

Recommendations

These recommendations take into consideration testimony originally coded to 17 (HuDesign)¹ and 19 (FacDesign)² as well as other sources.

- T1. To build safe, patient-centered care into their organizations, all health-care delivery organizations should seek ways to design, re-design, or modify their facilities, physical environments, and work processes to take into account human needs and limitations. Emphasis should be on identifying and preventing or correcting system defects in ways that respond to patient and staff needs, rather than training staff or teaching patients to accommodate poor system design. In particular, health-care delivery organizations should:
 - T1a. Make use of current knowledge and tools in error analysis and human factors engineering, such as health-care failure modes effect analysis (HFMEA), root cause analysis (RCA), and usability testing (UT).
 - T1b. Consider environmental factors such as noise, light, distances, fatigue and limits to human memory when designing or re-designing physical plants and care processes.
 - T1c. Promote accelerated adoption of known safer practices and health-care products designed for safety.
- T2. The Certificate of Need (CON) Commission should require that all health-care facilities that fall under its jurisdiction conduct an HFMEA or equivalent as part of the CON application process, with special attention to the areas of infection control, safety features in building design and location, and environmental conditions.
- T3. The Michigan Partnership for Safe Health Care should provide statewide leadership and direction in the following ways:
 - T3a. In collaboration with state and national centers of expertise on patient safety, disseminate current knowledge and tools for error analysis and low-/no-cost approaches to work design and re-design.
 - T3b. With Michigan educational institutions that have programs and expertise in human factors engineering and facility design, secure grants and funding to support the adoption of these tools in health-care settings
 - T3c. In collaboration with appropriate state-level licensure and regulatory agencies, explore ways to incorporate the use of HFMEA or its equivalent for facilities not covered under the CON process.
 - T3d. With a broad range of Michigan health-care stakeholders, explore incentives (financial and otherwise) for organizations that design safe facilities.

Rationale

The Commission received compelling testimony on this important topic.

In order to improve patient safety we must learn from errors and near misses. The knowledge that is generated from errors requires that the errors and near misses must be analyzed for system defects, and human factors that contribute to the occurrence of the events.... The State of Michigan has an historic opportunity to make good out of bad, to learn from mistakes, to design safety into care processes and to continue its tradition of progressive innovative care improvement opportunities....The identification of root causes of problems with the systems of care could provide the basis for identification of and implementation of solutions to

avert similar future adverse events. The public should be informed as providers implement the solutions. As solutions are implemented and fewer events occur patients benefit, providers benefit and the State benefits.³

Human error plays a role in patient injury and death due to adverse events. Eliminating all errors, however, is impossible. Indeed, that should never become the goal because it only reinforces the erroneous belief that medical practice can be error free, and results in the shame and blame approach to medical error, where there is more pressure to cover up mistakes than to admit them and learn from them. Correcting system errors, however, addresses root causes and can substantially reduce the probability of error.⁴

Errors may be active or latent, depending on their proximity to the action and the delay before effect. Active errors are those made closest to the human-system interface—the point of care—and have nearly immediate consequences. Latent errors are the delayed-action consequences of decisions taken further upstream in the organization and relate to the design and construction of facilities and equipment, organizational structure, task design, planning and scheduling, training and selection, and so forth.

While active errors are usually human, the root causes of these errors are often beyond the individual's control: they are accidents waiting to happen. Experts in error and human performance recognize that errors, active or latent, are most often the result of a poor fit between people, their environments and their tasks: “symptoms of system flaws and not of character flaws.”⁵ “Most errors result from the failure to use basic human-factors principles in the design of tasks and systems. Excessive reliance on memory, lack of standardization, inadequate availability of information, and poor work schedules all create situations in which individuals are more likely to make mistakes.”⁶ Solutions thus need to place greater focus on the system level and use tools and methods from human factors engineering and facility design, as well as experience in accident prevention from industries what have far better records than health care.

Health-care failure mode and effect analysis (HFMEA) and other types of prospective or retrospective error analysis tools are new concepts not yet fully embraced in health-care building designs, though they can contribute significantly to the safety and well-being of facility clients and residents. Using the Certificate of Need (CON) process is one of the key levers available to bring about change within health-care organizations. Building an error analysis requirement into the design process is part of the CON mission of ensuring health-care quality and access, and would enable the Health Facilities Engineering Section of the Michigan Department of Community Health to ensure safe, efficient and effective health-care delivery through review and oversight of health-care construction and modernization projects.

Designing for safe care allows health-care organizations to be deliberate in their attention to patient-centered care. Focus groups conducted by the Picker Institute and the Center for Health Design found that participants want acute, ambulatory, and long-term care settings that focus on patients' well being.^{7 8} This means environments that allow easy connection with staff, ensure confidentiality, pay attention to family needs, connect with the outside, and are safe and secure.^{9 10}

Of corresponding importance is the well-being of staff, not only for its impact on patients but to prevent injury among employees as well. The environment in which employees work is believed to affect patient care outcomes, and is also associated with the structure and process of care.¹⁸ The National Institute for Occupation Safety and Health (NIOSH) is particularly concerned with improving health-care facility environments to ensure the safety of staff as well as patients, and has made numerous recommendations to prevent injury.

Attention to system design brings tangible, substantial benefits to organizations as well. In 2000, the Center for Health Design launched the Pebble project, a program designed to promote the use of design factors shown to make a difference in improving care quality and patient safety, and to demonstrate and share information on their financial viability. The collective experience of

the many organizations in the project has shown that facility design improves quality of care, attracts more patients, helps to recruit and retain staff, helps to increase community and corporate support, and increases operation efficiency and productivity.¹¹

Evidence for harm reduction

There is evidence that when attention is paid to facility and human design, improvements can be achieved for a number of patient and safety outcomes, including fewer medication errors and patient falls, greater patient confidentiality and privacy, reduced lengths of stay, and overall increases in patient satisfaction and quality of care.

- The Karmanos Cancer Institute in Detroit, part of the Pebble project, collected data on two of its inpatient units in 1999 and 2000 and showed significant improvements in key patient safety and quality areas:
 - o Increase of 18% in patient satisfaction
 - o Drop in nurse attrition rate from 23% to 3.8%
 - o Lower daily variable costs per case
 - o Reduced pain medication requirements
 - o Decrease in medication variances
 - o 30% reduction in medical errors, a result of relocating and increasing space in the medication room, re-organizing medical supplies, standardizing visual cues, and installing acoustical panels to decrease noise levels
 - o 6% reduction in patient falls, a result of better visualization of patients due to angle of doorway, improved lighting, and room layout.¹²
- Using facility design processes that explicitly take into account patient safety, St. Joseph's Hospital in West Bend, Wisconsin, identified and corrected a host of latent conditions, such as lack of standardized equipment and procedures, poor visibility, high noise levels, and excessive movement of patients, that contributed to, or combined with, active conditions to result in error. They found that noise, for example, may negatively affect the quality of the healing environment for patients by increasing blood pressure and pain, altering sleep quality, and reduce overall patient satisfaction. St. Joseph's reduced noise through the use of stronger steel, carpeting, standardized single rooms with insulation between rooms, more sound-absorbent ceiling tiles, quiet-engineered mechanical systems, quiet-engineered equipment and technology, and elimination of overhead paging.

Assessment

Advantages

- While costs of modifications to facilities and physical plants can be high, studies have shown that costs can be recuperated within a short amount of time through improved staff performance and reductions in expenses from patient falls, patient transfers, infections and medical errors.¹³ Facilities designed around patient safety are likely to show a return on investment in two specific areas: greater efficiency due to standardization and reductions in near misses, adverse events, and errors.¹⁴
- The Michigan Health and Safety Coalition will be conducting a survey in 2005 to document current use by hospitals in Michigan of two error analysis tools: root cause analysis (RCA) and failure mode and effect analysis (FMEA). Information on the frequency, target and use of the results of these analyses will form the basis of a

collaborative plan to broaden the application of these tools in Michigan health-care facilities.

- An assessment of Certificate of Need (CON) applications for new or existing building designs would allow identification of safety barriers and potential solutions to improve patient environments and prevent errors. While a prospective building design or applicable CON standard with a HFMEA could apply to all health-care facilities, it would be especially significant across Michigan acute care general hospitals.
- Michigan is the home of several national experts and nationally recognized programs in patient safety and human factors engineering.

Barriers

- Health-care facility owners and management may express concerns related to perceived costs or delays attributed to an HFMEA analysis.
- The cost of remodeling, making improvements, or building a completely new facility would be a major concern to many health-care organization CEOs. The Center for Health Design estimated that a 300-bed hospital with single rooms, decentralized nursing stations, as well as other evidence-based design components would add between \$12 million and \$240 million to the building cost of the health-care facility. This is essentially a 5% increase over typical building costs.¹⁵
- Major obstacles to system redesign found in most hospitals include:¹⁶
 - The complexity of the overall system and its subsystems, with multiple stakeholders and no clear ownership.
 - Unavailability of information when and where needed, or in forms that are readily usable, such as for medication administration.
 - Tolerance of individualistic practices by clinicians, such as nonstandard medication orders and administration schedules that vary by nursing unit.
 - Infrequent occurrence of serious events, leading to complacency.
 - Fear of punishment, overt or covert, when mistakes are made or reported.

Implementation

Further research

- Several testimonies called attention to work tasks and the need to find ways to reduce the onus of documentation and paperwork (even 'electronic' paperwork). One informant asked that medical, nursing and other professional schools fund studies on "streamlining the documentation and care planning processes in organizations." While this informant's primary concern was the burden to nurses, other professionals face the same challenges¹⁷
- The Commission received the following specific request: "According to Michigan's Long Term Care Work Group, the non-elderly patient population is becoming the fastest growing sector in Michigan. While...technical advancements [have] produced longer life spans, and shorter hospital stays, the health-care industry [has] yet to recognize the need to research home care safety issues associated with all patient populations. [We lack] the understanding of how patients and caregivers work within the home care environment and this leads some patients to search for answers in countries like Canada or Sweden. In [these countries], home care research has guided the development of patient safety standards, while the American health-care industry uses a one-size-fits-all-patients model."¹⁸ There is a very big need for research in this area.

- Calls for resources and research on the impact of human factors theory on medical errors were made as well. See Resources, below.

Legislation and/or administrative rules

The following changes to Michigan law were proposed:

- A modification to the Certificate of Need program, which oversees the expansion of hospitals and many clinical services. Adopting a CON standard is achieved through the authority of this process.
- A consumer group representing the elderly requested the Commission's support of HB5537, which proposes to set a maximum temperature standard for Michigan's nursing homes. At present [Fall 2004, when the testimony was submitted], there was no such standard in existing federal or state law applying to the majority of the state's nursing homes, most of which were built and certified before 10/1/90.¹⁹ While the request for advocacy on this specific piece of legislation does not directly support the recommendations on designing for safe care, it promotes their intent. More broadly, it suggests an important advocacy role for the Michigan Partnership for Safe Health Care.

Resources

The following needs for resources were raised:

- "Professional societies, purchasers of care, and other third party payers could provide research grants, opportunities and funding to continue to explore the impact of human factors theory on medical errors. Research and evidence-based approaches are the hallmark for consistent high quality outcomes. Currently, research in patient safety is relatively new with little historical comparisons. Minimal research exists in nursing models of care, the impact of human factors, and the impact of existing process on patient errors and patient outcomes. Continued funding and resource assistance are necessary to expand research efforts."²⁰
- "In the face of a rapidly aging population, a shrinking health-care workforce, increasing complexity of care delivery and wholly inadequate health-care financing, the need for a rapid, significant and sustained investment in learning what works, sharing what is learned, and aligning incentives for high quality, safe care has never been greater."²¹

Incentives

- With a broad range of Michigan health-care stakeholders, explore incentives (financial and otherwise) for organizations that design safe facilities.^{22 23}

Specific steps and target dates

Following adoption of these recommendations, the following steps will take place:

- With respect to adoption of a new CON standard:
 - Within 3 months, the CON commission will create the Technical Advisory Committee to consider criteria for the standard.
 - Within 6 months, the Technical Advisory Committee and the Health Facilities Engineering Section at MDCH will meet with experts from the VA National Center for Patient Safety.
 - Within 9 months, the Technical Advisory Committee will identify recommended approaches for infection control, safety features in building design, location and environmental conditions.

- Within 12 months, the Technical Advisory Committee will review standards, conduct public hearings, and recommend final standards for action at the next scheduled CON Commission meeting.
- Within 12 months, the Partnership, in collaboration with the Michigan Health & Safety Commission, will explore ways to expand the use of error analysis tools in Michigan's health-care organizations.

Testimony overview

Summary

These recommendations were based on a total of nine separate recommendations submitted under Human Design (code 17: seven recommendations) and Facility Design (code 19: three recommendations); one recommendation was identical across both codes. Informants were hospitals (2), provider (1), consumer (1), insurer (1), professional associations (2), and research institute (1).

Key findings

- State government and health-care facilities were the two main targets of recommendations.
- Errors and near misses are learning opportunities; they need to be analyzed for system defects and human factors that contribute to them; this knowledge can then serve as a basis for identifying and developing solutions.
- Health-care organizations can and should borrow strategies and tools that have proven successful in other industries, such as forcing functions, bar codes, simulators for learning, and others; the State Commission (or other state-level patient safety organization) should work to dispel the myth that this knowledge can't be transferred.
- Financial incentives could be used to encourage organizations to design safe facilities, implement meaningful patient safety programs, and support evidence-based collaboratives.
- Accommodating human design will require training and the re-engineering of clinical processes which may be costly; one informant specifically called for uniform documentation forms (for therapists) and a uniform authorization process, with a minimum of written data.

Review Panel Round One

Scoring summary

In Round One, the Review Panel was asked to score each recommendation area on a scale of 1 to 5, where 5=extremely viable, 4=very viable, 3=somewhat viable, 2=potentially viable with changes, and 1=not viable for this project. Average score for relevant recommendation considered in Round One:

- Human/Facility Design: 4.0, (range 2-5)

Notes

Panel members' comments are summarized below; their recommendations and suggestions were accommodated in Round Two.

- Panel members felt it would be important to use a term other than "human factors engineering," and something clearer than "human/facility design."

- Use of existing financial means and grants should be emphasized.
- Process changes may require little or no cost compared to the design or re-design of facilities. Recommendations should be sensitive to cost and training issues, and should apply to all health-care settings, not just hospitals.
- Add consideration of environmental factors (e.g. noise, light) to the recommendation.
- Tie into licensure, if possible.

Endnotes

¹ Code 17 (Human Design) was used to identify testimony recommending the design and implementation of health care organizational processes and procedures in ways that acknowledge human limitations as well as the development of human resources.

² Code 19 (Facility Design) was used to identify testimony recommending the design and implementation of physical facilities in ways that support patient safety systems in health-care organizations.

³ Testimony 106W:36-38;59-68.

⁴ Leape LL (1999). A systems analysis approach to medical error. In Cohen MR, *Medication errors: Causes, prevention and risk management*. Sudbury MA: Jones and Bartlett, pp 2.1-2.14.

⁵ Leape, op cit., p.2.7.

⁶ Leape, op cit., p.2.6.

⁷ Gerteis M (1999). Conference overview: through the patient's eyes—improvement strategies that work. *Jt Comm J Qual Improv* 25(7):335-42.

⁸ Fowler E, MacRae S, Stern A, Harrison T, Gerteis M, Walker J, et al. (1999). The built environment as a component of quality care: understanding and including the patient's perspective. *Jt Comm J Qual Improv* 25(7):352-362.

⁹ Shepley MM, & Davies K (2003). *Nursing unit configuration and its relationship to noise and nurse walking behavior: An AIDS/HIV unit case study*. Retrieved 5.26.2004, from

<http://www.aia.org/aah/journal/0401/article4.asp>

¹⁰ Sturdavant M (1960). Intensive nursing service in circular and rectangular units. *Hospitals, JAHA* 34(14):46-48,71-78.

¹¹ The Center for Health Design (2005). The Pebble Project. Retrieved 5.30.05 from

<http://www.healthdesign.org/research/pebble/>

¹² The Center for Health Design (2005). Pebble Project Data Summary. Retrieved 5.30.05 from

<http://www.healthdesign.org/research/pebble/data.php>

¹³ The Center for Healthcare Design (2005). The Pebble Project. Retrieved 5.30.05 from

<http://www.healthdesign.org/research/pebble/>

¹⁴ Reiling JR (2005). Creating a culture of patient safety through innovative hospital design. Retrieved 5.31.05 from <http://www.ahrq.gov/downloads/pub/advances/vol2/reiling.doc>

¹⁵ The Center for Health Design (2005), op cit.

¹⁶ Leape, op cit.

¹⁷ Testimony 306W:70-72

¹⁸ Testimony 824W:19-21;36-39;66-68;72-75.

¹⁹ Testimony 413W: 48-51;282-285;138-141

²⁰ Testimony 110W:55-56;74-75;86-90; 102-123.

²¹ Testimony 906W:148-151.

²² Testimony 212W:259-261.

²³ Testimony 606W:273-274.