practice, we should also be developing ways to ensure they actually become part of these construction projects. Otherwise we will be wasting valuable effort in leading the horse to the water but not being able to make it drink.

Designing a Healthcare Setting With Infection Prevention in Mind

Linda L. Dickey, RN, MPH, CIC, and Judene Bartley, MS, MPH, CIC

The Infection Control Risk Assessment (ICRA) is a fairly young concept, although designing healthcare settings with the intent to prevent infections is certainly not a new idea.

In 1853 Florence Nightingale noted, “The essential feature of the pavilion construction is that of breaking up hospitals of any size into a number of separate

detached units. And the object sought is that the atmosphere of no one pavilion or ward should escape itself to any other pavilion or ward but should escape into the open air... while its place is supplied by the purest air obtainable.”

Certainly we're all the better for Nightingale's forward thinking in many respects. However, the obvious idea of using a *systematic process* to assess for infection risk in order to design and construct healthcare settings to prevent infectious outcomes was a long time in coming. And, like many novel ideas, it was initially met with resistance and skepticism: Where was the evidence this was necessary? That it was worth the costs? That it resulted in reduced infections? Fair enough, and therein lies the ongoing challenge even now, to not only show evidence of effective “prevention design” for infectious outcomes (as well as for other healthcare outcomes associated with the built environment) but also value in terms of operational and energy efficiencies.

Yet we know the basic principles of the ICRA make sense to apply—for a multidisciplinary group to consider the patient population to be served, the scope of work to be done, and to design and construct as best we know how, based on evidence we have on hand at the time. For example, we know clear evidence has been provided in multiple published papers of profoundly immune-suppressed patients who have developed infections due to construction dust exposure that resulted in devastating illness and loss of life. A significant paper determining that construction was an independent variable in such patients developing fungal infection was published by the Centers for Disease Control and Prevention 25 years ago (Weems, Davis, Tablan, Kaufman, & Martone, 1987).

The consequence of such papers resulted in the early steps of the ICRA process to focus on assessing patient risks during the actual construction process, implementing many dust control measures, as well as mitigation measures when damage had already occurred. Another more recently published example of an intensive care unit *Pseudomonas* outbreak has helped provide valuable clues for sink design and placement to prevent reoccurrence of these devastating events (Hota et al., 2009). This outbreak involved transfer of *Pseudomonas* splashing up from a sink drain to intensive care patients, despite the protection of a single room.

Clearly, showing evidence of prevented infectious outcomes has always been a public health challenge, particularly when the outcome is not always clearly defined (a

design or construction-related infection), easily measurable, or, as is many times the case, not easily recognized and thus not published. In this last case, the analysis took a long look back in order to identify the definitive cause and solution. Still, it is imperative to use what evidence that does emerge together with a clear process to apply the lessons learned to build a better care environment.

While still a young process, the ICRA has quickly matured in its 15 years of use and evolution. What began as a simple process to recommend special airflow rooms now serves to advise a project from functional programming through commissioning. For example, the ICRA considers anticipated business growth or change to help guide operational flow and capital purchases. The process considers the functional use of a space, the patient population, and staff movement—each of which may affect where design features may need to be placed or what surfaces and furnishings would be optimal for cleaning and sustainability. There are win-wins that can be found to optimize infection prevention and operational efficiencies, such as ventilation set backs in procedural areas. And as the ICRA process continues to evolve, it has already served as a springboard to expand even more broadly into risk assessment for overall patient quality of care and safety. It is merging rather than paralleling long-term and current initiatives of The Center for Health Design's evidence based design research, FGI Institute, and countless studies by architects, engineers, and related fields focusing on overall better patient outcomes.

An appendix with a brief history on the specific developments in the *Guidelines for Design and Construction of Health Care Facilities* from 1996 to further development planned for 2014 will be made available on the CHD and FGI websites.

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Perspectives on Designing for Patient Safety

James T. Lussier

Based upon my experience as a healthcare systems CEO as well as having intimate involvement on a number of major healthcare facilities design projects, I can attest to the fundamental importance of patient safety issues in the process of design and construction of all types of healthcare facilities. I believe there is a fundamental lack of sensitivity to the impact of facilities design on all types of operational issues, especially as they relate to patient safety. In part, that has led to significant safety issues that have plagued American healthcare for generations—high mortality and morbidity rates, healthcare-acquired infections, and patient falls, among others and, ultimately, to staff practices that lead to a multitude of patient safety concerns.

In my role as research and development chair for the Facility Guidelines Institute, which publishes the *Guidelines for the Design and Construction of Healthcare Facilities*, I have had an opportunity to participate in both research addressed directly to patient safety issues but also to participate in important conversations with expert designers, clinicians, and others on this very topic. I believe there are many opportunities to increase the sensitivities of both the designer–clinician partnership as well as actual facility design to address these issues to which this AHRQ conference is addressed.

In general, healthcare facilities are dangerous places. When one compares safety issues with any other sector of our service economy, healthcare stands out as a leader in documented patient safety incidents both generated by a combination of facility design and staff processes detrimental to patient care. One need only review the numerous initiatives addressed at improving patient safety by agencies like AHRQ and the Institute for Healthcare Improvement, as well as numerous others, to sample the range of patient safety issues being identified and the subjects of major patient safety initiatives.

While one must readily admit there are fully justifiable reasons to acknowledge healthcare’s invasive nature that contributes to significant exposure, that very nature amplifies the importance of maximizing what designers and clinicians can do to *design out* factors that negatively impact patient safety while contributing to

the optimization of a safe treatment environment upon which the best operational practices might be based.

A brief example of some of the major areas of design improvement that might have a significant impact on the physical and operational patient safety environment include

- design issues that relate to the inappropriate administration of medications,
- acoustical issues that optimize communication and minimize staff distraction,
- involvement of patient family members in the care of patients,
- designs that accommodate optimum infection control techniques,
- minimization of patient falls and other never events in the care environment, and
- designs that consider staff safety.

Designers and clinicians representing owners on a design team need to be cognizant of the primary issues that impact patient safety including miscommunication; work areas that do not allow appropriate concentration, privacy, and communication; designs that do not allow appropriate patient observation; and many other areas too numerous to mention here.

An example of a factor of importance is design that precludes the participation of a patient's family members in direct patient care. Such participation has proven to be instrumental in the reduction of issues such as patient medication errors, patient falls, and even the continuity of communication among facility staff members. A secondary but more subtle area of importance is the welcoming and empowering nature of both the facility's design and staff processes that invite both patient and family participation in overall care. While hard to measure, the historical division that discourages patient involvement in clinical decisions and even monitoring one's own care create an environment that contributes to a lack of sensitivity to potential patient safety issues.

In summary, patient safety issues that might be addressed in the facility design process range from conceptual changes about what is important in the process of patient care and the engagement of staff to details about what generates patient falls, infection exposure, and medication errors. What must first be established is

sensitivity to the importance of these issues and, in part, the cause-effect nature of design on patient care processes, staff orientations and attitudes, as well as patient and family orientation and participation in the patient experience.

The designers of patient care facilities and, subsequently, processes truly are care providers and share a responsibility to optimize the patient's safety, clinical outcomes, and overall experience that facilitates healing, not injury or error.

Perspectives on Designing for Patient Safety

John Reiling, Ph.D.

As most of you know, patient safety has become and continues to be a critical issue for the healthcare industry. Sparked by *To Err Is Human*, an Institute of Medicine report in 1999, important and growing awareness and focus have developed around patient safety. But in spite of this developed awareness and focus, adverse events have not declined. They seem to be at the same level as in 1999. Some believe they are higher (Dentzer, 2011).

Cognitive experts have contributed a growing body of knowledge about human cognition and human error. To err is human is true and necessary for human development. But for most healthcare providers and persons who support them, errors can lead to adverse events and harm to patients.

Two ways in which facility design with its equipment and technology can influence patient safety is through the creation of environments that potentially reduce human error or through the incorporation of specific design features that could affect adverse events.

The first is by utilizing researched conditions in which humans err more and conditions in which they err less. For example, interruption and noise can result in more error, and standardization, order, and quiet can result in less error. Designing around these conditions could influence human error and potentially lessen harm that patients and caregivers experience.

The second way to affect patient safety through design is by designing directly to reduce adverse events. Falls, medication error, and infection are examples of

prevalent adverse effects that harm and kill patients. But determining what design features to use is a complicated and complex issue.

Researched design features that have an effect on patient safety should be strongly considered. However, it is often difficult to conduct research on specific design features because there are many confounding variables; processes, culture, and Hawthorne effect (a phenomenon that individuals behaviors change because of the fact that they know they are being studied) are prominent examples. Features that reduce or kill bacteria can be more directly researched through laboratory experiments, but whether they will reduce patient-acquired infections is an open question. What high-performing organizations such as aviation and aircraft carriers have discovered is that high performance is a function of practical employee-based, nonresearched ideas. An article by Leape, Berwick, and Bates (2002) discusses this issue as it relates to healthcare.

There are two tools that I would like to highlight that have been used successfully to support the architect, contractor, and the healthcare organization's pursuit of the goal of developing facilities that create the conditions for safer care. These two tools are the matrix and design failure modes effect analysis (d-FMEA) (Reiling, 2005, 2007).

The matrix is modeled off a quality tool called *quality functional deployment*. One takes the Y axis (vertical), lists the principles of the project and develops relevant design features under each principle. So for example, under a principle of "safe and high quality," there might be "reduced adverse events," and under that might be "medication error," and under that "bar coding." On the X axis (horizontally), one would list the same principle and design features plus the criteria for evaluation. The criteria usually include capital cost and the level of the effect of the design feature. So for example, if a principle is to bring services to the patient vs. the patient to the services; this should minimize handoffs and be more patient centered. A suggested design feature is to design every room as private and create the ability to perform surgery in that room. The cost of each room is \$50,000 (high) and the effect on safety is low or medium. The evaluating group would probably decide not to pursue the design feature to have each room have the ability to perform surgery.

By having the same design features on the Y axis as the X axis, one can determine if a design feature affects other principles. For example, private rooms affect infections

and patients involved with care. The outcome of the exercise is to create, before the start of formal design, the design features, equipment, and technology that the healthcare organization, along with the design team, feels best meets the guiding principles of the project.

Most organizations create teams around design principles and safety principles contained within. Their responsibility is to research and populate the matrix with design features, equipment, and technology, and research the cost. After the matrix is fully developed, there is a mechanism to disclose it to the organization. Then the matrix is evaluated, usually by a group of persons, and the final matrix is formally approved. This is an effective process for all to gain greater understanding of safety issues, their causes, and how facility design can affect them. One final note, some of the brainstorm matrix ideas are not facility-related, but process- and culture-related. Usually the organization will park these and address them later.

The second tool is d-FMEA. This is a tool distinguished from p-FMEA (process failure modes effect analysis). Many are aware of p-FMEA but seldom has a d-FMEA been employed. A National Learning Lab recommended performing d-FMEAs at each design phase. Experience has modified that recommendation to employ it at three design stages:

1. Block diagrams (adjacencies)
2. Schematics
3. Design development

A FMEA is a way to assess potential failures, the likelihood of a failure occurrence, and detection and the changes that would correct the failure. d-FMEAs assume that the process performs accurately and the failure is in the design. For example, do the adjacencies cause failures (safety issues) that could be corrected by changing the adjacencies?

Again, this is an exercise that could have active participation by all the employees of the organization. The outcome is to detect potential failures that could lead to error and harm patients, and correct the potential failure before the design is complete, thereby ensuring that patients and caregivers are not affected by the “failures.”

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Design for Healthcare Is Not Special

Rob Tannen, PhD, CPE

Healthcare Is Not Special

Consider this industry where effective design is so critical for safety. An industry that serves virtually everyone, is highly regulated by safety specifications, and requires licensing to practice and insurance to participate (although some get by without it). Over recent decades, design and technology improvements have significantly reduced fatalities, but an estimated 40,000 Americans die annually due to potentially preventable errors.

This is the automobile industry. Between 1979 and 2002, U.S. automobile fatalities dropped 16%, even as the number of total drivers and vehicles increased (compare this with a 50% decline over the same period in Canada), according to the automobile safety page on Wikipedia. There are a number of factors behind these successful decreases: airbags, antilock brakes, mass media campaigns against drunken driving, etc. Measurable results were achieved in a relatively brief time span through effective design and resulting behavioral changes.

Over the years we have seen the healthcare industry adapt tools and processes from other industries toward the improvement of clinical outcomes and patient safety. For example, from aviation as described in Atul Gawande's *The Checklist Manifesto*.

Similarly, evidence-based design (EBD) methods and practices draw much from product design methods including ethnographic research. Consequently, design for healthcare environments should not be considered unique or special in either its approach nor context.

Healthcare Is Special

Given that EBD is a relative newcomer within research-driven design, one might assume that it lacks the experience and mature body of work to achieve effective results. But in many respects, EBD is an improved version of its antecedents.

- EBD has borrowed best practices that have already been vetted in other contexts.
- An emphasis on measurement of outcomes is a critical piece of the design process that is embedded in healthcare, but often lacking elsewhere.

We can compare user-centered design, the widespread practice of integrating user research and usability testing into the design of websites, software applications, and products with EBD. Because EBD is narrowly focused on healthcare environments, it has a centralized, standards-setting organization (The Center for Health Design), and its practitioners have developed a sharable, accessible ongoing body of research work (*Healthcare Environments Research and Design Journal*).

In comparison, software, and product design are broader, more diverse fields. While there are publications and conferences for those fields, it's challenging to find focused sources around the effective design of a specific type of product—vs. general design guidelines. And postlaunch outcomes measurement, a fundamental activity in EBD, is rarely a required part of any user-centered design process, and when it is done, it's rarely shared with fellow practitioners for proprietary reasons.

Evidence-based design also proactively addresses many of the methodological concerns that arise in qualitative, small-sample research, relevant to product design. For example, EBD makes the valuable point of considering research methods from the perspectives of both objectivity and context. Objective, quantitative methods, such as controlled laboratory studies or surveys, also tend to be the most removed from the actual design context. They provide scientific credibility, but may not account for the specifics of the particular situation. On the other hand, interviews

and ethnographic observation—while qualitative—can be performed contextually and provide deeper detail and relevance, albeit with less scientific rigor. Evidence-based design thoughtfully recommends a balance of both kinds of research. The thoughtful planning and the balancing of both qualitative and quantitative methods that EBD advocates may be the strongest takeaway for designers in other fields.

Safe Design Is Special

Ultimately, it doesn't matter whether research methods are original or unique, as long as they produce effective, actionable results. As a medical product designer, safety is among my highest priorities, and it can be realized in many ways, for example,

- design for safety to eliminate accidental injury,
- ergonomic safety to minimize fatigue and injury from repeated and long-term use, and
- usable design to reduce the probably of incorrect use.

Design for safety is accomplished by identifying potential safety conditions through injury reports, complaints, expert review, and user research. In the case of the Becton Dickinson SafetyGlide Needle, Bresslergroup was tasked to invent a new hypodermic safety needle that could be made absolutely safe, postinjection, without training, and using only one hand. This began with significant in-hospital observation and interviews with nurse technicians and phlebotomists. In formal medical product design testing, 99% of medical users tested were able to deduce how to deploy the safety feature within 2 seconds postinjection. A clear case of measurable outcomes measurement in medical product design.

Using Patient Simulation Within Mock-ups to Evaluate Room Design

Jonas Shultz, MSc

Designing a healthcare facility is a complex process. User input during the design phase is essential and traditionally has involved clinicians reviewing architectural drawings. Unfortunately, feedback during these exercises may be compromised due to the clinicians' difficulties with conceptualizing how the actual space will look, feel, and support both current and new healthcare procedures. In some cases a full-

scale mock-up, which is a physical representation of the actual space, is built and frontline staff are able to walk through the mock-up and provide their feedback to facility planners and architects. Although using a mock-up in this way facilitates better visualization of the available space and layout, potential design issues may remain hidden, especially if the space, once filled with equipment and supplies, is then used in unanticipated ways by other clinicians. By incorporating human factors methodologies and patient simulation as part of the design process to evaluate mock-ups, many of these design issues can be uncovered and corrected, thus leading to improvements in both patient safety and staff efficiency.

Simulation-based evaluations provide an opportunity for real-life staff to test drive a mock-up of the space during the design phase by performing representative clinical scenarios created by the evaluation team on fictitious patients. The scenarios are intentionally designed around specific evaluation criteria, which are essential in evaluating the overall space design to ensure it meets the requirements and objectives of the design team and frontline users. There are varying degrees of completion (or fidelity) to which the mock-up can be built to, determined by the questions that the design team wants answered. By incorporating real equipment and technologies in the mock-up, we can identify space conflicts and usability issues with equipment and technologies, as well as determine how interacting with these devices will impact staff workflow within the space. Changes to the physical design of the space can be made to improve these issues and support staff workflow.

During the scenario enactments, participants are asked to verbalize all thoughts and challenges encountered, using talk-aloud verbal protocols to generate feedback regarding the design. Focus groups are also conducted after the enactment of each scenario to provide another opportunity for feedback and allow both participants and observers to develop recommendations and brainstorm solutions to challenges encountered during the simulation.

Videotaping the scenario enactments captures the verbalized feedback, staff movements, and interactions throughout the space for more detailed analysis. Specifically, the videos are reviewed from each camera angle by multiple human factors specialists, who code specific issues. These include access to equipment, usability of equipment, visibility of monitors, bumps between equipment and/or

people, space requirements, or communication difficulties. Use of short snippets of video clips can be a powerful tool when demonstrating both areas for improvement and beneficial design features when communicating the findings back to the design team.

Using patient simulation to evaluate mock-up rooms has been successfully used in the design of interventional trauma hybrid operating rooms (Biesbroek, Shultz, Kirkpatrick, & Kortbeek, under review), intensive care unit patient rooms (Chisholm, et al., 2008), emergency department exam rooms (Mayer, Caird, Shultz, Chisholm, & Teteris, 2009), inpatient rooms (Watkins, Myers, & Villasante, 2008), and designated assisted living resident rooms (Shultz & Chisholm, 2010). Engaging healthcare providers and patients through clinical simulations enhances realism and raises awareness of the environmental and situational factors that should be considered in the design. The process also allows designers to better understand the clinical processes that the physical design is intended to support. This evidence-based approach is a valuable tool to identify facility design issues and alter the design before construction and, more importantly, before patient care.

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Desperately Seeking Safety in the Surgery and Imaging Environments

Bill Rostenberg

Magnitude of the Safety Challenge

In addition to the global financial crisis, the U.S. health system is plagued with an even greater crisis: an epidemic of medical errors and safety infractions. Over 100,000 preventable deaths occur in our hospitals every year; equal in magnitude to one 747 jumbo jet liner crashing every three days with no survivors aboard. While the built environment may not be a direct cause of errors, facility design can increase or diminish their frequency.

This is of particular importance in designing peri-operative settings (i.e., pre-op, surgical operating room, interventional procedure suite, recovery room). Recent medical advances are causing some traditional departmental boundaries to disappear, yielding new types of procedural spaces in which clinical care is delivered, and changing medical culture as specialists collaborate in ways that differ from in the past. Nowhere is this more apparent than in the convergence of surgery and interventional radiology (Rostenberg, 2006).

Three trends—the epidemic of preventable medical errors, the growing need for healthcare facilities designed for safety, and the convergence of surgery and imaging—are resulting in new types of space where medical technology is complex and where safe environments are essential.

Safety Concerns in Surgical and Imaging Environments

Among medical safety concerns in general, approximately 10.5% of all adverse

medical events and 19.7% of serious adverse medical events appear to be related to surgery (Andrews et al., 1997), while others appear to be related to medical imaging. These include

- wrong site surgery
- wrong person surgery
- radiation exposure
- magnetic resonance imaging (MRI) accidents, and
- hospital-acquired infections

Knowledge of how the built environment affects safety and medical outcomes is essential in designing healthcare facilities that do not further intensify preventable sentinel events.

Radiation Protection

On one hand, radiation-emitting devices continue to become safer. However, on the other hand, permissible accumulated levels of radiation exposure are rapidly becoming more conservative. As a result, radiation-shielding requirements continue to become more stringent, even as most radiology equipment is becoming safer. In addition, there is growing interest in associating the long-term effects of radiation exposure with an increased incidence of cancer.

While most imaging facilities are designed to ensure adequate radiation protection, surgical facilities are not always designed with this in mind. As surgery becomes increasingly dependent on image guidance, adequate radiation protection becomes more critical. For example, many operating rooms where x-ray technology is used typically rely on small ceiling-mounted lead shields and surgical staff wearing personal radiation protection. However, dedicated space is rarely provided for technologists who control the imaging equipment to work within a radiation-controlled zone. Anticipating the increased frequency and complexity of radiation-emitting devices being used within the operating room, some surgical suites are being outfitted with control rooms (similar to those found in interventional imaging departments) adjacent to the operating room.

MRI Safety

Accidents related to ferrous objects (those that contain iron) inappropriately brought into an MRI suite are one of the top 10 safety concerns of healthcare executives. While very few deaths caused by ferrous objects pulled into a magnet have been documented, accidents of this nature are known to occur frequently. As a result of one fatality in 2001, the American College of Radiology developed a white paper with guidelines for designing safe MRI suites. While these guidelines are relatively easy to apply to MRI suites used for diagnostic imaging, it is challenging to incorporate them into the design of intraoperative MRI (I-MRI) suites. This is because I-MRI procedures often require surgical instruments that are attracted by magnetic field to be used in proximity to the magnet itself. Therefore, the design of I-MRI suites requires that particular attention be placed on safeguards that alert staff when metal objects are brought into the general vicinity of the magnet.

Facility Design and Healthcare Safety

Surgical suites and imaging suites are areas where medical errors can easily occur and where the built environment has a profound impact on injuries and errors. As the practices of surgery and imaging are integrated into one comprehensive area—which is becoming increasingly more common—designing these spaces for safety and improved medical outcomes becomes increasingly more complex.

Because each medical specialty has different traditions of work flow, different regulatory guidelines that govern how they perform medical procedures, and often use different instruments and supplies (i.e., disposable vs. reprocessed instruments), the design process gets even more complex. Therefore, prioritizing the importance of safety as an essential component in the design of surgical and imaging environments is paramount.

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Patient Safe Healthcare Facilities by Design

Rosalyn Cama, FASID, EDAC

Safe environments rely on an integrated organizational culture of well-being and the human need to be connected to nature.

Patient safety concerns are top of mind for those designing healthcare facilities today. Evidence-based planners and designers typically center those thoughts to the control of the spread of infection and the reduction of falls and medical errors. There is, however, sufficient evidence to suggest that the design features that lead to a patient safe environment are also driven by an integrated organizational culture of well-being and the human need to be connected to nature or biophilia.

Organizational Culture of Well-Being

The concept of an organizational culture of well-being is driven by an integrated approach to systems operations. Good evidence-based design (EBD) planning—Step 1 in an EBD process—(Cama, 2009) that incorporates an understanding of a health facility’s culture aligned with operational efficiencies and effective care-delivery models creates the basis for design programming and planning where new design features are considered to mitigate safety risks. “First do no harm” often appears in an EBD program’s guiding principles.

The design of healthcare facilities therefore cannot be executed without an understanding of an organization’s culture, values, and operational processes and the industry’s best practices while constantly imagining its next practices. Shifts in the industry are stirring up change, and many institutions are seeking improvements to their operational systems. In so doing, the EBD movement has been running tandem to the lean processing, patient-centered care, and the continuous process improvement movements of the last few years.

The EBD process uses critical thinking while all intelligence is gathered and synthesized about an organization and the industry as a whole. It does so through an analysis of an institution's strategic directives and the best practices the field has to offer both through quantitative and qualitative data collections. Early in the EBD process these different yet intertwined organizational movements are aligned, and one can argue that a culture of well-being is achieved through design. Lean process engineers typically address offstage operations focused specifically on clinical services that offer just-in-time delivery to those in frontline services. It is those onstage ambassadors who, through continuous process improvement, need an efficient/flexible workplace in order to make their onstage presence seamless as they nurture their customers.

Healthcare customers (patient and family) expect nothing less than a safe, efficient delivery system that customizes its delivery to each individual patient because, in an infirmed state, it is, "all about me." Customization can only occur when an effective electronic database links customer profiling with offstage and onstage operational efficient flow of normal work production. The seamless flow of these systems has to be designed into a facility. It is then that those who receive care are served not only by a culture of well-being but also in a patient safe healthcare environment through EBD.

Biophilic Design

The concept for an improved patient safe healthcare environment by design is also embedded in findings that suggest stress, anxiety, and disorientation are factors that contribute to, among other outcomes, error in the workplace. The evidence-based movement has built its arguments around the work of Roger Ulrich and others who have made a strong case for the human need to be connected to nature in the delivery of and the receipt thereof during the healing process. This message has been heeded, and many of our best-practice healthcare facilities have created environments that have taken the studies quite literally and incorporated water features, plants, fish tanks, healing art programs, and infiltrated daylight deep into their interiors. I would like to suggest here that there is a deeper layer of understanding that has to be revealed in our work that will align with a more broadly defined concept for healthcare known as *biophilic design*.

Biophilic design is the deliberate attempt to translate an understanding of the inherent human affinity with natural systems and processes—known as *biophilia*

(Wilson, 1984; Kellert & Wilson, 1993)—into the design of the built environment (Kellert, Heerwagen, & Mador, 2008). As Kellert (2005, p. 25) states, “Contact with nature has also been reported to result in substantially improved quality of work, reduction of errors, fewer manufacturing defects, lower absenteeism, and lower sickness rates, all of which frequently produce significant economic savings.” A healthcare facility is a highly technical environment and typically thought of as negative, sterile, and devoid of its own brand of design. Although the EBD movement has done much to open the thinking around an outcomes-based approach to design decision making, it has just really laid the fundamental ground rules. The need to fully understand how best to improve the human condition, whether a caregiver or a patient/family member, lies in more directed research on how the built environment can replicate the healing effects of nature and all of its positive attributes.

Patient Safe Healthcare Facilities

It is, therefore, necessary to frame this discussion about a patient safe environment by first addressing the culture of well-being, and then branding the habitat that this culture resides in as one that is steeped in biophilic design. The next generation of healthcare facilities will launch a model of building that will be studied by other design sectors because of its highly effective yet remarkably restorative qualities for not only its customers but also for all who work and utilize its services. The 1999 mantra from the Institute of Medicine (IOM) to deliver safe, timely, efficient, effective, equitable, patient-centered care will then be realized (IOM, 1999).

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The Interior Designer as Safety Expert and Risk Manager

Jain Malkin

For many years the primary goal for interior designers of healthcare facilities has been to reduce the institutional appearance of hospitals to make them less intimidating through interior architectural detailing and the skillful selection of interior finish materials and by using furniture with wooden frames and woven upholstery fabrics instead of vinyl. Manufacturers of healthcare furniture and other products have worked very hard to marry aesthetics with durability, while also meeting stringent fire and sanitation codes.

The focus has shifted, however, from aesthetics to patient safety. That is not to say that these are mutually exclusive. Research indicates that the built environment can be a powerful force in reducing stress and enhancing coping skills, which leads to many physiological benefits for patients. What has changed is that there is a new mandate for interior designers that starts with a thorough understanding of patient safety and infection control issues that must be interlaced with code compliance, evidence-based design features, space planning options, and a bevy of other considerations.

Safety issues associated with the built environment are both macro and micro. Wayfinding is a macro issue that has ramifications for both visitors and staff as they struggle to find their destinations in what can seem like a maze. Newer hospitals and large ambulatory care centers combat this with good space planning but, over time, as additions and remodeling occur, the problem can emerge. Lighting is another macro issue. Poorly illuminated spaces can lead to falls, yet too much light overhead can create glare and have the same result, especially for the aging eye. However, a very high level of light is needed in rooms where medications are prepared to reduce errors.

Natural light cues many circadian functions for staff and patients causing the brain to increase or decrease the concentration of physiologically active hormones that, for patients, have the capacity to negatively impact healing and the perception of pain. An example of a micro lighting issue is the recessed nightlight in a patient's room:

The use of red or amber-colored LEDs is preferable as they are less stimulating and will not cause wakefulness, yet will provide enough illumination for safe navigation to the bathroom at night. Sleep/wake cycles are regulated by circadian rhythms. White light, which has a blue component, can interrupt sleep cycles. Because persons with color blindness may not be able to see red light, amber is considered a better choice. An additional safety measure can be affected by attaching a flexible strip of LED lights in a place where they are not visible, such as under the sink or vanity cabinet. This creates a soft glow of light.

Although HVAC system design as a macro issue impacts patient comfort and safety, the patient room is the locus where the management of hospital-acquired infections (HAI) can be most effective if one could only know what data can be relied upon. The Holy Grail is products that extinguish pathogens on contact, which has led to a frenzy of products developed to do just that. However, still in question is whether the in vitro lab data will be borne out in the real-world hospital setting and if a third-party independent lab can replicate the study with the same results.

Manufacturers see a great opportunity in developing solutions to deal with a very serious problem, while scientists and those responsible for patient safety demand evidence-based proof. Some of these products include solid-surface sink countertops containing antimicrobials and upholstery fabrics and cubicle curtains using AgION antimicrobial silver ion technology. A thinner-than-microscopic, nano-coating protective layer that can be applied to surfaces “purports to kill 99.9% of most microbes through a chemical reaction caused by exposure to visible light,” according to one group of researchers. There is, however, concern by some scientists and environmentalists that silver ions in antimicrobials can leach into the water supply and have other unintended consequences in the environmental lifecycle. Paints with antimicrobial additives are one such product. In the patient room there exists concern about cross-resistance in which bacteria become resistant to the antimicrobial itself and to antibiotic resistance.

Sinks and faucets in the patient room pose risks from biofilm buildup in infrared sink faucets and in sink drains when the faucet discharges directly over the drain, which causes biofilms containing viable organisms to splash on surfaces several feet away. Some manufacturers of plumbing fixtures have developed solutions to such problems through an auto-purging feature on a faucet that runs water very six hours.

To mitigate aerosolization of fecal matter when toilets are flushed, vendors are using silver ions in the glazing of the bowl. According to a scientist doing research for the Copper Development Association, a copper washer inserted into an infrared faucet will kill pathogens.

In fact, some of the most interesting research relevant to infection control centers on the use of copper alloys (60% copper) on the most critical touch surfaces in a patient room: the IV pole, tray table, bedrails, nurse call device, arms of high-back patient chair, and keyboard or input device. In studies conducted in 2011 at three prominent medical centers, copper has been shown to extinguish microorganisms. It appears to have innate antimicrobial properties. Funded by the Copper Development Association, the study research results were analyzed by a microbiologist at the Medical University of South Carolina who states that there is no leaching from metallic copper and it is totally recyclable. A copper nickel alloy will not tarnish. Compared to the ubiquitous stainless steel widely used in grab bars, but known to be microscopically able to harbor microorganisms in its uneven surface, copper alloy, although more expensive, would seem to be a better choice.

However, with so many critical touch surfaces in a patient room, unless one does all of them in copper alloy, how does one accurately analyze the return on investment? The cost of treating healthcare-acquired infections (HAIs) is significant and, depending on the pathogen, may extend a patient's hospital stay on average 26 days as opposed to the one-time capital cost of equipping vulnerable surfaces in the room with copper alloys. Perhaps manufacturers will start using copper in the bezels of physiological monitors and in bedrails, as examples, so that these products are more readily available and even become mainstream, which will drive the cost down. As of this writing, the preliminary findings indicate 69.1% fewer HAIs in patient rooms in which the six most high-touch surfaces were copper. It dropped to 61% in rooms in which some copper objects had travelled out of the room (Moran et al., 2011).

Copper alloys or other pathogen-mitigating finishes do not reduce the obligation to properly clean and disinfect surfaces in patient rooms. Numerous studies have documented poor compliance with effective discharge cleaning protocols, especially high-touch surfaces in patient bathrooms such as faucets, light switches, shower controls, and grab bars. HAI prevention is clearly a bundle of measures that includes handwashing compliance, use of antibiotic gels, management of

colonized and infected patients, environmental cleaning and disinfection, *in addition to* the proper selection and specification of effective products by the architect and interior design consultants.

Safety can be enhanced by proper installation techniques: How materials are joined to prevent crevices that cannot be disinfected, avoidance of a bump at the threshold to the bathroom that can create a tripping hazard, use of solid-surface sinks integral with the countertop to avoid joints and crevices where pathogens can collect, decorative trim or mouldings used in a headwall design if they cannot be easily cleaned, or vinyl wallcoverings used in a humid climate, which may support the growth of mold or fungi between the drywall and the back of the vinyl.

Patient room bathrooms have been the source of discussion for years. A room that seems so basic is actually quite complex when considering patient safety. Solve one problem and it leads to another: Eliminate the curb at the shower to reduce falls and get wet floors that might be slippery. A thoughtful discussion of this topic (Fink, Pak, & Battisto, 2010) along with a detailed checklist will be useful for design professionals and facility managers alike.

Clearly there are numerous intersecting issues and no easy answers. It is difficult to evaluate the many new products that carry claims of reducing or eradicating pathogens. Has the research been conducted by an independent lab? Was the methodology sound and appropriate? Healthcare interior designers will increasingly be relied upon to gather and evaluate this type of information and will become de facto safety experts and risk managers for the built environment.

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Designing the Hospital to Reduce Harm and Enhance Staff and Patient Well-Being

Paul Barach, MD, MPH

Safe Systems and a Culture of Safety

It is essential that we accept the construct that states that accidents are latent in systems, and, therefore, safety is a component of systems as well as their subcomponents. It follows that, if safety is a component of the system, it might also be described as a part of the culture of the system. The Institute of Medicine (IOM) report (2000), *To Err Is Human*, describes safety as an emergent characteristic of systems. It emerges not because one subsystem is near perfect, but because the aggregation of subsystems embodies it as a whole.

The challenge is to change the traditional hospital design process to incorporate the safety-driven design principles and to create or enhance the culture of safety. In planning for the new facility, we approach the hospital design process with a blank sheet of paper, an appreciation of the evidence that there is ample opportunity to improve hospital patient safety. We believe that improving hospital facility design will not only increase patient safety directly but also indirectly promote a safety-oriented organizational culture. The new foundation for understanding the occurrence of human errors considers that healthcare providers make mistakes because the systems, tasks, and processes they work in are poorly designed.

Organizational accidents have multiple causes involving many people operating at different levels. This translates into failures at the point of service (e.g., a physician ordering an allergenic drug for an allergic patient). Based on this idea, exceptional design of healthcare institutions will create a mindfulness that provides an environment that enables patient safety as well as a safety-oriented organizational culture. It will require a constant focus on safety by hospital leadership, physicians, and staff and will only be accomplished through a continuous cycle of evaluation and improvement of the facility, equipment, technology, and processes.

In addition to the overarching drive toward collective mindfulness, high-reliability organizations have two other features in common. First, after organizations identify potential deficiencies in safety processes, they eliminate these deficiencies through the use of robust process improvement methodologies to improve their processes.

Second, the organizations rely on a particular organizational culture to ensure the performance of improved safety processes over long periods of time and remain constantly aware of the possibility of failure. This may be called safety culture.

Changes to Traditional Design Process

The traditional design concepts can be summarized as follows.

- The physical environment for healing is a shelter, but has little special interaction with the healing process or operation. The healing environment is separate, but not particularly special.
- The physical environment for healing is an edifice or monument signifying the importance of an individual, a community, or an institution.
- The physical environment for healing is an asset whose value is seen in terms of its real estate characteristics.

In contrast, we propose our concept as follows.

- The physical environment for healing is an integral subcomponent of the care delivery process. Like other tools and resources, its design, use, and application either promote or hinder the attainment of high-quality, reliable care.

The characteristics of the physical environment interact with the care process through physiological, cultural, and psychological pathways. The interactions may directly or indirectly effect caregivers, patients, support personnel, equipment, and operational plans. Improving the physical environment layer in Reason's Swiss cheese lies in the process by which the physical environment is created.

Improving the Design Process

Why do deficiencies in the designed physical environment occur? While there are limited high-quality peer-reviewed studies of this question, the design process does have a number of characteristics that could be improved. Design professionals, in the course of study for their profession, generally do not study ergonomics, human factors, or the science of how human beings interact with their environment. One of the unstated conclusions of Donald Norman's book, *The Design of Everyday Things*

(2002), is that designers don't seem to know much about everyday users. Designers study design, not human beings and their affordances. This deficiency manifests itself in the results of their work. Aside from not having a deep understanding of human performance and its limitations (i.e., fatigue, stress, sensory degradation, etc.), designers are insulated from clinicians.

This happens because designers make assumptions about users based on their own (and not the users') experience and because those who commission designers are not willing to finance sufficient communication with users for an understanding to be developed, which leads to frustration among the users and the designers.

Healthcare building design projects often begin with a set of assumptions, made by the owners, the designers, or others, that are not tested before or during the design process. For example, a functional program may be created by the owner and stipulated to the designer as a given. No opportunity exists to question or test the contents of this program or to work with clinicians and others involved in care and support of care to find better methods. The process of design commonly used in healthcare is linear. It starts with the architect working with the givens, proceeds to a greater definition of the floor plan and massing, then adds equipment, information technology, building systems, furnishings, and other components. There is a natural and financial inclination not to loop back to look at evolving issues in a holistic light. It proceeds to a greater definition of the floor plan and massing, then adds equipment, information technology, building systems, furnishings, and other components.

There is a natural and financial inclination not to loop back to look at evolving issues in a holistic light. If the plan is done, the solution must be a different piece of equipment, a different furnishing, or, even worse, a process change. Likewise, after the equipment and technology are selected, usually just before construction begins, there is a determined resistance to changing any part of the design, which has been determined before. These characteristics of the process are further exacerbated by the fact that it is generally led by a single component of the design team, most frequently the architect. Another closely related scenario, for the purpose of this discussion, is that the team is led by a program manager, a construction manager, or by an owner's representative. The problem with this form of leadership is that, despite best intentions, it tends to focus on one aspect of the project (i.e., the budget, the schedule, or the design) to the detriment of others.

Another weakness of the current building design process is that it treats the building as an independent entity in isolation to the community. The process invariably becomes focused on revenue and return on investment. As soon as someone mentions a potential cost for the project, that number becomes fixed in the minds of all, particularly those in the hospital organization tasked with financial responsibilities. It makes little difference whether this number has been derived from a careful analysis of the scope and the building cost environment. The number is, to use the jargon of the trade, cast in concrete. No amount of discussion, logic, or pleading can change the now-rigid number. Any change is termed a *cost overrun*, which requires pinning the fault on some entity not connected with the original miscalculations.

Rather than trying to improve a process, which has demonstrably yielded inadequate results, we suggest that a new process be created. The design process for patient safety must include four goals:

- Reduce the risk of healthcare-associated (caused by treatment) injury to patients and healthcare providers.
- Remove or minimize hazards, which increase risk of healthcare-associated injury to patients.
- Educate the design team about the complexity of designing healthcare settings for safe outcomes.
- Engage the clinicians and community early and in a sustained manner.

The strategy that we advocate for achieving these goals incorporates the following concepts.

- Treat the creation of safety as part of a process that addresses the resilience and integration of all system components, i.e., as part of the culture.
- The creation of safety process involves users and stakeholders at all levels of the institution throughout the entire process.
- A complete array of disciplines and knowledge is necessary at the start of the project.
- Use a wide range of tools based on the organization's risk management data

including: failure modes and effects analysis, root cause analysis, mock-ups, simulation, testing, and data modeling.

- Create and require pre-July 17-19, 2011, master planning team training about the patient safety problems, about the process of building design, and about the process of collaboration with others to derive effective and efficient solutions.

The healthcare system has only recently begun to approach patient safety in a more systematic way. A major tension that characterizes this process is the attempt to achieve a balance between learning and control in complex systems with technical, social, and organizational components. Efforts to improve learning in healthcare are marked by better information flow, discovery, flexibility in thinking, embracing of failures as learning opportunities, and core incentives to promote voluntary participation of all stakeholders in the process. Organizational accidents have multiple causes involving many people operating at different levels, which translate to failures at the point of service (e.g., a physician ordering a drug to which a patient is allergic, patient falls due to use of over-smoothed surface materials). Based on this idea, exceptional design of healthcare facilities will provide an environment of patient safety as well as a safety-oriented organizational culture for staff. It will require a constant focus on safety by hospital leadership, physicians, and staff and will only be accomplished through a continuous cycle of evaluation and improvement of the facility, equipment, technology, and processes.

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Patient Safety Issues: The Critical Link Between Patient Safety and Staff Safety and the Inclusion of Human Factors Expertise in Healthcare Design

Mary W. Matz, MSPH, CPE

I propose that when you design for staff safety you are also designing for patient safety. The relationship between staff and patient safety is a substantial and critical one, however rarely considered by healthcare organizational leadership and much

less by design professionals. The status of staff safety should be raised to the level of patient safety. It should be of as much of a concern as patient safety. Interventions that promote staff safety impact patient outcomes, the quality of patient care, patient mobility, the number of patient days of care, staff retention, and of course, the health and well-being of caregivers.

Facility design features influence staff safety and ultimately patient safety. Floor surfaces, transitions, and inclines either facilitate or deter staff and patient slips, trips, and falls. Adequate space in patient toilet, treatment, diagnostic, and other rooms is required to utilize proper and safe lifting techniques even when using assistive devices. Adequate space negates the need to move equipment, beds, and other items to perform lateral and other patient transfers and moves. Adequate space includes space for maneuvering equipment and people in rooms but also in hallways, toilet rooms, shower/bath rooms, and around corners. Insufficient doorway dimensions prevent the use of mobile patient-handling lifts and other rolling equipment. Entry and exit, especially in emergency situations involving bariatric beds, are difficult in many healthcare facilities.

Inadequate storage space is universally problematic in healthcare facilities. Limited and inaccessible storage space for mobile patient-handling equipment significantly impacts staff compliance in the use of safe patient-handling techniques. Serious injuries may occur if the weight capacities of toilets, chairs, handrails, and other mounted objects in patient rooms, bath and shower rooms, hallways, waiting rooms, and elsewhere are not taken into consideration when there is potential for use by morbidly obese patients and visitors. Design features can also facilitate staff compliance in washing hands and using protective gloves, lifts, and other items necessary for staff protection.

Notable and increasingly understood staff/patient safety connections are related to patient handling and movement. Risks involved in manual patient handling lead to negative consequences for caregivers, patients, and organizations. In regard to staff, musculoskeletal injury rates from manually moving and lifting patients are higher than those of other seemingly more "risky" industries. Consequences of these multitude of patient-handling injuries are that staff provide care in pain, while medicated, while fearing injury or re-injury, ultimately at a less-than-desired level of care. Under these circumstances, the potential for errors increases, putting both patients and staff at higher risk.

Fortunately, great progress was made when the Facility Guidelines Institute, Health Guidelines Revisions Committee incorporated an ergonomic evaluation process, the Patient Handling and Movement Assessment (PHAMA), into its *2010 Guidelines for the Design and Construction of Healthcare Facilities* (Facility Guidelines Institute, 2010). This PHAMA provides designers and healthcare leadership/owners direction in determining what patient-handling equipment is necessary to reduce staff risk of injury, as well as offering considerations for design when including fixed lifting systems. As stated in Victoria Hospital's Industrial Association Advisory Service: Final Report and Evaluation (September 2005), "It is reasonable to conclude that design is critical to reducing lifting/transferring injuries and that it accounts for a significant part of the benefits realized."

As well, I propose that incorporation of human factors/ergonomic methods and interventions will provide a means to identify and design out the many inherent latent conditions that interact in complex ways and that result in adverse events (Reason, 2000). The inclusion of the ergonomic recommendations from a PHAMA is just the beginning. Incorporation of ergonomics/human factors principles into design is an underutilized strategy that will facilitate both staff and patient safety. Human factors methods analyze the whole of the interconnectivity of the physical environment and its impact on staff functions and patient care activities. Those with expertise in human factors should always be a part of the design team.

In summary, staff safety must influence healthcare design decisions and incorporation of the science of human factors/ergonomics must become the norm in healthcare design.

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Human Factors Systems Approach to Healthcare Facility Design

Pascale Carayon, Ph.D.

A recent study by Teltsch et al. (2011) shows how conversion from multibed rooms to single rooms in an intensive care unit (ICU) led to a reduction in the transmission of infections. This study shows how physical redesign of a healthcare setting (i.e., an ICU) can produce patient safety benefits in one domain. However, the physical space is used by multiple users (e.g., patients, family, nurses, physicians, unit clerk, housekeeping, biomedical engineering, X-ray technicians). This study did not examine the challenges experienced by, for instance, nurses when patients are in single rooms: nurses' workload may increase because of the distance between patients. In addition, the study documents benefits in one important domain, i.e., infection prevention, but did not assess the impact of the physical redesign on other patient safety domains. For instance, it is possible that the move to single rooms produced safety problems in other domains because of the reduced ability of clinicians to monitor multiple patients simultaneously? We propose that a human factors systems approach to healthcare facility design is necessary in order to improve overall patient safety.

Needs of the multiple users of healthcare physical environments should be considered in the healthcare facility design process. The outcome will be a physical environment that supports users' ability to perform their various tasks in the physical space and, therefore, produce a range of performance and safety benefits, including patient safety (Alvarado, 2007; Carayon et al., 2006; Carayon, Karsh, Alvarado, Weinger, & Wiklund, 2011; Karsh, Holden, Alper, & Or, 2006). The human factors user-centered design approach to healthcare facility design recognizes the importance of users and their characteristics, the tasks performed by the users, the various tools and technologies, and organizational factors (Carayon, 2009; Smith & Carayon-Sainfort, 1989). The physical environment is one of many other elements of the work system and needs to fit with the rest of the work system. According to the systems engineering initiative for patient safety (SEIPS) model of work system and patient safety, the work system (including the physical environment) can affect a range of care processes, which in turn can influence patient safety and employee and organizational outcomes (e.g., satisfaction with the space, individual performance) (Carayon et al., 2006) (see Figure 1).

According to the human factors and ergonomics literature (Carayon, Karsh, et al., 2011; Parsons, 2000), the following environmental issues are important for human performance, health, comfort, and safety: noise, lighting, temperature and humidity, vibration, space, and layout. All of these environmental issues need to be addressed in the healthcare facility design. In addition, the interactions between the physical environment and other elements of the work system need to be considered. The SEIPS model can guide the identification of work system factors that interact with the physical environment to influence human performance and safety.

- Characteristics of the users. Who are the users of the facility? What are their characteristics (e.g., height, reach envelop, individual differences)?
- Tasks. What are the tasks performed by the users? How often are the tasks performed? What space and other environmental characteristics influence the performance of these tasks (e.g., amount of space available to perform a task, visibility)?
- Tools and technologies. Is there sufficient space for the tools and technologies to be accessible and usable by various users including maintenance and housekeeping?
- Organization. Does the physical environment support teamwork and communication?

These questions are examples based on the SEIPS model and should be considered in the healthcare facility design process.

The SEIPS model can also be the basis for analytic methods that are used during the healthcare facility design process. Care processes should be analyzed and the work system factors involved in the care processes should be identified during the design process. Then, the proposed new design of the physical environment can be assessed in relation to the rest of the work system. This anticipatory design of healthcare facilities can be done using proactive risk-assessment methods such as failure modes and effects analysis (FMEA) (Carayon, Faye, Hundt, Karsh, & Wetterneck, 2011). We have developed and evaluated proactive risk-assessment methods to assess the safety risks associated with the following technologies before their implementation: smart infusion pump technology (Wetterneck et al., 2006) and computerized

physician order entry/electronic health record technology (Carayon, Faye, et al., 2011). The proactive risk-assessment methods rely on an in-depth understanding of the work system factors involved in specific care processes; this information can then be used to identify potential failure modes (or vulnerabilities) in the care process with the new technology. These methods could be adapted to identify potential safety problems associated with a proposed new physical environment. This type of analysis can be done during the healthcare facility design process before the final decisions are made about the physical environment.

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Design for Patient Safety: Thinking at the Intersection

Ron Smith, AIA, ACHA

For healthcare leaders responsible for the performance of healthcare delivery in an age of increasing accountability, and their teams who plan and design space, care delivery, and information technology (IT) systems to improve performance, I offer the following as food for thought. From my perspective of 25 years as a healthcare architect, the role of design ranges from the practical application of codes and guidelines to the exploration of innovations in care delivery and technology to define new configurations of space and workflow. It is a team effort involving domains of the architect/engineer team, clinical staff, and IT staff. In most cases it involves a series of handoffs of knowledge between domains. My intent here is to open a discussion on the value of integration of knowledge from these team domains to achieve higher levels of performance.

Space is often referred to in healthcare environment research as a *latent condition* that contributes to the occurrence of errors. Some latent conditions can be created when design solutions are based on policies and procedures that become obsolete, and the logic underlying them long since forgotten (Sargut & McGrath, 2011). Chaudhury, Mahmood, and Valente's (2009) review and analysis demonstrates a cause-and-effect relationship between certain environmental variables and errors in acute care settings.

As a designer of space, I would argue that as space is *designed*, it includes intentionality on the part of the design team to meet specific performance goals,

and that a key basis for its being a latent condition is that the design intent becomes disconnected from the intentions of active frontline processes of care delivery and health IT.

I see two ways in which we can keep space more clearly in view as part of the active conditions that promote safety.

1. Create a shared set of performance goals and design criteria by *connecting* space design thinking, care design thinking, and health IT design thinking in an interdisciplinary team, making them transparent across all three domains. The *2010 Guidelines for Design and Construction of Health Care Facilities Appendix 1.2-4* included a suggestion for patient safety risk assessment that is a good start in this direction.
2. Keep the design thinking alive and connected so to speak, through our ability to link and connect people and information in powerful ways with evolving technology.

To illustrate this potential, consider the situation of errors in the distribution and administration of medication, a process involving space, care delivery, and IT systems (Conrad, Fields, McNamara, Cone, & Atkins, 2010; Griffis, 2011; Madni, 2011). Design models are created for space, care delivery, and health IT. Scenarios of functionality, utilization, value stream mapping, safety controls, and efficiency are analyzed in the design process. Suppose that in the design process, the data from analysis in the multiple domains are evaluated together at key intervals by the same interdisciplinary design team that established the shared performance goals and design criteria, with the team doing its ongoing design work at this *intersection* of knowledge, evaluating the opportunities for medication safety improvements in each domain, and seeing the effects of each one on the other.

Once the facility is built and activated, we know that it's unlikely we'll eliminate all errors in a system involving humans (Madni, 2011). So, what if we keep the design models alive and keep the data connected after activation and continue to use them to evaluate errors, the causes, circumstances, and location where they occur in the system and enable the organization to identify points of work process and space that could be refined to further improve the overall outcomes?

By connecting knowledge from multiple domains in the design process, and *keeping* it connected, I believe that an organization could identify and rectify potential latent conditions in the healthcare environment (Reason, 2000) by helping to keep track of the design parameters that underlie the latent condition. This will allow the organization to understand the reasoning and intervene effectively as suggested by Madni (2011). And finally, if such information and outcomes data were made available to other design teams in a shared database, it could serve to encourage industry-wide research and development to improve patient safety.

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APPENDIX III: DESIGN TOOL SUMMARIES

1. Failure Modes and Effects Analysis (FMEA)

Definition/Brief Description

Failure modes and effects analysis (FMEA) is a systematic, proactive approach to evaluating a system, design, or process in order to identify potential failures; to evaluate relative effects and consequences of the failures; to identify the parts that are most in need of change; and to reduce or eliminate the failures, errors, and problems before they reach patients (Carayon, Alvarado, & Hundt, 2007; Grout, 2007; Institute Healthcare Improvement, n.d.; Reiling, Knutzen, & Stoecklein, 2003). There are two types of FMEA: process FMEA, which assesses potential process failures and their effects with the assumption that the product design is perfect; and design FMEA, which assesses the potential failures of product and their effects assuming that the process is perfect (Reiling et al., 2003).

History

FMEA was initially developed in the U.S. military. In 1949, it was included in the Military Procedure document Mil-P-1629. In 1960, FMEA was used in the aerospace industry during the Apollo missions. In 1970s and 1980s, U.S. automotive companies began to incorporate FMEA in the manufacturing processes for safety and regulatory considerations (Kmenta, 2002).

FMEA has been widely used in various industries, such as manufacturing, chemical industry, food services, and healthcare (Anthony et al., 2005). One successful example of applying FMEA in healthcare design is the construction of an 82-bed, acute care facility at St. Joseph's Hospital, West Bend, WI, which was opened in 2005. In this project, FMEA was utilized to optimize facility layout (interdepartmental relationships), patient room configuration (e.g., mirrored room vs. same-handed room), and patient room components (e.g., hardware, headwalls) in three stages of this project—adjacencies, schematic design, and design development (Reiling, 2005). Several national organizations, including the Department of Veterans Affairs (VA) National Center for Patient Safety (NCPS) and the Institute for Healthcare Improvement (IHI), have developed standard tools and processes to

facilitate FMEA applications in healthcare organizations (IHI, n.d.; U.S Department of Veterans Affairs (VA), n.d.a). Many healthcare organizations have used the above tools for the implementation of FMEA at their facilities (see examples at IHI FMEA tool website [Institute for Healthcare Improvement (IHI), n.d.a])

Process

Although some variations exist among the processes recommended by different organizations (e.g., Joint Commission's 6-step process, IHI's 7 steps, VA NCPS's 5 steps), a FMEA can generally be conducted in the following steps.

1. Select a process/product for analysis. The analysis of a complex process (medication management) may be tedious and take much time. In such cases, it is recommended to select a subprocess (e.g., medication dispensing).
2. Organize a multidisciplinary team. This should include individual workers involved at any point of the process.
3. Describe all steps in the process or functions using graphics (flowcharting). See Process Analysis.
4. List all potential failure modes for each step, and identify possible effects of these failures on patients. Brainstorming is a major method commonly used in this step. An alternative method—in situ simulation—may help identify those potential failures that are often missed in brainstorming in a more systematic and objective way and trigger participants' memory about past experiences with failures (Davis, Riley, Gurses, Miller, & Hansen, 2008). As examples, key failure modes found during the FMEA in the block design/adjacencies stage at St Joseph's Hospital can be found in Table 1.
5. Prioritize critical failure modes by subjectively rating potential failures on the severity of their effects (i.e., severity), the likelihood of occurrence (i.e., occurrence), and the likelihood of detection (i.e., detection) on a scale of 1-10. Simplified rating methods include scoring severity and occurrence as high, medium, and low (Reiling et al., 2003); scoring severity as catastrophic, major, moderate, and minor; and score occurrence as frequent, occasional, uncommon, and remote (VA, n.d.a, see Table 2). Typically, a risk priority number (RPN) was calculated (by multiplying the scores of severity, occurrence, and detection) for each potential failure. Then the RPNs of potential failures were ranked.

Improvement efforts should be focused on failure modes with the highest RPNs. Alternatively, VA NCPS recommends the use of a scoring matrix (see Table 2).

6. Plan improvement efforts based on priorities of potential failure modes. Root cause analysis (RCA) may be conducted to identify effective interventions to reduce risks. (RCA is another major safety design tool. See Table 3 for a comparison between RCA and FMEA.) Some interventions can be implemented relatively easier through rapid cycle improvement. Other interventions may need more extensive work and interdepartmental collaboration (Davis et al., 2008). RPNs can also be used to evaluate potential impact of the proposed changes and monitor improvement over time (Institute of Healthcare Improvement, n.d.). The failure modes, causes, effects, ratings (severity, occurrence, detection), RPNs, and interventions are typically documented on a FMEA form/spreadsheet. (Examples of design improvements resulted from FMEA at St. Joseph's Hospital are included in Table 1.)

Limitations

FMEA is a well-developed tool that is valuable in identifying potential problems at early stages and generating solutions for these problems before they cause actual harms. Correcting problems at early stages (e.g., design) is less expensive than improvements at later stages (e.g., after construction). However, it is time-consuming and laborious to conduct FMEA especially on complex processes/issues (Reiling et al., 2003). Because a FMEA process largely depends on subjective inputs, potential biases exist due to different perspectives of different individuals (Reiling et al., 2003). Further, FMEA focuses on failure modes one at a time, while adverse events often result from multiple failures and hazardous conditions (Spath, n.d.). Another criticism is that RPN is not a good measure of risk. Alternatives such as expected cost may more accurately estimate the risks (Kmenta, 2002).

Table 1 Failure Modes and Design Changes in Adjacencies Stage at St. Joseph's Hospital, West Bend, WI

Potential Failures/Effects Mode(s) (Day/Night)	Severity or Occurrence High-Med-Low	Adjacency Changes to Minimize or Eliminate Potential Failure/Effect	Recommend Adjacency Change
Traffic patterns for movement of materials cause food, waste, linen, etc., to cross paths	High	Create vertical transportation of these items to minimize service traffic in presence of patients	Designate garden level as nonpatient, for support services only
Transporting critical patients between services creates staff shortage	High	Minimize transport: Bring services to patient when possible or relocate services closer to patient	Locate intensive care unit and radiology in proximity
Potentially violent patients cause risk to mothers/babies in obstetrics	High	Create distance between vulnerable patients and higher risk patients	Locate obstetrics on 2nd floor and behavioral health on 1st floor
Potentially violent patients admitted through emergency department transported longer distance to behavioral health unit	High	Minimize distance for transport of behavioral health patients from emergency department to behavioral health unit	Locate emergency department and behavioral health on 1st floor
Breach of privacy for patients transported through public corridors to behavioral health unit	High	Minimize transport need in public corridors of behavior health patients	Locate behavioral health on 1st floor with separate entrance

Note. The table was adapted from: "Application of six sigma and DFSS for the ultimate patient safe environment." By K. Bruegman-May, 2005, March, Presented at the 3rd Annual Conference on Successfully Implementing Six Sigma in Healthcare, New Orleans, LA.

Table 2 VA NCPS HFMEA Scoring Matrix

Probability	Severity			
	Catastrophic (4)	Major (3)	Moderate (2)	Minor (1)
Frequent (4)	16	12	8	4
Occasional (3)	12	9	6	3
Uncommon (2)	8	6	4	2
Remote (1)	4	3	2	1

Note. From "Healthcare failure mode and effect analysis (HFMEA)" by the U.S. Department of Veterans Affairs, National Center for Patient Safety, n.d.a. Retrieved July 31, 2011, from <http://www.patientsafety.gov/CogAids/HFMEA/index.html>

Resources

Institute for Healthcare Improvement (IHI): Failure modes and effects analysis (FMEA) tool, <http://www.ihi.org/Workspace/tools/fmea/>

U.S. Department of Veterans Affairs National Center for Patient Safety healthcare failure mode and effect analysis, <http://www.patientsafety.gov/CogAids/HFMEA/index.html>

Joint Commission (2010). *Failure mode and effects analysis in health care: Proactive risk reduction* (3rd ed.). Chicago, IL: Joint Commission Resources.

2. Balanced Scorecard

Definition/Brief Description

The balanced scorecard is a relatively new approach to strategic management that integrates an organization's key initiatives, methodologies, and critical perspectives (Meliones et al., 2008; Shutt, 2003). It “translates an organization's mission and strategy into a comprehensive set of performance measures that provide the framework for a strategic measurement and management system” (Kaplan & Norton, 1996, p. 2). The balanced scorecard retains an emphasis on achieving financial objectives of traditional approach, but also includes the performance drivers of these financial objectives. The scorecard measures organizational performance across four balanced perspectives: financial, customers, internal business processes, and learning and growth. The balanced scorecard “enables companies to track financial results while simultaneously monitoring progress in building the capabilities and acquiring the intangible assets they need for future growth” (Kaplan & Norton, 1996, p. 2).

History

The balanced scorecard was developed by Robert Kaplan, a professor at Harvard Business School, and David Norton, a cofounder of the Nolan Norton Institute in 1990s. Previously, business management models had targeted finances or quality improvements only and emphasized historical information without considering organizations' intangible and intellectual assets. The balanced scorecard integrates and balances financial and nonfinancial performance measurement systems. It also educates employees across an organization (Shutt, 2003). It has been widely used in industry, business, government, and healthcare. Examples of successful

implementation of the balanced scorecard in healthcare include: Duke Children's Hospital in Durham, NC; Peel Memorial Hospital in Ontario, Canada; Hudson River Psychiatric Center in Poughkeepsie, NY; and so on (Shutt, 2003). One example of the balanced scorecard in healthcare design is the building performance evaluation (BPE) scorecard (Figure 1 and Table 4) developed by Government of Alberta, Canada (GoA, a CHD Pebble Partner). The BPE is applicable to different phases of a design/construction project—pre-design, design, construction, and post-occupancy (Steinke, Webster, & Fontaine, 2010).

Process

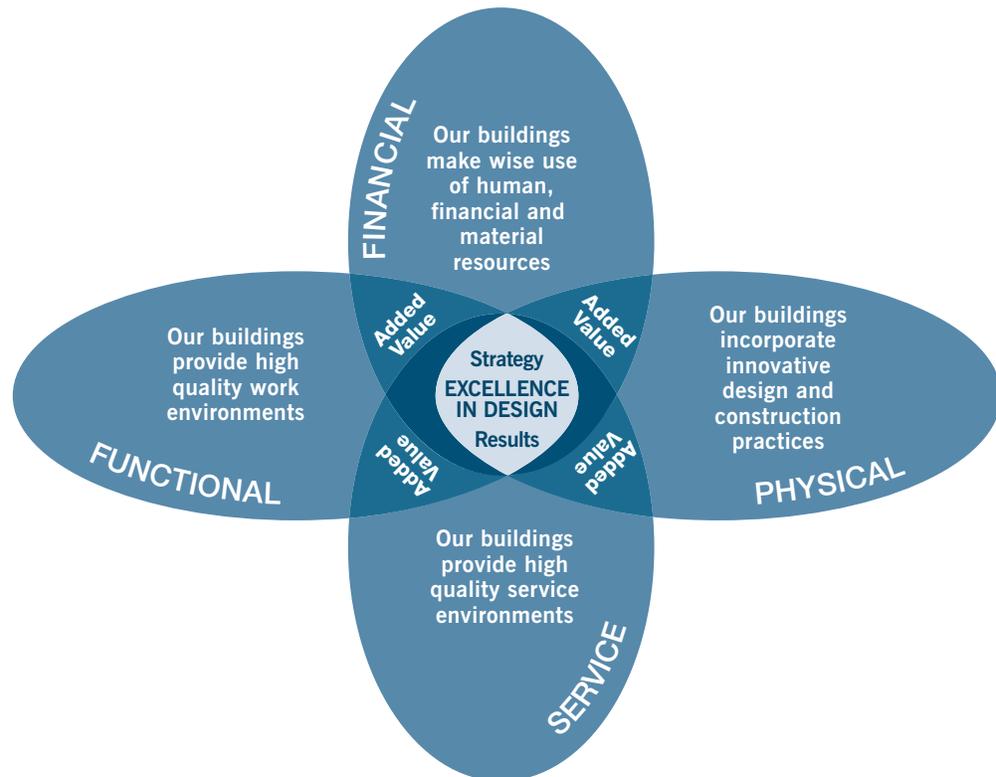
A characteristic of the balanced scorecard in healthcare is that it puts more emphasis on patient safety and quality of care rather than financial performance (Meliones et al., 2008). The process of designing and implementing the balanced scorecard can be summarized as follows (Meliones et al., 2008; U.K. National Health Service Institute for Innovation and Improvement, n.d.):

1. Develop the mission, vision, and strategic plan, and set strategic goals in multiple dimensions. The traditional balanced scorecard typically has four perspectives: financial performance, internal process, customer, and learning and growth. Financial performance is often the top priority. Significant modifications should be made to customize the balanced scorecard in order to serve the needs of specific healthcare organizations. The balanced scorecard perspectives at Duke Children's Hospital include: quality and patient safety, customer, finance, and work culture. Among these, quality and patient safety is the most important. The four perspectives in the BPE scorecard at GoA include: service performance, functional performance, physical performance, and financial performance (Steinke, Webster, & Fontaine, 2010).
2. Define specific objectives for each perspective (e.g., profitable growth). Limit three to four objectives per perspective to focus on initiatives driving the strategic plan.
3. Develop key metrics that measure performance (e.g., a metric for profitable growth is the growth in net margin) and set targets for each metric (e.g., 2% annual increase in net margin). Specify metrics that are measurable and can be collected at least quarterly. The metrics (e.g., morbidity, rehospitalization, infection rates, length of stay, daily census, hospital discharges, and the Hospital Consumer Assessment of Healthcare Providers and Systems [HCAPHS] or Press

Ganey score) can be derived from various databases such as hospital financial databases, patient safety internal reporting systems, and patient satisfaction survey data. A single score aggregated from all metrics can provide a balanced view of an organization's performance. When setting a target, it is recommended to choose a modest improvement from baseline.

4. Identify strategic initiatives to achieve targets.
5. Implement the balanced scorecard. Individual scorecards should be implemented at the service unit level and operation unit level in addition to the organization level. By this tiered approach, focused improvement efforts at direct patient care can be aligned with the overall strategic goals of the whole organization.

FIGURE 1
Four Perspectives of the Building Performance Evaluation (BPE) Scorecard, Government of Alberta, Canada



Note. From "Evaluating Building Performance in Healthcare Facilities: An Organizational Perspective," by C. Steinke, L. Webster, and M. Fontaine, 2010, *Health Environments Research and Design Journal*, 3, p. 73. Copyright 2010 by the Vendome Group. Reprinted with permission.

Table 3 The Building Performance Evaluation (BPE) Scorecard, Government of Alberta, Canada							
	Objectives	Indicators	Targets			Measurement	Evidence-Based Design Initiatives
			2008	2009	2010		
Service Do our buildings add value to the client experience?	<ul style="list-style-type: none"> ↑ Client satisfaction / comfort ↓ Length of stay 	<ul style="list-style-type: none"> • Client satisfaction / comfort • Length of stay 				<ul style="list-style-type: none"> • BPE questionnaire—clients • Recorded data 	
Functional Do our buildings add value to the work environment?	<ul style="list-style-type: none"> ↑ Staff satisfaction / comfort ↓ Turnover 	<ul style="list-style-type: none"> • Staff satisfaction / comfort • Turnover 				<ul style="list-style-type: none"> • BPE questionnaire—staff • Recorded data 	
Physical Do our buildings add value in terms of physical operations?	<ul style="list-style-type: none"> ↑ Energy consumption ↓ Water usage 	<ul style="list-style-type: none"> • Energy consumption • Water usage 				<ul style="list-style-type: none"> • BPE questionnaire • Recorded data • Physical measurements 	
Financial Do our buildings add value for money?	<ul style="list-style-type: none"> ↑ Energy costs ↓ Water costs 	<ul style="list-style-type: none"> • Energy costs • Water costs 				<ul style="list-style-type: none"> • Recorded data • Calculations 	

Note. From “Evaluating Building Performance in Healthcare Facilities: An Organizational Perspective,” by C. Steinke, L. Webster, and M. Fontaine, 2010, *Health Environments Research and Design Journal*, 3, p. 77. Copyright 2010 by the Vendome Group. Reprinted with permission.

Limitations

The success of the balanced scorecard tends to depend on the selection of metrics and targets. People may ignore important issues that are not included in the scorecards. This potential problem calls for a more balanced set of metrics (12manage, n.d.). Other challenges in implementing the balanced scorecard involves difficulties in gaining initial approval, obtaining executive time and commitment, gaining employees’ commitment, keeping the scorecard simple, and establishing performance measures without exacerbating employees’ fear (Shutt, 2003).

Resources

Balanced Scorecard Institute, <http://www.balancedscorecard.org/>

U.K. National Health Service Institute for Innovation and Improvement: Quality and service improvement tools, http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/balanced_scorecard.html

3. Work Sampling (Time-Motion Study)

Definition/Brief Description

Work sampling is a method of measuring time that workers spend in various activity categories (Groover, 2007). Another closely related method is time-motion study, which is a systematic study of work systems to optimize and standardize work system and methods, determine the time standard for a specific task or operation, and train the workers in the optimized method (Barnes, 1980). In some cases, data are collected on several domains including the percentage of time spent on various predetermined activities (activity), the purpose of the activity (function), and whom the individual contacts while performing the activity (contact). In these cases, work sampling is called multidimensional work sampling (Carayon, Alvarado, & Hundt, 2003, 2007).

History

Work sampling, time study, and motion study represent a key method of “scientific study of work” initiated in the 1910s (Carayon et al., 2003). The method originated from the time study developed by Frederick Taylor for determining time standards, and the motion study developed by Frank and Lilian Gilbreth for improving work methods (Carayon et al., 2003; Barnes, 1980). Work sampling was developed in manufacturing but has been applied in healthcare and other settings. For example, Linden and English (1994) examined the time spent by nurses on four categories of tasks and used the data to identify problems and improve work efficiency and nurse satisfaction. Carayon and Smith (2001) studied the impacts of electronic medical record (EMR) technology on various jobs by observing work activities, functions, and contacts before and after the implementation of EMR.

Process

The process of conducting a work sampling study includes the following steps (Carayon et al., 2003; Groover, 2007):

1. Identify the tasks to be examined.
2. Break a complex task into small, simple steps (task elements). To obtain a complete exhaustive list of tasks (task elements), job descriptions can be examined to develop a draft list of tasks. The list then can be modified based on feedback from workers and pilot tests.

3. Determine the details of observation process, including the tools to be used for data recording (e.g., radio frequency identification, personal digital assistant), number of observations, number of days/shifts, time for observation, information to be recorded, and number of observers.
4. Conduct observation to collect data about work activities (e.g., activity, function, contact, movement). A worker may be observed for several times at random or fixed time intervals.
5. Analyze data, report results, and make recommendations.

Limitations

One important assumption of work sampling is that the work tasks are observable, unambiguous, and mutually exclusive and exhaustive. This assumption is not always suitable for some work tasks including nursing jobs. In addition, the method can only record what can be seen but not what is inferred (Carayon et al., 2003).

4. Link Analysis

Definition/Brief Description

Link analysis is an ergonomics method of identifying and representing links (or relationships) between interface components of workspace to determine the nature, frequency, and importance of the links (Carayon, Alvarado, & Hundt, 2003; Stanton, Salmon, Walker, Baber, & Jenkins, 2005). The term *link* can refer to movements of attentional gaze or position between system components (eye, body, foot movement links), communication with other components (visual, auditory, tactile communication links, e.g., nurse-to-physician communication), and control links (e.g., access and use of bedside computer) (Carayon et al., 2003).

History

Link analysis was initially developed for the design and evaluation of process control rooms (Stanton et al., 2005). It has been used to optimize workspace layout in other settings including healthcare. For example, link analysis was used to evaluate nurse work tasks, track movements and connections, and identify traffic patterns. The information can help the development of environmental changes to improve work efficiency that may ultimately impact patient safety and quality of care (Carayon

et al., 2003). In one example of link analysis, movements among components (e.g., nurses, equipment, devices, furniture) in a soiled workroom were observed, and workroom layout was improved based on the analysis (Lu & Hignett, 2009).

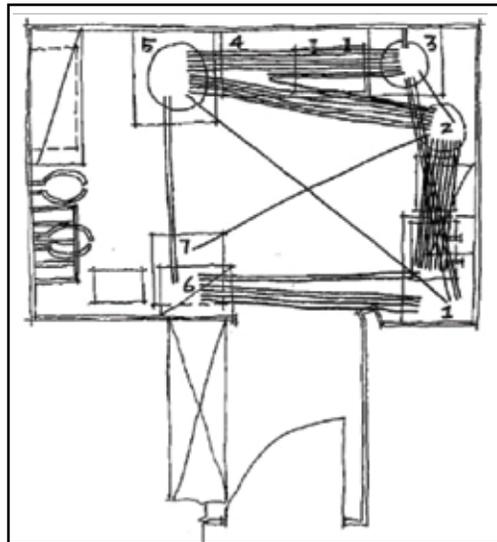
Process

The following is a process of link analysis recommended by Stanton and colleagues (2005).

1. Identify task(s) to be analyzed. When evaluating the design of a device or workspace, it is recommended to focus on a set of tasks representative of the full functionality of a device or workspace.
2. List task steps. Create a list of all the component task steps involved in the task performance.
3. Collect data. Perform a walkthrough of the task steps, conduct observation of workers performing tasks, and record the links between components and the number of times these links occur during task performance.
4. Construct link diagram and link table. The links between interface components recorded during data collection are represented as direct lines connecting the components on a schematic layout of the workspace. The frequency of a link is represented by the number of lines (see Figure 2 for an example of link diagram of a soiled workroom). The links can also be summarized in a link table with components located in the heads of the rows and columns and the number of links entered in the cells.
5. Propose design improvements. The redesign aims at reducing the distance between the linked interface components, especially the most important and frequently linked components.

FIGURE 2
Link Analysis of a Soiled Workroom

Note. From “Using Task Analysis in Healthcare Design to Improve Clinical Efficiency,” by J. Lu and S. Hignett, 2009, *Health Environments Research and Design Journal*, 2, p. 64. Copyright 2009 by the Vendome Group. Reprinted with permission.



- Note:**
1. Sink 1 with worktop
 2. Yellow-bag bin
 3. Water closet
 4. Sink 2 with worktop
 5. Bedpan disposal unit
 6. Shelving
 7. Commode chair under shelving
 8. Doorway

Limitations

Link analysis may require considerable time in conducting observation studies. It only considers the basic physical relationships that are observable but may not take in account cognitive processes and mechanisms.

5. Process Analysis (Process Chart/Flowchart)

Definition/Brief Description

Process analysis is a systematic quality improvement method to identify the steps/tasks of a process that lead from a certain set of inputs to an output. A process analysis often involves the production of a process chart or flowchart, which is a graphical representation of the steps that occur during the performance of a task or a series of tasks (Carayon, Alvarado, & Hundt, 2003; Stanton, Salmon, Walker, Baber, & Jenkins, 2005). A detailed process analysis is often needed at the beginning of a failure modes and effects analysis. There are two types of flowchart: high-level flowchart, which shows 6–12 steps and provides a panoramic view of major components and steps in a process, and a detailed flowchart, which shows dozens of steps and provides a close-up view of a process (Institute for Healthcare Improvement (IHI), n.d.a)

History

Process analysis (flowchart) was originally developed and used to examine the path of a product through the manufacturing process (e.g., the manufacturing of an automobile). In healthcare, it has been used to communicate how a process should be carried out and highlight delay and storage elements affecting safety and work performance in the actual processes (Carayon et al., 2003). Several examples of its application in healthcare include: the documentation of patient flow in an outpatient clinic (Kachhal, 2001), the improvement of the hospital discharge process that involved high risks of errors and adverse events (Anthony, Chetty, Kartha, McKenna, DePaoli, & Jack, 2005), and the identification of sources of potential errors during the process of administering heparin (Harder et al., 2005).

Process

A process analysis may involve the following steps (Harder et al., 2005; Stanton et al., 2005):

1. Collect data about the process. Important information about the inputs, outputs, steps, and tasks of the selected work process may be gathered through direct observation and other methods. For example, in order to analyze the process of administering heparin, Harder and colleagues (2005) observed nurses' working behaviors at different nursing stations, inspected the computer-user interface, and conducted individual and group interviews with nurses, the physician and pharmacists who developed the computerized heparin protocol, staff pharmacists, nurse educator, and nursing administrators.
2. List all steps/tasks. A comprehensive list of steps or tasks may be put into a chronological order. There may be variations in a healthcare process.
3. Classify task steps. The task steps can be classified into several categories: activity, decision, transportation, storage, inspection, delay, or combined operation.
4. Construct the process chart or flowchart. Represent each task by a box including the following information: the task, individual who performs the task, tools and technologies, the physical environment where the task takes place (Carayon, Alvarado, & Hundt, 2007). Different types of steps can be represented by different symbols. Link the steps in a chart (probably) and add narratives describing the task

steps. Further, identify confusing or ambiguous steps and potential sources of errors in order to improve the process (see Harder et al., 2005).

Limitations

Process analysis is more suitable to relatively simpler processes or subprocesses. It can become very time-consuming to analyze a complex task. The flowchart for a complex task may be too large to be manageable. A flowchart can only include a very limited amount of information. One potential misuse of process analysis is the overstandardization of process, which is against recommendations by many human factors theories.

Resources

IHI flowchart tool, <http://www.ihi.org/knowledge/Pages/Tools/Flowchart.aspx>

Online flowchart software service, <http://flowchart.com/>

U.S. Agency for International Development Health Care Improvement Project flowchart tool, http://www.hciproject.org/improvement_tools/improvement_methods/analytical_tools/flowchart

6. Simulation

Definition/Brief Description

Gaba (2004) defines simulation as a “technique, not a technology, to replace or amplify real experiences with guided experiences, often immersive in nature, that evoke or replicate substantial aspects of the real world in a fully interactive fashion.” Often a *simulator* as used in this context refers to a “device that presents a simulated patient (or part of a patient) and interacts appropriately with the actions taken by the simulation participant” (Gaba, 2004, p. i2). Simulation is proposed as a technique to enhance patient safety by enabling clinical teams to practice critical and complex operations and procedures in a simulated environment prior to working on an actual patient. In addition to educating, training, and sustaining clinicians, it is envisioned as a way to recruit and retain healthcare providers, as well as develop a culture of safety in healthcare organizations.

History

Simulation has emerged in the last two decades as an important tool to help enhance patient safety in healthcare. It has its roots in other nonmedical industries such as

commercial aviation and the military. Healthcare simulators are directly analogous to flight simulators. Like healthcare, the intrinsic hazards and complexities involved in task performance in these industries necessitate active training in real-world-like environments to obtain the expertise to perform successfully. Rosen (2008) provides a good overview of the use of simulation in nonmedical industries and its emergence in healthcare mostly in the past decade.

Process

Gaba (2004) suggests that current and future healthcare simulation applications are diverse and can be categorized along 11 dimensions, each of which represents a different attribute of simulation (Figure 5). While the process for conducting a simulation varies along these 11 different dimensions, in general, it involves simulating a clinical situation using a simulated patient (actor, computer/virtual patient, electronic patient) with the simulation participants responding to a set of cues from the patient and the environment (equipment, alarms, etc). These responses are then analyzed to support education, training, and other goals.

While most applications of simulation in healthcare focus on training and education for clinical staff, there are some examples of simulations being used to test the effectiveness of the clinical built environment in supporting clinical tasks and processes (Chisolm et al., 2008; Davis, Riley, Gurses, Miller, & Hansen, 2008; Henriksen & Patterson, 2007; Kobayashi et al., 2006).

Mock-up rooms that range from tape and foam-core environments to fully constructed and partially or fully functioning replicas of the new environment are frequently constructed during the design process for healthcare facility design projects. These mock-ups enable the design and clinical teams to visualize their new environment and to test drive different clinical tasks to evaluate if changes are needed to the environment to enable effective functioning. Based on feedback from these mock-up evaluations, changes are made to the design for the new environment. Usually, these mock-up evaluations involve walking through the mock-up space and providing feedback on different aspects of the space.

These types of mock-ups combined with simulation techniques offer an opportunity to identify undesirable built-environment latent conditions that impact patient and caregiver safety before construction and occupancy. Chisolm

and colleagues (2008) used simulation to systematically understand the interaction among equipment, physical environment, and healthcare providers. These created four patient simulation scenarios that were tested in two mock-up intensive care unit (ICU) rooms that included a range of innovations including ceiling-mounted patient lifts, a nursing station adjacent to a pair of ICU rooms, and two ceiling-mounted articulating arms designed to hold necessary equipment. The interactions between the patient simulator, healthcare providers, and environment in the four scenarios were videotaped. In addition, participants were asked to think aloud their actions as they engaged in different tasks and were asked to describe any difficulties they encountered with layout or equipment at the conclusion of each scenario. The data from video recordings along with the debriefings were analyzed to identify key categories of problems with the mock-up environments.

Davis and colleagues (2008) used a similar process, though their focus was not specifically on identifying built environment issues, but all latent conditions and active failures observed during the process. To facilitate that goal, they conducted a failure modes and effects analysis in conjunction with the simulation. The video recordings helped to identify additional latent conditions to those that were brainstormed using a typical FMEA process. The team also conducted a root cause analysis for each of the failure modes identified through this process. In another study, Kobayashi and colleagues (2006) used advanced medical simulation to evaluate the capacity of a new emergency department for emergent resuscitative processes and assist facility orientation before opening day. The process helped the team identify significant operational issues that were corrected before the facility opened.

Limitations

Some of the limitations to conducting on-site simulations include the need for administrative support required for supplies, equipment, and human resources; time commitment needed from multiple staff members; and potential disruption if conducted on a functioning patient care unit (Davis et al., 2008). Cost is a concern as well as availability and mobility of patient simulators for conducting simulation studies. Davis et al. (2008) also indicated that a Hawthorne effect may be in play with team members being aware that they were being watched and filmed, which may impact the ability to identify the full range of potential adverse events accurately.

Time

Simulation studies require time to develop simulation scenarios as well as for planning and engaging participants for the simulation exercises. Additionally, coding and data analysis for video data can be time-consuming.

7. Root Cause Analysis

Definition/Brief Description

Root cause analysis (RCA) is a nonstatistical method of analysis to identify conditions that can lead to harm (Carayon et al., 2003). It is a reactive process responding to a close call or sentinel event that involves a multidisciplinary team to identify and eliminate the contributing causal factors of systems, risks, and process (not individual performance) that contribute to patient safety problems. An RCA results in the development and implementation of effective recommendations to either prevent the problem from recurring or reduce the severity of the event in the same situation (Carayon, 2003; Friedman, Geoghegan, Sowers, Kulkarni, & Formica, 2007; Grout, 2007; U.S. Department of Veterans Affairs (VA), n.d.a).

History

Root cause analysis is used in engineering and was originally developed by Sakichi Toyoda. It was later used in developing Toyota's manufacturing methods and is part of the training delivered as part of the Toyota Production System. In 1975, it was implemented for quality control, error reduction, and risk management at the Federal Aviation Administration (FAA) through the establishment of Aviation Safety Reporting System (ASRS). Later, in 1986 it became part of six sigma, developed by Motorola (Grace, 2011).

More recently, it has been adopted by the healthcare industry. In 1997, it was mandated by the Joint Commission following sentinel events, and by 2007, 26 states required its use for serious adverse events and near misses where the risk of recurrence is great (Morse & Pollack, 2011). In New York State, for example, serious events warranting an RCA must be reported within 24 hours and the analysis completed within 30 days (Faltz, 2008). The method has been adopted by the U. S. Department of Veterans Affairs (VA) through its creation in 1998 of the National Center for Patient Safety (NCPS), which was based on the framework for the FAA's ASRS. By 2000, the system had been implemented in 173 VA facilities (Bagian et al., 2002).

The RCA process has been used following many types of patient safety events such as falls, errors, suicide attempts, missing patients, and death, among others. While it is most often considered for a single event, there are studies that document its use to define system vulnerabilities through multisite data collection, such as data collection through New York State (Faltz, 2008) or the VA (Stalhandske, 2008).

Process

The primary process associated with conducting an RCA includes the following questions (Carayon et al., 2003; Friedman et al., 2007):

- What happened?
- Why did it happen?
 - What are the most proximate factors (human factors, equipment, environmental, etc.)?
 - What systems and processes underlie those factors?
- What should be done to prevent it from happening again (action plan)?

A job analysis tool developed by Carayon and Smith (2001) identifies the following areas of consideration: characteristics of the job, tasks of the job, tools and technologies, the physical environment, and the organizational conditions (as cited in Carayon, 2003). Within the physical environment, characteristics to be recorded include: illumination, temperature and humidity, noise, vibration (hand tools), safety hazards (mechanical, electrical, etc.), and atmospheric conditions (fumes, odors, dust, etc.).

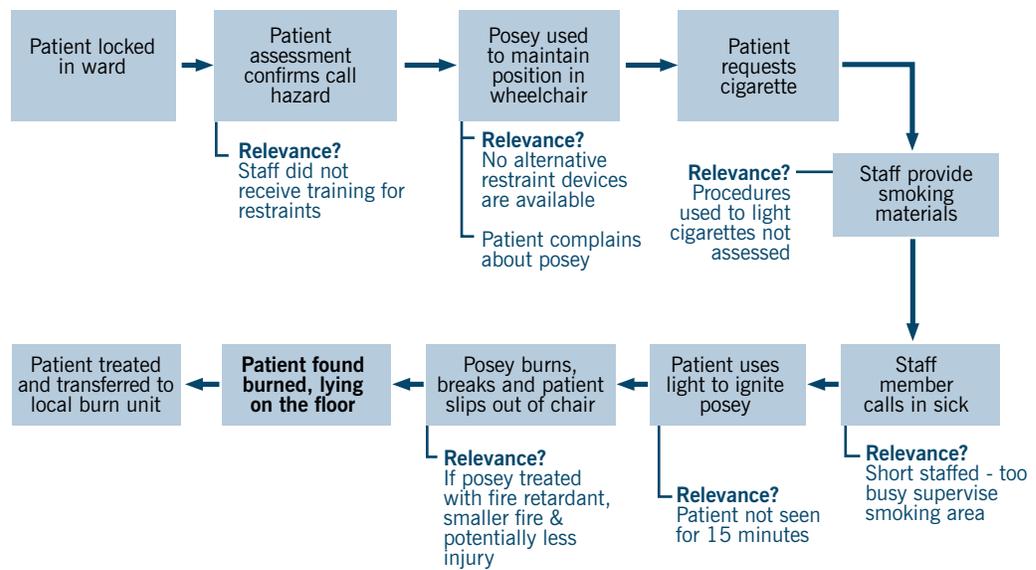
The VA NCPS also provides a step-by-step guide as “a cognitive aid to help teams in developing a chronological event flow diagram (an understanding of what occurred) along with a cause and effect diagram (why the event occurred)” (U.S. Department of Veterans Affairs, n.d.b). Steps include

- Event flow diagramming. Initial, intermediate, and final diagrams with related causal statements to ensure the same understanding of what occurred, avoiding differing interpretations of the same event.

- Cause and effect diagramming. Identify the problem, brainstorm causes, and complete diagrams to adequately describe the chains of causal links that will lead to the root causes/contributing factors of the problem.
- Refinement of causal statements.
- Development of an implementable action plan (with process owners) to address the root cause/contributing factor that is specific and concrete.

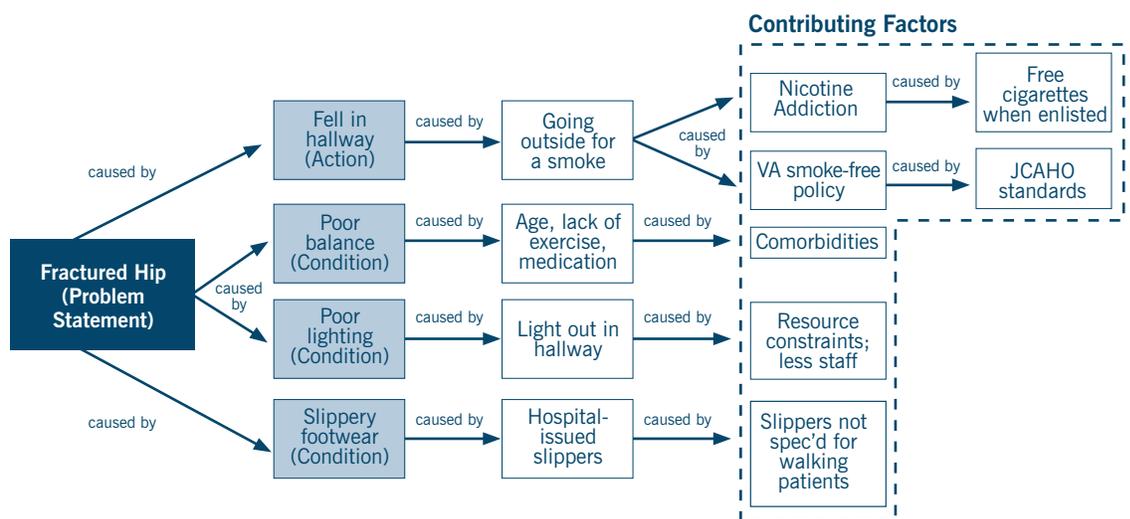
Samples from the VA website showing an event flow diagram and cause and effect diagram are shown in Figures 3 and 4.

FIGURE 3
Event Flow Diagram



Note. From "Root cause analysis tools" by U.S. Department of Veterans Affairs National Center for Patient Safety, n.d.b, retrieved August 29, 2011, from <http://www.patientsafety.gov/CogAids/RCA/index.html#page=page-1>

FIGURE 4
Cause and Effect Diagram



Note. From "Root cause analysis tools" by U.S. Department of Veterans Affairs National Center for Patient Safety, n.d.b, retrieved August 29, 2011, from <http://www.patientsafety.gov/CogAids/RCA/index.html#page=page-1>

The VA NCPS also outlines a recommended hierarchy of actions (Table 5). One of the stronger actions listed is changes to the architectural/physical plant.

Table 5 VA NCPS Recommended Hierarchy of Actions
Stronger Actions
<ul style="list-style-type: none"> • Architectural/physical plant changes • New device with usability testing before purchasing • Engineering control or interlock (forcing functions) • Simplify the process and remove unnecessary steps • Standardize equipment or process or caremaps • Tangible involvement and action by leadership in support of patient safety
Intermediate Actions
<ul style="list-style-type: none"> • Increase in staffing/decrease in workload • Software enhancements/modifications • Eliminate/reduce distractions (sterile medical environment) • Checklist/cognitive aid • Eliminate look- and sound-alikes • Read back • Enhanced documentation/communication • Redundancy
Weaker Actions
<ul style="list-style-type: none"> • Double checks • Warnings and labels • New procedure/memorandum/policy • Training • Additional study/analysis

When it Occurs

As a reactive process, an RCA is conducted following a specific event, however, it can become more of a proactive tool by considering the types of events and root causes at an organizational or system level to understand commonalities, vulnerabilities, and lessons learned to future potential events.

Limitations

There are several limitations for root cause analysis cited in the reviewed papers. Time and/or technical support is a consideration. Some estimates suggest that traditional manual RCA approaches can take 3 to 6 months, involving 50% administrative work, collecting the information, transcribing sticky notes and easel pad diagrams, organizing the information into reports and to management (Latino

& Flood, 2004). Others suggest the process takes 20-90 person hours (Morse & Pollack, 2011). Software programs (ranging from \$3,000-\$6,000) can expedite tasks, standardize input, and make information more readily available to share (Latino & Flood, 2004). Additionally, an RCA may only consider one instance of a circumstance or failure, when other circumstances can also lead to failure (Grout, 2007). It may also suffer from hindsight bias or fear of identification in the process (Carayon et al., 2003). Lastly, RCA has been criticized for the variability in strength of action plans, development and implementation rates, the time it takes to complete (that might be used for other quality improvement activities), and its dependence on a specific healthcare environment, including the support of leadership (Morse, 2011).

Resources

National Center for Patient Safety Root Cause Analysis Tools,
<http://www.patientsafety.gov/CogAids/RCA/index.html#page=page-1>

Joint Commission RCA tool,
<http://www.jointcommission.org/assets/1/18/rca-word-framework.doc>

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APPENDIX IV: SAFE DESIGN ROADMAP/CEO CHECKLIST

Poorly designed and operated healthcare environments contribute to adverse events and subsequent patient harm, such as healthcare-associated infections, medication errors, and patient falls. A large and growing body of evidence indicates that the physical environment impacts patient and staff safety, as well as stress and satisfaction, staff effectiveness, and organizational resource outcomes in hospitals and other healthcare settings. Facility replacement and renovation projects provide an opportunity to identify and eliminate built environment latent conditions that lead to active failures impacting patient safety.

The purpose of the safe design roadmap is to provide CEOs and their leadership teams with a facility project management tool that captures the opportunities to use physical environmental features to help improve patient safety outcomes. The tool is divided into sections that correspond to the facility lifecycle phases; each phase includes key questions and variables that shape facility planning and project decision making. Based on current research, the checklist variables guide senior leaders through the facility project management process, helping them to integrate facility design into patient safety programs, specify patient safety goals, and identify corresponding facility features to incorporate in the design. Necessary supporting care process and organizational culture transition activities are noted, as well.

CEOs and their teams are encouraged to read through the entire roadmap and supporting documents (Design Frameworks and Considerations) as one of the first facility strategic and business planning activities. Individual facility lifecycle phase variables can then be considered at the appropriate project phase to support timely decision making and avoid costly project changes. The tool provides a patient safety communication roadmap that drives facility project decision making to maximize facility investments and realize improved patient safety outcomes. Following the questions, additional detail is provided about the varied design phases and supporting information to answer the questions.

Prior to starting anything, it is important to evaluate whether there is a leader-led safety culture program and performance improvement initiative. Evaluate whether there is open communication within the organization about near misses, mistakes, and errors, and whether staff work within a system of accountability that supports safe behavioral choices. Establish how analyses and solutions developed around these events are shared within the organization.

15 Key Safety Questions to Ask Through the Facility Project Lifecycle

1. What is your current safety status for each risk category with regard to patient morbidity and mortality?
2. What financial impact do current patient harm, patient readmissions secondary to harm, and patient satisfaction have on your Centers for Medicare and Medicaid Services (CMS) and other reimbursement rates, as well as associated litigation and claim costs?
3. Is safety a topic included in the visioning session to launch the facility project?
4. What known physical environment safety features are currently missing in the present facility? Based on available research, what features need to be included?
5. What cultural transformation or clinical or business reengineering efforts are needed to maximize facility safety feature investments?
6. Is safety a focus of your operations plan? What culture and processes of care delivery are needed to complement safety features?
7. Are specific resources needed, such as mock-up rooms or virtual tools, to integrate safety culture, process, and environmental feature changes?
8. Does the functional program accommodate safety features/goals?
9. Does the team you've hired have expertise in patient safety?
10. Does the design support the desired safety concepts of operation from all perspectives: patients, family and visitors, the community, staff, material movement, and equipment and technology use?
11. Has a comprehensive safety-training program been developed for staff, patients, and family members? Have stakeholders (including patients and the community) been informed through marketing and press releases about the safety-focused design?

12. Have the baseline, pre-occupancy safety outcome measures been captured for those variables expected to be impacted by the proposed safety features?
13. Has the post-occupancy evaluation processes been defined to include evaluation of the safety features?
14. Have the post-occupancy evaluations of safety features been completed at the appropriate times?
15. Have the lessons learned been documented and shared broadly?

The Project Lifecycle Phases

	Phase	Phase Description
Planning Phases	Strategic planning	A strategic plan helps hospitals and systems adapt to market conditions and changes in healthcare environments. The CEO, along with the board of directors, has a leadership role in creating the strategic plan, which includes the development of the organization's mission, vision, strategy, and values statements; defining the critical strategic issues; making the transition from planning to implementation; communicating and rolling out the plan's findings and recommendations; and conducting an annual strategic plan update as part of an ongoing management process. (Synthesized from "Healthcare Strategic Planning, 2nd Ed., by A. N. Zuckerman, 2005, Chicago: Health Administration Press.)
	Facility master planning	Healthcare master planning is a guide for decision making prepared by identifying capital improvement needs that accommodate future growth of a facility that includes potential operational and infrastructure needs for delivering quality healthcare. It is a multiphase process undertaken by healthcare planners, architects, and other industry consultants to consider long-term strategies that consider logistical and financial feasibility, as well as flexibility to accommodate future change. It considers site/campus planning, zoning, existing building analysis, departmental analysis, projected workloads and demands, gross area sizes, and options for potential configurations. (Synthesized from a webinar presented on May 4 2010 by Eduardo Egea (HKS Architects) for AIA AHA Healthcare 101 Series. Available at: http://www.youtube.com/watch?v=hLNUf6eW-Ig&feature=relmfu .)
Pre-design Phases	Process and operational planning	Operational planning reflects current and future business and clinical processes, organizational structure, and technology after taking into account existing investments, process priorities opportunities for improvement, and change management implications. The operational plan establishes the operational link to strategic objectives by providing a common view and vocabulary of all relevant processes; aligns key metrics that assist the organization in documenting its current state (and track progress over time); ensures agreement between and buy-in from physicians, administration, and staff who are accountable for successful execution; and establishes an appropriate organizational/governance model with the authority to implement and sustain the required changes through continual process assessment and design of workflows.
	Programming	Architectural programming is the research and decision-making process that identifies the issues and problems that a design process must address and resolve. The result is interconnected on both a pragmatic and inspirational level that defines the scope of work to be designed by identifying existing condition evaluation, space requirements, overall building use requirements, zoning and community issues, the relationship between building components, measures for growth and change, and code summaries and regulatory requirements. (According to <i>Whole Building Design Guide</i> available at http://www.wbdg.org/design/dd_archprogramming.php and <i>The Architect's Handbook of Professional Practice</i> , 13th ed., by The American Institute of Architects, 2001, Wiley & Son) A functional program is required by the Facility Guideline Institute <i>Guidelines for the Design and Construction of Healthcare Facilities</i> and is described through (1) the purpose of the project (required services, environment-of-care components, delivery-of-care models, facility and service users, systems design, layout and operational planning, physical environment, and design process and implementation) and (2) the functional requirements (demand, space relationships, user needs, operational needs, space and equipment needs, and short- and long-term planning considerations (Facility Guidelines Institute, 2010).

The Project Lifecycle Phases (continued)

		Phase	Phase Description
Design, Construction, and Occupancy	"Traditional" Design Phases	Design	Design is considered in two phases, schematic design (SD) and design development (DD). During SD, an architect and client establish the scope, conceptual design, and scale and relationship of the project components to establish a clearly defined and feasible concept with a reasonable basis for estimating project cost. Design development uses the documents from the schematic phase and provides additional refinement and coordination. This phase lays out mechanical, electrical, plumbing, structural, and architectural details. This phase results in drawings that often specify design elements such as material types, location of windows and doors, interior elevations, wall sections, reflected ceiling plans, pertinent details, and more detailed specifications. Cost estimates are updated. (Summarized from <i>The Architect's Handbook of Professional Practice, 13th ed., by The American Institute of Architects, 2001, Wiley & Son.</i>)
		Construction documents	During construction documentation, final materials and systems are selected, while details and dimensions are finalized. (Summarized from <i>The Architect's Handbook of Professional Practice, 13th ed., by The American Institute of Architects, 2001, Wiley & Son.</i>)
		Construction	Several delivery methods are used for construction. In design-bid-build, a project is designed and documented with drawings and specifications, competitively bid to multiple general contractors, and then built by the general contractor, guided by a contract with the owner of the project. Design-build uses a single entity that holds a single contract with an owner for both the design and construction of a project. Construction management is a method that involves the coordination and management of the entire process via a single entity—from site survey through occupation. It encompasses the evaluation, selection, and management of all contractors, as well as the administration of the project budget relative to the implementation of design. <i>Whole Building Design Guide</i> construction may include phasing and temporary structures to ensure the safe and continuous operation of an existing facility. Requirements surrounding infection control and risk mitigation are required in many areas.
Pre-occupancy / Occupancy		Commissioning and Punch List	The American Society of Heating, Refrigerating and Air-Conditioning Engineers define commissioning as "a quality-oriented process for achieving, verifying, and documenting that the performance of facilities, systems, and assemblies meets defined objectives and criteria." It is typically used for dynamic systems such as HVAC (heating, ventilation, and air conditioning) and certain types of equipment. It is conducted prior to turning over the facility to the owner. The punch list typically is completed by the design team with a walk-through inspection at substantial completion. The punch list identifies incomplete or unsatisfactory work, as defined in the contract documents. The items are usually static in nature, such as drywall or paint irregularities, carpet stains, broken hardware, etc.
		Occupancy	Many states require an inspection prior to issuing a certificate of occupancy or temporary certificate of occupancy. After issuance, the owner takes control of the building and can begin moving furniture and equipment. In larger healthcare facilities, staff and clinicians use simulations, scenarios, and walk-throughs to ensure they are familiar with the new environment prior to full operation of the building, licensing, certification, and accepting or moving patients.

The Checklist

Phase	Key Safety Questions	Detail
Strategic planning	1. What is your current safety status for each risk category with regard to patient morbidity and mortality?	What is your current safety status for each risk category with regard to patient morbidity and mortality?
	2. What financial impact do current patient harm, patient readmissions secondary to harm, and patient satisfaction have on your reimbursement rate from Medicare, as well as associated litigation and claim costs?	What financial impact do current patient harm, patient readmissions secondary to harm, and patient satisfaction have on your reimbursement rate from Medicare, as well as associated litigation and claim costs?
Facility master planning	3. Is safety a topic for the visioning session to launch the project?	Set the visioning session stage with an overview that highlights the role of built environment research and safety features in the physical environment to help solve prioritized risk categories. Ensure all key stakeholders are active participants in the process, including patients. Communicate this vision to the board.
	4. What known physical environment safety features are currently missing in the facility? Based on available research, what features need to be included?	Based on existing safety data (raw metrics and root cause analysis) and inventory of missing environmental features, define the scope of the safety problem and list potential solutions for consideration in projects. Identify desired safety goals—make a list that you will use in each phase of the project to make sure you don't miss any of them. Consider the equipment and technology needed to support the goals, as well (standardized equipment, electronic health record, computerized physician order entry, bar coding, radio-frequency identification, hands-free communication, tele-applications, etc.) Provide a list of research references for each selected safety element/goal, which becomes the underpinning knowledge base for the project.
	5. What cultural transformation or clinical or business reengineering efforts are needed to maximize the facility safety features?	Ensure that there is broad stakeholder participation. Identify organizational reengineering/process improvement efforts already under way and consider what is both missing and available.
Process and operational planning	6. Is safety a focus of your operations plan? What culture and processes of care delivery are needed to compliment safety features?	Safety is the first consideration for a project. Review the organization's mission, vision, and values statements. If safety is not expressly stated, you are not driving its inclusion operationally. Identify the needed changes to maximize the facility investments to realize improved safety
	7. Are specific resources needed, such as mock-up rooms or virtual tools, to integrate safety culture, process, and environmental features	Care delivery processes are complex. Modeling, whether real or virtual, helps to ensure that all of the critical steps are considered and modified and used for staff orientation and training. Consider failure modes and effects analysis to understand risk magnitude and potential frequency.
Programming	8. Does the functional program accommodate safety features/goals?	The more precisely you identify required safety features, the more you know what their space requirements will be and can ensure that the program addresses them—otherwise, they may become an expensive retrofit and will not work as well.
	9. Does the team you've hired have expertise in patient safety?	Ask to see their prior work, literature review(s), and the results of pre- and post-occupancy evaluation measures specific to the targeted safety/risk priorities.

The Checklist (continued)

Phase	Key Safety Questions	Detail
Design	10. Does the design support the desired safety concepts of operation from all perspectives: patients, family and visitors, the community, staff, material movement, equipment, and technology use?	Patient representatives can provide an unvarnished view of what is important from the patient experience perspective. It is important to have representatives from each domain involved in design review. Be specific about what patients may be in each risk category and share this with the design team. The design process works from the general (such as adjacency diagrams) to the specific (such as hardware specification and furnishing selections). Make sure that the design team explains its design plan in terms that help you to understand when each of the safety features you have identified will appear in the design process.
Construction documents	11. Has a comprehensive safety training program been developed for staff, patients, and family members? Have stakeholders (including the community) been informed through marketing and press releases about the safety-focused design?	A comprehensive safety program (if it does not already exist) should begin the moment a decision is made to pursue the project. Equipment and environmental feature training must happen long before occupancy. This is when mock-ups and models become helpful. The more program development, training, and institutionalization that can happen in advance of occupancy, the better. Real change takes lots of time.
Construction	12. Have the baseline, pre-occupancy safety outcome measures been captured for those variables expected to be impacted by the proposed safety features?	Make sure that you are collecting the appropriate baseline pre-occupancy measures. Do not wait until the last 6 months of operations, when many activities are in play, potentially skewing safety outcomes. Reimbursements specific to hospital-acquired conditions should be included in the monitored metrics.
Commissioning / Punch List	13. Has the post-occupancy evaluation process been defined to include evaluation of the safety features?	Determine when and how frequently you will measure in the post-occupancy phase. Most wait at least 6-12 months before measuring to let routine operations settle in.
Occupancy	14. Have the post-occupancy evaluations of safety features been completed at the appropriate times?	As part of the hospital performance improvement program, include post-occupancy evaluation measures as a part of the improvement calendar, including the impact of the entire patient safety on reimbursement rates and monitor return on investment.

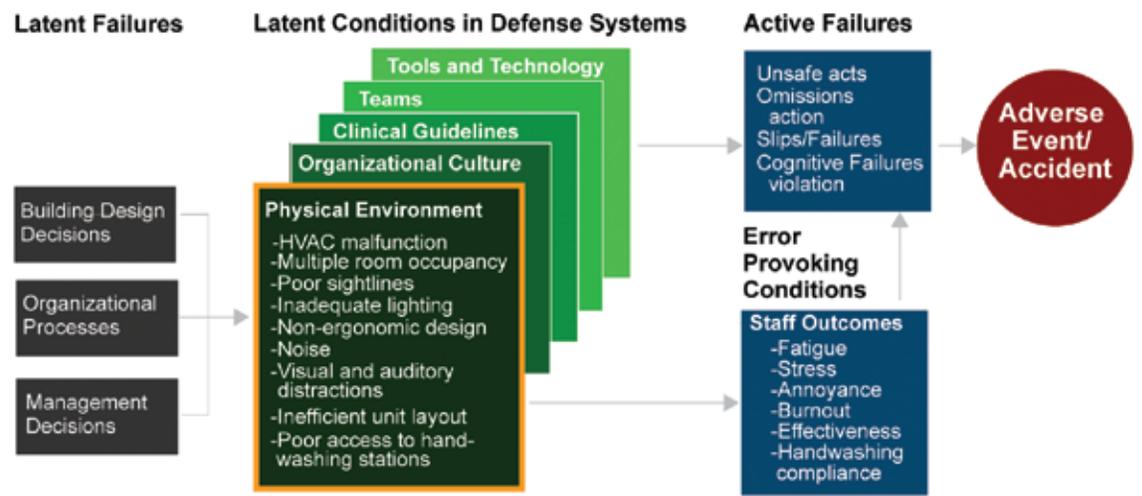
APPENDIX V: DESIGN FRAMEWORK AND CONSIDERATIONS

We cannot change the human condition but we can change the conditions under which humans work.

— James Reason, 2000

According to the National Health Services, Design for Patient Safety report published in 2003, good design can deliver products and services that are intuitive, simple to understand and use, and, consequently, less likely to lead to accidents.

FIGURE 1
Conceptual Model of Physical Environment Elements as Latent Conditions in Patient Safety



Conceptual model based on Reason's model showing the role of the environment as a latent condition or barrier to adverse events in healthcare settings. From "Designing for Patient Safety: Developing a Patient Safety Risk Assessment" by Joseph, A., & Taylor, E., 2010, Presentation at the 2010 Guidelines for Design and Construction of Health Care Facilities Workshops, Chicago.

In a systems approach, error reduction or prevention is achieved by strategically building defenses, barriers, and safeguards into the facility, equipment, technology, and processes that make up the system. Defenses, barriers, and safeguards can prevent a healthcare provider from committing an active failure or mitigate the effect of an active failure. (An active failure is an error at the level of the frontline operator and whose effects are felt almost immediately.)

The following pages outline a design framework and considerations for use in facility projects. The 10 topics are intended to stimulate thought without being prescriptive. Each topic includes latent conditions (errors in the design, organization, training, or maintenance that lead to operator errors and whose effects typically lie dormant in the system for lengthy periods of time), as well as environmental factors to be considered.



Provide Standardization

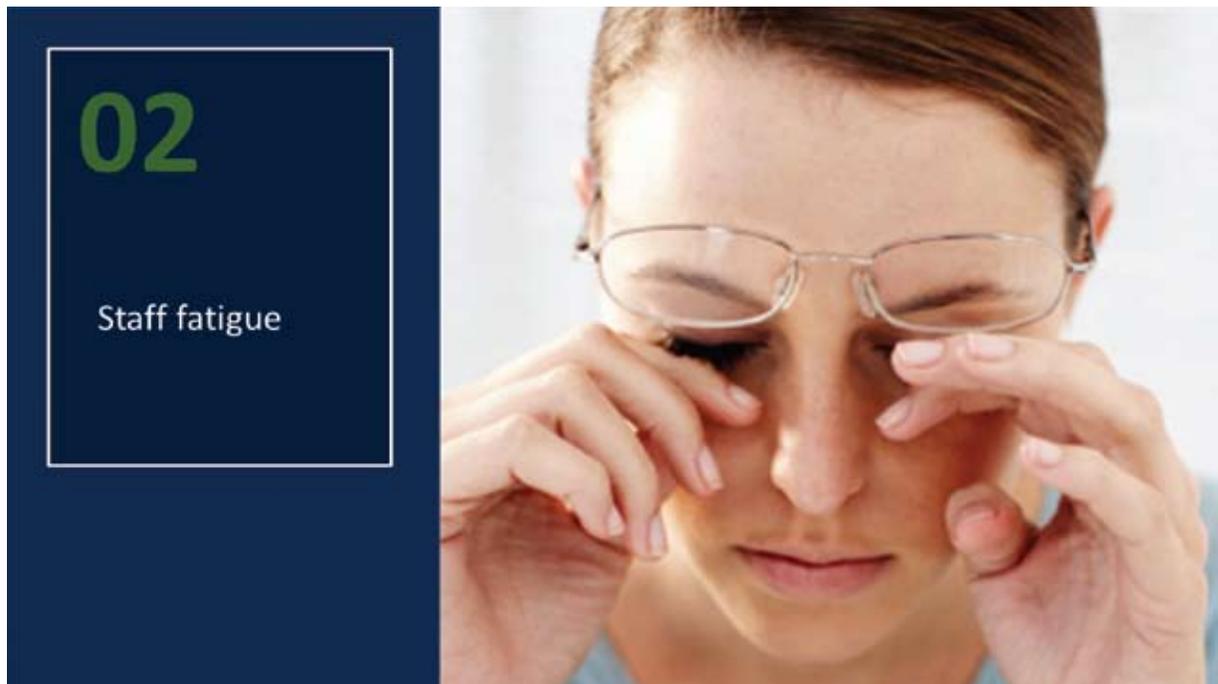
The presence of multiple locations of equipment and supplies as well as multiple ways of doing things adds to the cognitive burden on staff and increase chances of error.

Latent Conditions

- The presence of many different room configurations requires reorientation with each activity.
- Multiple location of devices and equipment wastes time and injects opportunity for distraction and error in decision making.
- Environments and processes nonstandard within the organization requires mental evaluation every time.

Environmental Factor Examples

- Unit layouts
- Room layout
- Location of equipment and supplies, especially those needed during high-risk-care episodes



Reduce Fatigue

Fatigue has a negative impact on alertness, mood, and psychomotor and cognitive performance, all of which are linked to active failures. Facility design can contribute to fatigue.

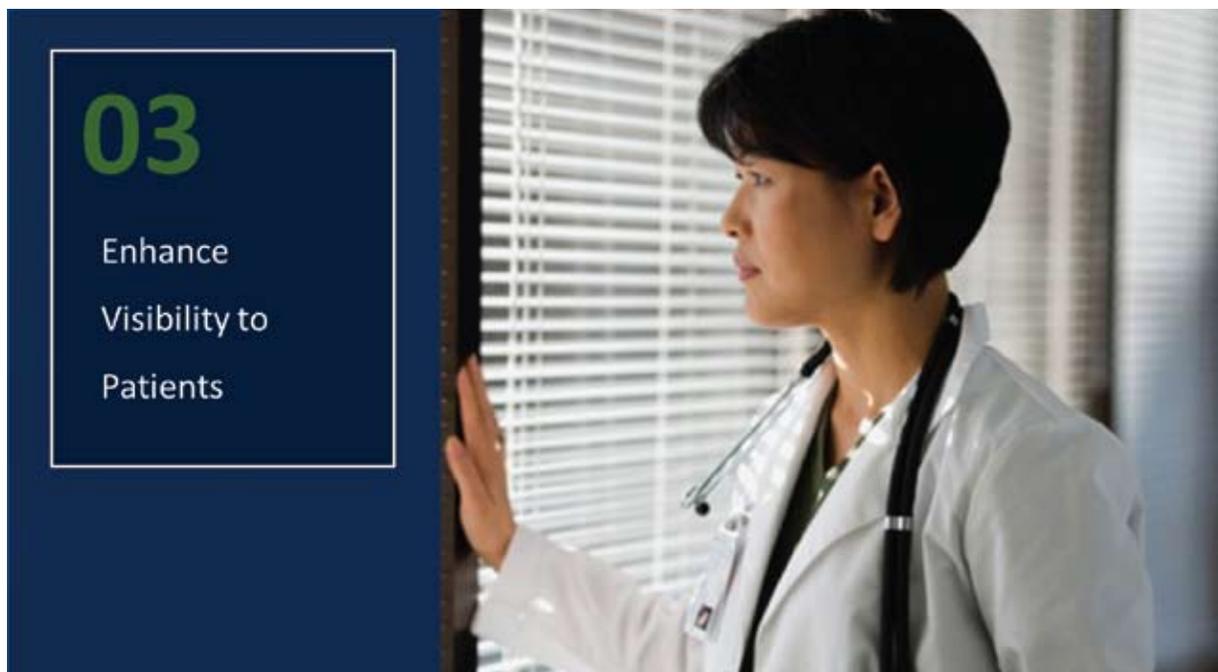
Latent Conditions

- Unit layout that requires extensive walking to hunt and gather supplies, people, etc.
- Unit layout that results in frequent work interruptions
- Ambulation/transport of obese or mobility-impaired patients
- High noise levels, sharp changes in noise
- Poor lighting

- Nonergonomic furniture and workspace design
- Hard floors

Environmental Factor Examples

- Unit layouts
- Modular adaptable furniture systems
- Materials
- Lighting



Improve Visibility

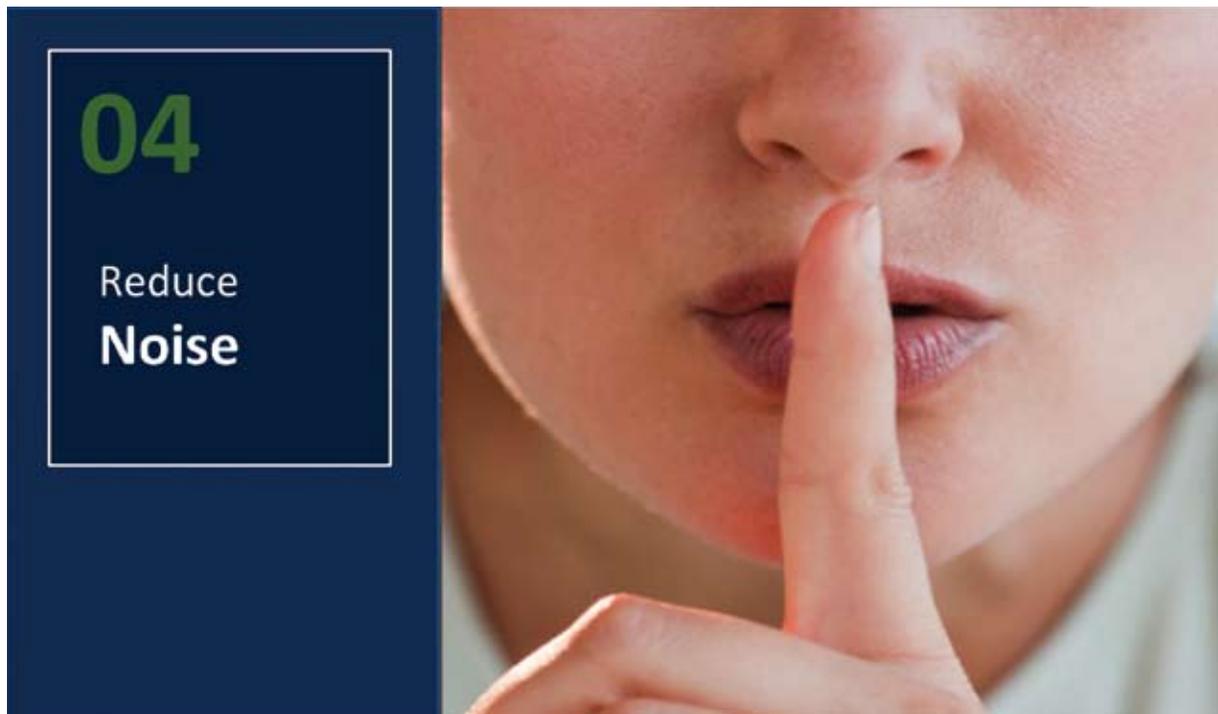
Staff depends on visual and auditory cues in order to respond to the needs of patients and prevent adverse events such as falls. Building design should facilitate visual access to patients.

Latent Conditions

- Patient room design that blocks sightlines from staff to patients
- Lack of visual and physical proximity to patient rooms from nurses' station due to unit design
- Changes in lighting and its effect on accurate assessment of skin color

Environmental Factor Examples

- Visibility to patient bed
- Centralized vs. decentralized nursing stations
- Solid vs. glass doors
- Lighting



Reduce Noise

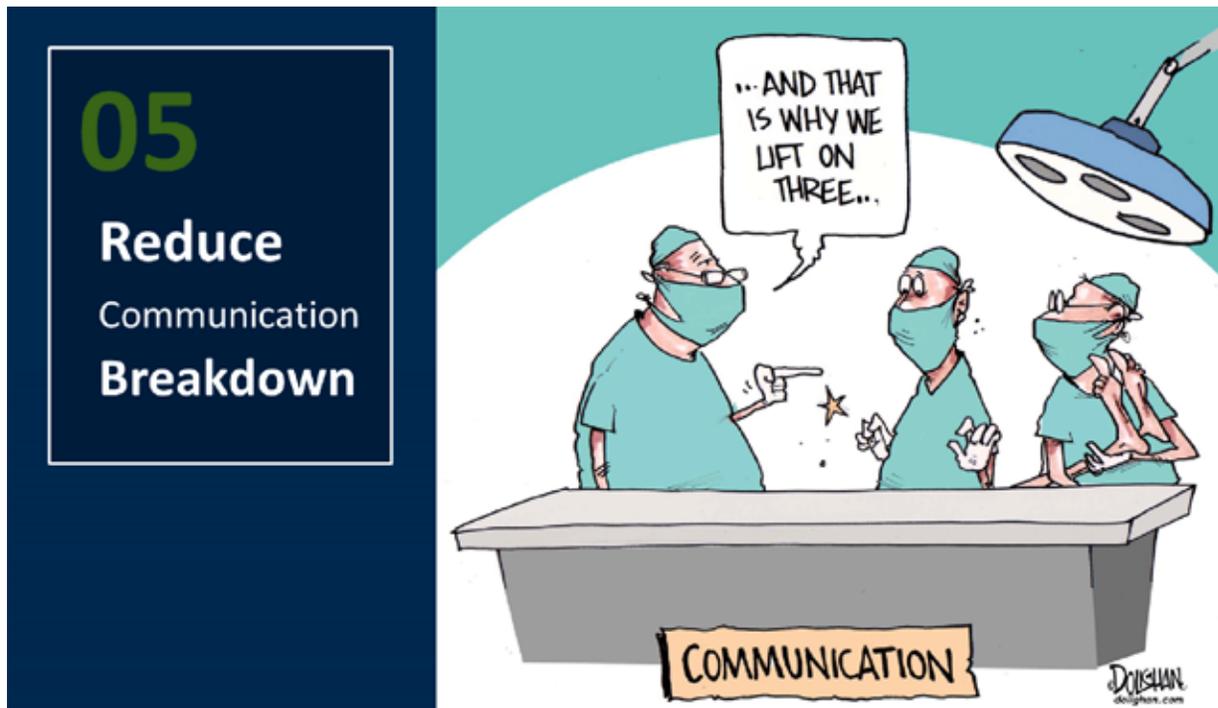
High noise levels result in staff stress, exhaustion, and burnout and also impact patient sleep and healing. Loud ambient noise levels also hinder speech intelligibility and communication, potentially resulting in errors.

Latent Conditions

- Hard surfaces (walls, floor, ceilings) that reflect sound
- Loud noise sources on the nursing floor (paging systems, ice machine, equipment alarms)
- Staff conversations
- Noise from other patients and visitors in multioccupancy rooms

Environmental Factor Examples

- Private patient rooms
- Team/charting areas (staff conversations)
- Medication safety zones
- Acoustical treatments (ceiling tile, soft surfaces, sound-absorbing furniture panels)



05

Reduce Communication Breakdown

Reduce Communication Breakdowns

Communication discontinuities and breakdowns and lack of timely access to critical information may adversely affect patient safety.

Latent Conditions

- Patient care processes and unit designs that require multiple patient transfers (and handoffs) during a hospital stay
- Noisy chaotic environments
- Environments where frequent interruptions take place
- Critical patient information (patient charts, medication access, and administration records) remote to the point of service

Environmental Factor Examples

- Acuity adaptable rooms (handoffs)
- Unit configuration
- Technology (Vocera, electronic whiteboards, etc.)



Control and Eliminate Sources of Infection

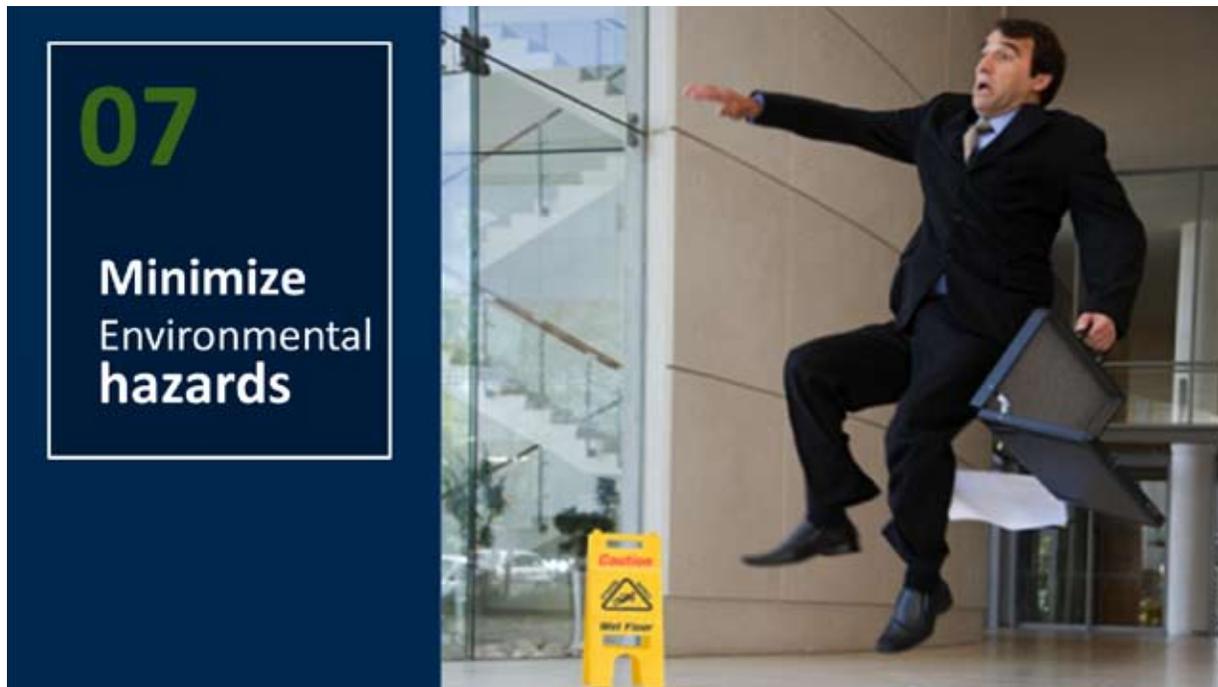
Vulnerable hospital patients may be exposed to harmful pathogens in the hospital environment. Most healthcare-associated infections are contact-transmitted to patients from the hands of healthcare staff and contact with contaminated surfaces.

Latent Conditions

- Air
- Water
- Contact conditions

Environmental Factor Examples

- Hand hygiene options
- Surface material selections
- HVAC and water system considerations



Minimize Environmental Hazards

Hazards in healthcare environments can result in slips, trips, and falls among patients as well as staff.

Latent Conditions

- Slippery surfaces
- Equipment, IV poles, furniture in the path of movement
- Low lighting levels
- Location and design of the bathroom relative to the patient bed

Environmental Factor Examples

- Flooring material selections
- Lighting

- Bath-to-bed relationship
- Storage to reduce hallway clutter



08

Automate
where
possible

Automate Where Possible

Healthcare information technology can facilitate flow of information and its availability at the point of care possibly reducing errors. Automation of certain tasks increases accuracy and reduces probability of error.

Latent Conditions

- Multiple handoffs of patient, information, or support
- Paper documentation in a central location rather than at point of care
- Complex repetitive tasks performed manually

Environmental Factor Examples

- Electronic medical record (EMR)
- Patient registration

- Patient information at the bedside
- Robots (pharmacy)
- Bar code technology
- Radio-frequency identification (RFID)
- Electronic whiteboards



Support Patient and Family Involvement in Care

Involvement and participation of patients and family members can help to reduce adverse events such as errors and falls.

Latent Conditions

- Patient room lacks accommodation for family visitation and overnight stays
- Multioccupancy rooms
- Patient information is not available to patient and family
- Lack of access to education opportunities (such as Internet access)

Environmental Factor Examples

- Private rooms
- Family space in rooms
- Education centers
- In-room Internet access for patients/families



Consider Adjacencies

Intrahospital transport (IHT) times and distances can lead to medical complications. Consider vertical and horizontal adjacencies to optimize processes, patient movement, and distribution of materials, equipment, and supplies.

Latent Conditions

- Cross traffic of patients and materials, food, waste, supplies
- Inefficient location of equipment and supplies can create delays
- Excessive patient movement to varied services
- Elevator reliability/ delays

Environmental Factor Examples

- Close unit proximities that minimize times for types of IHTs combining high-frequency and high-patient acuity or clinical instability (intensive care units, emergency departments, operating rooms)
- Elevator location redundancy
- Horizontal vs. vertical transport

DESIGN FRAMEWORK CATEGORIES & CONSIDERATIONS TOOL										
Design Response (Examples Only)	Standardization	Fatigue	Visibility	Noise	Communication Breakdowns	Sources of Infection	Environmental Hazards	Automation	Patient and Family Involvement	Adjacencies
Single patient rooms			X	X		X			X	
Decentralized supplies	X	X								X
Decentralized nurse stations		X	X	X						X
Visible handwash locations	X					X				
Additional feature										
Additional feature										