Risk Assessment as Standard Work in Design

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ABSTRACT

OBJECTIVE: This case study article examines a formal risk assessment as part of the decision making process for design solutions in high risk areas. The overview of the Failure Modes and Effects Analysis (FMEA) tool with examples of its application in hospital building projects will demonstrate the benefit of those structured conversations.

BACKGROUND: This article illustrates how two hospitals used FMEA when integrating operational processes with building projects: (1) adjacency decision for Intensive Care Unit (ICU); and (2) distance concern for handling of specimens from Surgery to Lab.

METHODS: Both case studies involved interviews that exposed facility solution concerns. Just-in-time studies using the FMEA followed the same risk assessment process with the same workshop facilitator involving structured conversations in analyzing risks.

RESULTS: In both cases, participants uncovered key areas of risk enabling them to take the necessary next steps. While the focus of this article is not the actual design solution, it is apparent that the risk assessment brought clarity to the situations resulting in prompt decision making about facility solutions.

CONCLUSIONS: Hospitals are inherently risky environments; therefore, use of the formal risk assessment process, FMEA, is an opportunity for design professionals to apply more rigor to design decision making when facility solutions impact operations in high risk areas.

KEYWORDS: Case study, decision making, hospital, infection control, strategy, work environment

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Healthcare environments are ironically and yet inherently laden with risk. Staff must be diligent in disposing of needles, solutions and biohazardous waste in appropriate receptacles. The high rate of hospital-acquired infections (HAIs) has increased the exposure of patients and healthcare staff to noxious cleaning solutions and chemically treated surfaces. These are well-known, day-to-day potential hazards that patients and staff encounter. Healthcare facility designers must stay abreast of new products on the market to alleviate the spread of infection from surface materials. This article examines the benefits of addressing potential physical environment risks as standard work in design projects.

Standard work is defined as a step-by-step description of the actions and tools needed to complete a task (Touissant & Gerard, 2010). For the purposes of this article, “task” involves the facility planning process. Standard work is established through analysis, observation, and employee involvement. Employees are involved because the people closest to the work understand it best (Manos & Vincent, 2012). As we strive to improve healthcare delivery processes, we can simultaneously seek better facility solutions that support safer environments. By incorporating risk assessment as standard work, design professionals can increase rigor of informed design and decision making.

**Background**

This case study article describes two examples of how risk assessments have been used in hospital design projects. Hospital A is a replacement critical access hospital with a total capacity of 25 beds accommodating medical/surgical, critical care, and obstetric patients. Hospital B is a rural integrated hospital and clinic with a phased replacement project with 50 beds.

In early 2000—at the urging of The Joint Commission—hospitals started using the Failure Mode and Effects Analysis (FMEA) to analyze medication errors. FMEA is a model used to prioritize potential defects based on their severity, expected frequency, and likelihood of detection (MoreSteam.com, 2013), with broad potential for application, including in design. John Reiling, past CEO of St. Joseph’s Hospital in West Bend, Wisconsin, that opened in 2005, authored several articles about the design process used to focus on safety. The use of failure mode and effects analysis, patient focus groups, mock-ups with employee evaluation, and checklist safety design principles (latent conditions and active failures) helped St. Joseph’s create the safest room they could envision (Reiling, Hughes & Murphy, 2008).

Begun in the 1940s by the U.S. military, FMEA was further refined by the aerospace and automotive industries. The purpose of the FMEA is to take actions to eliminate or reduce failures (American Society for Quality, 2013a). Failures in healthcare have become increasingly transparent via website reporting of infections and satisfaction comparison ratings. Healthcare reform has exposed the high incidence and unacceptable cost of preventable infections and injuries. Six
Sigma training includes FMEA as part of the “Define” and “Improve” phases (MoreSteam.com, 2013) of the DMAIC methodology:

- **Define** a problem or improvement opportunity;
- **Measure** process performance;
- **Analyze** the process to determine the root causes of poor performance;
- **Improve** the process by attacking root causes; and
- **Control** the improved process to hold the gains (American Society for Quality, 2013b).

With the continued high rate of harm in hospitals, design professionals must be alert to assessing risk potential in their design projects. The case studies presented here offer two examples of two questions raised: one during design, and one during occupancy planning, which should have been addressed during design. This article does not advocate one solution for each question, but rather promotes the risk assessment process to expose the best design decision for high risk areas.

**Method**

For Hospital A, the author conducted a current state workflow assessment at the start of pre-design that involved individual interviews and observation. Opportunities for improvement were documented and prioritized based on workflow issues with a space impact. The location of the intensive care unit was identified as a top priority. With differing opinions about the location of this high risk patient care area, the author recommended the FMEA process.

For Hospital B, during the occupancy planning phase, the author conducted Lean A3 problem solving training, then individual interviews with hospital leadership to assess their problem-solving process. The lab leadership interviews identified a workflow challenge created by design decisions that needed resolution prior to occupancy. The problem concerned the high risk handling of frozen specimens and the author recommended the FMEA process.

The FMEA process was recommended in both cases because of the time constraints related to the building projects. The intent of the just-in-time study with the FMEA tool was to influence decision making; the research involved the investigation of whether the FMEA process did benefit facility decisions. The process involved the following steps in a workshop setting facilitated by the author, a trained quality professional in Lean and Six Sigma, serving in a consultant role:

1. An interdisciplinary team was assembled, representing content expertise, executive leadership for prompt decision making, and at least one individual not familiar with the process who could ask probing questions.
2. The team was provided with just-in-time training about the FMEA tool with a healthcare example.
3. A high-level flow diagram of the process being analyzed was developed.
4. From the flow diagram, a process step was selected as a priority for the risk assessment.
5. Using the FMEA tool, the team:

- Discussed potential failures involved in the process step.
- Identified the effects of each failure.
- Scored the level of severity (on a scale of 1–10 with a definition of each level).
- Identified the potential causes of the failure.
- Scored the likelihood that each cause might occur (1–10).
- Identified the controls in place for the failure.
- Scored the probability that the controls would detect each cause (1–10).
- Multiplied each of the scores for the risk priority number (RPN), therefore: severity × occurrence × detection = RPN.
- Finally, documented the recommended actions.

Hospital A—Critical Access Hospital

Design question: Should the two-bed intensive care unit (ICU) be located adjacent to the emergency department (ED) or the medical/surgical (med/surg) inpatient unit? This question often arises in small hospitals that need to cross-train nursing staff to flex between units based on census.

A pre-design workflow and facility assessment of the existing hospital condition identified risks with the isolated location of ICU being staffed with only one or two nurses who needed to focus on patient care while also needing to retrieve supplies and equipment stored away from the ICU rooms. To provide a safer environment, hospital officials wanted ICU to be immediately adjacent to either the emergency department or the med/surg unit for improved access to other nursing staff, supplies, and equipment.

Results—Hospital A

After identifying the various support needs of ICU during the high-level flow discussion in the FMEA workshop (see Figure 1), participants agreed that the lack of proximity of supplies, equipment, and medications to nurses was the risk to analyze. The discussion identified the potentially serious implications of distant supplies, equipment, and medications as documented in the FMEA tool (see Table 1). Given the unacceptable cost of duplicating equipment, the adjacencies to ICU were essential in reducing risk. From this analysis, the decision was made to locate the ICU adjacent to Med/Surg based on (1) more similar care; (2) hospitalist overlap; (3) ICU nursing’s ability to provide expertise to Med/Surg; (4) shared supplies; (5) shared meds; and (6) shared technology. The FMEA benefit realized in this case was the clear depiction of commonalities between ICU and med/surg, leaving no doubt in decision making. This hospital is under construction at the time of this writing.
Figure 1. Hospital A—ICU primary support needs in consideration of best adjacency.
Hospital B—Rural Integrated Hospital and Clinic

Occupancy Planning Question: How can frozen specimens be transported safely and quickly from operating rooms (ORs) in a new building to the lab remaining in an attached facility? (See Figure 2.) During Lean A3 Problem Solving training sessions, this question was raised and the lab leadership agreed to hold an FMEA workshop because of the risks involved in handling frozen specimens. This question, as is the one for Hospital A, is frequently discussed during design when faced with the options of a STAT lab near surgery or a distance dilemma when timing is of the essence, as in this case, with a patient remaining in the operating room until pathology results are known. For this particular hospital project, it was decided late in design to remove the STAT lab (due to staffing and cost issues), though the operational impact was not addressed until occupancy planning was underway.

Results—Hospital B

The FMEA workshop participants discussed the risks involved when pathology is not alerted to a STAT specimen from the OR, whether the specimen transport occurs via pneumatic tube or walked by courier as documented in the FMEA tool (see Table 2). The pneumatic tube usage for specimens from the OR was a new process for this hospital to plan for with

Occupancy planning question: How can frozen specimens be transported safely and quickly from operating rooms in a new building to the lab remaining in an attached facility?
Table 1. Failure Modes and Effects Analysis (FMEA).

| ITEM: | Location of an Intensive Care Unit (ICU) in a Critical Access Hospital |
| LEAD: | Lean Six Sigma Consultant |
| CORE TEAM: | Team: Administration, Nursing, Facilities, Architect |

| PROCESS STEP: | Identify systems and functions |
| POTENTIAL FAILURE MODE: | What are the potential failure modes that could occur in this function? |
| POTENTIAL EFFECT(s) OF FAILURE: | What are potential effects of each failure mode? |
| SEVERITY: | Severity of effects |
| POTENTIAL CAUSE(s) / MECHANISM(s) OF FAILURE: | What are the potential causes of the failure mode? |
| OCCURRENCE: | Likelihood of each cause |
| CURRENT CONTROLS: | List controls for each failure mode |
| DETECTION: | Probability of detecting each cause with controls |
| R. P. N.: | Risk Priority Number S x O x D |

**Potential Failure Mode**
- IVs not on site
  - Life/death: med, supply, equipment (10)
  - Space constraints (10)
  - Par levels, centralized stock (10)
  - 
- No one available to help be a runner
  - Quality of care (9)
  - Financial constraints (duplication of equipment, par levels) (10)
  - 
- Don’t have what’s needed
  - Delay in care (8)
  - 
- Insufficient storage
  - Staff satisfaction (6)
  - Asset management (9)
  - Hospital formulary for each Pyxis (6)
  - 
- Don’t want to duplicate
  - Patient/family satisfaction (staff running around) (6)
  - Information management (9)
  - Supervisors (4)
  - 
- In use elsewhere (not enough due to cost)
  - Labor (9)
  - 
- Can’t locate what’s needed
  - 
- Par level out so no one to restock
  - 
- Meds not on premises
  - 
- No bariatric furniture
  - 

**Recommended Action(s):** ICU adjacency to med/surg based on (1) more similar care; (2) hospitalist overlap; (3) ICU can provide expertise to med/surg; (4) shared supplies; (5) shared meds; (6) shared technology.
the surgery department opening in a more distant location. The group realized they needed (1) more information from the pneumatic tube vendor about STAT alerts, and (2) to work with OR staff about calling to notify pathology of the OR specimen. This FMEA workshop occurred 5 months prior to occupancy.

The Lab Director of Hospital B (who had participated in the FMEA workshop) was interviewed 1 year post-occupancy and shared that:

All frozens are successfully tubed from the OR. It was a “change” that the surgeons had to get comfortable with and have confidence in the pneumatic tube. Initially, some continued to walk the specimens over, but that ended very quickly. The team took each type of specimen, met with the areas that would be sending that type of specimen, determined the best flow, and created a chart as a guide for how to package and how to transport. It is attached to the pneumatic tube policy.

Table 2. Hospital B—Failure Modes and Effects Analysis (FMEA).

| ITEM: Frozen Specimen from Surgery to Lab in a Rural Hospital — Distance Created with Design of Replacement Campus, Phase 1 |
| LEAD: Lean Six Sigma Consultant |
| CORE TEAM: Administration, Lab, Process Improvement, Quality |

| PROCESS STEP: Identify systems and functions |
| POTENTIAL FAILURE MODE: What are the potential failure modes that could occur in this function? |
| POTENTIAL EFFECT(s) OF FAILURE: What are potential effects of each failure mode? |
| SEVERITY: Severity of effects |
| POTENTIAL CAUSE(s) / MECHANISM(s) OF FAILURE: What are the potential causes of the failure mode? |
| OCCURRENCE: Likelihood of each cause |
| CURRENT CONTROLS: List controls for each failure mode. |
| DETECTION: Probability of detecting each cause with controls |
| R. P. N.: Risk Priority Number S x O x D |

| PROCESS STEP: Lab specimen processing courier |

| POTENTIAL FAILURE MODE: Specimen not marked STAT |
| POTENTIAL EFFECT(s) OF FAILURE | SEVERITY | POTENTIAL CAUSE(s) / MECHANISM(s) OF FAILURE | OCCURRENCE | CURRENT CONTROLS | DETECTION | R. P. N. |
| Delay in reporting | 7 | Human error | 7 | Call from OR | 2 | 98 |
| Delay in courier to pathology | 7 | Pneumatic tube does not alert (design failure from vendor) | 3 | Green form with specimen | 2 | 42 |
| Delay in OR (Note: Not the right attendees to address delay in OR) |

RECOMMENDED ACTION(S): (1) Do an FMEA on the current control identified: call from OR; (2) consult with vendor regarding pneumatic tube alert.
When asked about the follow-up needed and identified in the FMEA process, the Lab Director responded that:

The OR calls the pathology department when they are sending a frozen. This alert is working consistently and we have not had any delays. We are at 100% compliance for our turnaround goal of 20 minutes for frozen sections.

The formal FMEA risk assessment process helped the participants focus their discussion and prioritize next steps resulting in successful decision making and outcomes.

**Conclusion and Recommendation**

These two cases demonstrate the FMEA process informing facility decisions. For Hospital A, it resulted in locating the ICU adjacent to the medical/surgical unit and not the emergency department. For Hospital B, it resulted in transporting specimens from the operating room to pathology via pneumatic tube instead of physically walking the long distance. Both hospitals were faced with decisions that involved potential delays in patient care and the FMEA structured conversations generated solutions focused on safely integrating operations and the physical environment. The FMEA process brought clarity in situations in which the solutions were not obvious and there were differing opinions.

As referenced on The Joint Commission website, the physical environment is a cause of sentinel events (i.e., unexpected death or serious injury or the risk of these types of death or injury). There were a total of 901 sentinel events reported to The Joint Commission in 2012. The 10 most common root causes of these events are:

1. Human factors
2. Leadership
3. Communication
4. Assessment
5. Information management
6. Physical environment
7. Continuum of care
8. Operative care
9. Medication use
10. Care planning (Rodak, 2013)

Many of these categories can be influenced by healthcare design professionals who can explore with hospital leadership a broader role for risk assessment during the design process.
The evidence provided in this study suggests a compelling opportunity to increase rigor in making design decisions that have an impact on operations. Given the inherent risk in healthcare environments and the demonstrated benefit of the FMEA process for decision making, it is recommended that design professionals include risk assessment as standard work within the “task” of facility planning.

**Implications for Practice**

- Healthcare design teams are urged to include risk assessments as a routine and essential part of the facility planning process.
- As the pressure intensifies for hospitals to improve quality while reducing cost, facility planners need to understand the importance of risk analysis in decision making for design solutions.
- During pre-design, facility planners should bring forth the discussion with hospital leadership about who can fill the role as facilitator of risk assessment workshops as needed for design decision making.
- Structured conversations about potential risk add rigor to decision making about design solutions.
- Failure Modes and Effects Analysis (FMEA) is a proactive risk assessment process that can be included in a professional development training program.

**References**


