Disease or infection is the result of a chain of events. A source of infectious microorganisms must have an appropriate mode of transmission to an entry portal on a susceptible host. Microorganisms must reach a susceptible host before they can multiply and cause disease. Interrupting this chain at any level will prevent disease and/or infection. The goal of reprocessing instrumentation is to break the chain of infection by eliminating the source of microorganisms. A decontaminated instrument cannot be a microorganism conduit to a portal of entry on a new host.

**Standard of Care**

It is necessary that every health care provider, including physicians’ offices, provide the same standard of care to every patient. This means that instruments are reprocessed to the same level of disinfection or sterilization for every patient. Agencies that regulate how instruments are handled are the Occupational Safety and Health Administration (OSHA), Food and Drug Administration (FDA), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Regulations are mandatory. The regulations cover Standard Precautions and the Bloodborne Pathogen Standard (OSHA, 1992).

Many organizations have developed *Recommended Practices*. Recommended Practices describe the ideal standard. Sometimes, they need to be adjusted to a standard that is achievable in a particular practice setting. These are based on scientific principles and aimed at establishing a similar standard of practice among all health care providers. Recommended Practices are guidelines, therefore compliance is voluntary. The Centers for Disease Control (CDC), the Association of Operating Room Nurses (AORN), the Association for the Advancement of Medical Instrumentation (AAMI), and the Association of Practitioners in Infection Control (APIC) all have Recommended Practices that may be referenced in developing a Standard of Care for reprocessing endoscopic instrumentation.

**Endoscopic Instrumentation**

Urologic patients are exposed to a variety of endoscopic instruments in the office, clinic, and the operating room. These instruments may include cystoscopes, resectoscopes, ureteroscopes, laparoscopes, and a wide variety of accessory devices. The scopes may be flexible or rigid. Reprocessing may be easy or difficult depending on the size, shape, and configuration of a device. The materials used in manufacturing the device also affect the reprocessing procedure.

Reprocessing of reusable devices is a multistep procedure. Single-use devices should be discarded after use. The configuration and materials used in single-use devices may make cleaning and disinfection or sterilization difficult or impossible to achieve (AAMI, 1999).

Reusable devices must be cleaned and inspected prior to disinfection or sterilization as well as following the biocidal process to confirm that no damage to the instrument resulted during that process. The method of sterilization or disinfection will determine how the instrument should be stored prior to the next use.
The CDC uses Spaulding’s device classification to identify endoscopic devices as semi-critical or critical devices. Critical devices enter a sterile cavity or are exposed to blood and should be sterilized. Semi-critical devices come in contact with intact mucous membrane surfaces and high-level disinfection is acceptable for these devices. Sterilization may not be possible for every patient who needs a cystoscopy due to the expense and frequent use of cystoscopes and related endoscopic instrumentation. High-level disinfection is considered acceptable in these instances (CDC, 1985).

The FDA requires that every medical device be shipped with an operator’s manual. This manual contains instructions for use, care, handling, and reprocessing for the products; it should be used as a reference when choosing a reprocessing procedure. Certain instruments must be disassembled prior to reprocessing or may not be compatible with certain sterilization or disinfection processes (see Figure 1).

**Cleaning**

The first, and most important, step in the reprocessing procedure is cleaning. An appropriate cleaning process must be established using the instrument manual and the instructions for use of the cleaning product and disinfectant or sterilant (Rutala, 1996).

An enzymatic detergent is an excellent cleaning product for endoscopes. Enzymatic detergents contain one or more enzymes and soap to attack proteins, starches, and fats. The product label defines proper dilution and temperature to activate the enzymes. Skin cleansers and dish detergents may leave residues that inhibit the biocidal process and should never be used to clean instruments. Lumens must be cleaned with a brush if possible, and stopcocks or other components must be disassembled to assure adequate reprocessing. The cleaning process reduces the bioburden and facilitates the disinfection or sterilization process. Cleaning solutions should be used according to their label and not combined with other agents such as bleach. The cleaning solution must be thoroughly rinsed from the device prior to the biocidal process to prevent an unwanted chemical reaction between the cleaning solution and the biocidal agent. The biocidal process will determine if instruments need to be thoroughly dried after cleaning (see Figure 2).

**High-Level Disinfection**

High-level disinfection (HLD) is usually adequate and appropri-
ate for most endoscopic instrumentation. The chemical germicide must be in contact with all surfaces of the device in order to inactivate any remaining microorganisms after thorough cleaning. Some hospitals and clinics are choosing to eliminate high-level disinfection and move to a sterilization process. Physicians' offices, clinics, and even some hospitals may not have a sterilization process available for endoscopic devices. High-level disinfection may be the only alternative in these settings (see Figure 3).

Most high-level disinfectants have the ability to kill all microorganisms, including spores, given sufficient exposure time. Glutaraldehydes, peracetic acid preparations, and some peroxide solutions are examples of products that are classified as high-level disinfectants. Ortho-phthaldehyde (Cidex® OPA) is an example of a high-level disinfectant that is unable to sterilize. Quaternary ammoniums and phenols are intermediate level disinfectants and are not appropriate for use on endoscopic instrumentation. All of the solutions have specific recommendations for exposure time, temperature, and reuse guidelines. Some high-level disinfectant solutions contain additives, called surfactants, to extend the usage time of the solution. Surfactants are not recommended for endoscopic instruments as they may cause clouding of optics and leave residuals that are difficult to rinse. Additionally, some products are not compatible with certain metal alloys. It is very important to review the Material Safety Data Sheet and check with the instrument manufacturer for compatibility.

Rinsing
High-level disinfectants must be rinsed properly. Residues left on the instruments may result in harm to the patient or the health care provider. Rinsing is best accomplished using three separate basins of sterile water that should be changed following each procedure. It is important to agitate the instruments in each basin to remove as much of the chemical as possible. The authors recognize that this practice may not be achievable in all practice settings. An achievable policy or procedure should be established for the practice setting, based on available resources, and be strictly followed.

Sterilization
There are several different modalities available for sterilization in today's health care arena. Not every endoscopic instrument is compatible with all sterilization processes, so it is important to review the operator's manual for the device prior to using any sterilization process.

Steam. Steam is the most common and least expensive sterilization process, but it may cause significant damage to endoscopic instruments. Repeated steam sterilization may decrease the life of devices. Steam sterilization requires temperatures of 270°F (132°C) for 4 to 10 minutes for most endoscopic devices (due to complexity and lumens). Moisture left inside the channels will be transformed to steam and aid in the sterilization process.

Gas. Ethylene oxide gas is the least likely modality to cause damage to endoscopic devices. Due to the toxic and explosive properties of ethylene oxide, it can only be used in very controlled environments. Newer technologies are replacing this process in many health care facilities.

Ethylene oxide cycles require 2 to 4 hours for sterilization and an additional 8 to 24 hours for aeration. Instruments must be precleaned and completely dry prior to sterilization to allow adequate penetration and prevent the formation of toxic residues. Ethylene oxide is the only sterilization method in the United States that can sterilize a flexible endoscope and provide a shelf life (maintain sterility for use at a later time).

Sterrad. Sterrad™ employs a hydrogen peroxide vapor, which is converted to a plasma state. The cycle time for Sterrad is 35 to 75 minutes, depending on the unit. The FDA restricts its use in the United States. Endoscopic devices must be rigid, 12 inches or shorter in length, with a lumen of 4 mm or larger. Not all materials used in manufacturing endoscopic devices are compatible with the hydrogen peroxide plasma. Always consult the operator's manual prior to exposure. Instruments may be wrapped for processing in Sterrad,
Steris System I™ is a “just in time” liquid sterilization process and is compatible with most endoscopic instrumentation. Small lumen rigid and all flexible endoscopes require the use of a connector, called a “quick connect kit,” to deliver the fluid through the lumen. Most flexible devices should be leak tested prior to processing in the Steris. The cycle time is about 30 minutes and requires a hot water supply. Since this method is “just in time,” there is no shelf life for the instruments processed (see Figure 4).

Table 1.  
Comparison of Sterilants and High-Level Disinfectants

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Shelf Life</th>
<th>Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gas</strong></td>
<td>Ethylene oxide</td>
<td>99°-145° F (37°-63° C)</td>
<td>205-300 minutes</td>
<td>Yes</td>
<td>Toxicity, aeration, long cycles</td>
</tr>
<tr>
<td><strong>Steris System 1</strong></td>
<td>Chemical</td>
<td>55°-56° C</td>
<td>About 30 minutes</td>
<td>No</td>
<td>Items must be immersible</td>
</tr>
<tr>
<td><strong>Sterrad 100 S</strong></td>
<td>Hydrogen peroxide-plasma vapor</td>
<td>55° C</td>
<td>35 minutes</td>
<td>Yes</td>
<td>Lumen restrictions; unable to process flexible scopes in U.S.</td>
</tr>
<tr>
<td><strong>Sterrad 50</strong></td>
<td>Hydrogen peroxide-plasma vapor</td>
<td>55° C</td>
<td>55 minutes</td>
<td>Yes</td>
<td>Lumen restrictions; unable to process flexible in U.S.</td>
</tr>
<tr>
<td><strong>Glutaraldehydes</strong></td>
<td>Chemical Liquid</td>
<td>72°-80° F (20°-25° C)</td>
<td>20-45 minutes for HLD; 10 hours for sterilization</td>
<td>No</td>
<td>Ventilation</td>
</tr>
<tr>
<td><strong>Orthopthalaldehyde</strong></td>
<td>Chemical Liquid</td>
<td>Room</td>
<td>12 minutes for HLD</td>
<td>No</td>
<td>Unable to sterilize</td>
</tr>
<tr>
<td><strong>Hydrogen Peroxide (Sporox)</strong></td>
<td>Chemical Liquid</td>
<td>Room</td>
<td>30 minutes for HLD; 6 hours for sterilization</td>
<td>No</td>
<td>Unsafe for some metals</td>
</tr>
</tbody>
</table>


Chaos to Comprehension continued from page 332

Conclusion

Reusable endoscopic devices must be properly cleaned and disinfected or sterilized to ensure safe and effective reuse. A written policy or procedure detailing the steps for reprocessing should be established in each health care setting. The procedure must comply with regulations from FDA and OSHA and should reference Recommended Practices from a recognized organization. The procedure must be followed and records kept documenting maintenance of the procedure (see Table 1).

Nursing Implications

It is nurses’ responsibility as health care workers to provide the best possible care for patients while protecting co-workers and themselves. Endoscopic devices allow us to examine, diagnose, and treat patients using minimally invasive therapies. These devices are expensive and fragile and must be handled properly to prevent damage, ensure proper function, and prevent disease transmission. Reprocessing reusable endoscopic devices includes cleaning, inspection, and a biocidal process. Policies and procedures must detail the steps for reprocessing and be closely followed and documented in every practice setting. These policies and procedures must comply with FDA and OSHA regulations. Recommended practices from recognized organizations, such as AORN, APIC, and AAMI should be used for reference. A log should be developed to document training and compliance.

There are a variety of biocidal processes available. The method chosen should be appropriate to the practice setting. Clinic or office practices may not have an appropriate sterilization modality available and may be required to use high-level disinfection. The decision should be based on availability, product compatibility, cost, health care worker safety, and turnaround time. Whichever method is chosen (see Table 1), thorough cleaning will ensure the effectiveness of the process to deliver a safe device to the next patient. It is important to consider reprocessing time, cost, and method when evaluating the purchase of an endoscopic device.

A properly reprocessed endoscopic device is as important to our patients’ medical care as the education and attitude of the health care provider operating the device.

References

