Disinfection and Sterilization in Health Care Facilities: An Overview and Current Issues

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KEYWORDS

• Disinfection • Sterilization • Health care facilities

KEY POINTS

- All invasive procedures involve contact by a medical device or surgical instrument with patients' sterile tissue or mucous membrane.
- The level of disinfection or sterilization depends on the intended use of the object: critical (items that contact sterile tissue, such as surgical instrument), semicritical (items that contact mucous membranes, such as endoscopes), and noncritical (items that contact only intact skin, such as stethoscopes) require sterilization, high-level disinfection, or low-level disinfection, respectively.
- Cleaning must precede high-level disinfection and sterilization.
- Failure to properly disinfect devices used in health care (eg, endoscopes) has led to many outbreaks.
- Health care providers should be familiar with current issues, such as the role of the environment in disease transmission, reprocessing semicritical items (eg, endoscopes), and new technologies (eg, hydrogen peroxide mist).

INTRODUCTION

In the United States in 2010 there were approximately 51.4 million inpatient surgical procedures and an even larger number of invasive medical procedures.[1] In 2009, there were more than 6.9 million gastrointestinal (GI) upper, 11.5 million GI lower, and 228,000 biliary endoscopies performed.[2] Each of these procedures involves contact by a medical device or surgical instrument with patients' sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogenic

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microbes, which can lead to infection. Failure to properly disinfect or sterilize equipment may lead to transmission via contaminated medical and surgical devices (eg, carbapenem-resistant *Enterobacteriaceae* [CRE]).[3,4]

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. Because it is not necessary to sterilize all patient-care items, health care policies must identify whether cleaning, disinfection, or sterilization is indicated based primarily on each item's intended use, manufacturers recommendations, and guidelines.

Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization.[5] Failure to comply with scientifically based guidelines has led to numerous outbreaks and patient exposures.[6–8] Because of noncompliance with recommended reprocessing procedures, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) issued a health advisory alerting health care providers and facilities about the public health need to properly maintain, clean, and disinfect and sterilize reusable medical devices in September 2015.[9] In this article, which is an updated and modified version of earlier articles,[10–14] a pragmatic approach to the judicious selection and proper use of disinfection and sterilization processes is presented, based on well-designed studies assessing the efficacy (via laboratory investigations) and effectiveness (via clinical studies) of disinfection and sterilization procedures.

A RATIONAL APPROACH TO DISINFECTION AND STERILIZATION

Almost 50 years ago, Earle H. Spaulding[15] devised a rational approach to disinfection and sterilization of patient-care items or 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.[10–14] Spaulding thought that the nature of disinfection could be understood more readily if instruments and items for patient care were divided into 3 categories based on 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 used by the CDC's "Guidelines for Environmental Infection Control in Healthcare Facilities"[16] and the CDC's "Guideline for Disinfection and Sterilization in Healthcare Facilities."[13] These categories and the methods to achieve sterilization, high-level disinfection, and low-level disinfection are summarized in **Table 1**. Although the scheme remains valid, there are some examples of disinfection studies with prions, viruses, mycobacteria, and protozoa that challenge the current definitions and expectations of high-level disinfection (HLD) and low-level disinfection.[22]

In May 2015, the FDA convened a panel to discuss recent reports and epidemiologic investigations of the transmission of infections associated with the use of duodenoscopes in endoscopic retrograde cholangiopancreatography (ERCP) procedures.[23] After presentations from industry, professional societies, and invited speakers, the panel made several recommendations to include reclassifying duodenoscopes based on the Spaulding classification from semicritical to critical to support the shift from HLD to sterilization.[24] This change could be accomplished by shifting from HLD for duodenoscopes to sterilization and modifying the Spaulding definition of critical items from "objects which enter sterile tissue or the vascular system or through which blood flows should be sterile" to "objects which directly or secondarily (ie, via a mucous membrane such as duodenoscope) enter normally sterile tissue of the vascular system of through which blood flows should be sterile."[24,25] Implementation of this