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Reprocessing, CDC, and IPs:

LEVERAGING PUBLIC HEALTH SERVICES AND RESOURCES FOR STERILIZATION AND HIGH-LEVEL DISINFECTION OF MEDICAL DEVICES

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Sterilization and high-level disinfection (HLD) are highly technical processes informed by standards and guidelines. Improper reprocessing of medical devices puts patients at risk for healthcare-associated infections (HAIs), including those caused by bloodborne and bacterial pathogens. Commonly observed problems include failure to adhere to standards, guidelines, and manufacturer instructions for use; lack of understanding about how to monitor and interpret various quality indicators (e.g., sterilization parameters and controls); and complicated designs that make devices (e.g., some duodenoscopes) difficult to properly clean and disinfect. Adherence to best practices in the reprocessing of medical devices is a Standard Precaution and essential to facility HAI prevention and occupational health programs.

Local, state, and federal public health organizations provide important contributions to sterilization and HLD practices. The Centers for Disease Control and Prevention (CDC), in collaboration with local and state partners, provides a number of services and resources for reprocessing activities. In this article, we highlight select CDC resources and review CDC consultations on the reprocessing or reuse of medical devices.

BACKGROUND

The reprocessing of medical devices (sometimes referred to as medical instruments, equipment, or tools) requires trained personnel who can competently and consistently perform multistep tasks encompassing cleaning and decontamination, HLD, preparation and packing, sterilization, storage and transport, and quality assurance. The appropriate method of reprocessing is informed by the Spaulding Classification, which defines the minimum level of disinfection or sterilization that should be employed for types of devices.[1] The system is divided into three categories:

- Critical devices that enter normally sterile tissue or the vascular system require sterilization.
- Semi-critical devices that come into contact with mucous membranes or non-intact skin require HLD or sterilization.

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- Noncritical devices that contact only intact skin require low- to intermediate-level disinfection.

Reprocessing programs should be structured to meet the needs of different healthcare services (e.g., surgery, endoscopy, dentistry, podiatry) and may be managed internally within facilities or outsourced to off-site reprocessing services.

A wide range of resources is available to help healthcare facilities conduct internal or external assessments of reprocessing performance. Regular review of policies and procedures is considered a best practice and can be performed as part of accreditation and certification programs.

APPLICABLE STANDARDS, GUIDELINES, AND REGULATIONS

Duties performed by reprocessing managers and technicians are informed by a number of standards and guidelines, including those developed by the Association for the Advancement of Medical Instrumentation (AAMI) and adopted by the American National Standards Institute (ANSI). ANSI/AAMI standards pertinent to sterilization and HLD include:

- ANSI/AAMI ST79:2017: Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ANSI/AAMI ST58:2013/(R)2018: Chemical sterilization and high-level disinfection in health care facilities
- ANSI/AAMI ST9L2015: Flexible and semi-rigid endoscope processing in healthcare facilities
- AAMI TIR34:2014/(R)2017: Water for the reprocessing of medical devices

Other professional organizations such as the Association of periOperative Registered Nurses (AORN) and the Association for Professionals in Infection Control and Epidemiology (APIC) also provide guidance on best practices.

In the United States, reprocessing is subject to state and federal laws and regulations. At the federal level, both the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) participate in the regulatory framework for disinfectants and sterilants.[1] FDA also regulates medical devices such as sterilizers and automated endoscope reprocessors.

CDC AND REPROCESSING

Public health organizations are important stakeholders in sterilization and HLD practices as a function of their work in HAI prevention and healthcare worker safety. CDC provides a number of services and resources pertinent to medical device reprocessing, including but not limited to the following:

- Guidance and protocols to help define practices
- Tools, checklists, and trainings to assist with implementation

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- Consultation and other technical assistance to facilities and health departments to identify and address gaps

CDC healthcare infection control guidelines were developed with input from the Healthcare Infection Control Practices Advisory Committee (HICPAC), including representatives of APIC and other organizations with expertise in infection prevention and control (IPC), HAIs, epidemiology, policy, and related fields. Regulatory authorities and healthcare systems may require that facility policies align with CDC guidelines.

CDC works with health departments and other federal agencies to promote patient safety and respond to outbreaks in healthcare facilities. Additionally, all state health departments have CDC-supported HAI programs that support IPC efforts in facilities in their respective jurisdictions. CDC routinely provides remote consultation and laboratory support for facilities and health departments investigating HAI outbreaks or infection control breaches, including breaches serious enough to warrant patient notification. At the request of state and local partners, CDC may also provide on-site technical assistance, with activities ranging from epidemiological investigations to assessments of IPC. The CDC National Institute for Occupational Safety and Health (NIOSH) performs research on and provides technical assistance with workplace hazards and the use of personal protective equipment. When adverse events occur, it is important to comprehensively assess and correct as quickly as possible any associated gaps in training, monitoring, policies, or practices.

In 2016, state and local public health departments conducted an HAI outbreak response capacity self-assessment, and 58% of responding jurisdictions indicated that their HAI program would benefit from additional investigation forms, tools, and training materials related to reprocessing errors.[2] To support investigations and assessments in healthcare facilities, CDC creates freely available products such as tools and checklists that can be used by infection preventionists (IPs) and other public health professionals. A number of these products are specifically targeted toward or contain components related to medical device and instrument reprocessing. CDC also provides opportunities for continuing education through in-person trainings and online webinars with content encompassing sterilization and HLD.

IPS AND REPROCESSING

Following recommended sterilization and HLD practices is essential to a facility HAI prevention program.[3] As such, the IP is increasingly recognized to have a critical role in reprocessing. IPs can champion IPC by guiding medical device and equipment acquisition, consulting on facility design for new or remodeled reprocessing spaces, improving and implementing processes, and performing assessments and quality assurance.[4]

However, many IPs lack formal training in sterilization and HLD practices. The 2015 APIC MegaSurvey reported that 82% of IPs came from a background in clinical nursing, which may not provide exposure to many of the technical aspects of reprocessing programs.[5] Employees responsible for sterilization and HLD can pursue professional certifications to demonstrate competency in all aspects of reprocessing. Adult learning encompassing declarative and procedural knowledge is another supported paradigm for encouraging on-

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the-job education in these programs.[6] IPs can use these formal and informal training mechanisms to expand their working technical knowledge of reprocessing practices.

CDC SERVICES AND RESOURCES

In the following sections, we summarize CDC services and resources related to medical device reprocessing (see also Table 1), and we draw from our review of internal records of CDC responses and consultations from 2017 to highlight selected issues in recent reports of infection control concerns regarding the reprocessing or reuse of medical devices.

Guidance, statements, and protocols

Rutala, Weber, and HICPAC authored the comprehensive CDC Guideline for Disinfection and Sterilization in 2008 (Table 1.1). This evidence-based guideline has received several updates, most recently in 2017.

HICPAC recommendations are also available for the essential elements of a reprocessing program for flexible endoscopes (Table 1.2). Surveillance sampling and culturing protocols are available for duodenoscopes from FDA, CDC, and the American Society for Microbiology (Table 1.3).

Infection control guidelines for specific settings are available for dentistry (Table 1.4, 1.5) and podiatry (Table 1.6). CDC also funded external partners to create the best-practice guide, *Using the Health Care Physical Environment to Prevent and Control Infection*, which contains a chapter on reprocessing spaces (Table 1.7).

Consultation, response, and other technical assistance

CDC's Division of Healthcare Quality Promotion documented 285 consultations and responses related to HAI or IPC concerns with a date of first contact from January 1 to December 31, 2017. Of these, 48 (17%) were determined to involve an infection control concern specifically related to the reprocessing or reuse of medical devices. Thirty of the 48 reprocessing/reuse issues (63%) involved an acute care hospital and nine (19%) a specialty clinic.

Investigations identified infections including those caused by devices contaminated in manufacturing, deficient reprocessing of endoscopes or ventilators, and inappropriate device use or reuse. Actions included device recalls, improved infection control and device reprocessing, and patient notification and testing. While CDC is sometimes consulted about HAI and IPC concerns related to reprocessing, many investigations of HAI outbreaks and serious IPC breaches are handled at the state or local level without CDC involvement.

CDC has also performed on-site assessments of sterilization and HLD practices under the jurisdiction of state and local health departments and other federal partners. Recent examples of observed deficiencies included:

- Limited physical spaces in reprocessing areas
- Lack of adherence to a unidirectional flow from dirty to clean processes

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- Insufficient air exchange rates
- Lack of understanding about how to monitor and interpret various quality indicators (e.g., sterilization parameters and controls)
- Inadequate documentation of manufacturer instructions for use

CDC provides contact information for general inquiries (Table 1.8). Facilities identifying an IPC breach or HAI outbreak concern are encouraged to contact their state or local health department for assistance (Table 1.9).

CDC NIOSH offers on-site support in the form of Health Hazard Evaluations, which specifically evaluate possible health hazards in the workplace (Table 1.10).

Tools, checklists, and trainings

A number of practical assessment materials encompassing sterilization and HLD are available from CDC. The Infection Control Assessment and Response (ICAR) tools (Table 1.11) were developed to assist health departments in assessing IPC practices and guide quality improvement activities. ICAR tools may also be used by IPs for internal quality improvement audits and have sections specific to reprocessing across a variety of healthcare settings.

There are additional CDC tools for dental settings, including checklists (Table 1.12), mobile apps (Table 1.13), and safe care training modules (Table 1.14).

CDC also partnered with APIC to develop quick observation tools for infection prevention, which include forms for assessing HLD clean and dirty areas (Table 1.15).

CONCLUSION

IPs are increasingly recognized to have a critical role in reprocessing programs at healthcare facilities. Given their responsibilities, IPs are well positioned to employ CDC services and resources to strengthen their own competencies in sterilization and HLD, and serve as important links with public health organizations. We recommend that IPs become familiar with CDC activities related to the reprocessing of medical devices. Awareness of the highlighted CDC resources is beneficial for strengthening the ongoing partnerships between public health and healthcare facilities.

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Table 1.

Selected CDC Resources

	Public Health Service or Resource	Access Instructions
1	Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008	Available at www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html
2	Essential Elements of a Reprocessing Program for Flexible Endoscopes—Recommendations of the HICPAC, 2016	Available at www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessinfl.html
3	Duodenoscope Surveillance Sampling and Culturing—Reducing the Risks of Infection, 2018	Available at www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html
4	Guidelines for Infection Control In Dental Health-Care Settings, 2003	Available at www.cdc.gov/mmwr/PDF/rr/rr5217.pdf
5	CDC Statement on Reprocessing Dental Handpieces, 2018	Available at www.cdc.gov/oralhealth/infectioncontrol/statement-on-reprocessing-dental-handpieces.htm
6	Guide to Infection Prevention for Outpatient Podiatry Settings	Available at www.cdc.gov/infectioncontrol/pdf/Podiatry-Guide_508.pdf
7	Using the Health Care Physical Environment to Prevent and Control Infection: A Best Practice Guide to Help Health Care Organizations Create Safe, Healing Environments	Available at www.ashe.org/resources/UseHealthCarePhysEnvironPreventandControlInfection.shtml
8	CDC-INFO (the national contact center and publication fulfillment system, which offers live agents by phone and email to help you find the latest, reliable, and science-based health information)	Available at https://wwwn.cdc.gov/dcs/ContactUs/Form Call CDC-INFO at 800-CDC-INFO (800-232-4636), Monday—Friday 8:00 a.m–8:00 p.m. ET
9	Outbreak Investigations in Healthcare Settings and Patient Notifications	Available at www.cdc.gov/hai/outbreaks/index.html Contact your state or local health department at www.cdc.gov/hai/state-based/index.html
10	NIOSH Health Hazard Evaluations (HHE)	Available at www.cdc.gov/niosh/hhe Email NIOSH at HHERequestHelp@cdc.gov
11	Infection Control Assessment and Response (ICAR) Program Tools	Available at www.cdc.gov/hai/prevent/infection-control-assessment-tools.html
12	Infection Prevention Checklist for Dental Settings	Available at www.cdc.gov/oralhealth/infectioncontrol/pdf/safe-care-checklist.pdf
13	CDC DentalCheck mobile app for iOS and Android devices	Available at www.cdc.gov/oralhealth/infectioncontrol/dentalcheck.html
14	Infection Prevention and Control in Dental Settings: Basic Expectations for Safe Care Training Modules	Available at www.cdc.gov/oralhealth/infectioncontrol/safe-care-modules.htm
15	Quick Observation Tools (QUOTs) for Infection Prevention	Available at http://ipcobservationtools.site.apic.org or www.cdc.gov/infectioncontrol/tools/quots.html