FAILURE MODES AND EFFECTS ANALYSIS

Ms Rawia A. Abdalla
RN, MSN, CPHQ, CPPS
Head of Patient Safety Unit
OUTLINE

- Definitions
- Benefits of FMEA
- History of FMEA
- When to use FMEA?
- What does FMEA include?
- Steps in FMEA
- Common mistakes in FMEA
WHAT COULD GO WRONG?

FLAT TIRE
WHAT COULD GO WRONG?

- Medication Prescription
- Surgical procedure
- Blood transfusion
Failure Modes and Effects Analysis

- **Failure Modes:**
The ways or modes in which something might fail. It is a concise description of how a part of a process may potentially fail to perform its functions.

( Prescription errors: wrong dose, route or infusion time. Proper patient monitoring not ordered. Prescribed on wrong patient. No order received. Illegible writing. )

- **Effect Analysis:**
Studying the consequences of those failures. Failures are prioritized according to its frequency and seriousness.
DEFINITION

- **Failure Modes and Effects Analysis (FMEA)** is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change.

  *(Institute of Healthcare Improvement, 2004)*

- Preventing problems is cheaper and easier than cleaning them up!!!
What if you stopped going outside??
Benefits

- Get it right the first time
- Identify any inadequacies in the process
- Continuous improvement
- Team building
- Reduce the likelihood of complications
- Reduce maintenance costs
- Reduce the possibility of safety failures
- Greater customer satisfaction and reduced complaints
When to use FMEA?

- FMEA should be used:
  - at the conceptual stage
  - when changes are made to the design
  - when new regulations are instituted
  - when customer feedback indicates a problem
**History of FMEA**

Developed in the U.S. Military 1949, titled Procedures for Performing a Failure Mode, Effects and Criticality Analysis. Failures were classified according to their impact on mission success and personnel/equipment safety.

Formally developed and applied by NASA in the 1960’s to improve and verify reliability of space program hardware during the Apollo program.

Initial automotive adoption (Ford) in the 1970’s.


Now adopted by many other industries.
FMEA in the Literature 2006

Failure Mode and Effects Analysis

Using HFMEA to Assess Potential for Patient Harm from Tubing Misconnections

Judy Kimchi-Woods, Ph.D., R.N., M.B.A.
John P. Shultz, M.D.

Discussion: This proactive risk assessment project has identified failure modes and possible causes and solutions; several recommendations have been implemented. No tubing misconnections have been reported.
FMEA in the Literature
2007

CT Healthcare Failure Mode Effect Analysis (HFMEA®): The Misadministration of IV Contrast in Outpatients

By Kathy Ouellette-Piazzo, RT(R), CT, M, Ben Asfaw, MHA, and June Cowen, BS Ed, MSM

The HFMEA® process produced an “after market” byproduct of a process improvement team (PIT). A PIT was formed to act as a steering committee that would monitor the process improvements suggested by the HFMEA® team. The PIT members would identify and design training and interventions to lead continuous improvements within the CT department.
FMEA in the Literature
2011

Improving the Safety of Chemotherapy Administration: An Oncology Nurse-Led Failure Mode and Effects Analysis

Laura Ashley, PhD, Rachel Dexter, RN, Fay Marshall, RN, Brenda McKenzie, RN, Maggie Ryan, RN, and Gerry Armitage, RN, PhD

Conclusions: Although time and resource intensive, FMEA is a useful safety improvement tool.

Implications for Nursing: Nurses should be aware of and informed about FMEA as a tool they can use in partnership with management and other disciplines to proactively and collectively improve the safety of high-risk oncology procedures such as chemotherapy administration.
Designing a Safer Process to Prevent Retained Surgical Sponges: A Healthcare Failure Mode and Effect Analysis

VICTORIA M. STEELMAN, PhD, RN, CNOR, FAAN; JOSEPH J. CULLEN, MD

A total of 57 potential failures were identified, associated with room preparation, the initial count, adding sponges, removing sponges, the first closing count, and the final closing count. The most frequently identified causes of failures included distraction, multitasking, not following procedure, and time pressure. Most of the failures are not likely to be affected by an educational intervention, so additional technological controls should be considered in efforts to improve safety. AORN J 94 (August 2011) 132-141. © AORN, Inc, 2011. doi: 10.1016/j.aorn.2010.09.034
FMEA IN THE LITERATURE
2011

- PCA Over-sedation: Application Of Healthcare Failure Mode Effect Analysis (HFMEA™)

  Pam Cronrath, MN, RN, Timothy W. Lynch, PharmD, MS, FABC, Linda J. Gilson, BSN, RN, CAPA, Carol Nishida, BSN, RN, CMSRN, M. Colleen Sembar, MSM, BSN, RN, CCRN, Patricia J. Spencer, BSN, RN, BC, ONC, Daidre Foote West, BSN, RN, CPUM

- The changes implemented identified 16 failure points with a hazard score of 16 or greater. One year later, the established system HFMEA goal was met: Reduce oversedation events by 50% fiscal year end 2008
Applying HFMEA to Prevent Chemotherapy Errors

Chia-Hui Cheng • Chia-Jen Chou • Pa-Chun Wang • Hsi-Yen Lin • Chi-Lan Kao • Chao-Ton Su

risks in chemotherapy processes. Chemotherapy prescription errors significantly decreased from 3.34% to 0.40%. Chemotherapy is regarded as a high-risk process. Multiple errors can occur during ordering, preparing, compounding, dispensing, and administering medications. Subsequently, these can lead to serious consequences. HFMEA is a useful tool to evaluate potential risk in healthcare processes.
Since implementing the appropriate action plans, the NICU has experienced a significant decrease in CLABSI from 2.6 to 0.8 CLABSI per 1000 line days.

The process of HFMEA helped reduce the CLABSI rate and reinforce the culture of continuous quality improvement and safety in the NICU.
What does FMEA Include?

FMEA includes review of the following:

- Steps in the process
- Failure modes (What could go wrong?)
- Failure causes (Why would the failure happen?)
- Failure effects (What would be the consequences of each failure?)
Steps of FMEA

1. Select a process to evaluate with FMEA
2. Recruit a multidisciplinary team
3. Review the process
4. List failure modes and causes and its effect on patients
5. Assign Risk Code
6. Evaluate the results
7. Create actions to reduce risks
8. Assign responsibility for actions
9. Re-assign risk codes (residual risk)
10. Monitor the actions and risk reduction
Step 1: Select a process to evaluate with FMEA

- Evaluation using FMEA works best on processes that do not have too many sub processes!!

- Instead of doing FMEA on a large and complex process, such as medication management in a hospital, try doing an FMEA on sub processes like medication ordering, dispensing, or administration processes.

- Select processes with high risk, high cost, high volume or with wide variation in practice.

Process: Medication prescription by the physician
STEP 2: RECRUIT A MULTIDISCIPLINARY TEAM

- Be sure to include everyone who is involved at any point in the process.

- Some people may not need to be part of the team throughout the entire analysis, but they should certainly be included in discussions of those steps in the process in which they are involved.

- For example if you want to evaluate VAP prevention, you will include pulmonologists, respiratory therapy, infection control, pharmacy, nursing.

Process: Medication prescription by the physician
Team: Physician, nursing, pharmacy
Step 3: Review the Process

- It may take several meetings for the team to complete this part of the FMEA, depending on the number of steps and the complexity of the process.

- Flowcharting can be a helpful tool for outlining the steps.

- When you are finished, be sure to obtain consensus from the group.

- The team should agree that the steps enumerated in the FMEA accurately describe the process.
Medication Management

1. Prescription
   - 1.1 Physician checks results
   - 1.2 Physician prescribes medication

2. Dispensing
   - 2.1 Send order to pharmacy
   - 2.2 Enter order into computer
   - 2.3 Produce label
   - 2.4 Prepare medication
   - 2.5 Check medication before distribution
   - 2.6 Deliver medication to the units

3. Administration
   - 3.1 Receive order and transcribe onto medication record
   - 3.2 Obtain infusion pump
   - 3.3 Obtain medication
   - 3.4 Program infusion pump
   - 3.5 Check medication / pump settings before administration
   - 3.6 Administer medication
   - 3.7 Document administration
   - 3.8 Monitor side effects / adverse events

4. Laboratory Monitoring
   - 4.1 Laboratory request
   - 4.2 Serum blood sample
   - 4.3 Label sample
   - 4.4 Send to the laboratory
   - 4.5 Checking results by nurses
Step 4: List failure modes and causes and its effect on patients

- For each step in the process, list all possible “failure modes”—that is, anything that could go wrong, including minor and rare problems.

- For each failure mode listed, identify all possible causes

- Then, for each failure mode listed, identify all possible effects
<table>
<thead>
<tr>
<th>Sub process</th>
<th>Failure Modes</th>
<th>Failure causes</th>
<th>Failure Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician prescribes medication</td>
<td>Wrong dose, route or infusion time (fast, slow)</td>
<td>Clinical situation not considered (age, renal and endocrine functions, allergy, seizures, cardiac rhythm); concomitant use of oral drugs; knowledge deficit; mental slip; information on drug not available</td>
<td>Overdose; under-dose; improper route selection; ADR; allergic response; prolonged infusion time leads to delay in therapy; very fast infusion leads to side effects</td>
</tr>
<tr>
<td>Proper patient monitoring not ordered</td>
<td>Knowledge deficit; mental slip</td>
<td></td>
<td>Failure to detect problems early to prevent harm</td>
</tr>
<tr>
<td>Prescribed on wrong patient</td>
<td>Similar patient names; patient identifier not clear; no identifier verification</td>
<td></td>
<td>Wrong patient receives inappropriate drug and dose; ADR; allergic response</td>
</tr>
<tr>
<td>No order received</td>
<td>Unable to reach on call physician</td>
<td></td>
<td>Poor patient management</td>
</tr>
<tr>
<td>Illegible writing (use abbreviations, unclear handwriting)</td>
<td>Knowledge deficit; mental slip; no list of approved abbreviations</td>
<td></td>
<td>Wrong drug; Overdose; under-dose; improper route selection; ADR; allergic response; delay in treatment</td>
</tr>
</tbody>
</table>
**Step 5: Assign Risk Code**

- Risk Code = Severity X Occurrence

- **Severity:** (1 = Minimum, 5 = Serious)

If this failure mode occurs, how likely is it that harm will occur?

- **Probability of occurrence:** (1 = Rare, 5 = Frequent)

How likely is it that this failure mode will occur?
### 5 X 5 Hazard Scoring Matrix

<table>
<thead>
<tr>
<th>Probability</th>
<th>Severity</th>
<th>Severity</th>
<th>Severity</th>
<th>Severity</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Serious (5)</td>
<td>Major (4)</td>
<td>Moderate (3)</td>
<td>Minor (2)</td>
<td>Minimum (1)</td>
</tr>
<tr>
<td>Frequent (5)</td>
<td>25</td>
<td>20</td>
<td>15</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Likely (4)</td>
<td>20</td>
<td>16</td>
<td>12</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Possible (3)</td>
<td>15</td>
<td>12</td>
<td>9</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Unlikely (2)</td>
<td>10</td>
<td>8</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Rare (1)</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

- Failure modes with higher hazard scores should receive the highest priority.
<table>
<thead>
<tr>
<th>Sub process</th>
<th>Failure Modes</th>
<th>Failure causes</th>
<th>Failure Effect</th>
<th>S</th>
<th>P</th>
<th>Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician prescribes medication</td>
<td>Wrong dose, route or infusion time (fast, slow)</td>
<td>Clinical situation not considered (age, renal and endocrine functions, allergy, seizures, cardiac rhythm); concomitant use of oral drugs;; knowledge deficit; mental slip; information on drug not available</td>
<td>Overdose; underdose; improper route selection; ADR; allergic response; prolonged infusion time leads to delay in therapy; very fast infusion leads to side effects</td>
<td>4</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Proper patient monitoring not ordered</td>
<td>Knowledge deficit; mental slip</td>
<td>Failure to detect problems early to prevent harm</td>
<td>4 3 12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescribed on wrong patient</td>
<td>Similar patient names; patient identifier not clear; no identifier verification</td>
<td>Wrong patient receives inappropriate drug and dose; ADR; allergic response</td>
<td>3 2 6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No order received</td>
<td>Unable to reach on call physician</td>
<td>Poor patient management</td>
<td>2 2 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Illegible writing (use abbreviations, unclear hand writing)</td>
<td>Knowledge deficit; mental slip; no list of approved abbreviations</td>
<td>Wrong drug; Overdose; underdose; improper route selection; ADR; allergic response; delay in treatment</td>
<td>4 4 16</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Step 6: Evaluate the results

- **Hazard scores:**
  1 = Low risk, 25 = Extreme risk

- Failure modes with higher hazard scores should receive the highest priority and should trigger consideration of potential action to control the failure.

- These are the ones the team should consider first as improvement opportunities.
Step 7: Create actions to reduce risks

- Evaluate the causes and see if any or all of them can be eliminated.
- Modify other processes that contribute to causes.

Actions / Control Measures:

1. **Engineering/structural control**
   (Reconstruction, anti slippery floors, hood)

2. **Administrative changes**
   (policies, protocols, job descriptions)
<table>
<thead>
<tr>
<th>Sub process</th>
<th>Failure Modes</th>
<th>Failure causes</th>
<th>Failure Effect</th>
<th>S</th>
<th>P</th>
<th>Hazard</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician prescribes medication</td>
<td>Wrong dose, route or infusion time (fast, slow)</td>
<td>Clinical situation not considered (age, renal and endocrine functions, allergy, seizures, cardiac rhythm); concomitant use of oral drugs;; knowledge deficit; mental slip; information on drug not available</td>
<td>Overdose; under-dose; improper route selection; ADR; allergic response; prolonged infusion time leads to delay in therapy; very fast infusion leads to side effects</td>
<td>4</td>
<td>4</td>
<td>16</td>
<td>Clinical pharmacy program; pre-printed medications protocol with education on use; easy access to drug information; feedback mechanism on substitute drugs available</td>
</tr>
<tr>
<td>Proper patient monitoring not ordered</td>
<td>Knowledge deficit; mental slip</td>
<td></td>
<td>Failure to detect problems early to prevent harm</td>
<td>4</td>
<td>3</td>
<td>12</td>
<td>pre-printed medication protocols with monitoring guidelines</td>
</tr>
<tr>
<td>Prescribed on wrong patient</td>
<td>Similar patient names; patient identifier not clear; no identifier verification</td>
<td></td>
<td>Wrong patient receives inappropriate drug and dose; ADR; allergic response</td>
<td>3</td>
<td>2</td>
<td>6</td>
<td>Match result to patient condition; alert for a look-alike patient names; visible demographics on identifier</td>
</tr>
<tr>
<td>No order received</td>
<td>Unable to reach on call physician</td>
<td></td>
<td>Poor patient management</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>Proper physician coverage and communication channels</td>
</tr>
<tr>
<td>Illegible writing (use abbreviations, unclear hand writing )</td>
<td>Knowledge deficit; mental slip; no list of approved abbreviations</td>
<td></td>
<td>Wrong drug; Overdose; under-dose; improper route selection; ADR; allergic response; delay in treatment</td>
<td>4</td>
<td>4</td>
<td>16</td>
<td>pre-printed medication protocol; Health Information Systems; list of approved abbreviations</td>
</tr>
</tbody>
</table>
Step 8: Assign Responsibility for Actions

- Assign responsibilities for implementing the corrective and preventive actions.

- Set timelines, determine the project completion dates
**Step 9:**
**Re-Assign Risk Codes (Residual Risk)**

- Determine what is the risk code after implementing the actions for each failure mode.

- The aim is to assist the team in prioritizing actions and to determine if actions were effective or not.
<table>
<thead>
<tr>
<th>Sub process</th>
<th>Failure Modes</th>
<th>Failure causes</th>
<th>Failure Effect</th>
<th>S</th>
<th>P</th>
<th>Hazard</th>
<th>Actions</th>
<th>Responsibility</th>
<th>S</th>
<th>P</th>
<th>Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician prescribes medication</td>
<td>Wrong dose, route or infusion time (fast, slow)</td>
<td>Clinical situation not considered (age, renal and endocrine functions, allergy, seizures, cardiac rhythm); concomitant use of oral drugs; knowledge deficit; mental slip; information on drug not available</td>
<td>Overdose; under-dose; improper route selection; ADR; allergic response; prolonged infusion time leads to delay in therapy; very fast infusion leads to side effects</td>
<td>4</td>
<td>4</td>
<td>16</td>
<td>Clinical pharmacy program; pre-printed medications protocol with education on use; easy access to drug information; feedback mechanism on substitute drugs available</td>
<td>XXXXXX</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Proper patient monitoring not ordered</td>
<td>Knowledge deficit; mental slip</td>
<td>Failure to detect problems early to prevent harm</td>
<td></td>
<td>4</td>
<td>3</td>
<td>12</td>
<td>pre-printed medication protocols with monitoring guidelines</td>
<td>XXXXXX</td>
<td>2</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Prescribed on wrong patient</td>
<td>Similar patient names; patient identifier not clear; no identifier verification</td>
<td>Wrong patient receives inappropriate drug and dose; ADR; allergic response</td>
<td></td>
<td>3</td>
<td>2</td>
<td>6</td>
<td>Match result to patient condition; alert for a look-alike patient names; visible demographics on identifier</td>
<td>XXXXXX</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>No order received</td>
<td>Unable to reach on call physician</td>
<td>Poor patient management</td>
<td></td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>Proper physician coverage and communication channels</td>
<td>XXXXXX</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Illegible writing (use abbreviations, unclear handwriting)</td>
<td>Knowledge deficit; mental slip; no list of approved abbreviations</td>
<td>Wrong drug; Overdose; under-dose; improper route selection; ADR; allergic response; delay in treatment</td>
<td></td>
<td>4</td>
<td>4</td>
<td>16</td>
<td>pre-printed medication protocol; Health Information Systems; list of approved abbreviations</td>
<td>XXXXXX</td>
<td>3</td>
<td>4</td>
<td>12</td>
</tr>
</tbody>
</table>
Monitor the Actions and Risk Reduction

- Monitor to evaluate if the risk reduction strategies have reduced risk and take additional actions, if necessary, to further reduce risk.
USES OF FMEA

- Use FMEA to plan actions to reduce harm from failure modes

- Use FMEA to evaluate the potential impact of changes under consideration (check the residual risk code)

- Use FMEA to monitor and track improvement over time by calculating a risk code for the process and then set a goal for improvement.

For example, a team may set a goal of decreasing the risk code for the medication ordering process by 50% from the baseline.
<table>
<thead>
<tr>
<th>Processes &amp; sub processes</th>
<th>Potential Failure modes</th>
<th>Potential Causes</th>
<th>Potential Effects</th>
<th>Severity Score</th>
<th>Probability Score</th>
<th>Hazard score</th>
<th>Recommended Actions</th>
<th>Responsibility and target date</th>
<th>Severity Score</th>
<th>Probability Score</th>
<th>Hazard score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Process</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1 Sub-process</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2 Sub-process</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3 Sub-process</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4 Sub-process</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5 Sub-process</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Process</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1 Sub-process</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2 Sub-process</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.3 Sub-process</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.4 Sub-process</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5 Sub-process</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Common Mistakes in FMEA

- The quality department is the owner of FMEA
- The wrong people are selected to participate in the sessions of FMEA; inadequate team composition
- The FMEA are done at a wrong time
- The FMEA provides the wrong level of detail (missing the high risk areas or the root causes)
- Failure to drive any design or process improvement
- Failure to address all high risk failure modes
- Failure to produce action and control plans
- Improper FMEA procedure
- Lack of efficient use of time in the meetings
ADDITIONAL RESOURCES

Please Visit the Institute for Healthcare Improvement (IHI) Website to see an interactive FMEA Tool available on IHI.org.

PREVENTIVE MEDICINE IS LESS COSTLY THAN CURATIVE MEDICINE
REFERENCES