How to Assess Risk of Disease Transmission to Patients When There Is a Failure to Follow Recommended Disinfection and Sterilization Guidelines

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

BACKGROUND. Disinfection and sterilization are critical components of infection control. Unfortunately, breaches of disinfection and sterilization guidelines are not uncommon.

OBJECTIVE. To describe a method for evaluating a potential breach of guidelines for high-level disinfection and sterilization of medical devices.

METHODS. The appropriate scientific literature was reviewed to determine the frequency of failures of compliance. A risk assessment model was constructed.

RESULTS. A 14-step protocol was constructed to aid infection control professionals in the evaluation of potential disinfection and sterilization failures. In addition, a model is presented for aiding in determining how patients should be notified of the potential adverse event. Sample statements and letters are provided for communicating with the public and individual patients.

CONCLUSION. Use of a protocol can guide an institution in managing potential disinfection and sterilization failures.

In the United States in 1996, there were approximately 46,500,000 surgical procedures and a much larger number of invasive medical procedures. For example, there are about 5 million gastrointestinal endoscopies per year. Each of these procedures involves contact between a medical device or surgical instrument and a patient’s sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogenic microbes, which can lead to infection. Failure to properly disinfect or sterilize equipment has led to person-to-person transmission via contaminated devices (e.g., *Mycobacterium tuberculosis* transmitted via contaminated bronchoscopes). Thus, achieving disinfection and sterilization through the use of disinfectants and sterilization practices is essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients.

Deficiencies in disinfection and sterilization leading to infection have resulted either from failure to adhere to scientifically based guidelines or failures in the disinfection or sterilization processes. Patient notifications due to improper reprocessing of semicritical (e.g., endoscopes) and critical medical instruments have occurred regularly; these incidents generally involve single institutions, but may also involve multiple institutions (Table 1). The largest disinfection failure on record 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. It is our experience that the number of incidents that are published or 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 (e.g., incorrect setting of the temperature on a steam sterilizer or failure to clean items before disinfection), equipment or product failure, or systemic problems (i.e., an organizational, procedural, or environmental factor that facilitates the failure, such as the use of incorrect channel connectors). Equipment failure incidents may stem from problems with design, manufacture, maintenance, or storage, as well as from a lack of user competence. This article presents a scheme for performing an evaluation of possible failures of high-level disinfection or sterilization of patient care items. It will also provide a method for assessing patient risk for adverse events, especially infection.

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Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in healthcare facilities by either physical or chemical methods. Steam under pressure, dry heat, ethylene oxide gas, hydrogen peroxide gas plasma, and liquid chemicals are the principle sterilizing agents used in healthcare facilities in the United States. When chemicals are used for the purposes of destroying all forms of microbiological life, including fungal and bacterial spores, they may be called chemical sterilants. These same germicides used for shorter exposure periods may also be part of the disinfection process (ie, for high-level disinfection).

Disinfection describes a process that eliminates many or all pathogenic microorganisms, with the exception of bacterial spores, on inanimate objects. Disinfection is usually accomplished by the use of liquid chemicals or wet pasteurization in healthcare settings. The efficacy of disinfection is affected by a number of factors, each of which may nullify or limit the efficacy of the process. Some of the factors that affect both disinfection and sterilization efficacy are prior cleaning of the object, the organic and inorganic load present, the type and level of microbial contamination, the concentration and duration of exposure to the germicide, the nature of the object (eg, presence of crevices, hinges, or lumens), the presence of biofilms, the temperature and pH of the disinfection process, and, in some instances, the relative humidity of the sterilization process (eg, for ethylene oxide disinfection).

Cleaning, on the other hand, is the removal of visible soil (eg, organic and inorganic material) from objects and surfaces, and it normally is accomplished by manual or mechanical means using water and detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization, because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes.

Over 35 years ago, Earle H. Spaulding devised a rational approach for disinfection and sterilization of patient care items and equipment. This classification scheme is so clear and logical that it has been retained, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization. Spaulding believed that the nature of disinfection could be understood more readily if instruments and items for patient care were divided into 3 categories on the basis of the degree of risk of infection involved in the use of the items. The 3 categories he described were critical, semicritical, and noncritical. This terminology is employed by the Centers for Disease Control and Prevention (CDC) in their guidelines for environmental infection control and disinfection and sterilization in healthcare facilities.

Critical items are so categorized because there is a high risk of infection if the items are contaminated with any microorganism, including bacterial spores. Thus, critical items are those that enter sterile tissue or the vascular system and must be sterile because any microbial contamination could result in disease transmission. This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities.

Semicritical items are those that come in contact with mucous membranes or nonintact skin. Respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades, esophageal manometry probes, anorectal manometry catheters, and diaphragm fitting rings are included in this category. Thus, these medical devices should be free of all microorganisms (ie, mycobacteria, fungi, viruses, and bacteria), although small numbers of bacterial spores may be present. Intact mucous membranes, such as those of the respiratory tract or the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms, such as bacteria, mycobacteria, and viruses. Semicritical items minimally require high-level disinfection using chemical disinfectants (eg, glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, peracetic acid with hydrogen peroxide, or chlorine).

Noncritical items are those that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms; therefore, the sterility of items coming in contact with intact skin is not critical. Examples of noncritical items are bedpans, blood pressure cuffs, crutches, bed rails, linens, bedside tables, patient furniture, and floors. In contrast to critical and some semicritical items, most noncritical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area. There is virtually no documented risk of transmitting infectious agents to patients via noncritical items when they are used as noncritical items and

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**Table 1. Reprocessing Failures of Semicritical or Critical Medical Instruments Resulting in Patient Notification**

<table>
<thead>
<tr>
<th>Location or institution, year</th>
<th>Instrument involved</th>
<th>No. of persons exposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sacramento, CA, 2002</td>
<td>Endoscope</td>
<td>750</td>
</tr>
<tr>
<td>Toronto, ON, 2003</td>
<td>Endoscope</td>
<td>146</td>
</tr>
<tr>
<td>Seattle, WA, 2004</td>
<td>Endoscope</td>
<td>600</td>
</tr>
<tr>
<td>Sacramento, CA, 2004</td>
<td>Endoscope</td>
<td>1,351</td>
</tr>
<tr>
<td>San Francisco, CA, 2004</td>
<td>Endoscope</td>
<td>2,000</td>
</tr>
<tr>
<td>Long Island, NY, 2004</td>
<td>Endoscope</td>
<td>177</td>
</tr>
<tr>
<td>Charleston, NC, 2004</td>
<td>Endoscope</td>
<td>1,383</td>
</tr>
<tr>
<td>Toronto, ON, 2003</td>
<td>Prostate biopsy probe</td>
<td>900</td>
</tr>
<tr>
<td>Pittsburgh, PA, 2005</td>
<td>Endoscope</td>
<td>200</td>
</tr>
<tr>
<td>Leesburg, VA 2005</td>
<td>Endoscope</td>
<td>144</td>
</tr>
<tr>
<td>San Diego, CA, 2006</td>
<td>Endoscope</td>
<td>300</td>
</tr>
<tr>
<td>Augusta, ME, 2006</td>
<td>Prostate biopsy needle</td>
<td>481</td>
</tr>
<tr>
<td>Dept Veterans Affairs, 2006</td>
<td>Prostate biopsy equipment</td>
<td>2,075</td>
</tr>
<tr>
<td>San Diego, CA, 2006</td>
<td>Surgical instrument</td>
<td>82</td>
</tr>
</tbody>
</table>

*NOTE.* Modified from a presentation by Douglas Nelson, MD, at the 33rd Annual Conference and International Meeting of the Association for Professionals in Infection Control and Epidemiology; Tampa, Florida, 2006.
do not come into contact with nonintact skin or mucous membranes.

REPROCESSING OF ENDOSCOPES

Physicians use endoscopes to diagnose and treat numerous medical disorders. Although endoscopes are a valuable diagnostic and therapeutic tool in modern medicine and the incidence of infection associated with use has been reported to be very low (about 1 case per 1.8 million procedures), more healthcare-associated outbreaks of infection have been linked to contaminated endoscopes than to any other medical device. To prevent the spread of healthcare-associated infections, all heat-sensitive endoscopes (eg, gastrointestinal endoscopes, bronchoscopes, and nasopharyngoscopes) must be properly cleaned and, at a minimum, subjected to high-level disinfection following each use. High-level disinfection can be expected to destroy all microorganisms, although if high numbers of bacterial spores are present, a few spores may survive. Recommendations for the cleaning and disinfection of endoscopic equipment have been published and should be strictly followed. Unfortunately, audits have shown that personnel often do not adhere to guidelines on reprocessing, and outbreaks of infection continue to occur. To ensure that reprocessing personnel are properly trained, there should be initial and annual competency testing for each individual who is involved in reprocessing endoscopic instruments.

FIGURE 1. Protocol for exposure investigation after a failure of disinfection and sterilization procedures

<table>
<thead>
<tr>
<th>Step</th>
<th>Protocol for Exposure Investigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Confirm disinfection or sterilization reprocessing failure</td>
</tr>
<tr>
<td>2.</td>
<td>Impound any improperly disinfected/sterilized items</td>
</tr>
<tr>
<td>3.</td>
<td>Do not use the questionable disinfection/sterilization unit (e.g., sterilizer, automated endoscope reprocessor) until proper functioning can be assured</td>
</tr>
<tr>
<td>4.</td>
<td>Inform key stakeholders</td>
</tr>
<tr>
<td>5.</td>
<td>Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure</td>
</tr>
<tr>
<td>6.</td>
<td>Prepare a list of potentially exposed patients</td>
</tr>
<tr>
<td>7.</td>
<td>Assess whether disinfection/sterilization failure increases patient risk for infection</td>
</tr>
<tr>
<td>8.</td>
<td>Inform expanded list of stakeholders of the reprocessing issue</td>
</tr>
<tr>
<td>9.</td>
<td>Develop a hypothesis for the disinfection/sterilization failure and initiate corrective action</td>
</tr>
<tr>
<td>10.</td>
<td>Develop a method to assess potential adverse patient events</td>
</tr>
<tr>
<td>11.</td>
<td>Consider notification of state and federal authorities</td>
</tr>
<tr>
<td>12.</td>
<td>Consider patient notification</td>
</tr>
<tr>
<td>13.</td>
<td>Develop long-term follow-up plan</td>
</tr>
<tr>
<td>14.</td>
<td>Perform after-action report</td>
</tr>
</tbody>
</table>

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

We propose a sequence of 14 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 (Figure 1). Because failure to disinfect a noncritical patient care item (e.g., a 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.

**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 this, the infection control professional should review the circumstances of the reported failure, including the time and date of possible failure(s), the type of sterilization method used, and the evidence of failure, including review of process parameters and physical, chemical, and/or biological indicators. Some common failures include failure to subject the medical item to any disinfection or sterilization after cleaning, failure to expose the item to the proper temperature during the sterilization process, fail-
Figure 2. Sample script to be used when discussing potential exposure with a patient by telephone

I am Dr.………, may I please speak to………. I am calling to tell you that during your recent Obstetrics-Gynecology examination at………. you may have been examined using a speculum that was cleaned and disinfected but not high-level disinfected. We believe that the chance you could get any infection from this infection is extremely unlikely, almost certainly less than 1 in a billion. However, if you are concerned, we would be happy to see you at……. and provide free testing for viruses that could theoretically have been transmitted during your examination. We would offer testing now and again in 3 and 6 months.

The viruses we are talking about include HIV, and the viruses that cause hepatitis B and hepatitis C. We can also give you the hepatitis B vaccine if you desire. Again, all tests and the vaccine will be provided free.

We regret this occurred and have taken steps to assure that in the future all medical devices are both cleaned and disinfected before use.
cesses has been documented and possible patient exposure to a contaminated item has been identified, it is crucial to determine whether, in fact, the failure could result in an adverse patient event (eg, infection). For example, in our institution, we require 4 minutes for flash 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 that have been flash sterilized for 3 minutes to represent a hazard to patients with regard to increasing the risk of healthcare-associated infections. Many sterilization processes (eg, steam sterilization) have an enormous safety margin, and small deviations from standard practice may not represent a patient hazard. Assessments of 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 personnel, the medical and nursing director of the involved patient units, and personnel involved in disinfection or sterilization. Other persons who should be informed include staff in the public relations, healthcare administration, and legal departments.

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

Step 10. Initiate a more detailed study, if necessary, of possible adverse outcomes in patients. This may entail de-
signing a prospective cohort study. It may require reviewing medical records and/or examining patients for infections, chemical reactions (eg, colitis), or other adverse events. Specific laboratory tests may be necessary, such as performing cultures and/or testing for source patients and exposed persons to identify bloodborne pathogens, such as human immunodeficiency virus (HIV) (eg, HIV antibody testing at baseline, 12 weeks, and 24 weeks), HBV (eg, hepatitis B surface antigen testing at baseline and at 24 weeks), and HCV (eg, HCV antibody testing at baseline, HCV polymerase chain reaction viral detection testing at 4 weeks, and HCV antibody testing at 24 weeks). Access to specific tests and receipt of results should be made as easy as possible for patients.

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. 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 personnel, or an infection control professional. One should develop a script to be used for notification, to ensure that all patients receive the same information (Figure 2). Notification may be accomplished by a face-to-face meeting, telephone call, or letter sent by registered mail (Figure 3). A press release should be prepared in case it is needed, and a spokesperson appointed (Figure 4). The wording used in these communications may need to be simplified to ensure patients’ understanding. A Spanish version of these letters may be useful in areas of the country with a large Spanish-speaking population. Our sample notices (Figures 2, 3, and 4) are provided as examples of how to communicate with patients and the media and should not be seen as establishing the level of risk for which notification is required.

Multiple methods should be used simultaneously to ensure complete notification. The notification should include as much information as possible, such as 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 healthcare 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 charge to the patient. However, if the exposure resulted from failures outside the institution (e.g., receipt by the facility of inappropriately obtained or inadequately prepared tissue used for implants, or a nonsterile device), then the facility may want to offer the services, but provide them at the patient’s expense or at the product or instrument manufacturer’s expense.

Step 13. 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 14. Finally, a report of the event should be prepared for presentation to the appropriate hospital or healthcare system committees. Consideration should be given to publishing the evaluation if the lessons learned from the failure can help prevent the same mistakes at other institutions.

Assessing Risk

Assessing the probable risk to a patient after a potential exposure is crucial to deciding whether disclosure is warranted.
Further, if patient disclosure is warranted, 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 (Figure 5). Disease transmission resulting in infection requires a chain of events and circumstances including a microorganism pathogenic for humans, the presence of the pathogen in the environment, survival of the pathogen, presence of a portal of entry into the potential host, a sufficiently large inoculum, and failure of the immune system to prevent infection (ie, a susceptible host). Each of these must occur in the proper sequence, and each represents an independent step in the chain. If any step in the sequence fails to occur, this prevents infection (eg, if there is no portal of entry into the potential host). 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, with risk displayed using a logarithmic scale (Figure 5).

If a calculated risk of disease transmission is extremely small, such as 8 in 100 trillion, there may be no legal imperative to notify patients as there is, in effect, no clinically significant health risk. Although there is no fixed or accepted risk frequency that necessitates risk disclosure, the legal staff at our institution has reviewed several informed consent cases that cite a 1%-3% frequency as the lower limit for notifying patients about risks associated with medical procedures, such as surgery. North Carolina’s informed consent statute refers to “usual and most frequent risks” as those that should be mentioned in an informed consent discussion for a medical procedure. Although preprocedure informed consent is different than notification after a potential exposure, the orders of magnitude by which risks differ are instructive. Again, the risk frequencies may be so small (eg, 8 in 100 trillion, as displayed in Figure 5) that they are effectively, and legally, of no concern or are far lower than the risk frequencies associated with many other daily exposures we all encounter (B. Gilbert, JD, MPH, personal communication, January 2005). Even though with risks of this magnitude there may be no legal obligation to notify patients, healthcare facilities may decide in favor of disclosure.

**INTERPRETING RISK**

The risks encountered in everyday life have been described. For example, the risk of dying in a given year of selected causes is shown in Table 2. In assessing everyday activities (eg, driving, golfing, or flying), the most common approach we all use is to ask what level of risk we are willing to tolerate given the sometimes considerable benefits that the activity will provide. Similarly, physicians, when providing medications or recommending procedures, seek to assess the risk-benefit ratio.

Regulatory agencies are beginning to develop risk-based assessments of chemicals (eg, in foods), air pollutants, and medications. For example, the US Environmental Protection Agency generally deems a lifetime cancer risk from hazardous air pollutant emissions (eg, benzene) greater than 1 in 1 million to be unacceptable. This cancer risk benchmark has been used in their publications on the public health significance of hazardous air pollutants. A lifetime risk of health effects of 1 in 1 million or lower for chemical exposure is usually considered acceptable by regulatory agencies, either because it is small enough to be insignificant compared to other risks or because it is extremely difficult, if not impossible, to measure. Similarly, a guideline from the European Medicines Agency (CPMP/SWP/5199/02) provides a “threshold of toxicological concern (TTC)” for the assessment of acceptable limits of genotoxic impurities in pharmaceutical preparations, which corresponds to a 1 in 100,000 risk of cancer.

Risk is inherent in the practice of medicine, whether it is associated with medication, 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 failures in instrument reprocessing and implement procedures that minimize or prevent patient exposures to improperly reprocessed medical and surgical instruments.

**DISCUSSION**

Potential exposure events due to possible failures of disinfection or sterilization are not unusual in healthcare institutions (Table 1). Healthcare institutions must take such potential failures seriously, as multiple outbreaks have been reported in the literature that resulted from failure to comply with recommended practices. Such failures may occur as a result of human error, equipment malfunction, or system failure. Healthcare institutions must have a well-thought-out plan for dealing with such events. We have provided a blueprint for evaluating and correcting potential failures of disinfection and sterilization. If any step in these events fails to occur, this prevents the potential event. If a calculated risk of disease transmission is extremely small, such as 8 in 100 trillion, there may be no legal imperative to notify patients as there is, in effect, no clinically significant health risk. Although preprocedure informed consent is different than notification after a potential exposure, the orders of magnitude by which risks differ are instructive. Again, the risk frequencies may be so small (eg, 8 in 100 trillion, as displayed in Figure 5) that they are effectively, and legally, of no concern or are far lower than the risk frequencies associated with many other daily exposures we all encounter (B. Gilbert, JD, MPH, personal communication, January 2005). Even though with risks of this magnitude there may be no legal obligation to notify patients, healthcare facilities may decide in favor of disclosure.

<table>
<thead>
<tr>
<th>Type of injury or event</th>
<th>Lifetime odds of death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transportation accident</td>
<td>1 in 77</td>
</tr>
<tr>
<td>Pedestrian</td>
<td>1 in 612</td>
</tr>
<tr>
<td>Car occupant</td>
<td>1 in 228</td>
</tr>
<tr>
<td>Drowning</td>
<td>1 in 1,081</td>
</tr>
<tr>
<td>Fall</td>
<td>1 in 229</td>
</tr>
<tr>
<td>Exposure to smoke, fire, flames</td>
<td>1 in 1,179</td>
</tr>
<tr>
<td>Venomous snake or lizard bite</td>
<td>1 in 1,241,661</td>
</tr>
<tr>
<td>Accidental poisoning</td>
<td>1 in 212</td>
</tr>
<tr>
<td>Lightning</td>
<td>1 in 56,439</td>
</tr>
<tr>
<td>Flood</td>
<td>1 in 413,887</td>
</tr>
<tr>
<td>Intentional self-harm</td>
<td>1 in 118</td>
</tr>
</tbody>
</table>

**NOTE** National Safety Council estimates based on data from the National Center for Health Statistics and the U.S. Census Bureau. To determine the odds per year, multiply by 77.3 years (eg, the annual odds of dying as a result of injury caused by lightning are 1 in 4,362,735).
infection or sterilization. The key aspects of the evaluation are that it ought to 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 the mechanism of sterilization failure and evaluation of patients for adverse outcomes).

We have provided a general guideline in this article. However, each potential exposure event is unique, and one must be flexible in adapting our recommendations to a specific situation. The intent of an evaluation should be to discover the factor(s) that led to the potential exposure and to protect patients from adverse events, as appropriate, and not to assign blame to a particular person or persons. These are very stressful events for patients, and sensitivity and empathy toward patients should be paramount. These events are also anxiety provoking for healthcare staff associated with the failure and the staff involved with the corrective measures. In hospitals, staff may fail to report incidents because of time constraints, fear of punishment, and a lack of perceived benefit. As has been the case with pilots and aviation safety officials, reporting of these failure events should be encouraged, and staff should be immune from disciplinary action if they reported the failure promptly. Of course, if gross negligence (eg, alcohol- or drug-impaired performance) is uncovered, the hospital’s human resources policies should be followed. Employee performance and the ability to follow hospital procedures should be evaluated periodically and, if deficient, employees should be retrained or the institution should follow the appropriate human resources policies. If personnel feel that reporting potential exposures will lead to negative personal consequences, they are unlikely to report potential events, to the detriment of both the institution and patients. It is important to rapidly identify potential exposures and institute corrective action for the disinfection or sterilization procedures.

As with everything we do in infection control, prevention is preferable to correction of a deficiency in procedures that can result in potential exposure. The keys to preventing failures of disinfection and sterilization include the following. First, adhere to authoritative guidelines. Specific guidelines are available from various US agencies (eg, the Centers for Disease Control and Prevention and the Food and Drug Administration) and professional organizations (eg, the Association for Professionals in Infection Control and Environmental Epidemiology and the Society of Gastrointestinal Nurses and Associates). Manufacturers may also have reprocessing recommendations that should be reviewed. Second, personnel who perform disinfection and sterilization should be properly trained (at the commencement of employment and at least annually after that) 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. For example, the manufacturer’s representative or supervisors should train reprocessing technicians regarding the presence of auxiliary channels and in the appropriate reprocessing of each new endoscope model. Fourth, proper monitoring of equipment should be performed, following the recommended schedule (eg, for automated endoscope repellers) to ensure the equipment is functioning according to the manufacturer’s specifications. Periodically ensure that the high-level disinfectant exposure time for automated endoscope reprocessors is set properly and that the values 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 where disinfection or sterilization is carried out should be performed to assure 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 must be learned from previous failure incidents involving medical devices. Staff must understand what caused these failures and develop procedures that prevent recurrence.

A key component of actual exposure events is assessing the potential risk of disease transmission. Once a risk has been determined, individual institutions must decide whether the magnitude of the risk warrants patient notification. Factors in addition to risk that may need to be considered include local policies, legal recommendations, state or federal regulations, availability of postexposure prophylaxis, potential consequences of infection, time frame for infection, and communicability of the disease. The final decision about whether to notify patients should be made by key stakeholders, partly on the basis of risk information provided by infection control professionals. If notification is planned, it should be done in an organized way, and multiple avenues should be used to assure that all potentially exposed persons are notified.

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