Disclosures

- Consultant/Speaker: 3M Healthcare, Bioseal, UltraClean Systems, oneSOURCE, ReadySet Surgical, Halyard Health, TS03, Madacta, Millennium Surgical

Objectives

- Identify some of the latest requirements from accrediting organizations relating to sterilization and HLD of instrumentation and medical devices.
- Discuss the most current standards and guidelines for best practices in reprocessing instruments and equipment.
- Describe new sterilization and disinfection technologies that may have current and/or future application to dentistry
Hundreds of Wisconsin VA dental patients possibly exposed to HIV, hepatitis

Were dozens of VT dental patients exposed to disease?
http://www.wcax.com/story/34000529/were-dozens-of-vt-dental-patients-exposed-to-disease

The state Department of Health is warning about 1,000 former patients of a closed eastern Pennsylvania dental practice to get tested for hepatitis and HIV, the virus that can lead to AIDS.

LaJolla dentists face accusations of possible patient exposure to HIV, Hepatitis in Pennsylvania

Colorado dentist accused of possibly exposing patients to HIV by reusing syringes

Tomah VA urging hundreds of veteran dental patients to get screened for HIV, hepatitis Contaminated dental instruments

Anaheim Dental Clinic Accused of Causing Infection to Children Closed Down Again

Standards, Recommendations and Guidelines

- CDC – Dental Instruments Classified into 3 Categories
  1) Critical - penetrate soft tissue or bone, contact the bloodstream or other normally sterile tissue = should be sterile.
  2) Semi-critical - do not penetrate soft tissues or bone but contact mucous membranes or non-intact skin. These devices also should be sterilized. If sterilization not feasible, high-level disinfection (HLD) may be used.
  3) Non-critical - contact only with intact skin (e.g., external components of x-ray heads, blood pressure cuffs and pulse oximeters) - intermediate-level or low-level disinfection.
University of Michigan Health System researchers found that surgical suction tubes retain human tissue and other debris. Impossible to Clean

University of Michigan Health System researchers cut this surgical suction in half, and found the device packed with debris.

University of Michigan Health System researchers examined the insides of 350 surgery-ready suction tips. All of them contained blood, bone, tissue or rust.
TJC National Patient Safety Goals
Goal 7: Reduce Risk of HAIs

NPSG.07.05.01
• Implement evidence-based practices for preventing healthcare-acquired infections (HAIs).
  – Implements policies and practices aimed at reducing the risk of HAIs. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines (for example, the Centers for Disease Control and Prevention [CDC] and/or professional organization guidelines).

The Joint Commission (TJC)

Standard IC.01.03.01
• The facility identifies risks for acquiring and transmitting infections.

Element of Performance # 4
• The facility reviews and identifies its risks at least annually and whenever significant changes occur with input from, at a minimum, infection control personnel, medical staff, nursing, and leadership.

CDC and FDA Alert  Sept. 11, 2015

Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices
• Arrange for a healthcare professional with expertise in device reprocessing to immediately assess their reprocessing procedures.
• The following actions should be performed:
  – Training
  – Audit and feedback
  – Infection Control Policies and Procedures

http://emergency.cdc.gov/han/han00382.asp
Sterilization is a Complex Process

- Requires:
  - Environmental controls
  - Appropriate equipment and supplies
  - Adequate space
  - Qualified, competent personnel - ongoing training
  - Monitoring for quality assurance
- TJC engineer on site
  - Review environmental concerns such as:
    - Temperature, humidity and traffic controls, ventilation etc.

Best Practices Standards & Guidelines

- AAMI
  - ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
  - ST56:2013 Chemical sterilization and high-level disinfection in health care facilities
  - ST40:2003 Table-top dry heat (heated air) sterilization
- AORN Guidelines for Perioperative Practices, 2017
- CDC:
  - CDC Recommendations form the Guidelines for Infection Control in Dental Health-Care Settings, 2013.

ANSI/AAMI ST79

- Comprehensive guide encompasses:
  - cleaning,
  - transport,
  - quality monitoring,
  - storage,
  - product evaluation,
  - equipment maintenance,
  - personnel considerations
- in all health care facilities, including, hospitals, ambulatory surgery facilities, physicians' offices, cardiac catheterization laboratories, endoscopy suites, radiology departments, dental offices, and other areas where sterile products are reprocessed, stored, and used.
1.1 Scope: Guidelines intended to promote sterility assurance and to assist health care personnel in the proper use of processing equipment.
   • NOTE—"health care facilities" means hospitals, nursing homes, extended-care facilities, free-standing surgical centers, clinics, and medical and dental offices.
   • 2.90 office-based health care facility: Health care facility designed for short-term treatment of ambulatory patients (e.g., freestanding surgical centers, clinics, and medical and dental offices).

Moisture assessment (Wet Packs)
• Updates to 8.8.6
  – Handling and inspection
  – Checking for moisture
• New Annex P
  – Check list – wet packs
  – Flow chart

CDC Guideline for Decontamination and Sterilization
• Every outpatient setting must have an individual with training as an Infection Preventionist (IP)
  ✓ Regularly available to the facility
  ✓ Involved in the development of policies based on:
    • regulations,
    • evidence-based guidelines, and
    • national published standards.

CDC - Guide to Infection Prevention for OUTPATIENT SETTING — Version 2.2 November 2015

IC.02.02.01 Noncompliance 2009-2016 half-year

Make Infection Control Improvement Your 2017 Resolution

Lisa Waldowski, MS, APRN, CIC
Enterprise Infection Control Specialist, TJC Standards Interpretation Group

The BoosterPak™ for HLD and Sterilization provides detailed to help address compliance issues in:
  • Leadership
  • Risk Assessment
  • Sterilization
  • Environment of Care
  • High-Level Disinfection
  • HR – Competency and Training

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TJC Facilities Out of Compliance

1. Not using current evidence-based guidelines (EBG) (IC.01.05.01 EP 1)
2. Orientation, training, and competency not conducted by personnel trained on recent evidenced based guidelines (IC.02.02.01)
3. Lack of quality control and manufacturers' instructions for use (IFU) - using nonvalidated conditions (concentration, exposure times, and temperatures) (IC.02.02.01)
4. Lack of participation and collaboration with IPC (IC.02.02.01)
5. Recordkeeping - "incomprehensible" or non-standardized logs (IC.02.02.01 EP 2)

- Traceable path to the patient and product identification in the event of a recall


George Mills MBA, FASHE, CEM, CHFM, CHSP
Joint Commission Director of Engineering

- Beginning Jan. 1, 2017, HTM departments must have documentation on-hand for specific devices at the time of a survey.
- If they ask for it and you don't have it, they will write you a finding.

Most Frequently Scored Standards

56% IC.02.06.05
Safe and Functional Environment
EP 10 Temp. and Humidity
- Staff know required temperature and humidity parameters
- Log each day (paper or automation)
- Must have mandatory feedback

53% EC.02.05.01
Risks with Utility Systems
Positive vs. Negative airflow
- Staff know what it is and what they can do to maintain appropriate pressure

52% IC.02.02.01
Reduce Risk of Infection
Cite any deviation from perfect compliance
- More places performing sterilization or HLD the more risks you have
  - AAMI ST58 2013

36% EC.02.02.05
Manage Risks Related to Hazardous Materials
Eyewash in Immediate Area
- Plumbed
- Inspection and documentation weekly
- Evaluate new products
TJC Personnel Considerations

HR.01.06.01: Staff are competent to perform their responsibilities

- EP 1. The facility defines the competencies it requires of its staff...
- EP 3. An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence.
  - Subject Matter Expert (SME)

Subject Matter Expert (SME)

The Joint Commission. 2017 Accreditation Standards

HR.01.06.01: EP 3

- Note: "When a suitable individual cannot be found to assess staff competence, the facility can utilize an outside individual for this task. Alternatively, the facility may consult the competency guidelines from an appropriate professional organization to make its assessment."

Attire for Decontamination

- PPE
  - Heavy-duty utility gloves,
    - Not procedure or surgeons gloves
  - Liquid-resistant covering with sleeves:
    - Jumpsuit, apron with sleeves, or gown
  - Any risk of splash or splatter
    - Fluid-resistant face mask
    - Eye protection
    - Safety glasses wrap around the eye, or
      - Face shield
- Hands must be washed after removing PPE


Section 4.5.2
Leadership Standards and EPs

• LD.03.01.01: Leaders create and maintain a culture of safety and quality throughout the hospital.
  – EP1. Leaders regularly evaluate the culture of safety and quality using valid and reliable tools.

• LD.03.06.01: Those who work in the facility are focused on improving safety and quality.
  – EP. 3 Leaders provide for a sufficient number and mix of individuals to support safe, quality care, treatment, and services.

The Joint Commission. 2017 Accreditation Standards

Leadership Standards and EPs

• LD.04.01.11: The facility makes space and equipment available as needed for the provision of care, treatment, and services.
  – EP 2. The arrangement and allocation of space supports safe, efficient, and effective care, treatment, and services.
  • Need for sufficient space to adequate reprocess
  – EP 5. The leaders provide for equipment, supplies, and other resources.

The Joint Commission. 2017 Accreditation Standards

Design Considerations

• Space proportioned to expected volume (3.3.1)
• Floors and walls endure frequent cleaning (3.3.6.1)
• Ceilings recessed and enclosed pipes (3.3.6.2)
• Doors, windows and pass throughs closed (3.3.6.3)
• Handwashing stations conveniently located in both clean, and decontamination areas (3.3.6.8)
• Eye wash stations (3.3.8)
  • Within 10 seconds travel time
  • Ability to flush both eyes for 15 minutes
  • Water temp. 60-100ºF

Non-Hospital HC Facilities (ST79)

- In non-hospital health care facilities, clinics, and dental or medical offices, it may not be possible to physically separate the decontamination area from the clean work area.
  - Procedural barrier separation (not generally desirable), could be adequate, provided
    - Work practices prevent splashing, production of aerosols, and the contamination of clean items and work surfaces,
    - Ventilation and air-handling systems move air from the clean side of the room to the decontamination side (see 3.3.6.4).
Manufacturers Obligations for Reusable Medical Devices

- Manufacturers responsibility to provide complete and comprehensive written instructions:
  - Handling,
  - Cleaning,
  - Disinfection,
  - Testing,
  - Packaging, and
  - Sterilization


HC Personnel Responsibility for Reusable Medical Devices

- Obtain and review manufacturers’ current data
- Contact device MFR Quality Control or Regulatory Affairs
- Internet-based electronic copies
  www.oneSOURCEdocs.com
- Ensure that they have the necessary resources to follow manufacturers’ IFU
Centers for Medicare and Medicaid Services

September 4, 2009 - CMS released a memo to state survey agency directors regarding sterilization practices.

“If manufacturers’ instructions are not followed, then the outcome of the sterilizer cycle is guesswork, and the ASC’s practices should be cited as a violation of 42 CFR 416.44(b)(5).” (CMS, 2009)

Point-of-use Care and Handling

- Cleaning begins at the point of use
- Remove gross soil – wipe with sterile water and soft cloth
  - Blood, other body fluids, and saline are highly corrosive and can cause pitting of instruments.
  - If left to dry, they can be difficult to remove and can prevent adequate sterilization.
- Irrigate all lumens
  - Cannulated instruments or instruments with lumens can become obstructed with organic material.

Cleaning and Decontamination Processes

- Instruments should NOT be decontaminated in scrub or hand sinks
- Instruments kept moist until they are cleaned
• Appropriate cleaning and decontamination solutions
  ◦ Proper dilution - water lines in the sink or automatic dosing system

• Appropriate cleaning processes
  ◦ Sharps and delicates separate
  ◦ Brushing occurs under water

AORN Care of instruments 2017

Decontamination

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• Brushes and other cleaning implements should be cleaned and
decontaminated:
  – at least daily or, preferably, after each use.

• Whenever possible, single-use brushes should be used and then
disposed of afterwards.

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Ultrasonic Cleaners

• Designed for fine cleaning
  – not for disinfection or sterilization.

• Used only after gross soil has been removed

• Change cleaning solution before it becomes heavily soiled
  – ultrasonic cleaning is inhibited by soil

• Follow by thorough rinsing
  – Final rinse:
    • sterile,
    • distilled, or
    • deionized water

AAMI ST 79 J 5.2.3 Mechanical cleaning

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Just because it looks clean does not mean it is clean

- You can't see biofilm or microbes
- You can't see biological residues
- You can't see inside narrow lumens

Cleaning Verification

- Test mechanical instrument washers:
  - Before initial use
  - Weekly during service
  - After major maintenance
- Evaluate manual cleaning
  - Periodically (e.g., weekly), and
  - When new instruments are reprocessed

Visual Inspection
User Verification of Cleaning Processes

- Efficacy testing
  - Visual inspection
  - Protein detection
  - ATP
- Mechanical cleaning equipment
  - Washers
  - Ultrasonics, etc.


Water Quality

- Water quality must meet the manufacturers’ requirements
- Water quality helps:
  - Prolong the life of instruments
  - Minimize risk of infection
- Water impurities
  - Stains on instruments
  - Negative impact disinfectants
  - Affect steam quality (wet packs)
  - Impact effectiveness and life span of cleaning equipment


AAMI TIR34:2014
Water for the reprocessing of medical devices
4.2 Categories of water quality

- **Utility Water** = tap water
- **Critical Water**
  A multistep water treatment process may include:
  - carbon bed,
  - softening,
  - deionization (DI),
  - reverse osmosis (RO), and/or
  - distillation

**Final Rinse and Steam Generation**

ANIS/AAMI TIR34:2014 Water for the reprocessing of medical devices

Annex G - Typical presentation of water quality issues during the reprocessing of medical devices

Troubleshooting potential problems

- Observed problem
- Examples of causes
- Recommendations

Reprinted with permission from AAMI TIR34:2014, Water for the reprocessing of medical devices. Copyright AAMI. Further reproduction prohibited

Steam and Water Quality

- Steam and water quality have an impact on:
  - Wet packs
  - Sterilization failures
  - Staining and corrosion of instruments and containers
Instrument Surface Stains

- Multi-color “Rainbow” Stains
  - Excessive silicates or salts in water supply
  - Excessive heat (over 280°F, uncommon)
  - Poor rinsing

- Marbling
  - Impurities in steam condensate
  - Insufficient steam quality

Pitting and Surface Corrosion

- Most commonly caused by saline and chlorine/chloramine exposure
- Cannot be treated
- Reject for patient use

Newer instrument soaked in saline for several hours

Stress/Corrosion Fractures

- High stress areas: rivets, welds, hinges
- Improper repairs
- Prolonged exposures to surgical residues, drugs, prolonged soaking
- Sterilization with ratchets in the locked position
- Cannot be repaired - Reject for patient use
Bluish/Black to Gray/Black

- Mixing metals in the sonic
- Prolonged exposure to substances
- Normal oxidative changes in high carbon and titanium instruments

Reddish-orange stains

Rust or Residual Blood? Rust with Pitting

Instruments with signs of rust or blood should be rejected for patient use and the cause investigated

A Word on Water Spots

- Causes:
  - Inadequately treated water for the final rinse
  - Minerals in water settle on the surface
  - A "wet pack" that has dried

Reject packages that show signs of water spots on outside or moisture on inside.
Manual Cleaning – Solution Dilution

7.5.2 Cleaning agent
- Follow manufacturer’s written IFU for water/solution temperature
  - Routinely monitor and document (7.5.3.2)

General Considerations
- Jointed instruments should be unlocked with ratchets not engaged
- Multipart instruments should be disassembled for sterilization
  - Unless the device manufacturer has provided validated written IFU to the contrary

Paper–Plastic Pouches

"Paper-plastic pouches should not be used within wrapped sets or containment devices because they cannot be positioned to ensure adequate air removal, sterilant contact, and drying. The practice of confining instruments in paper-plastic pouches and then including them in wrapped or containerized sets has not been validated as appropriate and efficacious by packaging and container manufacturers."
Alternate Method to Hold Small Items

Solution – validated containment devices

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Peel Pouches

• Paper-plastic pouches should be used only for small, lightweight low-profile items
  – Double peel pack – Not recommended
    • Only if validated documentation from MFR
      – Two sequentially sized pouches
      – Do NOT fold
      – Plastic faces plastic and paper faces paper
      – CI placed inside each inner package

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10.1.2 Paper-plastic pouches

• Paper-plastic pouches should stand on edge in relation to the cart or shelf
  – Holding racks or baskets specifically designed for pouches may be used.

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Seals must be totally intact

Hot Air/Dry Heat Sterilization

- Sterilize anhydrous (ie, waterless) items that can withstand high temperatures
- No longer represents the state of the art
  - Still used in isolated cases
  - High temp (above 185°C (365°F))
  - Destroys lubricating properties
  - Reduces instrument functionality
  - Corrosion hazard
  - Risk of loss of hardness
  - Plastics can be destroyed in higher temperatures

- Packaging manufacturers should be consulted for compatibility of the packaging material for dry-heat sterilization.
- Most types of tape are not designed to withstand the high temperatures of dry-heat sterilization.
- Items should be placed within the sterilizer chamber according to the sterilizer manufacturer’s IFU.
- Packages should be cooled before being handled or removed from the dry-heat sterilizer.
Steam Sterilization

- Saturated steam usually 135°C (275°F)
- Need critical water

Loading the Sterilizer

- Similar items requiring same cycle parameters can be grouped together
- Do not place metal items above textiles
- Ensure adequate air removal and steam penetration
- Sterilizer manufacturers written IFU should be followed

All Packages Must Be Cooled

- Do not touch packages till adequately cooled (room temperature).
- Cooling time should take into account:
  - Type of sterilizer, device, room temp., humidity and package type
  - Minimum cooling 30 minutes
  - May require 2 hrs or more
  - Table top sterilizers Minimum cooling 10 minutes

Infrared temperature guns commercially available
1. Sterility assurance of processed instruments should be routinely verified using three (3) types of indicators:
   1) Physical
   2) Chemical
   3) Biological

Physical Monitors

• 10.5 Sterilization process monitoring devices
  – Sterilizers that do not have recording devices should not be used
    • real-time assessment of cycle conditions
    • permanent records
    • detect malfunctions ASAP so that appropriate corrective actions can be taken.
  – Mark with correct date and sterilizer identification at beginning of cycle
  – Read & verify by initialing at end of cycle
  – If not correct, do not release load.

Routine Load Release

• Physical monitors (tape or printout)
• External process indicator (Type 1) on outside of every package (unless internal CI is visible)
• Internal CI (inside each package)
• PCD (test pack) with a type 5 or 6 (in every load)
  – May also contain the BI
  – Must be opened and evaluated prior to releasing the load
• Implants
  – BI and a type 5 CI

BI and Positive BI Controls

Incubate a positive BI control each day in each incubator:
- Verifies
  - Proper incubation conditions,
  - Viability of spores, and
  - Medium sufficient to promote growth
- Positive control BI should be from same lot number as test BI
- Document control and BI lot number

Sections 10.7.2.3, 10.7.3.3, 10.7.4.3

Sterilization Documentation

- Sterilizer identification
- Type of sterilizer and cycle used
- Lot control number
- Load contents
- Critical parameters for specific sterilization method
- Operator’s name, and
- Results of the sterilization process monitors (physical, CI, BI)

Quality Assurance

Sterilizers can mechanically fail, however, human error is the leading cause of sterilizer failure, e.g.
- Cold start
- Wrong cycle
- Overloading
- Improper packaging

According to the CDC, sterilizers that fail the routine BI test should not be used until a passed test is recorded.
Sterilization Process Failures

- AAMI ST79
  - Decision Tree for conducting investigations of sterilization process failures
  - BI, CI, and physical monitors
    - Clarify steps and provide additional guidance
  - Checklist for identifying reasons for process failure
    - Clarify steps and provide additional guidance
      - Operator errors,
      - Sterilizer, or
      - Utilities malfunctions

Storage Facilities

- Temperature not over 24°C (75°F)
- At least 4 air exchanges per hour,
- Relative humidity should not exceed 70%
- Traffic should be controlled
- Stored in a way that reduces the potential for contamination
  - Closed or covered cabinets recommended for the storage of seldom-used supplies

Sterile Storage

- Event-related
  - Dependent on the amount and type of handling, and storage conditions
- 18" below the level of sprinkler heads
- 8-10" above the floor
  - Prevent contamination during cleaning
  - Bottom shelf solid
- 2" for outside walls
  - Condensation may form on interior surfaces of outside walls
Sterile Storage

Outside shipping containers and web-edged corrugated cardboard boxes should not be allowed in the sterile storage area
- Collect dust, debris, and insects during shipping

*Photo courtesy of Department of Entomology, University of Nebraska-Lincoln. Photographer: Jim Kalisch.

Sterile Storage

Mature Indian Meal Moth Larvae Pupating in Corrugated Cardboard

More storage issues...

2016 Problems Reported by TJC

- Failure to measure chemical solution dilution
- Mixing clean and dirty instruments
- Missing biohazard labeling
- Failure to ID your clinical practice guideline
- No oversight by infection control
- Failure to document competency
- Leaving hinged items in the closed position during sterilization
- No documentation of washer and sterilizer PM and cleaning
- Failure to document biological indicator
- Use of double peel packs where inner pack is folded over

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New technologies - AAMI ST58
Chemical sterilization and high-level disinfection

- LCSs/HLDs and gaseous chemical sterilization systems known to be commercially available
- FDA cleared products with general claims for processing reusable medical and dental devices

ANSI/AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities

Chemical sterilization and high-level disinfection

- AAMI ST58 Covers
  - Work area design considerations
  - Staff qualifications
  - Criteria for selecting LCSs/HLDs
  - Decontamination and prep of instruments
  - Safety considerations
  - Storage and transport
  - Quality control methods
  - Quality process improvement

Section 5.3 LCS/HLD types
- Active ingredients (various brand names and concentrations):
  - glutaraldehyde (Annex B)
  - glutaraldehyde with phenol-phenate (Annex B)
  - hydrogen peroxide (Annex C)
  - sodium hypochlorite–hypochlorous acid (Annex F)
  - ortho-phthalaldehyde (Annex D)
  - combinations of peracetic acid and hydrogen peroxide
Chemical sterilization and high-level disinfection

- 5.4 Gaseous chemical sterilization types
- Chemical sterilants active ingredients (various brand names):
  - alcohol and formaldehyde (Annex G)
  - hydrogen peroxide (Annex H)
  - Hydrogen peroxide/ozone (Annex I)

Ethylene Oxide (EtO)

- AAMI ST41:2008 (R2012)
  Ethylene Oxide Sterilization
  In Health Care Facilities: Safety And Effectiveness

UV light

- Environmental disinfection
- Pass through window for manual cleaned items
• Clean and reprocess according to IFU.
  – If no IFU, the device may not be suitable for multi-patient use.
• Subject matter expert
  – Assign responsibilities only to competent staff
• Wear appropriate PPE
• Create and maintain a safe environment (clean/dirty separated)
• Use mechanical, chemical, and biological monitors according to IFU
• Maintain sterilization records in accordance with state and local regulations.

References

- CDC Guideline for Decontamination and Sterilization in Healthcare Facilities 2008
- Recommendations for the Guidelines for Infection Control in Dental Health Care Settings - 2013. CDC
- ST40 - Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities. ANSI/AAMI ST40:2004/(R)2010
- The Joint Commission: 2017 Hospital Accreditation Standards [H45]
- The Joint Commission: 2017 Comprehensive Accreditation Manual for Ambulatory Care (CAMAC)
- Sterile Processing in Healthcare Facilities: Preparing for Accreditation Surveys, AAMI 2014