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Sterilization & infection control

A risk analysis of the steam sterilization process can improve patient safety

The steam sterilization process is complex and includes a number of important steps: decontamination, preparation and packaging, sterilization, quality control, sterile storage, and product distribution. The effectiveness of this process cannot be determined by inspection or testing of each product, and because sterility assurance is a probability function, it must be assumed that at some time a failure will occur. Don't let that happen. You can avoid compromising patient safety if you conduct a risk analysis to identify potential problems and correct them before something goes wrong.

Why do a risk analysis?

The Joint Commission states in Standard IC.01.04.01 that hospitals need to identify risks to minimize transmission of infections associated with the use of medical equipment, devices, and supplies, which will improve the quality of patient care. In Standard IC.01.03.01, the Commission states that facilities should review and identify risks at least annually and whenever significant changes occur. In addition, at least every 18 months, the hospital should select 1 high-risk process and conduct a proactive risk assessment. To reduce surgical site infections (SSIs), the Commission states in NPSG.07.05.01 that periodic risk assessments for SSIs should be conducted in a time frame determined by the hospital.

A steam sterilization risk analysis should be proactive (eg, do not wait until a failure occurs) and performed each year and whenever major changes are made (eg, when you have new cleaning or sterilization equipment, a change in packaging, new complex instrument sets, etc). Before undertaking a risk analysis at your healthcare facility, read AAMI ST79 Section 11 and the 2 references by Sue Klacik listed on p 28.

Staying up to date on the manufacturer's written instructions for use (IFU) as well as evidence-based and professional organization guidelines will assist in this process. The results of the risk analysis can be presented to the stakeholders to provide a better understanding of the complexity of the steam sterilization process and the risks that could affect patient safety.

How is a risk analysis done?

A risk analysis includes a risk assessment, risk management, and risk communication. A team consisting of staff working in the sterile processing (SP) area is formed to do this risk analysis because they should be able to:

- identify risks
- state the reasons for risks
- determine which risk is the biggest threat
- suggest ways to reduce this risk
- be knowledgeable about recommended best practices and written IFUs.

During a risk assessment, the team identifies which sterilization process failures

Cleaning/ decontamination	Packaging	Sterilization	Continuous quality improvement
New equipment (2)	Set weighing >25 lbs (2)	Immediate-use steam sterilization (IUSS)	Loaner trays do not arrive on time (6)
Equipment maintenance	Holes in wrappers (4)	New equipment	Staff education and competencies
Old equipment	Use of disposable textiles for large instrument sets	Not using required extended steam sterilization cycle	Inconsistent monitoring of manual cleaning
Change in disinfectants	Container lids not fitting properly	Rust on sides of IUSS sterilizers	Change in management
Undetected debris in lumens (3)	Validation of orthopedic trays in Genesis containers	Sterilizer looks dirty	New staff
No precleaning at point of use	Wrong weight of wrapper	Equipment maintenance	Not processing trays in a timely manner for next day first-case start
Foreign bodies in sets	Inspection of rigid containers prior to placement on sterile field	Chalky film on instruments after sterilization	Not enough cystoscopes for the day
Debris left on instruments (orthopedics) (2)		Improper loading of sterilizer	No verification of sterilization container systems
Instructions for use not available in decontamination		Wet loads (2)	Not enough specialty sets—reprocessing consistently
Debris in lumens of trays received from other hospitals		Old equipment	Early release of implants
Increased complexity of instruments makes cleaning difficult (2)			Equipment maintenance
Change in cleaning chemistries			Old equipment
Bioburden			Staff not using a computer system to access manufacturer's instructions for use
Detergent and milk mixed up in washer			Improperly educated/trained staff in sterile processing

Source: Martha Young

could occur (eg, overloading the sterilizer or choosing the wrong cycle for the load contents). Once the risks are identified, the team places them into the following categories:

- cleaning/decontamination
- packaging
- sterilization
- quality monitoring/continuous quality improvement, which includes cleaning and sterilization process monitoring, IFUs, policies (eg, loaner policy), and procedures.

During a workshop at the 2013 OR Manager Conference, participants walked through the risk analysis process. Attendees were divided into 6 teams that identified steam sterilization process failures and their categories (see sidebar, p 25). Some risks were placed in 2 categories (eg, old equipment). If multiple teams identified the same failure, the number is noted in parentheses.

With just 1 hour for the workshop, we chose the top 4 risks identified and made the risk from cleaning/decontamination a more generic statement (eg, inadequate cleaning).

Risk	Probability of occurrence	Potential severity or risk of failure	Likelihood of undetected failure	Risk score
Holes in wrappers	3	5	3	11
Loaners do not arrive on time or with instructions for use	4	4	2	10
Inadequate cleaning	4	5	5	14
Continuous staff education and competency testing	3	5	3	11

Source: Martha Young

Suggested resolution for inadequate cleaning	Ballot	Action to be taken
Review instructions for use (IFU)	1	
Test mechanical equipment	1	
Review standards	0	
Do ATP testing of instruments	4	
Identify difficult to clean instruments	7	Check IFU and audit compliance Monitor/verify the effectiveness of cleaning equipment Educate OR staff about the significance of precleaning in OR Monitor/verify using ATP cleanliness of instruments Check IFU for washer
Check brushes and other equipment	0	
Conduct an inservice in OR on significance of precleaning	1	
Have an observation audit	3	
Education/competencies in sterile processing	2	

Source: Martha Young

The SP team may choose to rank all the risks identified or may choose some of the top 5 or 10 identified. Next, the team votes to determine the probability of occurrence for each risk listed, the potential severity of harm that could occur from a failure, and the likelihood that the failure could go undetected, thereby increasing the risk to the patient (eg, debris in lumens). (See the results from the OR Manager workshop in the sidebar on p 25.)

All scores are added to create the total risk score for each identified risk. A 0-3, 1-5, or 1-10 ranking system can be used, with the lowest number representing the least risk.

For the OR Manager workshop, we used the 1-5 ranking, and for risk management we used the highest rated risk of inadequate cleaning to suggest solutions to eliminate the risk and actions to be taken for each solution (sidebar, p 28). Because of time constraints, we listed only the actions to be taken for inadequate cleaning. (An SP team doing a risk analysis should have time to complete the risk management information for several of the identified risks.)

The final step is to present the findings of the risk analysis to everyone with an interest in the risk. This typically includes infection prevention, OR, and the SP staff,

and could also include administration. Teams should request additional resources such as staff, equipment, tools, and time to take the actions needed to reduce the identified risks that could lead to steam sterilization process failures and potential SSIs.

The result of the risk analysis is that stakeholders will have a better understanding of the complexity of the steam sterilization process, the risks that could occur daily and affect patient safety, and the importance of providing the staff, equipment, tools, and time needed to reduce the identified risks. A risk analysis of the steam sterilization process creates a win-win situation. ✣

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