Risk Analysis Workshop

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Disclosure Statement

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- Midwest and North Central Region

CE Program Sponsored by 3M
Learning Objectives

1. Discuss the purpose of performing a risk analysis
2. Discuss the organizations that recommend or require a risk analysis
3. Identify risks for sterilization process failures
4. Develop a risk analysis
Quality Process Improvement


Section 11
Quality process improvement

11.2.2 Risk analysis
The Joint Commission (TJC)

☑ Require hospitals to conduct a risk assessment

“The hospital’s written infection prevention and control goals include the following:

- Limiting the transmission of infections associated with the use of medical equipment, devices and supplies.”

Standard IC.01.04.01

“Based on the identified risks, the hospital sets goals to minimize the possibility of transmitting infections.”

Element of Performance 4
“The hospital identifies risks for acquiring and transmitting infections.”

Standard IC.01.03.01

“The hospital reviews and identifies its risks at least annually and whenever significant changes occur with input from, at a minimum, infection control personnel, medical staff, nursing, and leadership.”

Element of Performance 4
The Joint Commission (TJC)

“The hospital has an organization-wide, integrated patient safety program within its performance improvement activities.”

“At least every 18 months, the hospital selects one high-risk process and conducts a proactive risk assessment.”

Standard LD.04.04.05

Element of Performance 10

Example high-risk: releasing an implant before BI results are available
The Joint Commission National Patient Safety Goals

“Implement evidence-based practices for preventing surgical site infections.”

NPSG.07.05.01

“As part of the effort to reduce surgical site infections:
   — Conduct periodic risk assessments for surgical site infections in a time frame determined by the hospital.”

Example: conduct risk assessment 6 months after implementing an action plan

Element of Performance 4
“Inadequate sterilization of surgical instruments has resulted in SSI outbreaks.... The importance of routinely monitoring the quality of sterilization procedures has been established. Microbial monitoring of steam autoclave performance is necessary and can be accomplished by use of a biological indicator.”

Example: **John Harrison, 63 y/o**
- 2009- Repair right rotator cuff
- Routine procedure
- Dirty Arthroscopic shavers

Sterilization Process Failure Risk Analysis

Be proactive

• Do a risk analysis each year and whenever major changes are made
• Do not wait for a sterilization process failure to do this analysis
• Stay up to date on manufacturers’ Instructions for Use
• Stay up to date on evidence-based and professional organization guidelines
Quality Improvement

Objective is to identify the risks to reduce the likelihood of a sterilization process failure and HAIs

Risk analysis = Risk assessment + Risk management + Risk communication
Risk Analysis

Risk analysis is part of a quality process because sterilization is a process that you cannot determine its effectiveness by inspection and testing of each product.

Control the variables you can to verify the effectiveness of sterilization.

The following are used to determine the effectiveness of the sterilization process:

- Validated processes (validated by equipment and medical device manufacturers)
- Routine monitoring with physical monitors, BI and CIs
- Equipment maintenance

Risk Analysis

Risk assessment (1st step)

Since sterility assurance is a probability function, it must be assumed that at some time a failure will occur

- Identify source of sterilization failure
- Estimate likelihood that such a failure will occur
- Assess the consequences if that failure does occur
- Assess how to prepare the facility to manage the failure

Figure 12 – Decision tree for conducting investigations of steam sterilization process failures

CI Failures

- Quarantine load, remove sterilizer from service, and investigate cause of failure

BI Failures

- Review scope/extent of failure
  - If cause of failure is immediately identified (usually operator error) and confined to one load or one item within the load (internal CI), correct the cause and reprocess the load. If cause of the failure is not immediately identified, quarantine the load and recall all loads back to the last negative BI.

- Determine cause of failure
  - Sterilizer/utilities malfunction (10.6.4, 10.8)
    - Determine cause of sterilizer/utilities malfunction
      - Repair sterilizer/utilities
        - Minor repair
          - Run 3 consecutive BI PCD tests (all sterilizers). For dynamic air removal sterilizers, also run 3 consecutive Bowie-Dick tests.
          - Test results fail
            - Return sterilizer to service
          - Test results pass
            - Return sterilizer to service
        - Major repair
  - Positive BI (10.6.4)
  - CI failure (10.5.2.2)
  - Operator error
  - Unknown

- Failure cannot be attributed to cause other than sterilizer/utilities malfunction
  - Minor repair

- Failure can be attributed to cause other than sterilizer/utilities malfunction
  - Correct error

Physical Monitoring Failures

- Quarantine load, remove sterilizer from service, and investigate cause of failure
Table 8 – Checklist for identifying reasons for steam sterilization process failures

- Operator errors (85%)
- Sterilizer (10%) or Utility Malfunctions (5%)


Personal Communication, Charles Hancock, President, Charles O. Hancock Associates, Inc.
Risk Analysis

Risk management (2nd step)

• Determine which of the sterilization process failures identified require management because they are the biggest risk
• Select and implement the plans or actions needed to ensure those failures are controlled
• AAMI ST79 describes the accepted means of managing these risks throughout the document
Risk Analysis

Risk communication (Final step)

- SPD/CSSD informs OR and ICP of the risk analysis and the plan of action
- Interactive Dialogue
Risk Analysis of the Sterilization Process

Team consists of SPD/CSSD personnel who are working in the department and should be able to:

• Identify risks
• Outline reasons for the risks
• Determine which risk is the biggest threat
• Suggest ways to reduce the risks
• Be knowledgeable of recommended “Best Practices”
Risk Analysis of the Sterilization Process

Team capability will depend on:

• Whether the department policies and procedures meet evidence-based and professional organization guidelines
• Whether the manufacturer’s IFUs are up to date
• Training and competencies
Risk Analysis of the Sterilization Process  (Team Breakouts)

Team will:

• Identify risks (based on your experience) that could lead to potential sterilization process failures
• Categorize them (i.e., cleaning / decontamination, sterilization, quality monitors, packaging)
Risk Analysis of the Sterilization Process

List risks and determine the highest risks to resolve:

- Undetected debris in lumens (C/D)
- Receiving loaners the day of surgery (QM/CQI)
- Not enough eye sets for the day’s surgery (S)
- Instrument sets over 25 pounds (P)
- IFUs not always available (C/D or S)
- Early release of implants (S)
- Delay in processing flexible endoscopes (C/D)
- L&D sets sent to SPD/CSSD with dried-on debris (C/D)
### Risk Analysis – Sterilization Process Failures

<table>
<thead>
<tr>
<th>Risk</th>
<th>Probability of Occurrence</th>
<th>Potential Severity or Risk of Failure</th>
<th>Likelihood of Undetected Failure</th>
<th>Risk Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undetected debris in lumens</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td><strong>15</strong></td>
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<tr>
<td>Holes in wrappers</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td><strong>8</strong></td>
</tr>
<tr>
<td>Delay in processing flexible endoscopes</td>
<td>2</td>
<td>5</td>
<td>5</td>
<td><strong>12</strong></td>
</tr>
<tr>
<td>Late loaners</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td><strong>10</strong></td>
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</tbody>
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Risk Management

Identify Failures

- After identifying potential sterilization process failures, investigate solutions by consulting standards and recommended practices for guidance, including:
  - AAMI
  - AORN
  - CDC
  - EPA
  - OSHA
  - The Joint Commission
Risk Management of the Sterilization Process

Team develops ideas or suggestions to eliminate the risks (risk management)

- Select the highest scored risk
- Brainstorm solutions
- Final task is to correct the problem and report the action (risk communication)
### Risk Management

Process Improvement Highest Rated Risk Identified: Undetected Debris in Lumens

<table>
<thead>
<tr>
<th>Suggested Solutions</th>
<th>Ballot</th>
<th>Action to be taken</th>
</tr>
</thead>
</table>
| Have all brush sizes available               | 30     | • Review IFUs to determine correct brush size  
• Purchase brushes  
• Organize brushes for quick and easy identification |
| Install spray gun with lumen adaptors        | 30     | • Research available types and ask for input from facilities to assure it will be workable |
| Implement a method to check lumens for debris| 30     | • Research types of lumen checks available  
• Train staff in use  
• Include lumen check in policy |
| Include lumen cleaning in training program   | 28     | • Revise training program to include in-depth lumen training                        |
The findings of the risk analysis are then communicated to everyone that has an interest in the risk. Typically, these include:

- Infection Prevention
- OR
- SP/CSSD staff
Summary

1. A risk analysis should occur annually or whenever major changes occur or more frequently if determined necessary.

2. A risk analysis consists of a risk assessment, risk management, and risk communication.

3. Decision making and corrective action should be based on the standards and recommended practices from AAMI, AORN, and CDC.
Summary

4. The SP/CSSD staff is involved in a risk analysis, since they are close to the issues and are able to identify potential sterilization process failures and corrective action.

5. Communication is critical, so that all stakeholders are aware of the issues and changes.
Eliminating Risks of a Sterilization Process Failure

Improving Patient Safety
Questions?
Thank you
Sample Worksheets
### Risk Analysis
Sterilization Process Failures

<table>
<thead>
<tr>
<th>Cleaning / Decontamination</th>
<th>Sterilization</th>
<th>Quality Monitoring/CQI</th>
<th>Packaging</th>
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**Risk Management**
*Process Improvement Highest Rated Risk Identified:*

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<th>Suggested Resolution</th>
<th>Ballot</th>
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ANSI/AAMI ST79

Association for the Advancement of Medical Instrumentation (AAMI)

AORN Guidelines for Perioperative Practice (2015)

- Instruments and Powered Equipment – Cleaning and Care of
- Disinfection – High-Level
- Environmental Cleaning
- Flexible Endoscopes – Cleaning and Processing
- Packaging Systems – Selection and Use
- Sterilization
- Sterile Technique
Evidence-Based Guidelines


Risk Analysis of the Sterilization Process Resources

In-service articles

• Risky business: Risk analysis in CSSD by Sue Klacik (IAHCSMM representative to AAMI and co-chair of the PCD working group) Published in Healthcare Purchasing News August 2010 http://www.hpnonline.com/ce/pdfs/1008cetest.pdf

• Worth the Risk: Performing a Risk Analysis in CSSD by Sue Klacik Published in HealthVIE.com May 2011 http://solutions.3m.com/wps/portal/3M/en_US/Sterilization/3MSterileU/
Other References

Microbiology

• [http://en.wikipedia.org/wiki/Microbiology](http://en.wikipedia.org/wiki/Microbiology)

Sterilizer testing

Device Reprocessing References

Device Reprocessing References

Disinfection Testing References


Sterilization Monitoring Reference

Sterilization monitoring

References

• The Joint Commission, *Hospital Accreditation Standards* 2015

• Joint Commission Perspectives®, July 2009, Vol. 29, Issue 7. Copyright 2009 Joint Commission on Accreditation of Healthcare Organizations
  http://www.ingentaconnect.com/content/jcaho/jcp/2009/00000029/00000007;jsessionid=1jbtxsooxtvio.alice

• Personal communications with hospitals that have had surveys
Thank You!
Questions/Comments?