Medical Equipment, Devices, & Supplies

BPHC Community Health Centers
December 7, 2017

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Joint Commission Enterprise
Learning Objectives

At the conclusion of this presentation, the participant will be able to:

1. Describe how to conduct Risk Area tracers for medical equipment, devices, and supplies that require low, intermediate, high-level disinfection, and sterilization.

2. Relate the appropriate Standards to breaches identified with low, intermediate, high-level disinfection, and sterilization processes.
EP6. Everyone who works in the organization has responsibilities for preventing and controlling infection
IC.02.02.01 Noncompliance
2009-2017 half-year

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## STD IC.02.02.01 EP2 Noncompliance
### 2009-2017 half-year

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Low-level Disinfection of Non-Critical Items IC.02.02.01 EP1

- Device, equipment examples
  - BP cuffs
  - Glucometers (may require intermediate level disinfection, confirm with manufacturer instructions for use)

- Manufacturer instructions for use
- Evidence-based guidelines
- Policy & Procedure
- Education
- IC involvement
- Oversight
Glucometers, lancets, fingerstick devices

- Fingerstick devices (lancing devices) should **never** be shared.
- NOT SHARED = the lancet (i.e., the sharp instrument that actually punctures the skin) and the pen-like device that holds the lancet.
- Neither should be used for more than one person.
Glucometers, lancets, fingerstick devices

- Whenever possible, blood glucose meters should **not** be shared.
- If they must be shared, the device should be cleaned and disinfected after every use, per manufacturer’s instructions.
- If the manufacturer does not specify how the device should be cleaned and disinfected then it should not be shared.
Cleaning and disinfection of blood glucose meters

- Refer to blood glucose meter instructions for use.
- EPA-registered disinfectant for disinfection purposes.
  - Effective against HIV, Hepatitis C, and Hepatitis B virus.
- If manufacturers are unable to provide this information then the meter should not be used for multiple patients.

https://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html
Risk Assessment

Has the organization risk assessed (IC.01.03.01):
- Endoscopes – all locations
- Endocavitary probes – all locations
- Sterilization processes – all locations

Based on risk, what about inclusion in their IC activities? (IC.01.05.01, IC.02.01.01, IC.03.01.01)
Endoscopes

- Inventory
- Instructions for use
- Quality monitoring
- Storage
High-level disinfection Semi-Critical Devices

- Device examples:
  - Some endoscopes
  - Endocavitary Probes

- Manufacturer instructions for use
- Evidence-based guidelines
- Policy & Procedure
- Education
- IC involvement
- Oversight
High-level Disinfection -

High-level disinfection should occur at appropriate **temperature**, **contact time**, and **length of use** following solution activation.
HLD – Other Devices, Equipment

– Vaginal and rectal probes
Probe Findings

- No high-level disinfectant used for reprocessing.
- Not following manufacturer instructions for use.
- Documentation lapses or omissions.
- Storage – not properly stored.
## Non-Endoscope HLD Documentation Comparison – Major Elements

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<tr>
<th>Elements</th>
<th>AORN</th>
<th>AAMI ST:58</th>
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<tr>
<td>Patient Identifier (name, MRN if available)</td>
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<td>Procedure and Physician name</td>
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<tr>
<td>Load contents, item description, serial number</td>
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<tr>
<td>HLD used, lot #, minimal effective concentration (MEC)</td>
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<tr>
<td>Time and temperature of HLD</td>
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<tr>
<td>HLD activation date, re-use life of solution</td>
<td>*</td>
<td>*</td>
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<tr>
<td>Name/initials of individual performing HLD</td>
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Probe Storage

- AAMI ST:58 *Chemical Sterilization and high-level disinfection in healthcare facilities*
  - Stored in a manner that minimizes recontamination
  - Store per manufacturer instructions for use

- AORN *Recommended Practices for High-level Disinfection*
  - HLD items should be protected from contamination until the item is delivered to the point of use
Sterilization

- Quality monitoring
- Training, competency
- IUSS (Immediate-use steam sterilization)
- Storage
Sterilization Critical Devices

Examples:
- Some endoscopes
- Surgical instruments
- Dental instruments

- Manufacturer instructions for use
- Evidence-based guidelines
- Policy & Procedure
- Education
- IC involvement
- Oversight
Quality Monitoring Parameters

**Physical/Mechanical**
- Gauges, thermometers, timers, recorders, and/or other devices that monitor their functions.
- Initialed/reviewed

**Chemical**
- Verifies exposure to a sterilization process
- Visible on the outside of every sterilized package, if the internal CI is not visible

**Biological**
- Assurance that sterilization conditions have been achieved
- Performed at least weekly, preferably on a daily basis (each day sterilizer is used)
- All implant loads
Pre-cleaning at Point-of-Use

- **Point-of-use** is described as the location where the procedure is performed.

- **Pre-cleaning** is described as the means of removal of gross blood, body fluids, and/or bioburden in order to prevent hardening of debris or the development of biofilm due to processing delays.

- 'As soon as possible' and 'delays' are important terminology to understand and clarify in the pre-cleaning at point-of-use process step to promote standardization, frontline staff compliance, and education.
Transport of contaminated items

Contaminated reusable items are placed into specifically labeled containers to prevent exposure of personnel to potentially infectious materials and to prevent contamination of the environment. The specified characteristics of containers for sharps and other contaminated items are based on OSHA regulations (29 CFR 1910.1030).

AAMI ST:79

Comprehensive guide to steam sterilization and sterility assurance in health care facilities
Transport of contaminated items

AAMI ST:79

- Contained during their transport from the point of use to the decontamination area
- Type of container that should be used depends on the items being transported
- Puncture-resistant, leakproof, closable, impermeable

- Must be marked with a biohazard label or other means of identifying contaminated contents; a red bag or container may also be used to denote that the contents are hazardous
Hinged Instruments

- In open, unhinged position during cleaning in decontamination.
- Sterilized in the open position.

- Opened during pre-cleaning only if product manufacturer instructions for use state to apply product in the open, unhinged position.
Immediate Use Steam Sterilization (IUSS)

- Evidence-based indications
- Premature release
- Frontline staff competency/training
- Oversight/surveillance
- Patient Safety
Human Resources

- HR.01.02.01 Defines staff qualifications.
- HR.01.04.01 Provides orientation to staff.
- HR.01.05.03 Participate in ongoing education and training.
- HR.01.06.01 Staff are competent to perform their responsibilities.
  - EP3 An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence.
Leadership

- LD.01.03.01 Governing body ultimately accountable for safety and quality of care, treatment, services.
- LD.04.01.05 Effectively manages its programs, services, sites, departments.
- LD.04.01.11 Makes space and equipment available as needed for the provision of care, treatment, services.
Leadership Oversight

- Routine interaction and reporting of areas conducting HLD and sterilization
  - IC data report (s) from rounding, infection rates.
  - Managerial/Supervisory report on “near misses”, number of times instruments/trays are returned to central sterile processing due to contamination issues, safety culture issues.
  - Facilities/ENG
    - Sterilizer/equipment maintenance (EC.02.04.03 EP4)
Resources

- Infection Prevention and HAI Portal
  - Quick Safety: Improperly sterilized or HLD equipment
  - FAQs
- Ambulatory Care Infection Prevention and Control Standards
- Publications
  - APIC/JCR Infection Prevention and Control Workbook
- High-level Disinfection and Sterilization Booster Pak
Questions

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