

FMEA, RISK ASSESSMENT & ROOT CAUSE ANALYSIS

CONDUCTING A RISK ASSESSMENT OR FAILURE MODE & EFFECTS ANALYSIS (FMEA) TAKES A PROACTIVE APPROACH TO PROBLEM RESOLUTION, EVALUATING ISSUES BEFORE AN EVENT HAPPENS.

ROOT CAUSE ANALYSIS IS THE REACTIVE METHOD TO EVALUATE WHAT HAPPENED, TO PREVENT FUTURE OCCURRENCES.

THIS SESSION ASSISTS ATTENDEES TO ANTICIPATE ADVERSE EVENTS, THEN THE ABILITY TO ADDRESS THOSE ADVERSE EVENTS IF THEY DO OCCUR.

George Mills, Director
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OVERVIEW

- ▶ **Risk Assessment**
 - ❑ Problem solving approach to determine appropriate response
 - ❑ Preventive strategies to address potential issues
- ▶ **Root Cause Analysis (RCA)**
 - ❑ Reactive response
 - ❑ Post event review
 - ❑ "Hindsight Bias"
- ▶ **Failure Mode & Effects Analysis (FMEA)**
 - ❑ Proactive assessment of potential events and
 - ❑ Preventive strategies to avert and adverse event
- ▶ **Seven-step Processes:**
 - ❑ FMEA: 7 Steps
 - ❑ Risk Assessment: 7 Steps
 - ❑ RCA: 7 Steps

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RISK ASSESSMENT



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RISK ASSESSMENT

Conducting a Risk Assessment takes a proactive approach to problem resolution, evaluating issues before an event happens.

A proactive risk assessment evaluates a process to identify the "weak link" and adjust to improve reliability

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**RISK ASSESSMENT IS THE
BASIS OF YOUR PLANNING ASSUMPTIONS**

- ✔ You can't manage everything
- ✔ Risk is inherent to people and processes
- ✔ Often no clear resolution (*gray areas*)
- ✔ Range from high incidence/low risk to low incidence/high risk
- ✔ Educated guess that drives your assumptions

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CONDUCTING A RISK ASSESSMENT

- ✔ Joint Commission utilizes Risk Assessments when a specific Standard is not available
- ✔ Use to evaluate any issue that lacks a clear decision
- ✔ Clearly document the process
- ✔ Determine when to re-assess the issue
- ✔ Suggested 7-step process

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EC.02.01.01 EP 1

- ✔ The hospital identifies safety and security risks associated with the environment of care that could affect patients, staff and other people coming into the hospital's facilities.
- ✔ *Is there a risk assessment process?*
- ✔ *Quality of the risk assessment process*

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EC.02.01.01 EP 1

▀ Risk identification


- Internal sources such as ongoing monitoring of the environment, results of root cause analysis, results of annual proactive risk assessments of high-risk processes

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EC.02.01.01 EP 1

▀ Risk identification

- Credible external sources such as Sentinel Event Alerts. (See also EC.04.01.01 EP 14).
 - Governmental agencies and evidence-based guidance
 - OSHA: <https://www.osha.gov/dsg/hospitals/>



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SENTINEL EVENT ALERTS

▀ 17 out of 52 Alerts impact the environment of care, including:

- #9: Infant Abductions
- #15: Infusion Pumps
- #22: Preventing needlestick and sharps injuries
- #37: Emergency elect. power system failures
- #39: Preventing surgical fires
- #45: Violence in the health care setting
- #46: Preventing suicide in med/surg units and ED
- #47: Radiation risks of diagnostic imaging
- #50: Medical device alarm safety

▀ Free Sentinel Event downloads at Joint Commission Home Page, Topics, Sentinel Event Alerts: http://www.jointcommission.org/sentinel_event.aspx

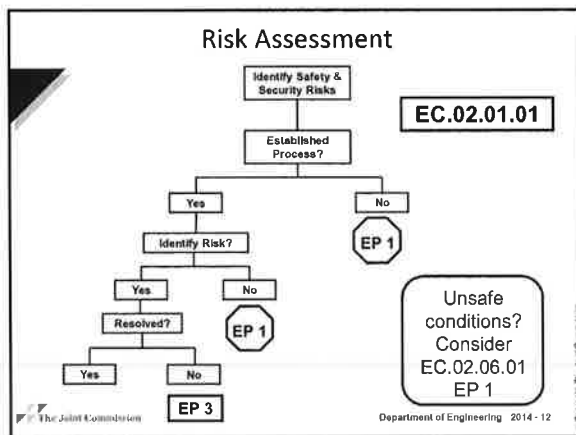
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EC.02.01.01 EP 3

The hospital takes action to minimize or eliminate identified safety and security risks in the physical environment. **R**

Did the organization respond to the risk assessment and correct the identified risk?

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EC.02.06.01 EP 1

Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment and services provided.

Unsafe patient care areas

- Behavioral Healthcare Unit: Clinical or Physical?
 - Ensure the risk is not being managed clinically
 - Does not include outdoor areas

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Risk Assessment In The Physical Environment

- ▀ Several tools exist to facilitate risk assessment in the Physical Environment
 - Environmental Tours
 - ILSM / ICRA
 - Observe the environment
 - Manage By Walking Around
 - Documentation
 - Inspect, Test & Maintain
- ▀ Evaluate the effectiveness of the processes
 - Occupant feedback (review corrective work orders)

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Environmental Risks
EC.02.06.05; LS.01.02.01

Proactive Infection Control Risk Assessment
Construction or renovation in occupied healthcare facilities can result in environmental problems such as:

- Noise
- Vibration
- Creation or spread of contaminants
- Disruption of essential services
- Emergency Procedures
- Air quality

ILSM (Interim Life Safety Measures)

- Fire Watch and Exits regardless of ILSM policy
- ILSM Policy: whenever Life Safety Code deficiencies exists
- Administrative actions

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Risk Assessment

- ▀ Secure sensitive areas
- ▀ Infant/pediatric abduction
- ▀ Hazardous Materials Inventory is risk based
- ▀ Managing hazardous materials is based on risks
- ▀ Statement of Conditions™ is based on risk assessment and responding to identified deficiencies
- ▀ Medical Equipment and Utilities Management inventories are based on risk assessments

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CONDUCTING A RISK ASSESSMENT: SEVEN STEPS

1. Identify the issue
2. Develop arguments in support of the issue
3. Develop arguments against the issue
4. Objectively evaluate both arguments
5. Reach a conclusion
6. Document the process
7. Monitor and reassess the conclusion to ensure it is right conclusion

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Risk Assessment Worksheet

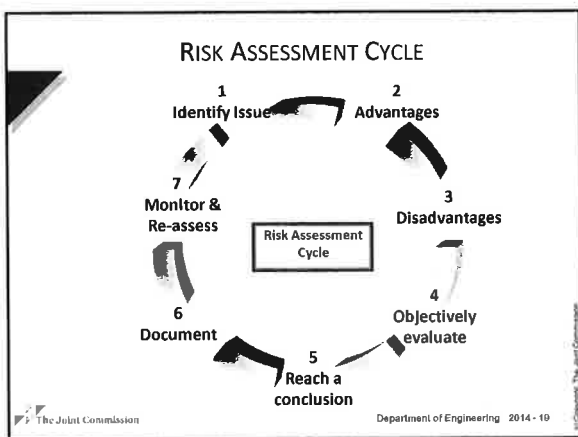
Issue: _____

Assessment Questions	Advantages	Disadvantages	Comments
Impact on patient care delivery			
How the issue affects the staff			
How the issue affects the work environment			
How the issue affects any existing information systems			
Impact on public safety			
Financial impact of the issue on the organization			
Impact on the physical structure including buildings, departments, units, or other areas			
Does the issue affect the entire environment including air, fire, exit routes, buildings, grounds, landscaping?			
Impact on equipment, including air, fire, food, food service, and other			
Impact on external physical systems			

Conclusion: _____

Occasionally a process under consideration includes other components or methods.

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SAMPLE RISK ASSESSMENT WORKSHEET:

RISK ASSESSMENT WORKSHEET


ISSUE:

SUGGESTED QUESTIONS	ADVANTAGE	DISADVANTAGE	CONCLUSION
Impact on patient care delivery			
How the issue affects the staff			
How the issue affects the work environment			
How the issue affects any visitors, volunteers, etc.			
Impact on public safety			
Financial impact of the issue on the organization			
Impact on the physical structure, including Buildings, Departments, Units or other areas			
Does the issue affect the exterior environment; including access, exit from buildings, grounds, rest areas, etc.			
Impact on equipment, including its use, function, serviceability, other			
Impact on internal physical systems			

CONCLUSION:

Occasionally a process under consideration involves several components or methods.

FAILURE MODE & EFFECT ANALYSIS
(FMEA)



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FAILURE MODE EFFECT ANALYSIS (FMEA)

- ▀ Defined responses to various types of unanticipated adverse events and processes for conducting **proactive** risk assessment/risk reduction activities
- ▀ Hospitals should proactively seek to identify and reduce risks to the safety of patients. Such initiatives have the obvious advantage of *preventing* adverse events rather than simply reacting when they occur. (Introduction to the LD chapter)
 - At least every 18 months the organization selects one high-risk process and conducts a proactive risk assessment (LD.04.04.05 EP 10)

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SEVEN STEPS IN A FMEA

1. At least every 18 months select at least one high-risk process
2. Describe (i.e. diagram) intended and actual performance
3. Identify potential ways the process could breakdown or its failure modes
 - a. potential risk to patients, including severity, and
 - b. potential cause of breakdown or failure modes of the process
 - c. prioritize these potential risks of breakdown or failure
4. Prioritize these potential risks of breakdown or failure
5. Redesign the process
6. Implement and testing of the redesigned process
7. Monitor the effectiveness of the redesigned process

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STEP 1: SELECT ONE HIGH-RISK

Decision making process of choosing a high risk issue:

- Non-standardized process
- Input from many sources
- Complex issues acceptable, if able to breakdown to root
- ▶ High risk processes may be
 - Heavily dependent on human intervention
 - Hierarchical verses team (i.e. process mandated)
 - Tight time constraints
 - Loose time constraints
- ▶ High risk/Low volume
 - New processes
 - New equipment

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STEP 2: DESCRIBE INTENDED AND ACTUAL PROCESS

- ▶ Define current 'high-risk' process and what makes it high-risk
- ▶ Define the desired outcome or proposed changes in the process
- ▶ Use of the following may be useful:
 - Flow charts
 - Matrixes
 - Narratives
 - Other Performance Improvement tools

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STEP 3: IDENTIFY POTENTIAL PROBLEMS

- ▶ Assemble a team to assist in identifying the current high-risk process
 - Once the team is together, review Step 2, and discuss
- ▶ Ask "What if. . ." questions
- ▶ Ask "Why . . ." questions
- ▶ Determine potential risk to patients, staff or visitors
- ▶ Determine potential break down conditions or
- ▶ Determine potential failure modes of the process

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STEP 4: PRIORITIZE POTENTIAL RISKS

- Rank potential risk to patients, including severity
- Rank potential causes of breakdown or failure modes of the process discussed in Step 3
- Prioritize these potential risks of breakdown or failure modes by severity and actual risk

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STEP 5: REDESIGN THE PROCESS

- Describe an action for each potential failure mode or breakdown to prevent it
- Assemble these actions with desired outcome or proposed changes in the high-risk process
- Identify outcome measures that will be used to analyze and test the redesigned process

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STEP 6: IMPLEMENT & TEST THE REDESIGNED PROCESS

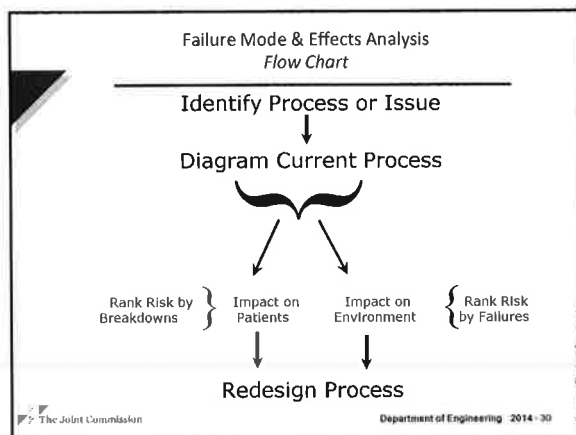
- Under controls, implement the redesigned process
- Involve the team that reviewed the high-risk process
- Gather comments from those participating in the redesigned process to supply data for analysis
- Initiate the testing process to gather data for analysis

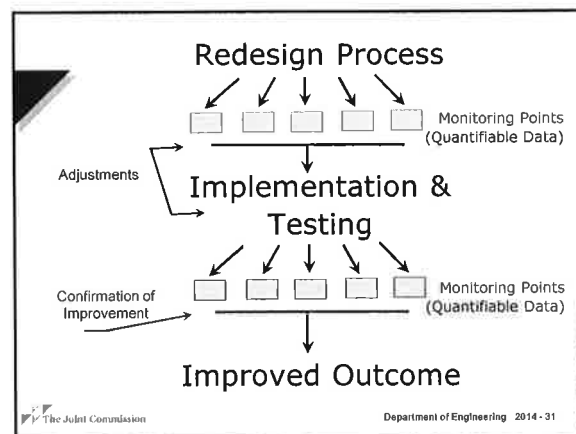
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STEP 7: MONITOR THE EFFECTIVENESS

- ▀ Evaluate the effectiveness of the redesigned process by reviewing data gathered under Step 6
- ▀ Determine if the high-risk has been reduced
- ▀ If the high-risk is reduced, then design larger implementation strategies
- ▀ Communicate to leadership outcomes

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ROOT CAUSE ANALYSIS

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ROOT CAUSE ANALYSIS

- ▶ Introduced as a strategy to identify cause of Sentinel Events within healthcare
- ▶ Root Cause Analysis is a reactive process for identifying the basic or causal factors that underlie variation in performance, that may contribute to the actual or potential occurrence of an adverse (i.e. Sentinel) event

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ROOT CAUSE RESOURCES

- ▶ SE Chapter
- ▶ LD.04.04.05 EP 7 – 9

7. The leaders define “sentinel event” and communicate this definition throughout the organization.

NOTE: the definition may include any process variation that does not affect the outcome or adverse event, but for which a recurrence carries significant chance of serious adverse outcome or result in an adverse event, often referred to as a near miss.

8. The organization conducts thorough and credible root cause analysis in response to sentinel events

9. The leaders make support systems available for staff who have been involved in an adverse or sentinel event.

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SEVEN STEPS IN A ROOT CAUSE ANALYSIS

1. Define the event
2. Describe the processes involved/affected
3. Analyze the supporting processes
4. Identify all potential 'root causes' that contributed to the variation of outcome
5. Suggest potential process improvements
6. Create action plan to mitigate future events
7. Create a strategy to measure effectiveness

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STEPS 1 & 2

- Step 1: Define the event
- Step 2: Describe the processes involved
 - The use of flow charts, matrixes, etc may be useful in defining the processes involved.
 - Identify staff involvement
 - Identify equipment involvement
 - Identify process that directly impacted in the event

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STEP 3: IDENTIFY SUPPORTING PROCESSES

- Review those processes that are associated with the main (obvious) processes
- Look for potential weaknesses in the supportive processes
- Address the following for potential contribution to the event:
 - Behavioral & Physical Assessment process
 - Patient Identification & Observation procedures
 - Care planning process
 - Staffing levels & Orientation/training of Staff

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STEP 4: IDENTIFY POTENTIAL ROOT CAUSES

- ▀ Review External environmental factors outside of the control of those involved in the event
- ▀ Review any organizational or management involvement that may have contributed to the event
- ▀ Identify any special causes that may have contributed to the event
 - Especially those causes that are outside the control of those involved in the event

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STEP 5: SUGGEST PROCESS IMPROVEMENTS

- ▀ Develop alternative processes at the supportive process level
- ▀ Redesign those affected processes that were identified as the root cause

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STEPS 6 & 7

- ▀ Step 6: create an implementation strategy
- ▀ Step 7: create a strategy for measuring effectiveness and implementation success
 - Monitor the effectiveness of the implementation strategy
 - Redesign if necessary
 - Determine how long process will be monitored

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RISK ASSESSMENT ACTIVITY

- ▣ Break into groups
- ▣ Determine an issue of environmental risk in healthcare not specifically addressed in the standards
- ▣ Discuss and complete the worksheet

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QUESTIONS?

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