HEALTHCARE PURCHASING NEWS

SELF-STUDY SERIES

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Learning Objectives

At the completion of this self-study module the reader should be able to:

1) Discuss the various methods of decontamination

2) Understand the relationship between the disinfection level and the types of microorganisms destroyed

3) Identify the levels of disinfection

4) Select the appropriate decontamination process for a particular medical device

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Decontamination methods and selection

by Heide Ames, product manager, STERIS Corporation

What is "decontamination?"

Is it bed pans being processed through a washer? A colonoscope being soaked in glutaraldehyde? Perhaps it's a container of instruments being processed in a sterilizer. Actually, all of these activities are examples of decontamination. The Occupational Safety and Health Administration (OSHA) describes decontamination as "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal." The medical community expands on this definition by defining decontamination as the removal of pathogenic organisms so that the instrument or surface is safe for use or further processing. This is generally defined on two levels; sterilization and disinfection. Sterilization is well understood as the destruction of all pathogenic microorganisms, which renders the item sterile. Disinfection is the destruction of *some but not all* microorganisms, which renders the item safe to handle or use in specific situations. Regardless of whether a sterilization or disinfection method is used, an effective pre-cleaning regimen is required to ensure that the chosen decontamination process can effectively reach and destroy microorganisms on the surfaces of a medical device or item.

Steam sterilization

What is "disinfection?"

The Center for Disease Control and Prevention (CDC) defines disinfection as "the destruction of pathogenic and other kinds of microorganisms by thermal or chemical means." In the healthcare environment, disinfection is performed using heat or chemistries that have been cleared by both the Environmental Protection Agency and the Food and Drug Administration. All disinfection processes fall into one of three categories; low level, intermediate level or high level. The levels of disinfection are identified by the type and quantity of microorganism that is destroyed by the process.

Microorganism basics

Microorganisms cannot be seen by the naked eye. These organisms include bacteria, fungi, viruses and other microscopic forms.

Bacteria are single-celled organisms. The majority of bacteria exist in the vegetative form, a state of being that allows them to grow and reproduce. It is the vegetative form of pathogenic bacteria that causes disease in animals and humans.

Some bacteria can also change their state by becoming an endospore, a dormant state in which the bacteria do not grow or reproduce. The endospore state protects the bacteria and allows them to survive extreme environmental conditions, including conditions that would normally kill the vegetative state of the organism.

Some pathogenic bacteria are capable of producing endospores. The spore state protects these dangerous bacteria during their transport between host individuals. It is not uncommon for endospores to be viable for many years outside of a host animal or human. Furthermore, both vegetative and endospore forms of an organism are typically present in an individual presenting with a disease.

Fungi also have vegetative and spore forms. The vegetative state is either yeast or a multicellular mold structure. Fungal spores are only produced from the

multicellular state. Fungal spores can withstand harsh environmental conditions, and like endospores, are present in individuals presenting with a disease. In comparison to endospores, a fungal spore is less resistant to harsh conditions. However, like an endospore, a fungal spore can stay viable for many years.

Viruses are very simplistic structures that infect cells in order to make more viruses. Viruses have only one state, but can be divided into two categories; hydrophobic (lipid shell) and hydrophilic (non-lipid shell). The classification depends on the composition of the virus's external shell. The shell composition determines the susceptibility of the virus to environmental conditions, including various methods of disinfection.

Which disinfection levels kill which microorganism(s)?

The microorganisms have different levels of resistance to being killed. The following microorganisms are listed from least resistant to most resistant:

- **Hydrophobic Viruses**
- **Vegetative Bacteria**
- **Fungi**
- **Hydrophilic Viruses**
- **Bacterial Endospores**

The more resistant the organisms destroyed by a particular disinfection process, the higher its classification level for disinfection. Low-level disinfection (LLD) destroys hydrophobic viruses, vegetative bacteria and some fungi. Intermediate-level disinfection (ILD) destroys all the LLD organisms, plus hydrophilic viruses and some endospores, in particular vegetative mycobacteria. High-level disinfection (HLD) destroys all the listed organisms including low levels of bacterial spores. HLD should not be confused with sterilization, which destroys *all* spores. HLD is limited to low levels of spores. Table 1, below, lists the levels of decontamination and the type of microorganisms destroyed by each method.

Selecting a decontamination method

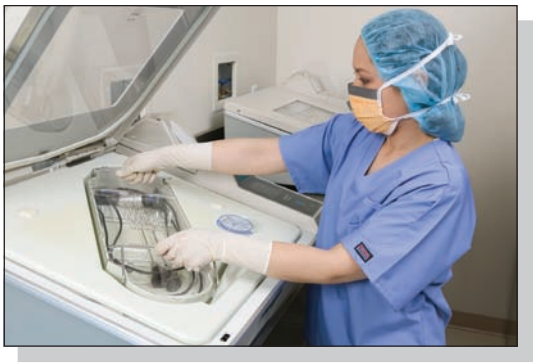
Selecting the appropriate level of disinfection or sterilization process for a potentially contaminated item ensures that the item is safe to be used or handled for further reprocessing. In practice, all levels of decontamination are employed. After initial cleaning and disinfection, further decontamination may be required to make the item safe for reuse on a patient. The determination of the extent of the decontamination required for an item depends upon the intended use of that item.

All items used for patient care can be placed in one of three categories; Noncritical, Semi-critical and Critical. This classification system, first proposed by Dr. E. H. Spaulding, is based on the potential risk of a processed item to cause infection. This classification system has been adopted by the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC) and professional organizations like the Association for Professionals in Infection Control and Epidemiology (APIC).

Noncritical items

Noncritical items are items that touch the patient's intact skin. Items include stethoscopes, bed pans and bed linen. Intact skin has the best defenses against infection. Noncritical items have the lowest risk of causing infection.

Noncritical items require LLD, which must be performed daily but is not required between patients. However, this does not eliminate the requirement to *clean* the item between patients. LLD can be performed both manually and in an automatic processor. A wide variety of antimicrobial soaps and detergents are available for these applications. Some examples include iodophor germicidal detergents and quaternary ammonium germicidal detergents.



Peracetic acid-based low-temperature liquid sterile processing

Semi-critical items

Semi-critical items are those that enter areas of intact mucus membranes. Semicritical items may encounter compromised tissue but ordinarily would not contact such areas. These include items like endoscopes, laryngoscopes, respiratory therapy equipment and anesthesia equipment. Mucous membranes have natural defenses against infection, so the risk of infection is lower for these types of tissues.

Semi-critical items require HLD, which must be performed after each patient use. HLD can be accomplished through exposure to a chemical germicide that has been cleared by the FDA as a high-level disinfectant, or through exposure of the item to temperatures capable of delivering high-level disinfection. Two delivery methods are available; soaking and automated reprocessing. Typically, soaking methods are used in facilities that do not use automated washers and endoscope reprocessors. Whenever a high-level disinfectant is used, it is important to follow the manufacturer's recommendations for soak time, temperature, and monitoring of the soak solution. Some examples of high-level disinfectant solutions include glutaraldehyde, accelerated hydrogen peroxide and peracetic acid formulations. Washers typically use thermal HLD processes while endoscopic reprocessors use many of the same germicides used in soaking applications. All high-level disinfectants are capable of destroying viruses, fungi, bacteria and low levels of endospores.

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TABLE 1: METHODS OF DECONTAMINATION AND THE MICROORGANISMS DESTROYED AT EACH LEVEL

Level	Hydrophobic Viruses	Vegetative Bacteria	Fungi	Hydrophilic viruses	Low levels of Bacterial Endospores	All Bacterial Endospores
Low Level Disinfection (LLD)	Yes	Yes	Some	No	No	No
Intermediate Level Disinfection (ILD)	Yes	Yes	Yes	Yes	Some	No
High Level Disinfection (HLD)	Yes	Yes	Yes	Yes	Yes	No
Sterilization	Yes	Yes	Yes	Yes	Yes	Yes

Self-Test Answers: 1. C, 2. D, 3. C, 4. A, 5. B, 6. D, 7. D, 8. B, 9. A, 10. C

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TABLE 2: COMMON PATIENT CARE ITEMS AND RECOMMENDED DECONTAMINATION PROCEDURES

Item	Method	Decontamination Procedure
Scalpels, forceps, tissue clamps, etc.	Sterilization	Prevac steam sterilization at 270° F for 4 minutes
Gastroscope	High-level Disinfection	Automatic endoscope reprocessor using peracetic acid-based high-level disinfectant, following manufacturer's recommendations
Oral Thermometer	Low-level Disinfection	10-minute soak in 70% isopropyl alcohol
Bed Pan	Low-level Disinfection	Washed using an antimicrobial detergent

Critical items

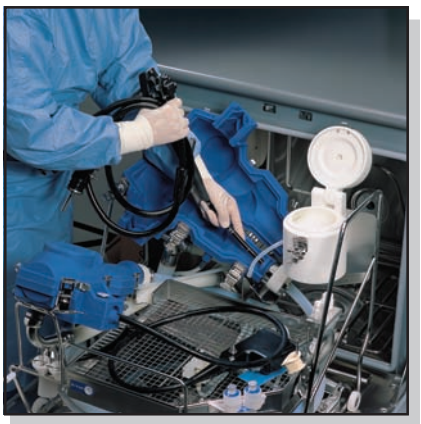
Critical items are items that enter the body's sterile tissues and vascular system. These would include items like needles, scalpels, arthroscopic instruments and implants. The risk of infection is highest with these types of instruments because they could potentially place pathogenic organisms into the most susceptible parts of the body.

Critical items require sterilization between patients. Steam sterilization is the preferred method and should be used whenever possible. However, some delicate medical devices would be damaged by high temperatures. For these devices, ethylene oxide, vaporized hydrogen peroxide/plasma and peracetic acid-based sterile processing systems are among the low-temperature sterilization processes that can be used. All of these processes are capable of destroying all microorganisms, including all endospores.

Table 2, above, provides examples of some common items and their appropriate decontamination procedures.

Exceptions to the rule

In a perfect world, all items would fall into one category and require only one standard of care. In reality, medical devices can cross categories. For example, endoscopes are typically considered semi-critical devices. However, they are occasionally used to collect biopsy samples or enter areas containing compromised mucus membranes. In these instances the items could be considered critical and could require sterilization prior to use.



High-level disinfection in an automated endoscope reprocessor

Other exceptions include the exposure of a medical device or instrument to specific organisms of interest. Examples include the endospore-forming *Clostridium difficile* or methicillin-resistant *Staphylococcus aureus* (MRSA). These organisms may require additional treatments like sterilization or a higher level of disinfection. CDC recognizes three such instances for noncritical items: (1) items that are grossly soiled with blood or other bodily fluids; (2) items that contact patients infected or colonized with vancomycin-resistant enterococci (VRE) or other drug-resistant organisms; (3) items that contact patients infected with highly virulent microorganisms. In these instances, the items should go through, at minimum, LLD between patients.

When are intermediate-level disinfectants used?

Intermediate-level disinfection is classified outside of Dr. Spaulding's three main categories, and is used for specific cases involving recognized contagious agents that can be easily spread within a hospital. ILD is used primarily for surfaces when known cases of tuberculosis, MRSA or other infectious agents have been identified. It is important to confirm that the intermediate-level disinfectant being used is effective for the organism of interest. Different ILD agents will have different claims.

What should be considered when choosing a disinfectant?

Based on this general understanding of decontamination processes and their various uses in healthcare settings, there are five questions that should be answered before an appropriate disinfectant can be selected:

1) What classification does the item to be disinfected fall under during normal use?
2) Does the disinfectant destroy the specific organisms of interest in your facility?
   a. Review the test data provided by the manufacturer
   b. Review this data against your facility's epidemiology reports
3) Is the product cleared by the FDA for the purpose listed (specific to high-level disinfectants and sterilants)?
   a. Review the FDA website at htpp://www.fda.gov/cdrh/ode/germlab.html
   b. Ask for the FDA 510(k) number and confirm clearance
4) Is the product registered with the EPA as a low-level, intermediate level or high-level disinfectant?
5) What exceptions may occur and how will those exceptions be identified and decontaminated?

Conclusion

Decontamination is the process by which a medical device or instrument is rendered safe to be handled or used on a patient. There are multiple levels of decontamination, from low-level disinfection through sterilization. Selection of a decontamination method must be based on the typical use of an instrument or medical device and its resulting Spaulding classification. However, decontamination methods should also be selected based on any known presence of specific infectious agents of interest in the hospital. The optimal decontamination methods would provide appropriate disinfection or sterilization of medical devices for all potential risk levels in a given facility. HPN

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1. Centers for Disease Control and Preventions (CDC); Recommendations for Sterilization or Disinfection of Medical Devices; Division of Healthcare Quality Promotion (DHQP); Aug. 20, 2002.

2. Favero MS, Bond WW. Disinfection of medical and surgical materials. In: Block SS, editor. Disinfection, sterilization and preservation. Philadelphia: Lippincott Williams & Wilkins 2001.

3. American Society for Gastrointestinal Endoscopy; Position Statement: Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes.

4. Association for Professionals in Infection Control and Epidemiology; Disinfection and Sterilization Principles; 2005.

5. Muscarella L.F. "Reprocessing Flexible and Rigid Laryngoscopes", Lawrence F., PhD.

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Decontamination methods and selection

Circle only one answer:

1) Which of the following are not considered to be a form of medical decontamination?
a. Processing bed pans through an automated thermal washer
b. High-level disinfection of a bronchoscope
c. Putting used syringes in a medical sharps container
d. Soaking an oral thermometer in 70% isopropyl alcohol

2) Endospores are dormant forms of bacteria that ...
a. Protect the bacteria from extreme environmental conditions
b. Protect the bacteria while being transmitted from one individual to another
c. Are present in an individual showing signs of infection
d. All of the above
e. None of the above

3) Which microorganism represents the greatest challenge to destroy?
a. Virus
b. Fungal spore
c. Endospore
d. Vegetative bacteria

4) Which list represents the three types of disinfection?
a. Low level, intermediate level, high level
b. Low level, high level, sterilization
c. Low level and high level only
d. Low level, medium level and high level

5) Low-level disinfection destroys which of the following organisms?
a. Vegetative bacteria, all virus and some fungi
b. Vegetative bacteria, lipid viruses and some fungi
c. Vegetative bacteria, lipid viruses and all fungi
d. Vegetative bacteria, lipid viruses, some fungi and some endospores

6) Intermediate-level disinfection destroys which of the following organisms?
a. Vegetative bacteria, lipid viruses and some fungi
b. Vegetative bacteria, lipid viruses and all fungi
c. Vegetative bacteria, lipid viruses, some fungi and some endospores
d. Vegetative bacteria, all viruses and all fungi

7) High-level disinfection destroys which of the following organisms?
a. Vegetative bacteria, all virus and some fungi
b. Vegetative bacteria, lipid viruses and some fungi
c. Vegetative bacteria, lipid viruses and all fungi
d. Vegetative bacteria, all viruses, all fungi and some endospores

8) Dr. E. H. Spaulding defines the classification of medical items into which three categories?
a. Vascular, Mucosal, and External Contact
b. Critical, Semi-critical and Noncritical
c. High Risk, Medium Risk and Low Risk

9) Which of the following items require high-level disinfection?
a. Naso-pharyngo-laryngoscopes
b. Artificial Hip
c. Bed Pan
d. Bed Rails

10) Which of the following would require the use of an intermediate-level disinfectant?
a. Disinfection of bed rails
b. Disinfection of a bronchoscope
c. Disinfection of a stethoscope used on a patient with tuberculosis
d. Disinfection of a scalpel

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