AHCA/NCAL Infection Preventionist Hot Topic Brief

Spaulding Classification for Medical Devices

Focal Problem or Issue

Infection Preventionists in Long-Term Care Facilities should be familiar with the Spaulding classification for medical devices and instruments. This classification is an important concept for the Infection Preventionist because it categorizes patient care items and environmental surfaces according to the type of cleaning and disinfection that is needed before their use or reuse. The manufacturer's instructions for use (IFU) are the gold standard for cleaning and disinfecting medical equipment and devices; however, the principles used in the Spaulding Classification can be helpful when IFUs are not available.

Background and Scope

Earle H. Spaulding developed an approach to disinfection and sterilization of patient-care items and equipment several years ago. This classification has been successfully adopted and used by Infection Preventionists for decades to determine the correct level of disinfection and sterilization for items used and reused in healthcare. As part of his classification system, he introduced three categories for medical devices and instruments. The categories include critical, semicritical, and noncritical. Each category is assigned according to the degree of infection risk as well as how the items will be used. Don't let the term noncritical fool you, these items are still a potential reservoir for infectious germs and require cleaning and disinfection to protect residents, staff and others from infection.

Suggestions for Practice and Resources

Critical items pose the highest risk for infection because they enter sterile parts of the body, and any germ on them could cause an infection. These items must be sterile which means they are free from all living microorganisms. Items in this category should be purchased as sterile or sterilized before use.

This category includes podiatry equipment that encounters blood, or some debridement equipment used in wound care, urinary catheters, and ultrasound probes used in sterile body cavities.

Semicritical items pose a lesser risk of infection than critical items because they come in contact with parts of the body that are not sterile and that do not easily become infected by bacterial spores that may be present on them. Examples of these parts of the body include mucous membranes or the gastrointestinal tract. These medical devices should receive high-level disinfection which is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores.

Glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, chlorine dioxide, and peracetic acid (OPA) with hydrogen peroxide are cleared by the Food and Drug Administration (FDA) and are high-level disinfectants.

This category includes some endoscopes like colonoscopes and bronchoscopes laryngoscope blades, and ultrasound probes that enter nonsterile spaces like the esophagus.

Noncritical items come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms so the devices do not have to be sterile. Some patient care items can be cleaned and reused by the same resident. These items should be cleaned and disinfected according to manufacturer's instructions. In contrast to critical and some semicritical items, most noncritical reusable items may be cleaned and disinfected where they are used and do not need to be transported to a central processing area. Low or intermediate level disinfectants approved by the EPA are appropriate for hard, nonporous surfaces including noncritical devices and the environment. Low-level disinfection destroys all vegetative bacteria lipid viruses, some nonlipid viruses, and some fungi, but not bacterial spores. Intermediate level disinfectants have a claim against tubercle bacilli and can be used to kill hardy organisms.

Noncritical items are divided into noncritical patient care items and noncritical environmental surfaces. Examples of noncritical patient-care items, blood pressure cuffs, pulse oximeters, wheelchairs, and crutches. Noncritical environmental surfaces include bed rails, food utensils, bedside tables, and patient furniture. High touch surfaces are items that are frequently touched and easily contaminated like doorknobs, light switches, and toilet grab bars.

Additional Considerations

While there have been some caveats identified in which the Spaulding Classification is not the only consideration, CDC frequently uses this classification when considering what level of disinfection is needed.

Most medical equipment used in LTC will be classified as non-critical or some as semi-critical. Equipment that is considered semi-critical or critical requires special methods of labeling and storage. It is important to make sure all workers that use this equipment are trained in how to confirm it is sterile, and how it should be stored, used, and if reusable, safely returned for reprocessing at the facility.

It is also important to make sure when cleaning noncritical medical equipment for reuse that you follow manufacturer's instructions for use and check the disinfectant label for the specific type of organism that it kills. Visit Environmental Protection Agency – Selected EPA-Registered Disinfectants for an up-to-date listing of products approved for various pathogens.

References

Centers for Disease Control and Prevention. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Updated May 2019. Accessed April 12, 2024.

Environmental Protection Agency – Selected EPA Disinfectants. Last Updated March 26, 2024. Accessed April 18, 2024.