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LEARNING OBJECTIVES

1. *Describe the chain of infection and modes of disease transmission.*
2. *List and describe the steps in instrument reprocessing.*
3. *List the types of sterilizers typically used in the dental setting and which devices require sterilization.*
4. *List and describe the types of tests that monitor sterility assurance.*

SELF-STUDY SERIES

Device reprocessing in the dental setting

by Joyce Moore BSDH, RDH, CRCST

There is a significant risk of disease transmission within the dental setting that puts dental healthcare providers and patients at risk. To reduce this risk, government agencies and other professional associations have created recommendations, guidance and regulations. Device reprocessing has a number of necessary steps that must be done correctly in order to render devices non-infectious and ready for use on subsequent patients. Monitoring the sterilization process must be done and documented to show compliance with regulations.

Introduction

Device reprocessing is critical to patient and dental health care provider (DHCP) safety. Understanding the process of disease transmission and prevention methods helps ensure sterile devices and a safe work environment.

Chain of Infection

In order for disease to occur, a number of conditions must exist. This is referred to as the chain of infection and includes -

1. A portal that allows entry of a pathogen into a new host
2. A person that is not immune to the pathogen
3. A sufficient number of pathogens to cause infection
4. A reservoir for the pathogen to reside and multiply
5. A way for the pathogen to leave the reservoir and move to a new host

Modes of transmission

Disease can be transmitted between a patient and DHCP, patient and patient, DHCP and DHCP, and DHCP and patient.

Transmission often occurs through occupational exposure, via:

- Direct contact with blood, bodily fluids, body tissues or otherwise potentially infectious material (OPIM)
- Indirect contact with contaminated objects such as environmental surfaces, instruments or equipment
- Droplet contact to the eyes, nose or mouth with droplet of spray or spatter generated by an infected person
- Inhalation of suspended airborne microorganisms

Basic principles

There are four basic principles that significantly reduce microbial transmission and help break the chain of infection.[1]

1. *Take action to stay healthy* by using good hand hygiene practices, being vaccinated and following the Centers for Disease Control and Prevention (CDC) guidelines[4] for work restrictions when ill.
2. *Avoid contact with blood and body fluids.* The CDC offers guidance on the use of standard precautions, the use of personal protective equipment (PPE), use of engineering controls, use of work practice controls and postexposure management after an exposure incident.
3. *Limit the spread of contamination* by disinfecting environmental surfaces, the use of barriers and thorough housekeeping measures.
4. *Make objects safe for use* by correctly cleaning and sterilizing devices and instruments that will be reused with subsequent patients.

Recommendations, Guidance and Regulations

There are many sources of guidance, recommendations and regulations provided by different agencies and associations. Government agencies that are commonly linked to the dental setting are the U.S Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), and the CDC.

The FDA is responsible for ensuring the safety and effectiveness of medical devices. They regulate the manufacturing and labeling claims of medical devices used in the dental setting, including dental handpieces and implants, sterilizers, ultrasonic cleaners, biological and chemical indicators, gloves, etc.

OSHA's charge is to protect U.S. workers from physical, chemical and infectious hazards in the workplace. They are known for their Bloodborne Pathogens Standards, which guide DHCP on how to handle contaminated instruments and waste. The use of PPE falls under these standards requirements. OSHA is a regulatory agency that can levy a fine for non-compliance with their standards.

The CDC is not a regulatory agency, but provides many recommendations that are followed in the field of dentistry. These recommendations are widely accepted by dental boards and incorporated into many state dental practice acts, thus becoming the standards of care.

The Association for the Advancement of Medical Instrumentation (AAMI) is an organization that develops sterilization standards, including those related to the use and monitoring of steam sterilization.

It is important to know what guidance, recommendations and regulations that your workplace follows.

Standard precautions

The aim of infection control measures is to prevent microbial contamination and disease transmission.[2] Standard Precautions are infection prevention practices which are followed to guard against exposure to all body fluids, except sweat. These apply when treating all patients and include hand hygiene; the use of PPE (including protective eyewear, face shields, surgical masks, gloves and barrier attire) and the safe handling of potentially contaminated equipment or surfaces in the patient environment.[1]

During care, the treatment area is susceptible to microbial contamination produced by equipment and patients. Handpieces and ultrasonic scalers generate microbe contaminated aerosols, which land on surfaces, and when touched can be transferred to the DCHP's hands. If the DHCP then touches other items, surfaces, persons or themselves, the contamination can be transferred. The spreading of microbes between persons and environmental surfaces is referred to as cross contamination.[2]

Device reprocessing

Device reprocessing is a major component of safe care and involves many steps that must be performed correctly, in order to produce sterile devices.

In order to know how to properly reprocess devices, they must be divided into categories of use. These categories are critical, semi-critical and non-critical (See Table 1). Most items used in dentistry are either critical or semi-critical.

Handpieces

Dental handpieces are one of the most essential items used in practice. They are complex and costly devices with internal and external surfaces that become contaminated during use. If not properly cleaned and sterilized, microbial contamination can be expelled into a subsequent patient's oral cavity and transmit infection from patient to patient.[4]

The CDC 2003 Guidelines stated, although all handpieces (including high and low speed motors, contra/prophy angles and ultrasonics) are considered semi-critical items, they should always be heat sterilized between uses.[4]

In 2018, the "CDC Statement of Reprocessing Dental Handpieces" was published offering three recommendations.[3]

1. Clean and heat sterilize handpieces and other intraoral instruments that can be removed from air lines and water lines of dental units.
2. For handpieces that do not attach to air lines and water lines, use FDA-cleared devices and follow the validated manufacturer's instructions for reprocessing these devices.
3. If a dental handpiece cannot be heat sterilized and does not have FDA clearance with validated instructions for reprocessing, do not use that device.

Instrument preparation and transportation

Prior to touching contaminated items in the treatment area, all appropriate PPE needed for the task should be applied. This includes heavy-duty utility gloves, in order to prevent injury to the skin, mucous membranes or chemical exposure. Disposable sharps (e.g. dental burs, scalpel blades) should be disposed of in a sharps container located within the treatment room, as soon as treatment is completed.[4] Non-sharp disposables and other waste should be disposed of according to state and local regulations.

Next, items should be pre-cleaned at the point-of-use to remove bioburden and gross debris. Based on the facility policy, accreditation standards, or if items cannot be cleaned soon after use, the use of a precleaning solution or spray may be warranted. These reduce proteins from drying on items and soil, which improves cleaning effectiveness and protects instruments. Handpieces should be wiped externally to remove debris and burs removed before lubrication, packaging and sterilization. Per OSHA's Bloodborne Pathogens Standard, contaminated instruments and devices should be transported to the sterilization area in a closed, puncture-proof container with solid sides and bottom, labeled with a biohazard label.

Instrument Processing Area

The instrument processing area should be centrally located in the facility and have a one-way flow to reduce the possibility that contaminated and sterile items will be inadvertently mixed. The instrument processing area includes 4 distinct areas:

1. Receiving, Cleaning and Decontamination
2. Preparation and Packaging
3. Sterilization
4. Storage[4]

Receiving, cleaning, and decontamination

Contaminated items transported to this area will be sorted and cleaned. There are two vital cleaning methods. The first, and less preferred method due to risk of injury, is manual cleaning. This involves hand scrubbing items in a sink, using a long-handled brush and under a bath of water or solution to reduce aerosol production. Automated instrument cleaning methods are safer and more effective and include ultrasonic cleaners, washers or washer/disinfectors. If handwashing or using an ultrasonic, items should be rinsed with clean water to remove residual detergents and chemicals that can cause damage, and left to dry completely.

All items, regardless of what cleaning method was used, should be inspected for debris or damage and if necessary, be cleaned again. Any debris left behind will render sterilization ineffective. As with all FDA-cleared devices, the manufacturer's instructions for use (IFU) must be followed and will include guidance on regular maintenance and equipment testing.

Preparation and packaging

In this area, clean devices and supplies will be wrapped, packaged or placed into container systems for sterilization. Packaging

Table 1. Categories of medical devices[9]

Category	Definition	Dental Item	Reprocessing Method
Critical	Penetrates soft tissue and bone, enters into or contacts the bloodstream or other normally sterile tissues.	Dental burs, scalpel blades, chisels and periodontal instruments	Sterilization
Semicritical	Contacts mucosa or non-intact skin	Mirror, plugger	Sterilization or EPA high-level disinfection
Non-critical	Contacts intact skin	X-ray tube head blood pressure cuff	Low to intermediate-level disinfection

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

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materials, including peel pouches, instrument wraps and chemical indicators made for the intended type of sterilization to be used will be stored in the area. Packaging materials are medical devices cleared by the FDA, and must allow sterilant penetration and maintain sterility after sterilization. The materials used should be the appropriate size for the items, so the package will not be strained. All ratcheted items should be sterilized in the unlatched position, and items disassembled to the smallest parts. The IFU should be followed for correct package sealing or wrapping. Packages should be labeled with the sterilization date, sterilizer number (if using more than one), cycle number, and the types of instrument if they cannot be seen. This will facilitate instrument retrieval in case of a sterilization failure.[1]

Sterilization

Sterilization is the elimination of microbial life. Based on the type of instruments and the needs of the facility, three types of sterilization are typically used in the dental setting; steam under pressure (autoclave), dry heat, or unsaturated chemical vapor. It is important to follow instrument manufacturers' validated instructions for sterilization. Steam is the most common method. It is inexpensive, safe, quick, effective, and easy to use. Whichever method of sterilization is used, the sterilizer IFU should be followed for proper loading methods, monitoring and routine maintenance for equipment. The most common reason for sterilizer failure is operator error, including overloading, improper packaging, or an incorrect cycle chosen for the items being sterilized.

Efficacy monitoring

Steam sterilization monitoring involves the use of physical monitors, chemical indicators (CI) and biological indictors (BI) to verify if the sterilization process is working correctly. A high-level overview of the sterilization process monitoring recommendations contained in AAMI ST79:2017 is provided in Table 1, reprinted above.[6] The table includes the familiar column headers: routine load release; routine sterilizer efficacy monitoring; qualification testing; and product quality assurance testing.

The use of physical monitors involves watching the equipment's time, temperature and pressure gauges to make sure cycle readings are correct or by the use of a printout or recording device. AAMI ST79:2017, Section 13.5.1, states that "sterilizers that do not have recording devices should not be used, with the exception of sterilizers used together with accessory recording devices or printouts".

Table 1—Sterilization process monitoring recommendations

Routine load release (see 13.5 and 13.6)		Routine sterilizer efficacy monitoring (see 13.7)	Sterilizer qualification testing (after installation, relocation, malfunctions, major repairs, sterilization process failures) (see 13.8)	Periodic product quality assurance testing (see 13.9)
Nonimplants	**Implants**			
Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle	Physical monitoring of cycle
External and internal CI monitoring of packages	External and internal CI monitoring of packages	External and internal CI monitoring of packages	External and internal CI monitoring of packages	Placement of BIs and, CIs within product test samples
Optional monitoring of the load with a PCD containing one of the following: • a BI • a BI and a Type 5 integrating indicator • a Type 5 integrating indicator • a Type 6 emulating indicator	Monitoring of every load with a PCD containing a BI and a Type 5 integrating indicator	Weekly, preferably daily (each day the sterilizer is used), monitoring with a PCD containing a BI. (The PCD may also contain a CI.) For sterilizers larger than 2 cubic feet and for table-top sterilizers, monitoring is done in a fully loaded chamber. In IUSS cycles, monitoring may be done in an empty chamber. For dynamic-air-removal sterilizers, daily Bowie-Dick testing in an empty chamber, if applicable (see 13.7.6)	For sterilizers larger than 2 cubic feet and for IUSS cycles, monitoring of three consecutive cycles in an empty chamber with a PCD containing a BI. (The PCD may also contain a CI.) For table-top sterilizers, monitoring of three consecutive cycles in a fully loaded chamber with a PCD containing a BI. (The PCD may also contain a CI.) For dynamic-air-removal sterilizers, monitoring of three consecutive cycles in an empty chamber with a Bowie-Dick test pack, if applicable (see 13.7.6)	

NOTE—See Section 15 for general guidelines on how to assess the specific label claims of new products that become commercially available.

Chemical indicators (CI) can be external or internal and consist of heat or chemical sensitive ink impregnated to an indicator strip, tape or embedded on the surface of a peel pouch. CIs can determine that the sterilant reached that area and differentiate between processed and unprocessed load items, but not that sterilization was achieved.

The CDC recommends that external indicators be used along with internal indicators, unless the internal indicator is visible from the outside of the package. AAMI standards recommend use of CIs both the inside and outside of every pack. There are six indicator types. A Type 5 is an integrating indicator that reacts to all critical variables, giving the user more information, and is equal in performance to a BI, but does not replace routine biological monitoring.

A BI (or spore test) is used to test for routine sterilizer efficacy monitoring by using viable microorganisms that are resistant to the sterilization process. If BI spores are killed, it can be assumed that the microorganisms on the instruments and devices have also been killed. This test can either be performed in-office or mailed away for processing. The in-office version is simple to use and provides results quickly, which allows you to address a sterilization process failure right away.

The CDC guidelines state that biological monitoring must be conducted at least weekly as well as every time an implant is sterilized, while AAMI ST79:2017, Section 13.6.1 states "A BI process challenge device (PCD) should be used at least weekly and preferably daily." Best practice would suggest the use of a BI with each load. The BI PCD should be representative of the package or tray routinely processed and the most difficult to be sterilized. It should be placed in a full load in the cold point of the sterilizer or located according to the IFU.

AAMI ST79:2017, Section 13.7.5 provides guidance about "actions to take when BIs, CIs or physical monitors indicate a sterilization process failure." If anything, including a positive BI, failed physical monitor, or a failed CI in a PCD, indicates a problem with a load, the facility should begin an investigation. If the cause of the failure is figured out right away, the issue is corrected and that load is reprocessed. But if the cause of failure is not immediately identified, the load should be quarantined, and all loads back to the last negative BI should be recalled.

Storage

Dry sterile items should be removed from the sterilizer with clean dry hands, or wicking may occur. Wicking is when microorganisms or other particles are drawn through a wet wrap or pouch, and contaminate the items inside.[2] Items should then be stored in a clean, dry location like a closed drawer or cabinet away from sinks and sterilizers. Packaging will maintain sterility unless it becomes wet or damaged and if so, items should be recleaned, repackaged and sterilized. Unwrapped items should not be considered sterile; therefore, it is best to package items individually or in a set, rather than in bulk and opening the pouch to

disperse items to each treatment room. A sterile package should not be opened until just prior to use.

Documentation

Each sterilizer that is used should have accompanying documentation to prove that sterilization procedures are being followed. Sterilization monitoring logs should include identifying information for the sterilizer used, date, and load number in order to help retrieve instruments from that load in case of a failure. Biological monitoring logs should have the date, load number, sterilization parameters, who placed the BI and the control BI and test BI results, at minimum. Lastly, an equipment and maintenance log should be kept to show that regular unit maintenance is being performed (including repairs) according to the IFU.

Conclusions

Dental device sterilization is a complex process that relies on human and equipment factors. All the steps involved in this process must be done correctly to ensure DHCP and patient safety. Having strong policies, procedures and thorough documentation of records is key. HPN

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CONTINUING EDUCATION TEST • FEBRUARY 2020

Device reprocessing in the dental setting

Circle the one correct answer:

1. **What is the term to describe a series of conditions that must exist in order for disease to occur?**
   a. Chain of disease b. Chance of infection
   c. Chain of infection d. None of the above

2. **DHCP should wear this type of gloves when handling sharp items:**
   a. Exam b. Surgical
   c. Utility d. Heat resistant

3. **Instruments that penetrate soft tissue, contact bone, contact the blood stream or other normally sterile tissue of the mouth are classified as:**
   a. Critical instruments
   b. Semi-critical instruments
   c. Non-critical instruments

4. **The CDC clarified the sterilization process for dental handpieces in 2018, when publishing the "CDC Statement on Reprocessing Dental Handpieces."**
   a. True b. False

5. **The best way to clean instruments for reuse is hand scrubbing:**
   a. True b. False

6. **Ratcheted instruments should be unlatched prior to sterilization:**
   a. True b. False

7. **Sterilizers can be monitored with which methods:**
   a. Chemical indicators b. Physical monitoring
   c. Biological indicators d. All of the above

8. **What is the most common reason for sterilizer malfunction?**
   a. Operator error
   b. Overloading
   c. Excessive packaging
   d. Improper packaging

9. **AAMI ST79 states that sterilizers without recording devices or printouts should not be used.**
   a. True b. False

10. **Sterile items should be stored in open cabinets and in a humid location.**
    a. True b. False

CONTINUING EDUCATION TEST SCORING

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