



Original research article

Assessing the risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines

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Medical devices that enter body tissues should be sterile, whereas devices that contact mucous membranes should be high-level disinfected between patients. Failure to ensure proper cleaning and sterilization or disinfection may lead to patient-to-patient transmission of pathogens. This paper describes a protocol that can guide an institution in managing potential disinfection and sterilization failures.

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Each year in the United States, approximately 101 million medical procedures are performed, including approximately 10.8 million gastrointestinal endoscopies and approximately 440,000 bronchoscopies.¹ All invasive procedures involve contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogens that can lead to infection. Failure to properly disinfect or sterilize equipment carries not only the risk associated with breach of host barriers but also a risk for person-to-person transmission (eg, hepatitis B virus, hepatitis C virus, *Salmonella* spp, *Mycobacterium tuberculosis*) and transmission of environmental pathogens (eg, *Pseudomonas aeruginosa*, non-tuberculous mycobacteria, environmental fungi). Thus, achieving disinfection and sterilization through the proper cleaning of used medical devices followed by proper use of disinfectants and sterilization practices is essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients.^{2,3}

More than 45 years ago, Spaulding devised a rationale approach to disinfection and sterilization of patient care items or equipment.^{2–4} This classification scheme is so clear and logical that it has been retained and refined and continues to be used when planning methods for disinfection and sterilization. Spaulding divided medical devices into 3 categories (ie, critical, semicritical, noncritical) based on the risk of infection involved in the use of the items.

Critical devices are items that enter sterile tissue or the vascular system and include surgical instruments, implants, and intravenous or intra-arterial catheters. Items in this category should be purchased as sterile or should be sterilized by steam sterilization (preferred). Semicritical items are those that come into contact with mucous membranes or nonintact skin and include gastrointestinal endoscopes, bronchoscopes, laryngoscope blades and handles, and diaphragm fitting rings. These medical devices should be free of all microorganisms (ie, mycobacteria, fungi, viruses, and bacteria), although small numbers of bacterial spores may be present. The minimal requirement for semicritical items is high-level disinfection using US Food and Drug Administration-cleared, high-level chemical disinfectants. Noncritical items are those that come in contact with intact skin but not mucous membranes (eg, bedpans, blood-pressure cuffs, bed rails). Such items should be undergo low-level disinfection after use when shared by different patients. The Spaulding classification provides an excellent guide for disinfection and sterilization of medical devices, but it should be noted that the scheme is an oversimplification and that preventing transmission of infection by medical devices may require additional modifications.^{3,5}

Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization.³ Failure to comply with scientifically based guidelines has led to numerous outbreaks. Deficiencies leading to infection have occurred either from failure to adhere to scientifically based guidelines or misuse of the disinfection or sterilization processes.^{6–9} Patient notifications because of improper reprocessing of semicritical (eg, endoscopes) and critical medical instruments have occurred regularly and generally involve single institutions but may also involve multiple institutions.¹⁰ Seoane-Vazquez et al reported

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that, between 1974 and 2005, 63 outbreaks related to contaminated endoscopes led to more than 21,000 exposed patients.⁸ The impact of even a single outbreak can be enormous. For example, the largest disinfection failure involved the distribution of an inactive lot of glutaraldehyde disinfectant solution that had been used by 60 hospitals in Belgium and involved 34,879 patients. In this incident, 25,589 patients were screened for infection with hepatitis B virus (HBV) and hepatitis C virus (HCV), and no acute infections were observed.¹⁰ It is the authors' experience that the number of incidents that are published or are reported in the press represent a small fraction of the disinfection and sterilization instrument reprocessing failure incidents that result in patient notification. These failures may result from human error (eg, incorrect temperature setting on a steam sterilizer, failure to clean items before disinfection), equipment or product failure, or system problems (ie, organizational, procedural, or environmental factor that facilitates the failure such as the use of incorrect channel connectors). Equipment failure incidents may stem from design, manufacture, maintenance, storage, or lack of user competence. This paper provides an update of our protocol published in 2007 that provided a scheme for performing an evaluation of possible failures of high-level disinfection or sterilization of patient care items¹¹ and expands on our 2012 commentary on managing exposure events from inappropriately reprocessed endoscopes.¹

RISKS OF ENDOSCOPY

Endoscopes represent the medical devices most commonly linked to health care-associated outbreaks and pseudo-outbreaks.^{6–10,12–15} Flexible endoscopes represent high-risk devices because they often have high levels of bacterial contamination, require low-temperature sterilization or disinfection methods, and their design poses substantial challenges to adequate cleaning and disinfection. Because of the body cavities they enter, flexible endoscopes often acquire high levels of microbial contamination (bioburden) during each use.³ For example, the bioburden on flexible gastrointestinal endoscopes after use has ranged from 10⁷ colony-forming units (CFU)/mL (colony forming units per milliliter) to 10¹⁰ CFU/mL, with the highest levels found in the suction channels. The average load on bronchoscopes before cleaning was 6.4 × 10⁴ CFU/mL. Unfortunately, most current flexible endoscopes are heat sensitive and must either be sterilized using a low-temperature method (eg, ethylene oxide) or high-level disinfected (eg, glutaraldehyde, peracetic acid, orthophthalaldehyde), methods that are less robust than steam sterilization. In addition to high bioburden, flexible endoscopes present a challenge for low-temperature sterilization or high-level disinfection because they have long narrow lumens, cross connections, mated surfaces, sharp angles, springs and valves, occluded death ends, absorbent material, and rough or pitted surfaces. The causes of endoscopy-related outbreaks have been comprehensively reviewed.^{7–9} Excellent guidelines are available that provide detailed recommendations for the appropriate cleaning and disinfection/sterilization of endoscopes.^{3,16} However, procedures for the cleaning and disinfection of endoscopes are complex, and the guidelines must be adapted for the specific endoscope and method of disinfection.

PROTOCOL FOR EVALUATING AND MANAGING POTENTIAL FAILURES OF ADEQUATE STERILIZATION OR DISINFECTION

Although exposure events because of possible failures of disinfection or sterilization are often unique, one should approach evaluation of potential failure using a standardized approach. As with evaluation of microbial outbreaks, one must be prepared to assess the unique aspects of each possible disinfection or sterilization failure by adapting the following recommended approach.

Table 1

Protocol for exposure investigation after a failure of disinfection and sterilization processes

1. Confirm failure of disinfection or sterilization reprocessing
2. Immediately embargo any possibly improperly disinfected/sterilized items
3. Do not use the questionable disinfection/sterilization unit (eg, sterilizer, automated endoscope reprocessor) until proper functioning has been assured
4. Inform key stakeholders
5. Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6. Prepare a line listing of potentially exposed patients
7. Assess whether the disinfection/sterilization failure increases a patient's risk for infection
8. Inform expanded list of stakeholders of the reprocessing issue
9. Develop a hypothesis for the disinfection/sterilization failure and initiate corrective action
10. Develop a method to assess potential adverse patient events
11. Consider notification of appropriate state and federal authorities (eg, health department, FDA)
12. Consider patient notification
13. If patients are notified, consider whether such patients require medical evaluation for possible postexposure therapy with appropriate anti-infectives. In addition, appropriate follow-up to detect infection (eg, HIV, hepatitis B, hepatitis C) should be offered, if warranted.
14. Develop a detailed plan to prevent similar failures in the future
15. Perform after-action report

FDA, US Food and Drug Administration.

We propose an expanded sequence of 15 steps that form a general approach to the evaluation of a possible failure of disinfection or sterilization that could result in patient exposure to an infectious agent (Table 1). Because failure to disinfect a noncritical patient care item (eg, blood pressure cuff) is very unlikely to result in a patient exposure, reference to disinfection in the following section refers to high-level disinfection of semicritical items such as endoscopes.

Step 1: The first step in assessing a possible disinfection or sterilization failure is to confirm whether the suspected failure did in fact occur. To do so, the infection control professional should review the circumstances of the reported failure including the time and date of possible failure(s); type of sterilization method; and evidence of failure including review of process parameters and results of physical, chemical, and/or biologic indicators. Maintaining a detailed record of all sterilizer/disinfector runs, process measures, and results of indicators is crucial to allow determination of whether a sterilizer/disinfector failure has occurred. Some common failures include failure to subject the medical item to any disinfection or sterilization after cleaning, failure of the sterilization process to reach proper temperature, failure to provide the proper duration of disinfection, failure to expose the instrument to the disinfectant at the proper concentration, or failure to clean the item prior to disinfection. If the initial evaluation reveals that no medical items that were potentially inadequately processed were used in patient care, then one can limit the evaluation to determining whether the disinfection process failed and correct the processing error (ie, there is no patient safety issue involved). All potentially inadequately processed items must, of course, be reprocessed. If a disinfection or sterilization failure is not confirmed, the investigation may be concluded.

Step 2: If a possible disinfection or sterilization failure has occurred, one should immediately embargo any medical items that may not have been appropriately disinfected or sterilized (ie, do not allow such items used in patient care). Maintaining a log of all items processed in each individual sterilizer/disinfector during each run is crucial to being able to retrieve possible inadequately processed items. All items reprocessed since the last successful processing (as demonstrated by process measures and/or physical, chemical, or

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