FMEA and FTA Analysis
Why it is Coming to Your Hospital and Your Laboratory

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Agenda

• Background on requirements for risk management
• Tools to meet the requirements- Process Maps, FMEA and FTA
  • Basics
  • Example
  • When to use, Benefits, Limitations
• Next steps and where to get help
Background

• In-hospital deaths from medical errors at 195,000 per year*
• About 1.14 million patient safety incidents occurred in the 37 million Medicare hospitalizations*
• 12.5% of incorrect and delayed lab results adversely impact patient health (Clin chem 2002;48:691-698)

* Healthgrades study, 2004 spanning 2000-2002

2008 National Patient Safety Goals (excerpt)

• Improve the accuracy of [patient] identification
• Improve the safety of using medications
• Reduce the risk of health care – associated infections
• Reduce the risk of [patient] harm resulting from falls
• Reduce the risk of surgical fires
• Prevent health-care associated pressure ulcers
• The organization identifies safety risks inherent in its [patient] population
JCAHO Requirements - 2001

• LD 5 - The leaders ensure implementation of an integrated patient safety program throughout the organization
• LD 5.2 - Leaders ensure that an ongoing proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented
  – Includes requirement to evaluate “events, failure modes, analysis and correction” in at least one high-risk process per year.

High Risk Processes

• PI 4.2 – Processes that involve risk or may result in sentinel events
  – Medication use
  – Operative or other procedures
  – Use of blood and blood components
  – Restraint use
  – Seclusion, when part of care
  – Care/services provided to high risk populations
  – Resuscitation
Process Required by JCAHO

1. Identify process steps (Process map)
2. Identify where “undesirable variation” may occur (failure modes)
3. For each identified failure mode identify the effects on patients and how serious the effect is “criticality – severity and probability of occurrence”
4. For most critical items conduct root cause analysis (FTA or fishbone)

Process Required by JCAHO, continued

5. Redesign the process and/or underlying systems to minimize the risk of the failure mode or protect patients from the effects (control measures)
6. Test and verify redesigned process
7. Identify and implement measures of effectiveness (metrics or key indicators)
8. Implement a strategy for maintaining effectiveness (monitor and adjust)
ISO 15189:2007 Medical laboratories

• Particular requirements for quality and competency
  – Requires Continual Improvement Process (4.12)
  – Requires identification potential sources of non-conformance (4.12.1)
  – Requires improvement to those areas, review, and monitoring (4.12.2, 4.12.3, 4.12.4.)

Why Risk Management?

• Improves the safety of your organization
• Improves the quality of your processes
• Improves the quality of your output
• Can have significant return on time investment (in cost avoidance)
So, how do we get there from here?........

Process Mapping
Process Mapping

- Tool to visually illustrate how the work flows
- Includes inputs of people, methods, machines, and materials
- Starting point to look for where additional analysis is required

Two Parts to Process Mapping

- Flow chart and table of process steps work together to support areas for further analysis.
- Flow chart shows what; process table includes what and expands to who and how.
Steps for Process Mapping

• Determine the boundaries (beginning and end)
• List the steps (Use verbs for actions)
• Sequence the steps
• Draw appropriate symbols around the steps
• Chart the steps (Use sticky notes)
• Check for completeness
• Finalize the flowchart
• Fill out the table of who and how

Process Map Symbols

• Terminator - start or ends
• Process stage or step
• Off page connection
• Decision point
• Document
Example – In-Patient Blood Collection

Start

Collection list / labels generated

Patient identified

Blood collected

Specimens labeled

Specimens transported to lab

Example from CLSI GP2-A4, contributed by Client Services Workgroup, Sutter Health Laboratory Integration Project, Sacramento, CA

Process Table

<table>
<thead>
<tr>
<th>What</th>
<th>Who</th>
<th>How</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection list / labels generated</td>
<td>Lab assistant</td>
<td>Automated process</td>
</tr>
<tr>
<td>Patient identified</td>
<td>Phlebotomist</td>
<td>Human interaction with patient</td>
</tr>
<tr>
<td>Blood collected</td>
<td>Phlebotomist</td>
<td>Trained phlebotomist</td>
</tr>
<tr>
<td>Specimens labeled</td>
<td>Phlebotomist</td>
<td>Human interaction with label and tube</td>
</tr>
<tr>
<td>Specimens transported to lab</td>
<td>Phlebotomist</td>
<td>Pneumatic tube on each floor</td>
</tr>
</tbody>
</table>
The Process

1. Select high risk process
2. Map the process
3. ID failure modes
4. Find root cause of critical failure modes
5. Redesign process
6. Test and implement
7., 8. Measure and monitor

Process Table

<table>
<thead>
<tr>
<th>What step</th>
<th>Who</th>
<th>How</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Select high risk process</td>
<td>Leaders in hospital or lab</td>
<td>Joint Commission list</td>
</tr>
<tr>
<td>2 Map the process</td>
<td>Multi-disciplinary group</td>
<td>CLSI GP2-A5</td>
</tr>
<tr>
<td>3 ID failure modes and effect</td>
<td>Multi-disciplinary group</td>
<td>HFMEA or equivalent</td>
</tr>
<tr>
<td>4 Find root cause of critical failure modes</td>
<td>Multi-disciplinary group</td>
<td>FTA or fishbone diagram</td>
</tr>
<tr>
<td>5 Redesign process</td>
<td>Multi-disciplinary group</td>
<td>Option analysis</td>
</tr>
<tr>
<td>6 Test and implement</td>
<td>Process owners</td>
<td>Various site specific methods</td>
</tr>
<tr>
<td>7 &amp; 8 Measure and monitor</td>
<td>Leaders in hospital or lab</td>
<td>Event report, improvements, near misses</td>
</tr>
</tbody>
</table>
When to use Process Maps

• When you are initiating a new process
• When making improvements to a current process
• When you need to visualize a current process
• When you need to stop a process (to evaluate impact to other processes)
• When you are evaluating human involvement in a process

Benefits of Process Maps

• Maps are intuitive
• Easy to Understand
• Unambiguous
• Shows entire process in one picture
• Shows man/machine interactions
Limitations of Process Maps

• Can be too distracting - based on size and detail
• Can take on a life of their own and be more important than the process itself
• Is not a stand alone analysis/control tool. It is a beginning step to further risk analysis (FMEA, HACCP or FTA)
• Critical points not identified unless part of the plan

Failure Mode and Effects Analysis (FMEA)
FMEA Terms

• **Failure** – When a system performs in a way which was not intended
• **Effect** - The impact the failure has on the process or end patient
• **Severity** – How bad the effect is
• **Occurrence** - How often will the cause happen
• **Detection** – Ability to **know** that the failure has occurred

Steps to perform the Process FMEA

1. Identify the process to be analyzed
2. Map the process steps
3. List potential failure modes (how can the step go wrong)
4. List potential effects of the failure
   – What happens when this failure occurs?
   – Also known as severity
Steps to perform the FMEA

5. Perform root cause analysis of the failures determine likelihood of occurrence
   - Consider using a Fault Tree Analysis or cause and effect diagram to ferret out causes

6. Prioritize the failures based on predetermined severity, likelihood of occurrence (and ability to detect) ratings

7. Determine control measures (fix the process)

Example FMEA

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential Failure Mode</td>
<td>Potential Causes for Failure</td>
</tr>
<tr>
<td>Incorrect collection list generated</td>
<td>Incorrect data entered</td>
</tr>
<tr>
<td>Incorrect labels generated</td>
<td>Software failure</td>
</tr>
<tr>
<td>Incorrect data entered</td>
<td>Incorrect date requested</td>
</tr>
<tr>
<td>Incorrect patient drawn</td>
<td>Software failure</td>
</tr>
</tbody>
</table>


**When to use FMEA**

- When starting a new process to help uncover potential problem areas in the process and insert controls
- When resources are limited and you want to focus on the highest risk items (determined by RPN)
- When you understand the function of each specific task or item and the associated failure modes

**Benefits of FMEA**

- Allows for a very structured analysis
- Captures multiple causes and effects of failures
- Links control (measures) plans within one analysis/planning document
- Allows relative risk ranking for prioritization of control activities
Limitations of FMEA

• Examination of human error is limited
  – Traditional FMEA uses potential equipment/system failures as the basis for the analysis.
  – Use errors that do not cause equipment failures are often overlooked in an FMEA.

• Analysis is for single fault error
  – Misses interactions between faults

• Often misses external influences

Fault Tree Analysis
Fault Tree Analysis (FTA)

- A top down analysis that starts with the effect and evaluates all the potential causes of that event.
- Creates a logical “tree” of events
- Lowest “root” is the root cause or transfer to another analysis
- Forces analysis of interactions

Definitions

- **Failure** – When a system performs in a way which was not intended
- **Control Measure** – something done to lower the risk of a failure or effect of the failure
Symbols used in Fault Tree Analysis

Event - either primary failure or intermediate failure event

Cause - root event that drives the failure

“OR” gate - failure occurs if any of the input events occurs

“AND” gate - failure occurs if all of the input events occurs

The FTA Process

• Determine and document the top adverse event. (e.g., incorrect patient results released to a physician)
• Build the tree by considering the “whys” to the top event.
  – Use process flows and any FMEA’s already performed as supporting information
• Continue to build based on conditions that exist or co-exist to create the events.
Example FTA

Incorrect patient result reported to physician

What can cause this to happen?

Example FTA

Incorrect patient result reported to physician

Incorrect specimen tested

Incorrect result generated by test

Incorrect result attached to patient ID-post analysis

Do these happen independently or must 2 or more happen together to cause this failure?
Example FTA

Incorrect patient result reported to physician

or

Incorrect specimen tested
(Branch 1)

Incorrect result generated by test
(Branch 2)

Incorrect result attached to patient ID-post analysis
(Branch 3)

Building on the Tree
Branch 1

Incorrect Specimen Tested

Damaged bar code label used
Branch 1.1.

Wrong patient drawn
Branch 1.2.

Incorrect test ordered
Branch 1.3.
Building on the Tree
Branch 1.1.

1.1. Damaged bar code label used

Bar code label damaged

Label not inspected prior to use

System Related

Human Use Related

Branch 1.1.1.

1.1.1. Bar code label damaged

Label generator failure

Damaged en-route to or from the lab

or

System Related

Human Use Related

Branch 1.1.1.1

Transfer to equipment FMEA or Process FMEA for label generator

Branch 1.1.1.2

Transfer to tube transport task analysis
When to Use FTA

- To brainstorm root causes
- When you want to evaluate the interactions between systems and humans or several systems/processes
- When you want a variety of options of where to place control mechanisms
- When you are better suited to visuals than words.

Benefits of FTA

- Helps to identify many causes of a failure mode
- Helps to identify interrelationships between multiple causes
- Allows the analyst to determine the most effective area to put a control measure
- Allows the analyst to determine multiple controls
- Can be qualitative or quantitative
Limitations of FTA

- Each tree has a narrow focus
- It is an art in addition to a science.
  - Details vary by analyst
- Any quantification will require data and expertise
- Remember to consider human factors
- How do I know when to stop? – Consider going to a “5 Whys” level

Next Steps to Compliance

1. Pick a High Risk Process in your functional area
2. Map the process
3. Find and fix the weak links using
   - FMEA
   - FTA (or cause and effect diagram)
4. Control and monitor the process
5. Repeat steps 1-4 on next process
Where To Get Help

- [www.va.gov](http://www.va.gov) - Templates and training on Healthcare FMEA

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Thank you!
Questions?