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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.

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 items[11] 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 10^7 colony-forming units (CFU)/mL (colony forming units per milliliter) to 10^{10} CFU/mL, with the highest levels found in the suction channels. The average load on bronchoscopes before cleaning was 6.4×10^4 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

biologic indicators) should be embargoed. Retrieving all items may require visiting all areas where the medical/surgical items may be stored or used including central processing, patient units including community-based clinics, operating rooms, and store rooms. Embargoed items should be retrieved and stored where they cannot be released for use and clearly labeled to prevent inadvertent use.

Step 3: The implicated disinfection or sterilization unit should be immediately placed off line and not used for disinfection or sterilization of medical or surgical devices until such time as its proper functioning can be assured. This may entail several runs with an assessment of process parameters and physical, chemical, and/or biologic indicators. Medical engineering or the manufacturer's representative usually performs repairs and an evaluation of the unit. Repair work may require that the device be returned to the manufacturer.

Step 4: All key stakeholders including risk management (ie, legal), the medical director and nursing director of the involved medical/surgical units, and personnel involved in disinfection or sterilization should be informed of the current problem(s). It is often easier to arrange a face-to-face conference to assure complete communication of the facts with feedback from attendees than to use e-mail or telephone consultation. At this meeting, all parties should agree on the steps to be taken to assess possible patient exposure to pathogens and mitigate the effects of any exposures.

Step 5: A complete and thorough evaluation of the possible disinfection or sterilization failure should be rapidly completed. An infection control professional should review the exact circumstances of the possible disinfection or sterilization failure including the dates and results of all process measures and physical, chemical, and biologic indicators obtained in the recent past going back far enough to assess the time and date of first possible malfunction. Process measures may include time, temperature, sterilant concentration, and pressure. Common problems with automated endoscope reprocessor (AERs) have included failure to properly clean the item, set the correct duration of exposure to the high-level disinfectant or sterilant, attach the channel connectors properly, and use of the correct channel connectors.

Step 6: Once a failure of disinfection or sterilization has been documented, it is important to initiate the evaluation of potential patient exposures. The first step is to create a line listing of all possible patients who may have been exposed to possibly contaminated medical/surgical devices. The line listing should include at a minimum the following: patient name, identification number, date(s) of exposure, contaminated device used, underlying risk factors for infection, development of a health care-associated infection (including pathogen, body site), and other potential adverse events. To develop a line listing of possibly exposed patients in the event of a potential sterilization or disinfection failure, health care facilities must have tracking methods in place to allow retrospective linkage of high-risk equipment with specific patients (eg, which patients were evaluated with a specific endoscope). With the expanded use of bar code-labeled equipment and scanning, the ability to link high-risk equipment to patients should become more common in the future.

Step 7: Once a failure of disinfection or sterilization process has been documented with possible patient exposure to a contaminated item, it is crucial to determine whether, in fact, the failure could result in an adverse patient event (eg, infection). For example, we use 4 minutes for flash sterilization (now referred to as immediate use steam sterilization). We would consider flash sterilization for 3 minutes a breach of our policy. However, some recommendations would state that 3 minutes provides adequate sterilization of an unwrapped item. Thus, we would not consider items flash sterilization for 3 minutes as representing a hazard to the patient with regard to increasing the risk of health care-associated infections. Many sterilization processes (eg, steam) have an enormous safety margin, and small deviations from standard practice may not represent a patient hazard. Assessing risk should always be based on a review of the scientific literature and/or compliance with national guidelines.

Step 8: All stakeholders should be kept informed of the progress of the investigation, especially if an increased risk to patients is possible or documented. Key stakeholders include risk management, the medical and nursing director of the involved patient units, and personnel involved in disinfection or sterilization. Other persons who should be informed include public relations, health care administration, and legal.

Step 9: One should develop a hypothesis regarding the potential mechanism(s) of the disinfection or sterilization failure. Corrective actions (eg, repairs, improved training, and others) should be initiated to correct the deficiencies in reprocessing. Reprocessing of any item that may not have been appropriately disinfected or sterilized must be done.

Step 10: Initiate a more detailed study, if necessary, of possible adverse outcomes in patients. This may entail designing a prospective cohort study. It may require reviewing medical records and/or examining patients for infections, chemical reactions (eg, colitis), or other adverse events.[17] Specific laboratory tests may be necessary such as cultures and testing source patients and exposed persons for bloodborne pathogens such as HIV, HBV, and HCV. Access to specific tests and receipt of results should be made as easy as possible for patients. The most recent guidelines from the Centers for Disease Control and Prevention for the postexposure evaluation of persons exposed to bloodborne pathogens should be followed if HIV, HBV, or HCV exposure could have occurred.[18]

Step 11: In conjunction with the legal department, notify appropriate state and federal authorities if required by regulation or law.

Step 12: Consider whether patients should be notified of the disinfection or sterilization failure. If it is determined that the failure could result in adverse patient events, then patients should be notified. Fear of litigation, loss of business, and damage to the hospital's reputation should not be deterrents to reporting these events to patients.[19] Determine who will notify the patients. Choices include the patient's local medical provider, the medical director of the clinic, the attending physician at the time of disinfection or sterilization failure, risk management, or an infection control professional. One should develop a script to be used in notification to ensure all patients receive the same information.[11] Notification may be accomplished by face-to-face meeting, telephone, or registered mail.[11] A press release should be prepared in case of need and a spokesperson appointed.[11] The wording used in these communications may need to be simplified to ensure patient understanding. A Spanish version of these letters may be useful in areas of the country with a large Hispanic population.

More than one method may be used to ensure complete notification. The notification should include as much information as possible such the following: an assessment of the risk, possible adverse events that may occur (eg, wound infection), symptoms and signs of the adverse event, time range for the adverse event, risk to other contacts, possible prophylactic therapy (including benefits and risks), and recommended medical follow-up. The health care facility must decide who will provide these services and whether the facility will cover the cost of care. In general, we recommend that, if the facility was responsible for the failure, then it should provide these services at no patient charge. However, it the exposure resulted from failures outside the institution (eg, receipt by the facility of inadequately obtained or prepared tissue used for implants, or nonsterile device), then the facility may want to offer the services but at the patient's expense or product/instrument manufacturer's expense.

Step 13: Prior to notifying patients, a mechanism should be devised to provide a medical evaluation and follow-up of exposed patients. As noted above, the most recent Centers for Disease Control and Prevention guidelines should be followed for post-exposure management of patients exposed to HIV, HBV, and HCV. Health care facilities will need to decide whether patients will be encouraged to return to the facility for their evaluation or whether they will be referred to the primary care provider or the public health department. Furthermore, health care facilities should decide whether they will cover the cost of the medical evaluation and postexposure therapy if indicated. Patients should be informed of who will bear the costs of their evaluation. All providers to whom patients are referred should be provided with recommendations for proper evaluation. In addition to possible postexposure therapy for bloodborne viruses, in some cases antibacterial or antifungal prophylactic therapy may be indicated, depending on the nature of the exposure and degree of risk.

Step 14: Once the problem leading to the disinfection or sterilization failure has been identified and corrective action initiated, it is crucial to assess whether these interventions have eliminated the problem over the long-term. This may require long-term surveillance, changes in current policies or procedures, development of new policies or procedures, or evaluation of current equipment.

Step 15: Finally, a report of the event should be prepared for presentation to the appropriate hospital or health care system committees. Consideration should be given to publishing the evaluation if the lessons learned from the failure can avoid the same mistakes at other institutions.

ASSESSING AND INTERPRETING RISK

Assessing the probable risk to a patient following a potential exposure is crucial to deciding whether disclosure is warranted. Furthermore, if patient disclosure is warranted, the proper counseling of the patient requires assessing the risk. In many cases, the probable risk may be determined by a careful review of the literature and construction of an algorithm that determines the independent probabilities of disease transmission.[11] Disease transmission resulting in infection requires a chain of events including a microorganism pathogenic for humans, the presence of the pathogen in the environment, the survival of the pathogen, a portal of entry into the potential host, an inoculating dose, and the failure of the immune system to prevent infection (ie, susceptible host). Each of these events must occur in the proper sequence, and each represents an independent event. Failure of any step in the sequence prevents infections (eg, no portal of entry). In many cases, actual probabilities for each of these events (or a range of probabilities) can be determined from the scientific literature. The risk of infection is calculated by adding the independent probabilities when risk is displayed using a logarithmic scale.[11]

When a calculation of risk of disease transmission is extremely small, such as less than 1 in 1 million, there may be no legal imperative to notify patients because there is, in effect, no clinically significant health risk. Although there is no fixed or accepted risk frequency that necessitates risk disclosure, our legal staff has reviewed several informed consent cases that cite a 1% to 3% frequency as the lower limit of frequency for patient notification for risks associated with medical procedures such as surgery. The risk of an adverse outcome following a failure of sterilization or disinfection must be compared with the risks of dying from other causes in a given year.

The risk of everyday life has been well described. For example, the risks of death in a given year for selected events are shown[19] in Table 2. In assessing everyday activities (eg, driving, walking, flying), the most common approach we all engage in is to ask what level of risk we are willing to tolerate given the considerable benefits that the activity will provide. Similarly, physicians when providing medications or recommending procedures seek to assess the risk/benefit ratio. Risk is inherent in the practice of medicine, whether it is associated with medication administration, surgical or radiological procedures, medical diagnostic procedures, or diagnosis. Safe practice requires that risks be minimized or, ideally, prevented. Infection control professionals should understand the causes of disinfection and sterilization instrument reprocessing failures and implement procedures that minimize or prevent patient exposures because of improperly reprocessed medical and surgical instruments.

Table 2
Odds of death because of injury, United States, 2006

Type of injury or event	One year odds of death
Unintentional Injury	1 in 1,643
Motor vehicle accident	1 in 6,584
Fall	1 in 4,077
Intentional self-harm	1 in 8,960
Accidental poisoning	1 in 10,837
Assault	1 in 16,064
Pedestrian injury	1 in 48,420
Accidental drowning and submersion	1 in 83,365
Exposure to smoke, fire, and flames	1 in 95,968
Exposure to electric current, radiation, temperature	1 in 731,282

NOTE. Data from the National Safety Council.[19]

EXAMPLE OF A RISK ANALYSIS

A recent paper by Holodniy et al demonstrates the use of our protocol for managing exposures after sterilization/disinfection failures and assessing risk.[20] This paper describes 4 specific events that led to possible patient-to-patient transmission of pathogens. Calculation of risk using the method described above resulted in risks ranging from 8 in 10 million to 2.4 in 1 billion, depending on the event and the bloodborne virus. Despite these very low risks, patients were notified of the sterilization/disinfection failures and offered testing for bloodborne viruses. The scale of evaluation is indicated by the fact that approximately 10,000 persons were tested; viral genetic testing was performed for case/proximate pairs to determine relatedness. The investigation did not detect any viral transmission.

SUMMARY

We have provided a blueprint for evaluating and correcting potential failures of disinfection or sterilization. The key aspects of the evaluation are that it be done in an organized fashion and in a rapid and timely manner. Maintaining communication among key stakeholders is crucial to the process. Although we have described the evaluation in a linear fashion, multiple steps are usually done simultaneously (eg, evaluation of mechanism of sterilization failure and evaluation of patients for adverse outcomes). Each potential exposure is unique, and one must be flexible in adapting our recommendations to a specific situation.

As with everything we do in infection control, prevention is preferable to correcting a deficiency in procedures that can result in potential exposure. The keys to preventing potential failures of disinfection and sterilization include the following. First, adhere to authoritative guidelines. Specific guidelines are available from US agencies (eg, Centers for Disease Control and Prevention, Food and Drug Administration) and professional organizations (eg, Association for Professionals in Infection Control and Epidemiology, Society of Gastrointestinal Nurses Association). Manufacturers may also have reprocessing recommendations that should be reviewed.

Second, personnel performing disinfection and sterilization should be properly trained (at commencement of employment and at least annually) and supervised to ensure they consistently follow the facility's specific procedures. Competency testing of personnel responsible for endoscope reprocessing is recommended. Third, appropriate equipment should be used, and training for newly purchased equipment should be obtained. Fourth, proper monitoring of equipment should be performed on the recommended time schedule (eg, AER) to ensure the equipment is functioning according to manufacturer's specifications. Periodically ensure that the AER high-level disinfectant exposure time is set properly and that the valves and connectors are delivering the proper amount of disinfectant and rinse water. Fifth, proper documentation of equipment use for specific devices must be maintained. Sixth, regular infection control rounds of areas that utilize disinfection or sterilization should be performed to ensure that actual practice is consistent with policy and procedures. Seventh, the scientific literature must be routinely reviewed by infection control professionals with regard to potential outbreaks and sources of potential exposures, and lessons from previous failure incidents involving medical devices must be learned. Staff must understand what caused these failures and develop procedures that prevent recurrence.

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