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
The Joint Commission (TJC)

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’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."

The Joint Commission: 2014 Hospital Accreditation Standards (HAS)

The Joint Commission (TJC)

Standard IC.01.03.01

- "The hospital identifies risks for acquiring and transmitting infections."
Element of Performance #4

- "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."

The Joint Commission: 2014 Hospital Accreditation Standards (HAS)

The Joint Commission (TJC)

Standard LD.04.04.05

- "The hospital has an organization-wide, integrated patient safety program within its performance improvement activities."
Element of Performance #10

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

The Joint Commission: 2014 Hospital Accreditation Standards (HAS)

The Joint Commission

National Patient Safety Goals

NPSG.07.05.01

- "Implement evidence-based practices for preventing surgical site infections."
Element of performance #4

- "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."

The Joint Commission: 2014 Hospital Accreditation Standards (HAS)
Centers for Disease and Control and Prevention (CDC) Guideline

Guideline for the Prevention of Surgical Site Infections, 1999

• “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.”


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

Risk analysis =
Risk assessment +
Risk management +
Risk communication

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

Section 11.2.2

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.
• 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**
  - 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

**Table 8—Checklist for identifying reasons for steam sterilization process failures**

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

**Risk management**

- 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**
  - SPD/CSSD informs OR and ICP of the risk analysis and the plan of action

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
    - 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
  - If the department policies and procedures meet evidence-based and professional organization guidelines
  - If the manufacturer’s IFUs are up-to-date
  - Training and competencies

Risky business: Risk analysis in CSSD. HPN Aug 2010

Risky business: Risk analysis in CSSD. HPN August 2010
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>15</td>
</tr>
<tr>
<td>Holes in wrappers</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Delay in processing flexible endoscopes</td>
<td>2</td>
<td>5</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>Late loaners</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>10</td>
</tr>
</tbody>
</table>

Risk Management

• Identify Failures
  After identifying potential sterilization process failures, investigate solutions by consulting standards and recommended practices for guidance.
  • 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 IFU’s to determine correct brush size  
|                                             |        | • Purchase brushes  
|                                             |        | • Organize brushes for quick & 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  

#### 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.

---

### Risk Communication

- 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

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 Work Sheets
Risk Analysis
Sterilization Process Failures

<table>
<thead>
<tr>
<th>Cleaning/Decontamination</th>
<th>Sterilization</th>
<th>Quality Monitoring/CQI</th>
<th>Packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Risk Management Process Improvement
Highest Rated Risk Identified:

<table>
<thead>
<tr>
<th>Suggested Resolution</th>
<th>Ballot</th>
<th>Action to be taken</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

References
ANSI/AAMI ST79

- Association for the Advancement of Medical Instrumentation (AAMI)

AORN Perioperative Standards and Recommended Practices (2014)

- 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


  Available at:
  http://www.cdc.gov/hicpac/Disinfection_Sterilization/13_0Sterilization.html

Risk Analysis of the Sterilization Process Resources

In-service articles

1. 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

2. 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 2014
• Personal communications with hospitals that have had surveys