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Safe By Design

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Prescriptions for Excellence in HEALTH CARE

A COLLABORATION BETWEEN JEFFERSON MEDICAL COLLEGE AND ELI LILLY AND CO.

Safe By Design

By John Reiling, PhD

To Err is Human: Building a Safer Healthcare System awoke the health care industry to the fact that many patients die from preventable conditions - and many more patients experience a preventable adverse event. One in every 30 patients admitted to a US hospital suffers from a preventable adverse event, and 1 in every 300 patients admitted to a US hospital dies from a preventable condition or circumstance.

Could a hospital facility's design, technology, and equipment affect the safety of patients? Could a hospital facility create conditions under which caregivers provide safer care?

The Learning Lab Experience

To answer these questions and others, SynergyHealth St. Joseph's Hospital of West Bend, WI, convened a National Learning Lab in April 2002. More than 100 people attended, the major participants being high-level leaders from key organizations involved in the patient safety movement, including: American Hospital Association (AHA), American Medical Association (AMA), American Pharmaceutical

Association (APhA), American Society for Quality (ASQ), Institute for Healthcare Improvement (IHI), Institute for Safe Medication Practice (ISMP), The Joint Commission (JCAHO), Medical Group Management Association (MGMA), National Patient Safety Foundation (NPSF), Patient Safety Institute (PSI), University of Minnesota (U of MN), University of Wisconsin-Milwaukee (UW-Milw), Veterans Administration, Midwest Patient Safety Center of Inquiry (VA), Veterans Healthcare Administration (VHA), and Wisconsin Hospital Association (WHA).

The multiple presentations that formed the background for The Learning Lab focused on human error and its causes, and James Reason's theories of latent conditions and active failures.

*"To err is human. Fallibility is an inescapable part of the human condition."*¹ *"Correct performance and systematic errors are two sides of the same coin."*² Human error has been studied for many years by many different professionals. The collective work of cognitive psychologists James Reason, Jens Rasmussen, and Donald Norman forms the basis of a widely accepted theory of why humans err. This work has

inspired environmental designs that minimize the occurrence of errors and the harm they can cause. Lucian Leape describes this as "the pathophysiology of error."³

The organizational issues that create the conditions for error are called **latent conditions**. According to Reason, "These latent conditions are adverse consequences which may lie dormant within the system for a long time, only becoming evident when they combine with other factors to breach the system's defenses."¹ Examples of latent conditions are poorly designed facilities, including their technology and equipment, system design issues, training gaps, staff shortages or improper staffing patterns, and poor safety culture. These are what Reason describes as "blunt end" occurrences.

Errors made by doctors, nurses, pharmacists, and other personnel at the point of service are called **active failures**. Reason describes these as "sharp end" occurrences, and their effects are felt almost immediately.¹ Examples are incidents such as a nurse delivering the wrong medication, or a physician performing wrong-site surgery.

Latent conditions are present in all organizations and are usually

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created by upper management by way of their responsibility for design systems, staffing, and policies. Active failures are committed by employees as they interface with patients and the systems or facilities. Active failures happen one at a time; latent conditions can precipitate multiple adverse events. Eliminating or minimizing latent conditions has a greater impact on human error than focusing on an individual active failure.

Hazards are inherent in health care as with any complex organization. In *Managing the Risks of Organizational Accidents*, James Reason developed a model of error reduction.

Defenses could include technology, equipment, well-designed facilities, systems with standardized protocols, or human checks of a process. The more complicated or linked (tightly coupled) the defenses are, the more likely the defenses will fail.⁴

Multiple defenses exist in most health care processes; for example, most medication systems have multiple checks (eg, physician orders, nurse checks, pharmacist checks, nurse rechecks). Potential errors that could result in the wrong drug being delivered to the wrong patient are generally caught at one of the checkpoints. This method for catching an error before it causes harm is defined as a “near miss.”

Errors periodically escape all the defense checks, resulting in an active failure and/or adverse event. Analysis of active failures or adverse events suggests that the root causes are latent conditions. Figure 1 shows how the various causes of error can penetrate defenses and result in error. This model also illustrates how decreasing latent conditions

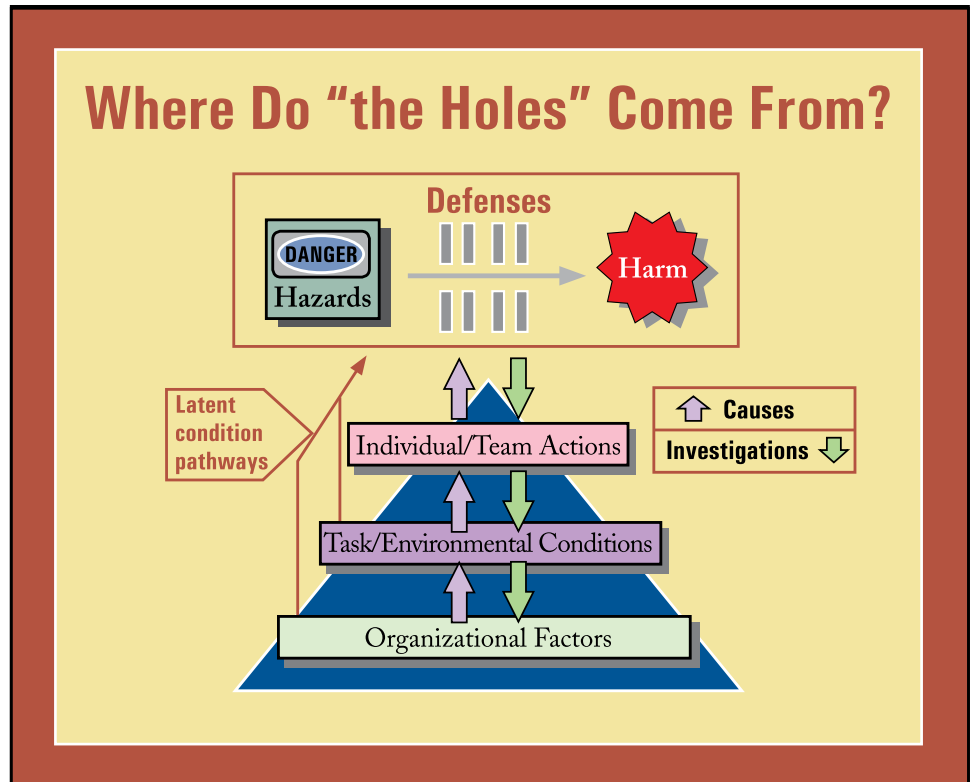


Figure 1. Where Do “the Holes” Come From?

Source: Adapted by John Wreathall, from James Reason, *Managing the Risks of Organizational Accidents* (Aldershot, England: Ashgate Publishing, 1997)

and active failures would lower error rates that lead to harm, thus raising the level of patient safety.

Patient safety will be enhanced by improving human factors through facility design that minimizes the latent conditions and cognitive failures that lead to adverse events. This will entail developing a strong safety culture, and redesigning systems or facilities - including their equipment and technology - with a focus on either eliminating the conditions of cognitive errors or helping caregivers correct an error before it leads to harm.

Translating Theory into Practice

The Learning Lab participants believed that facilities, with their technology and equipment, could affect the safety of patients and the caregiver’s ability to deliver safe care. They recommended designing

around specific latent conditions and specific active failures with the goal of lowering harm to patients by creating conditions wherein safe care can be delivered. They recommended other nontraditional approaches throughout the facility design process (Table 1). Finally, the Learning Lab participants recommended that the facility design process be engineered to enhance or create a safety culture that they defined.

The Learning Lab results are being applied in many facilities design processes. To date, the institution that has most fully implemented the recommendations of the National Learning Lab is SynergyHealth St. Joseph’s Hospital of West Bend. In redesigning their medical/surgical room, they applied the design process recommendations, taking

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Table 1. Design Recommendations

Design Recommendations		
<p>Latent Conditions</p> <ul style="list-style-type: none"> Noise Reduction Scalability, Adaptability, Flexibility Visibility of Patients to Staff Patients Involved with their Care Standardization Automation Where Possible Minimizing Fatigue Immediate Accessibility of Information, Close to the Point of Service Minimizing Patient Transfers/Handoffs <p>Active Failures</p> <ul style="list-style-type: none"> Operative/Post-op Complications/Infections Inpatient Suicides Correct Tube – Correct Connector – Correct Hole Placement Events 	<ul style="list-style-type: none"> Medication Error-Related Events Wrong-Site Surgery Events Oxygen Cylinder Hazards Deaths of Patients in Restraints Transfusion-Related Events Patient Falls MRI Hazards <p>Safety Design Process Recommendations</p> <ul style="list-style-type: none"> Matrix Development (post Learning Lab) Failure Mode and Effect Analysis (FMEA) at each Stage of Design Patients/Families Involved in Design Process Equipment Planning from Day 1 Mock-ups from Day 1 Design for Vulnerable Patients Articulation of a Set of Principles for Measurement 	<ul style="list-style-type: none"> Establishment of a Checklist for Current/Future Design <p>Safety Culture Recommendations</p> <ul style="list-style-type: none"> Shared Values and Beliefs about Safety Within the Organization Always Anticipating Precarious Events Informed Employees and Medical Staff Culture of Reporting Learning Culture Just Culture Blame-Free Environment Recognizing Human Fallibility Physician Teamwork Culture of Continuous Improvement Empowering Families to Participate in Care of Patients Informed and Active Patients

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into account latent conditions and active failures. Personnel who provide patient care were integral to the design process. Using mock-ups and Failure Mode and Effect Analyses (FMEA), they focused on standardization, visibility, and prevention of medication errors, infections, and falls in the room design.

Conclusion

Hospitals can become safer places. A focus on safety by design can create conditions wherein care

is delivered safely and patients are harmed less often.

Dr. Reiling is President and CEO of Safe by Design. He can be reached at jreiling@safeydesign.net.

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