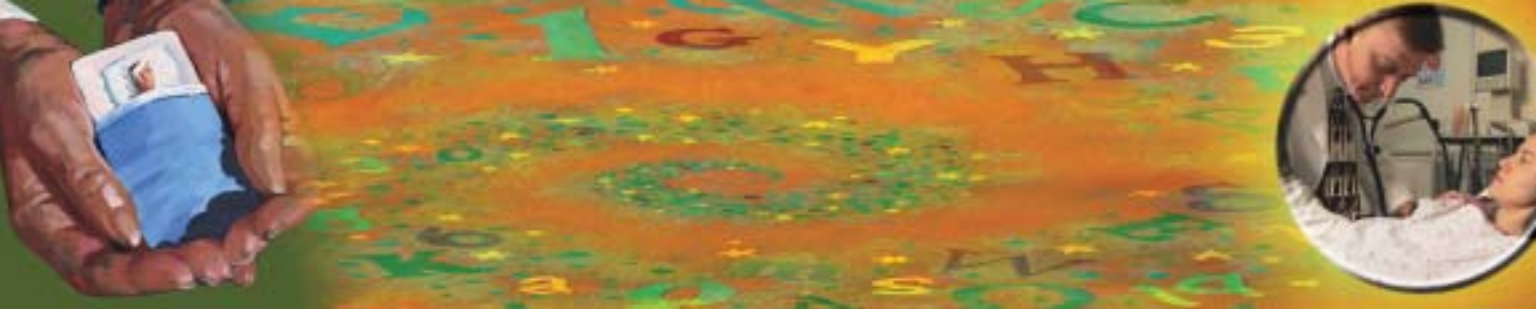


HEALTHCARE

FMEA—the Cure For Medical Errors

by **John G. Reiling and Barbara L. Knutzen, with Mike Stoecklein**

St. Joseph's Community Hospital in West Bend, WI, will close in the next few years to make room for a new hospital. This replacement facility will represent a breakthrough in hospital design.

Inspired by the Institute of Medicine report *To Err Is Human*,[1] we recognized the opportunity to increase patient safety and promote a patient safe culture through facility design, something not traditionally done in healthcare.

In 50 Words Or Less

- **Failure mode and effects analysis can be a valuable tool in healthcare facility design.**
- **St. Joseph's Hospital has used FMEA to create a replacement facility aimed at reducing errors and promoting patient safety and satisfaction through design.**

According to the report, 44,000 to 98,000 people a year die in hospitals from preventable medical errors. This means there is one death in every 343 to 764 admissions. In comparison, aviation averages one death for every 8 million flights. The report also says more people die every year as a result of medical errors than from motor vehicle accidents, breast cancer or AIDS.

In April 2002, St. Joseph's administration hosted a conference titled "Charting the Course for Patient

Safety, a Learning Lab." The conference was sponsored in part by a grant from the healthcare administration program at the University of Minnesota's Carlson School of Management. Leaders in systems, engineering, healthcare administration, human behavior, research, hospital quality improvement and accreditation, hospital architecture, medical education, pharmaceuticals, nursing and medicine attended.

By the end of the conference, we had a top 10 list of recommendations for St. Joseph's replacement facility:

1. Use failure mode effects analysis (FMEA) at each design stage.
2. Standardize location of equipment, supplies, room layout and care processes.
3. Consider patients and their families in the design process.
4. Use an established checklist for current and future design.
5. Use adaptive systems that will function in the future.
6. Articulate a set of principles by which everything is measured.
7. Bring critical information for decision making, such as medical records, to the patient's bedside.
8. Reduce noise.
9. Begin equipment planning immediately.
10. Begin mock-ups immediately.

The first recommendation, using FMEA at each design stage, would be the starting point to fulfilling the other nine.

FIGURE 1 Sample FMEA Form

Potential failures/ effects mode(s) (day/night)	Severity/occurrence High-medium-low	Adjacency changes to minimize or eliminate potential failure/effect	Recommend adjacency change

FMEA and Healthcare

FMEA is a systemic group of activities intended to do three things:

1. Recognize and evaluate the potential failures of a product or process and the effects of those failures.
2. Identify actions that could eliminate or reduce the chance of the potential failures' occurring.
3. Document the entire process.

There are two types of FMEAs: process FMEAs and design FMEAs. Process FMEAs assume the product works perfectly and assess potential process failures and their effects. Conversely, design FMEAs assume the process works perfectly and assess the product and its potential failures and effects.[2]

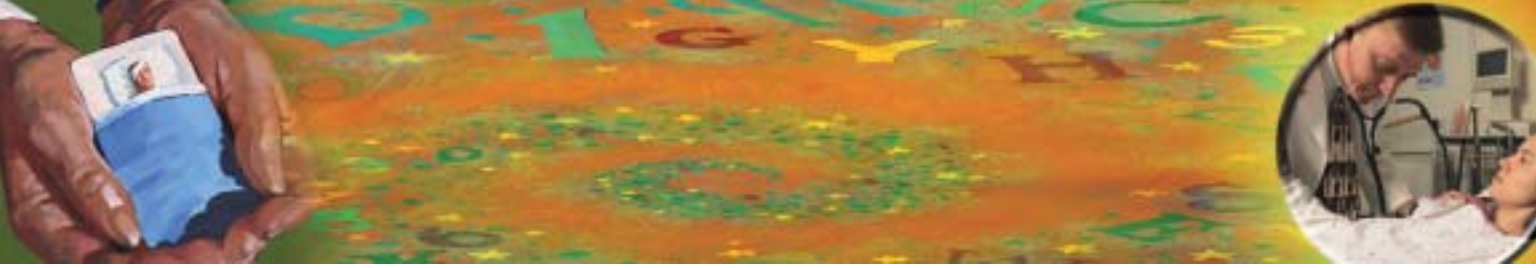
Many industries have successfully used FMEA for systems and facility development. The healthcare industry has recently begun using FMEA as a process improvement tool. The Joint Commission on Accreditation of Healthcare Organizations now requires every hospital to use FMEA as one means to improve its processes. In addition, the American Hospital Association, National Patient Safety Foundation and Veterans Administration support its use.

Design FMEA had not, however, been applied to facility development in healthcare. In the past, healthcare facility development has followed a traditional three-step design process—block diagrams, schematics and design development (see "Tradintional Healthcare Facility Development").

To improve patient safety, St. Joseph's redefined the traditional healthcare facility design process to include the application of FMEA at each stage.

Faced with no experience in FMEA's application to healthcare facility design, we looked to other industries for expertise and guidance. ASQ and an expert from General Motors gave support, and representatives from the design and architect/construction teams attended process FMEA training.

The teams determined the traditional FMEA approach was too complex for healthcare facility design and developed a



modified approach. They began by simplifying the FMEA spreadsheet to use a revised severity/occurrence scoring system (see Figure 1). Instead of using traditional numerical scoring, teams were asked to score failure occurrence and effects as low, medium or high. This modified process clearly identified potential failures of design and their relative priority.

Traditional Healthcare Facility Development

Stage 1: **Block diagrams—the layout of the hospital as a whole, otherwise known as adjacencies.**

Stage 2: **Schematics—the layout of individual departments.**

Stage 3: **Design development—the detailed design of each room.**

Stage One: Block Diagrams

We established guiding principles for facility design at the onset of the project. Our key goal of patient safety would be achieved by separating public, patient and service traffic and by minimizing the need for patient transportation.

When we evaluated the movement of materials to and from patients, we discovered key failures. Mainly, significant horizontal traffic of materials and services was occurring on patient floors. Materials such as food, pharmaceuticals, linen and waste were crossing with patients.

After testing various scenarios involving the movement of materials to and from the patient, we realized we had to focus on bringing the service to the patient whenever possible, rather than bringing the patient to the service.

We achieved this by designating the garden level (ground level) as a nonpatient, strictly support service floor. Horizontal transportation of food, pharmaceuticals and linen would occur on the garden level. Only vertical transportation of these items would occur elsewhere in the hospital, minimizing service traffic in the presence of patients.

The result of FMEA on patient transfer also yielded valuable findings. Transporting critical patients between services requires skilled staff. This causes key services, such as the intensive care unit (ICU), emergency department (ED) and surgery, to be short-staffed during those periods. When staff is away, the potential of a serious event's occurring increases. Occurrence of this scenario was rated as medium/high and severity as high.

Another major potential failure was found in transportation distance of vulnerable, critically ill patients. We tested various scenarios, including:

- A critically ill ED patient requiring radiology and direct admission to ICU.
- A critically ill ICU patient in need of radiology and surgery.
- An unstable medical/surgical patient being urgently transferred to ICU.
- A violent behavioral health patient brought to the ED and then admitted directly to the locked behavioral health unit.

For behavioral health, two issues related to adjacency were raised. First, the lack of a direct adjacency to ED led to the potential of violent, disturbed patients being transported through public corridors, risking breach in privacy and injury to staff. The contributing factors were distance and time requirements. The occurrence was rated medium/high and the severity high. In addition, a concern about the planned adjacency of the behavioral health unit to the obstetrics unit was identified. Child and mother safety (occurrence low, severity high) was the greatest issue.

The tested scenario with the fewest failures and effects was the urgent medical/surgical patient transfer to ICU. In this scenario, a patient's condition worsens during care on a medical/surgical unit and he or she needs to be transferred to ICU. A medical/surgical nurse goes with the patient. The only failure found was elevators not working properly (occurrence low/medium, severity

medium/high). The medical/surgical staff has many more nurses than other departments, so the absence of a nurse for the transfer period did not create the potential for any major failures.

The proposed design plan evolved to minimize the occurrence and severity of the failures identified using FMEA. Changes from the original adjacencies to the revised adjacencies (see Figure 2) reflect the following recommendations:

- Place mental health next to ED.
- Put ICU next to radiology.
- The first floor should house surgery, radiology, mental health, ICU and other services.
- The second and third floors should have medical/surgical rooms.
- Place obstetrics (new life center) on the second floor with its own cesarean room.

FIGURE 2 A Comparison of the Original And Revised Adjacency Recommendations

Original	Revised
Third floor	***Third floor***
• Medical/surgical	• Medical/surgical
Second floor	***Second floor***
• Mental health	• Medical/surgical
• Obstetrics	• Obstetrics
• Intensive care unit	
First floor	***First floor***
• Lab	• Radiology
• Radiology	• Emergency
• Emergency	• Surgery
• Surgery	• Mental health
• Pharmacy	• Intensive care unit
Garden level	***Garden level***
• Administration	• Administration
• Support services	• Support services
• Materials management	• Materials management
• Linen	• Linen
• Kitchen/cafeteria	• Kitchen/cafeteria
• Loading dock	• Loading dock
	• Pharmacy
	• Lab

Stage Two: Schematics

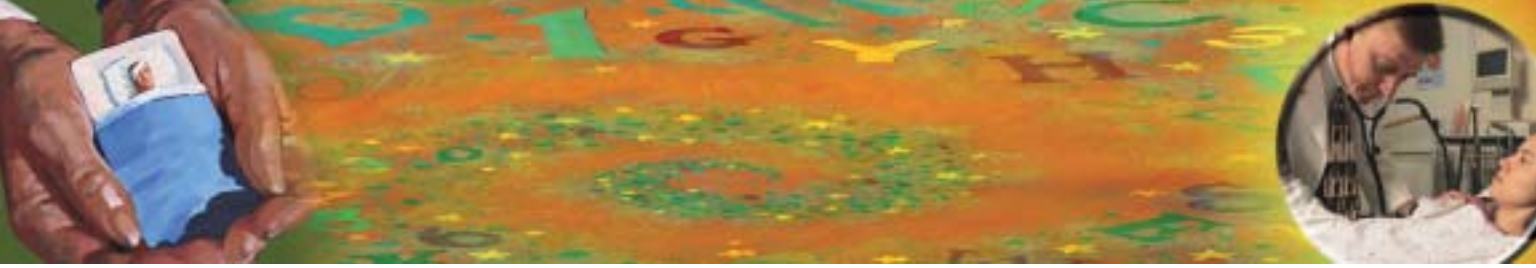
Numerous FMEAs were conducted on alternative designs of patient rooms, otherwise known as medical/surgical rooms, giving us a deeper understanding of the unique challenges of designing complex rooms where patients, technology, equipment and staff interface. We assessed the failures and effects of meeting our guiding principles in the patient room. This involved the interfacing of a vulnerable patient with staff to minimize errors and maximize the following facility safety design principles:

- Visibility of patients to staff.
- Standardization.
- Automation where possible.
- Scalability, adaptability and flexibility.
- Immediate accessibility of information, close to the point of service.
- Noise reduction.
- Patient involvement with care.
- Design for the vulnerable patient.
- Low staff fatigue.
- Design around precarious events.

Many configurations of patient rooms were tested: back-to-back (mirrored) rooms, rooms with different shaped entrances, one-door entrances, two-door entrances, single alcoves, double alcoves, no alcoves and showers separate from the rest of the bathroom.

The following design features of the patient room reflect the application of FMEA around facility safety principles:

- True standardization in room size and layout for all patient rooms.
- In-room sink, allowing physician and staff hand washing in patient view.
- Charting alcove with window, increasing patient visibility for nurses, physicians and staff.
- Supplies in alcoves and carpeted floors, reducing staff fatigue.
- Computers in alcoves, providing information close to the patient.
- Private rooms, reducing infections and noise.
- Close proximity between bed and bathroom, reducing the potential for patient falls.
- Bedside computers, allowing patient access to records and involvement with care.



- Oversized windows, increasing natural light, making patients more visible to staff and physicians and promoting a healing environment.
- Ceiling heights and room sizes that allow adaptability and scalability.
- Sitting area and guest fold-out bed to encourage family support and involvement with care.
- Noise reduction through carpet, special ceiling tile and enforced steel that reduces vibration.

Stage Three: Design Development

As the physical groundwork for our new hospital is being laid, we now enter this final stage. Implementing FMEA in design development results in a greater focus on failures and effects caused by the patient room and its components, such as hardware, headwalls, bathroom fixtures and location of outlets, coupled with the normal processes performed in the area.

We are also testing scenarios involving vulnerable patients and situations in the rooms. Sample questions addressed include, "What is the likelihood of the call button's failing, and what is the effect?" and "Are all the fixed equipment outlets and switches in the right location if a vulnerable patient is in the room?" In essence, we are conducting a process FMEA and design FMEA on an individual room.

Recommendations

Although FMEA can be laborious and time consuming, it is a valuable tool in designing a healthcare facility that focuses on patient safety. It will also result in increased architect, owner and contractor awareness. This change in culture of the contracted design teams results in the reinforcement of the patient safety design principles and helps the teams become true partners with hospital staff to achieve the goal of a safety focused design.

However, we caution users of FMEA for facility development to recognize the potential for bias. What one person considers a high severity, another might consider medium or low. What is a failure to one person might not be a failure to others.

A major challenge of facility design is balancing all guiding principles, some of which may be in opposition to one another. The importance of all valid design principles, such as efficiency, healing environments, patient focus and staff focus must not be lost. It is becoming more apparent, however, that a focus on patient safety through design will create facilities that are both patient and staff focused and will increase efficiency while promoting a healing environment.

REFERENCES

1. Linda Kohn, Janet Corrigan, Molla Donaldson, eds., *To Err Is Human: Building a Safer Health System*, National Academy Press, 2000.
2. *Potential Failure Mode and Effects Analysis (FMEA) Reference Manual*, DaimlerChrysler Corp., Ford Motor Co. and General Motors Corp., 2001.

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