Bureau of Primary Healthcare: Infection Control Update

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IC Standards: Ambulatory Healthcare Centers (AHC)

80% of surveyed AHC had at least 1 finding in the IPC chapter during 2018

SAFER Distribution of all Requirements for Improvement (n=3010)

<table>
<thead>
<tr>
<th>Likelihood to Harm a Patient/Staff/Visitor</th>
<th>Immediate Threat to Health and Safety</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>1.76% 3.51% 4.92%</td>
<td>10.19%</td>
</tr>
<tr>
<td>MODERATE</td>
<td>13.47% 22.42% 11.71%</td>
<td>47.6%</td>
</tr>
<tr>
<td>LOW</td>
<td>18.74% 11.83% 9.37%</td>
<td>39.93%</td>
</tr>
<tr>
<td></td>
<td>33.96% 37.76% 26%</td>
<td></td>
</tr>
</tbody>
</table>

LIMITED  PATTERN  WIDESPREAD
Most Frequently Cited Infection Control (IC) Standards: AHC

- High-Level Disinfection
- Standard Precautions
- Cleaning / Low Level Disinfection
- Storage
- Identifies Risks: Populations, Services, Data
- Written Goals
- Implement IC Plan
- Evaluate Activities as Least Annually
- Equipment and Supplies to Support IC
- Document Prioritized Risks
- Goal to Reach 90% Influenza Vaccination
Objectives

– Discuss the top two infection control causes of Immediate Threats to Life and Safety

– Review an approach to ensuring compliance with infection control related standards

– Provide links to resources that were developed for the outpatient setting and are available at no cost

– Review survey challenges specific to Bureau of Primary Health Care facilities and how they might be avoided
IC Standard Related to Immediate Threat to Health and Safety

Situational and dependent on a combination of factors, some examples include:

IC.02.02.01 EP 1 Medical Equipment, Devices and Supplies

- Did not follow the minimum standards for reprocessing based on intended use
- Failure to follow manufacturer’s instructions for use
- Lack of staff training, education and competency assessment related to high level disinfection and sterilization

IC.02.01.01 EP 2 Standard Precautions

- Used single dose medication vial for more than one patient
- Took a multi-dose vial into the patient treatment room or area and then used it on a subsequent patient
### Cause of Immediate Threats in Ambulatory Settings: Failure to Follow Spaulding Classification

<table>
<thead>
<tr>
<th>Level</th>
<th>Risk of Infection</th>
<th>Description</th>
<th>Examples of Items</th>
<th>Reprocessing Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>High</td>
<td>Item comes in contact with or enters sterile tissue, sterile body cavity, or the vascular system</td>
<td>Surgical and dental instruments, some endoscopes, inner surfaces of hemodialyzers, urinary catheters, biopsy forceps, implants, and needles</td>
<td>Sterilization</td>
</tr>
<tr>
<td>Semi-Critical</td>
<td>Moderate</td>
<td>Item comes in contact with mucous membrane or non-intact skin</td>
<td>Respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades, esophageal manometry probes, vaginal ultrasound probes and specula, and diaphragm fitting rings</td>
<td>Minimum: High Level Disinfection (sterilization may be needed in certain cases*)</td>
</tr>
<tr>
<td>Non-critical</td>
<td>Low</td>
<td>Item comes in contact with skin</td>
<td>Patient care Items: bedpans, blood pressure cuffs, crutches, incubators&lt;br&gt;Environmental Surfaces: bed rails, bedside tables, patient furniture, counters, and floor</td>
<td>Clean or disinfect</td>
</tr>
</tbody>
</table>
Manufacturer Instructions

READ CAREFULLY; must identify minimum level of reprocessing required based on Spaulding classification

**Cleaning**
- Rinse: Immediately upon removal from patient's eye, thoroughly rinse in cool or tepid water.
- Wash: Place a few drops of mild soap on a moistened cotton ball. Gently clean with a circular motion.
- Rinse: Thoroughly rinse in cool or tepid water, then dry carefully with a non-linting tissue.
- Then: Proceed with either disinfection or sterilization instructions.

**Disinfection**
- **Glutaraldehyde**
  - Soak In:
    - 2% or 3.4% aqueous solution
    - Temperature per manufacturer instructions
  - Minimum exposure time = 20 minutes
  - **Caution**: To avoid damage to the lens, do not soak in the conjunctiva.
- **Bleach**
  - 10% solution mixed at:
    - 1 part bleach to 9 parts cool tepid water
  -时间 = 10 minutes

**NOTE**
- Known to be compatible with: Asepti-Wipe, Cavi-cide, Clorox, Clorox OPA, DisCide Wipe, Enviro-cide, H₂O₂ - 3%, and Opti-Cide

**Caution**
- If used on an ulcerated cornea, must be STERILIZED before next procedure.
How to Find a High Level Disinfectant

FDA Website
https://www.fda.gov/medicaldevices/deviceregulationandguidance/represingofreusablemedicaldevices/ucm437347.htm

FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices - March 2015

Section VI. of FDA's Final Guidance for Industry and FDA Staff, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling outlines six criterion that should be addressed in reprocessing instructions. Criterion 4 recommends that reprocessing instructions should include devices and accessories that are legally marketed. On this page is a table of FDA-cleared liquid chemical sterilants and high level disinfectants, last updated September 2015.
**Cleaning**

**Rinse:** Immediately upon removal from patient’s eye, thoroughly rinse in cool or tepid water.

**Wash:** Place a few drops of mild soap on a moistened cotton ball. Gently clean with a circular motion.

**Rinse:** Thoroughly rinse in cool or tepid water, then dry carefully with a non-linting tissue.

**Then:** Proceed with either disinfection or sterilization instructions.

**Disinfection**

<table>
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<tr>
<th>GLUTARALDEHYDE</th>
<th>OR</th>
<th>BLEACH</th>
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<tr>
<td>2% or 3.4% aqueous solution</td>
<td>10% solution mixed at:</td>
<td>1 part bleach to 9 parts cool tepid water</td>
</tr>
<tr>
<td>Temperature per manufacturer instructions</td>
<td>Recommended exposure time = 20 minutes</td>
<td></td>
</tr>
<tr>
<td>Minimum exposure time = 20 minutes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Caution**

*To avoid damage to the lens, do not exceed recommended exposure time.*

**Then:** Rinse lens thoroughly to remove disinfection solution.

3 cycles of 1 minute, with cool or tepid water is recommended.

Dry carefully and place in a dry storage case.

**NOTE**

This lens is known to be compatible with: Asepti-Wipe, Cavi-cide, Cidex, Cidex OPA, DisCide Wipe, Enviro-cide, $H_2O_2$ - 3%, and Opti-Cide

**Caution**

*If used on an ulcerated cornea, lens must be STERILIZED before next procedure.*

Only FDA approved High Level Disinfectants in this list
Manufacturer Instructions

Instructions from another product listed as compatible but not a high level disinfectant

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization/high-level disinfection.
CDC Core Practices

Standard Precautions

– Hand hygiene
– Environmental cleaning and disinfection
– Injection and medication safety
– Appropriate use of personal protective equipment
– Minimizing potential exposures
– Reprocessing of reusable medical equipment between each patient and when soiled

Using a “Standard” Approach to Infection Prevention and Control
Approach to IC Related Standards for BPHC

- Regulation
- Manufacturer Instructions
- Evidence based standards or guidelines
- Consensus documents or position statements
- Incorporate into facility based risk assessment and policy
Regulation
Regulations

Some Sources

- Occupational Safety and Health (OSHA)
- State or local Health Departments
- Food and Drug Administration
OSHA

- Bloodborne Pathogens Standard
  - Requires an exposure control plan that includes how the organization has implemented
    - Universal Precautions;
    - Engineering and work practice controls, e.g., safer medical devices, sharps disposal containers, hand hygiene;
    - Personal protective equipment;
    - Housekeeping, including decontamination procedures and removal of regulated waste.

Scoring Example

- Observation: The surveyor asks about staff exposures in the clinic. He is told that there have been 3 workers in the dental clinic exposed to blood splashes of the face during care of pediatric patients in the last 4 months. When he asked what kind of Personal Protective Equipment (PPE) employees were required to wear to prevent splash exposures, he was told that PPE was available but there was no policy and it was not addressed in the facility exposure control plan.

IC.02.01.01 EP2 Standard precautions

- No policy or exposure control plan: The organization did not evaluate the type of exposure anticipated and determine the type of gown required based on the anticipated exposure when caring for a patient as required by OSHA.
State and Local Health Rules and Regulations

- Get to know your local health department contacts
  - Can be helpful in providing references for state or local requirements
  - Source of information on infection control issues for your risk assessment

- Every state has a designated State HAI Coordinator
  - List by State is located on the CDC website at https://www.cdc.gov/hai/stateplans/prevention-activity-infrastructure.html#nh
Regulations: Infection Control

Must know your state requirements

New Jersey § 8:43A-14.2. Infection control policies and procedures

- ...develop, implement, and review, every three years or more frequently as necessary, written policies and procedures regarding infection prevention and control...

- ...Infection control practices, including universal precautions, in accordance with the Occupational Safety and Health Administration (OSHA)

- ...Aseptic technique, employee health in accordance with N.J.A.C 8:43A-3.7, and staff training in regard to infection control

http://www.njcl.us/images/Ambulatory_Care_Facilities_Standards.docx
Regulations: Disinfection and Sterilization Requirements

Must know your state requirements

New Jersey § 8:43A-14.4 Sterilization of patient care items

– Methods for processing reusable medical devices shall conform with ...:
  The Association for the Advancement of Medical Instrumentation (AAMI) requirements...

– Emphasis shall be placed on cleaning of these devices prior to sterilization or disinfection.

– ...The manufacturer's instructions for cleaning, testing, disassembly, and sterilization of equipment shall be readily available and followed by employees.

http://www.njcl.us/images/Ambulatory_Care_Facilities_Standards.docx
Regulations: Food Sanitation

- The Food Code is a model for safeguarding public health

- Provides a link to food sanitation regulations by states...
  https://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm122814.htm
Manufacturer Instructions for Use (IFUs)
Manufacturer Instructions

- Organization must know how instruments and equipment will be used
- Staff must have access to instructions for use, including reprocessing
- Even if a provider is bringing in the equipment, the facility is responsible
- When conflicts are identified, organization must resolve them
  - Contact equipment manufacturer
  - Contact product manufacturer(s)
Manufacturer Instructions

- Medical Device Manufacturers
  - experts on their own devices
  - responsible for validating the specific cleaning, disinfection and sterilization methods
- Biologic compatibility does not mean a disinfectant or process is chemically or functionally compatible
Evidence based Guidelines
Evidence Based Guidelines and National Standards (EBG)

- Facilities must use evidence based guidelines and standards (EBG) when developing infection prevention and control activities (IC.01.05.01)

- Facilities should be able to articulate the source of their IC practices if they are based on multiple EBG, for example a facility might choose:
  - CDC Guideline for outpatient facilities

- EBG should be available (IC.01.02.01 EP 1)
Key Evidence Based Guidelines


- CDC Guide for Infection Prevention for Outpatient Settings: *Minimum Expectations for Safe Care*

- CDC or WHO Hand Hygiene Guidelines for NPSG 7
CDC: Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings

- Hand hygiene
- Environmental cleaning and disinfection
- Injection and medication safety
- Risk assessment with use of appropriate personal protective equipment (e.g., gloves, gowns, face masks) based on activities being performed
- Minimizing Potential Exposures (e.g. respiratory hygiene and cough etiquette)
- Reprocessing of reusable medical equipment between each patient and when soiled
Guide to Infection Prevention for Outpatient Settings

- Administrative
- Education and training
- HAI surveillance
- Hand hygiene
- Personal protective equipment
- Safe injection practices
- Environmental cleaning
- Disinfection and sterilization
- Respiratory hygiene/ cough etiquette
## Section 2: Infection Control Program and Infrastructure

### I: Infection Control Program and Infrastructure

<table>
<thead>
<tr>
<th>Elements to be assessed</th>
<th>Assessment</th>
<th>Notes/Areas for Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Written infection prevention policies and procedures are available, current, and based on evidence-based guidelines (e.g., CDC/HICPAC), regulations, or standards. Note: Policies and procedures should be appropriate for the services provided by the facility and should extend beyond OSHA bloodborne pathogens training</td>
<td>Yes □ No □ Other</td>
<td></td>
</tr>
<tr>
<td>B. Infection prevention policies and procedures are reassessed at least annually or according to state or federal requirements, and updated if appropriate.</td>
<td>Yes □ No □ Other</td>
<td></td>
</tr>
<tr>
<td>C. At least one individual trained in infection prevention is employed by or regularly available (e.g., by contract) to manage the facility’s infection control program. Note: Examples of training may include: Successful completion of initial and/or recertification exams developed by the Certification Board for Infection Control &amp; Epidemiology; participation in infection control courses organized by the state or recognized professional societies (e.g., APIC, SHEA).</td>
<td>Yes □ No □ Other</td>
<td></td>
</tr>
<tr>
<td>D. Facility has system for early detection and management of potentially infectious persons at initial points of patient encounter.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Other CDC Resources


Other CDC Resources

- Resources for Dental Facilities
  https://www.cdc.gov/oralhealth/infectioncontrol/index.html

- Summary of Infection Prevention Practices in Dental
  https://www.cdc.gov/oralhealth/infectioncontrol/pdf/safe-care2.pdf
Basic Expectations for Safe Care Training Modules

This training series covers the basic principles of infection prevention and control that form the basis for CDC recommendations for dental health care settings. It complements CDC's Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care, and was developed to increase adherence to established infection prevention practices.

The slide series is divided into 10 modules

https://www.cdc.gov/oralhealth/infectioncontrol/safe-care-modules.htm
Other CDC Resources

Module 7 - Sterilization and Disinfection
- Sterilization and Disinfection of Patient-Care Items and Devices Presentation [PDF - 1MB]
- Sterilization and Disinfection of Patient-Care Items and Devices Presenter’s Script [PDF - 113KB]

Module 8 - Environmental Infection Prevention and Control
- Environmental Infection Prevention and Control Presentation [PDF - 550KB]
- Environmental Infection Prevention and Control Presenter’s Script [PDF - 103KB]

Module 9 - Dental Unit Water Quality
- Dental Unit Water Quality Presentation [PDF - 455KB]
- Dental Unit Water Quality Presenter’s Script [PDF - 106KB]

Module 10 - Program Evaluation
- Program Evaluation Presentation [PDF - 1MB]
- Program Evaluation Presenter’s Script

https://www.cdc.gov/oralhealth/infectioncontrol/safe-care-modules.htm
Position Statements that Impact Outpatient Settings

Recommendations for Ophthalmic Surgery Centers

Ophthalmic surgery centers under the purview of the Joint Commission should be familiar with the Position Statement on Steam Sterilization as well as the Centers for Disease Control/Hospital Infection Control Practices Advisory Committee Guideline for Disinfection and Sterilization in Healthcare Facilities.

SPECIAL REPORT

Recommended practices for cleaning and sterilizing intraocular surgical instruments

From the American Society of Cataract and Refractive Surgery and the American Society of Ophthalmic Registered Nurses

Toxic anterior segment syndrome (TASS) is an acute inflammation of the anterior chamber, or segment, of the eye following cataract surgery. A variety of substances have been implicated as causes of TASS. These substances can be divided into extraocular substances that inadvertently enter the anterior chamber during or after surgery (topical anti-septic agents, tale from surgical gloves, topical ophthalmic ointment²), and special intraocular preparations (mitomycin-C, intraocular lens³), and irritants on the surfaces of intraocular surgical instruments that have accumulated as a consequence of inadequate or inappropriate instrument cleaning (denatured ophthalmic viscosurgical instruments at every cataract surgical facility. In fact, this challenge is not always satisfactorily addressed, resulting in single-facility outbreaks of TASS that frequently subside when the cleaning and sterilization steps are improved (N. Mamalis, MD, H. Eddlehauser, PhD, personal communication, September 2006). Careful review of a number of facilities reporting cases of TASS to the Intermountain Ocular Research Center at the University of Utah in the spring of 2006 identified many opportunities to lower this risk for TASS through improving the steps of the cleaning and sterilization process.²¹

The goal of these recommended practices for cleaning and sterilizing intraocular surgical instruments is to prevent single-facility outbreaks of TASS related to contaminated or degraded instru-
Policies and Procedures
Facility Policy and Procedure

- Facilities should use the recommended approach and available resources to develop IC related policies and procedures.

- Care should be taken to address the unique aspects of their organization:
  - Care settings
  - Equipment, products and supplies
  - Physical space
  - Staffing
  - Facilities in multiple states
Impacts of Facility Policies

Facility Policy: Patients with a cough
All patients with a cough will be given a mask at arrival and instructed to sit in a segregated area with the mask on at all times, the mask will remain on until the patient is assessed by a physician and instructed that they can remove the mask.

Surveyor will expect:
- Same process for coughing patients
- All who are coughing will be wearing a mask and sitting in a segregated area
- All coughing patients will be assessed by a physician who will decide if they can take the mask off
Impact of Facility Policies

Revised Facility Policy: Patients with a cough
Masks will be provided at a kiosk at the entrance with a sign indicating that they should practice good respiratory hygiene (wear a mask or cover their cough) while they are in the facility.

Patients who are coughing will also be offered a mask in the registration area and if they refuse, they will be asked to cover their cough.

Surveyor will expect variation in how process is implemented depending on situation and location
Disinfection and Sterilization
Separate Functions & Processes

Sterilization

High Level Disinfection (HLD)

High Level Disinfection
Endoscopes

Point of Use Cleaning
- Wipe
- Flush
- Inspect

Transport
- Contain
- Label Biohazardous

Leak Test
- Wet or dry
- Lighting

Brush and Flush
- Compatible supplies
- Dispose or reuse

Rinse
- Water Quality
- Sinks

Inspect
- Adequate lighting
- Rejection criteria

High Level Disinfect
- Compatible supplies and Equipment
- Documentation
- Traceability

Dry
- Alcohol
- Filtered air
- Lint Free Towel

Store
- Prevent contamination
- Manufacturer Instructions

Transport to Procedure
- Protect from contamination

Document
- Compatibility
- Competency
Key Guidelines and Standards

Instruments

- AAMI
  - ST79 (Steam sterilization)
  - ST58 (Chemical sterilization)
- AORN:
  - Cleaning and care of surgical instruments
  - Selection and use of packaging
  - Sterilization
- CDC:
  - Disinfection and Sterilization, 2008

Endoscopes

- AAMI
  - ST91 (Flexible and semi-rigid endoscopes)
  - ST58 (High level disinfection)
- AORN
  - Processing flexible endoscopes
  - Manual chemical high level disinfection
- CDC
  - Essential Elements of a Reprocessing Program for Flexible Endoscopes
Key Risks for Sterilization Failure

Leading the Way to Zero

- Sterilant cannot reach all surfaces
  - Cleaning and decontamination process
  - Disassembly and packaging
- Failure of the sterilizing equipment
  - Use
  - Monitoring
  - Maintenance
- Product availability
  - Load release
  - Product use
How can we minimize risk?

- Ensure compatibility with the process
- Ensure parameters match equipment manufacturer and product IFUs
- Monitor and verify process (e.g., time, temperature and pressure)
- Quality control and preventative maintenance
- Loads must be trackable (e.g., load log and item label)
Sterilization: Minimum Monitoring

- Ensure that IFUs are being followed for all products
- Quality control and preventative maintenance of equipment and process
  - Physical Cycle: time, temperature and pressure and IFU
  - Biologic: consistent with regulation and IFU
  - Chemical: functional testing (e.g., bowie dick, soil challenge test), internal indicator (external if internal not visible) in every pack and IFU
- Documentation: legible and complete
- Competent Supervision: Leadership and Infection Control
Key Risks for HLD Failure

Leading the Way to Zero

Outbreaks of infection, colonization and inflammation have been linked to:

- Not following manufacturer’s instructions for use
  - Improper or inadequate pre-cleaning/cleaning procedures
  - Inappropriate use or choice of detergent or disinfectant
  - Use of a untreated or contaminated water supply
  - Failure to completely dry channels
  - Lack of routine maintenance

- Flaws in the mechanical design
High Level Disinfection: Minimum Monitoring

- Ensure that IFUs are being followed for all products
- Cleaning verification
- Quality control and preventative maintenance of equipment and process
  - Physical monitors: temperature of products, exposure time, cycle parameters, etc.
  - Testing of minimal effective concentration
  - Storage
- Traceable from patient through reprocessing
- Documentation: legible and complete
- Competent Supervision: Leadership and Infection Control
Standard Precautions
CDC Core Practices

Standard Precautions

- Hand hygiene
- Environmental cleaning and disinfection
- Injection and medication safety
- Appropriate use of personal protective equipment
- Minimizing potential exposures
- Reprocessing of reusable medical equipment between each patient and when soiled

Standard Precautions Frequent Findings

- Lack of hand hygiene
- Use of a hand hygiene sink for disposal or cleaning of equipment
- Use of single dose medication vials on multiple patients or availability for use after opening
- Taking a multi-dose vial into a patient room and then using it for a subsequent patient
Standard Precautions Frequent Findings

- Failure to
  - scrub the hub of an IV line or medication vial
  - provide PPE at point of use
  - use or incorrect/inappropriate use of PPE
  - follow aseptic technique
Challenges for BPHC
Key Issues Identified in BPHC

- Failure to use any personal protective equipment (PPE) including protective gowns or eye shields
Key Issues Identified in BPHC

- Not following manufacturers’ Instructions for use (IFU) for medical and dental equipment, instruments and supplies
  - Not using the correct cycle parameters
  - Lack of an accurate means of measurement for pre-cleaning detergent and enzymatic
  - Lack of a process to ensure that brushes used in the decontamination area were cleaned when soiled
  - Not performing required sterilizer preventative maintenance and cleaning
Key Issues Identified in BPHC

- Not following evidence based guidelines
  - Premature release of instruments.
  - Inconsistent use of chemical indicators in paper-plastic peel pouches
  - Not monitoring sterilization parameters (time, temperature, pressure)
Key Issues Identified in BPHC

- Leadership/ Administrative Oversight
  - No IFUs available
  - Blanks on sterilization logs (e.g., parameters for cycles
  - Instruments in the procedure room sink
  - No physical or defined separation of contaminated and clean
Questions and Comments?