Disinfection/Sterilization in the Ambulatory Clinic Setting:

Infection Prevention Challenges and Opportunities

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Presenter has no conflict of interest

Objectives:

1. Assess infection control risks and strategies related to instrument/device reprocessing in the medical office setting
2. Describe basic principles of cleaning, disinfection, sterilization
3. Identify required monitoring of high-level disinfection and sterilization processes
4. Discuss Infection Control essentials related to environmental cleaning

Risk Assessment

- Annual and continuous
- Assess patient population
- Identify vulnerabilities in high risk patients
- Evaluate services provided
- Assess routine IC practices
- Patient care equipment
- Environmental control
  - Office Design, sinks, waiting areas, exam rooms
- Sterilization, Disinfection and Antisepsis
- Occupational Health
- Leadership & staff accountability for Infection Prevention

Probability

Impact

Current Situation

Definitions

Operating Room

- Restricted Area
- For invasive procedures that require an aseptic surgical environment
- Any form of anesthesia may be administered

Procedure Room

- Unrestricted area
- For procedures that do not require an aseptic surgical environment, but may require use of sterile instruments or supplies
- No general anesthesia

Spaulding Classification

Spaulding Classification	Definition	Example	Disinfection
Critical	Object enters sterile tissue or bloodstream	Surgical instruments	**Sterilization** Sterilant/disinfectant Sporicidal, chemical prolonged contact
Semi-critical	Object contacts mucous membranes or non-intact skin	Rectal or vaginal probes, diaphragm fitting rings, respiratory therapy equipment endoscopes,	High-level Disinfection Sterilant / disinfectant Sporicidal chemical; short contact
Non-critical	Object contacts intact skin	Blood pressure cuff, glucometer, stethoscope	Low-level Disinfection Hospital disinfectant

Reprocessing of Reusable Instruments and Devices

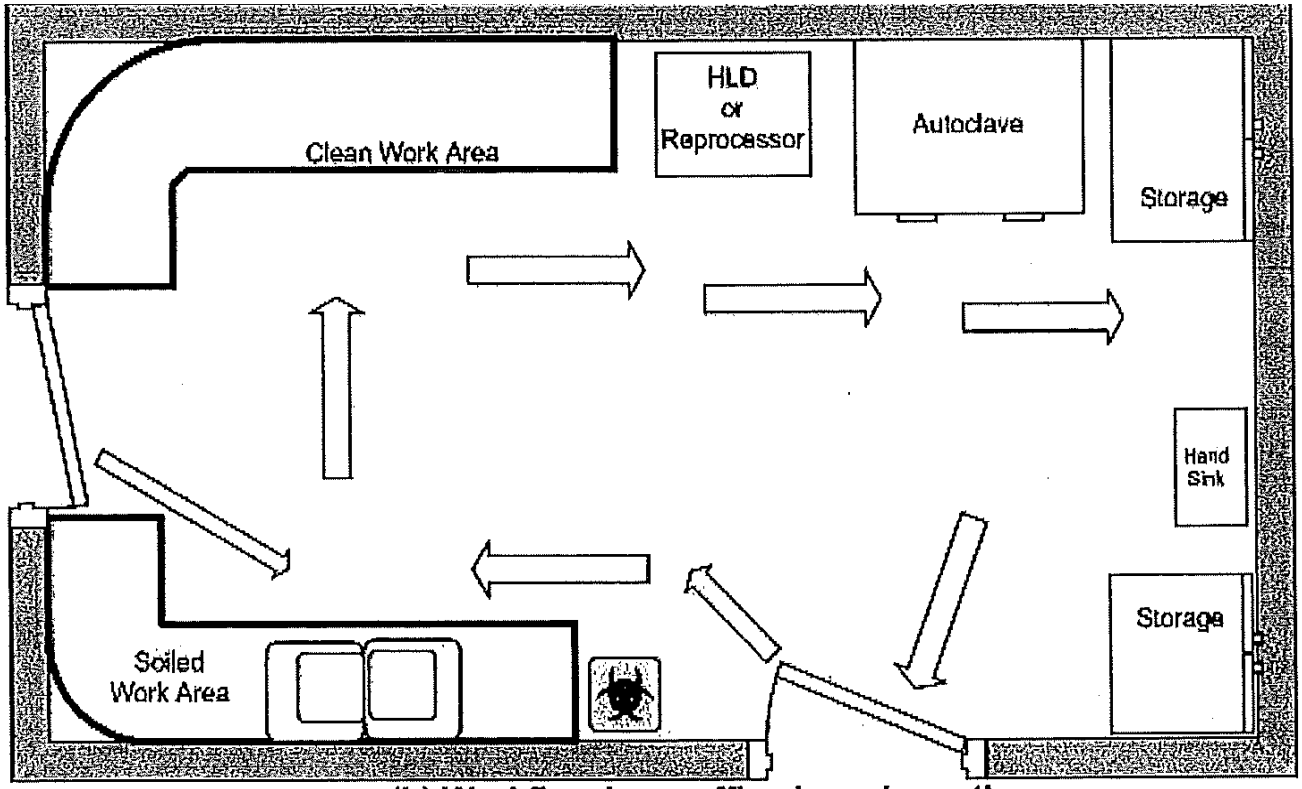
- Follow manufacturer instructions
- Discard single-use devices after use

Reprocessing area has a workflow pattern – clear separation between soiled & clean workspaces

- 2 areas: decontamination & clean
- One way traffic: dirty ⟶ clean
- Sink separated from clean work area by:
  - 4 feet from edge of sink or
  - A separating wall or screen
- 2 separate decontamination & hand hygiene sinks
- No clean supplies stored in dirty area

Functional Work Flow Patterns In Office-based Facilities

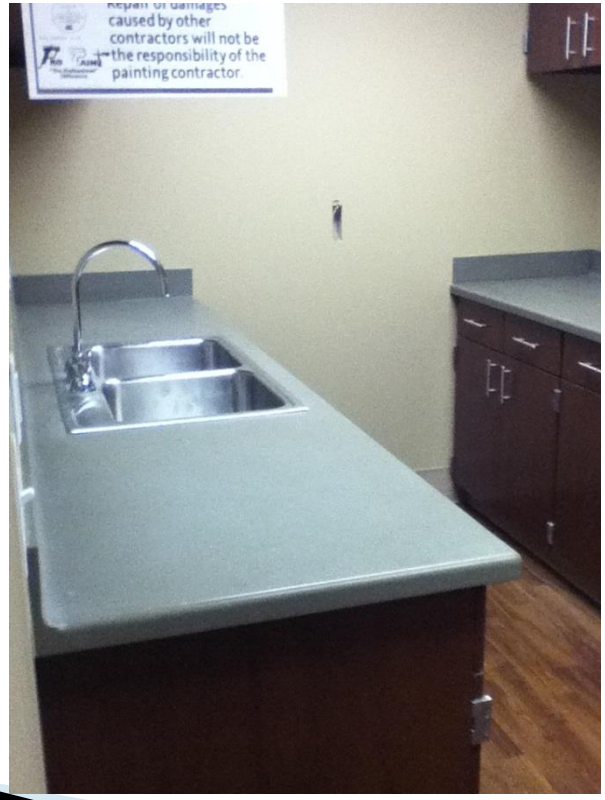
2011 ANSI/AAMI ST79:2010 & A1&A2

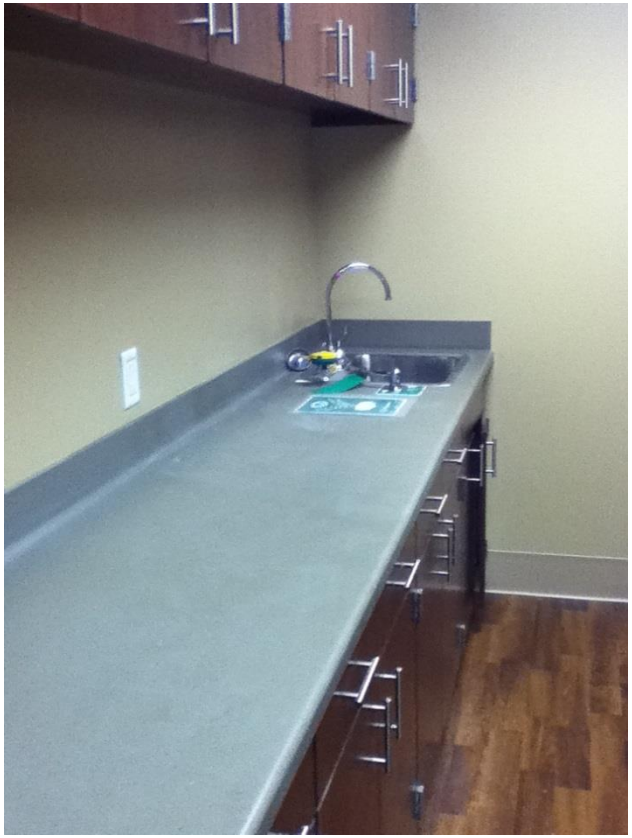


(b) Workflow in an office-based practice

Figure 2—Workflow

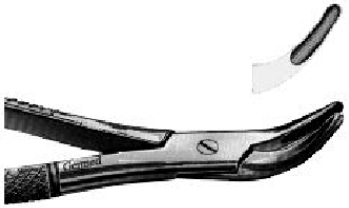
Reprocessing area has workflow pattern – clear separation between soiled & clean workspaces





Reprocessing Basics

- Items pre-cleaned first by manufacturer's instructions or evidence-based guidelines
- Devices visually inspected for residual soil and re-cleaned as needed



- After reprocessing, store items in designated clean area so sterility is not compromised

Autoclave Operation

- Load autoclave according to manufacturer guidelines:
  - Do not overload or crowd items –
    - do not layer items
    - Items cannot touch each other
  - Do not allow packaging to come in contact with side of door of chamber
  - Separate items or arrange loosely in chamber
  - Autoclave using run time & temperature guidelines per item
  - Do not use an autoclave that is not working properly
  - Follow manufacturer's instructions for care & maintenance
  - Testing procedures for monitoring autoclave performance

To ensure proper sterilization of items, these general guidelines must be followed. This will ensure that steam circulation and adequate drainage of condensed steam can take place.

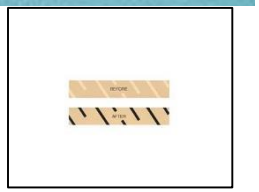
Not This

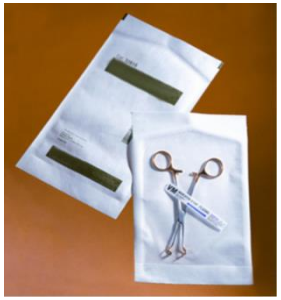
This

Sterilization Monitoring

Chemical Indicators – respond w/ chemical – change to ≥one or more physical conditions sterilizer chamber –incorrect loading or packaging or sterilizer malfunctions lethality

External & Internal chemical monitoring





Biological Indicators
Used weekly & with all implantable loads

Direct measure of the of the sterilization process

Mechanical Indicators – time, temperature & pressure recorders

Maintain, date, initial, time & temperature recording chart, printer or tape

Real-time assessment of cycle conditions

Instrument Decontamination at the Point-of-Use

S

SOIL

Apply gloves, wipe gross **soil** from re-usable instruments, de-glove, perform hand hygiene

T

TRANSPORT

Cover instruments / safely **transport** to dirty utility room

E

EQUIPMENT

Don Personal Protective **Equipment** - gloves and eye protection or face shield required

E

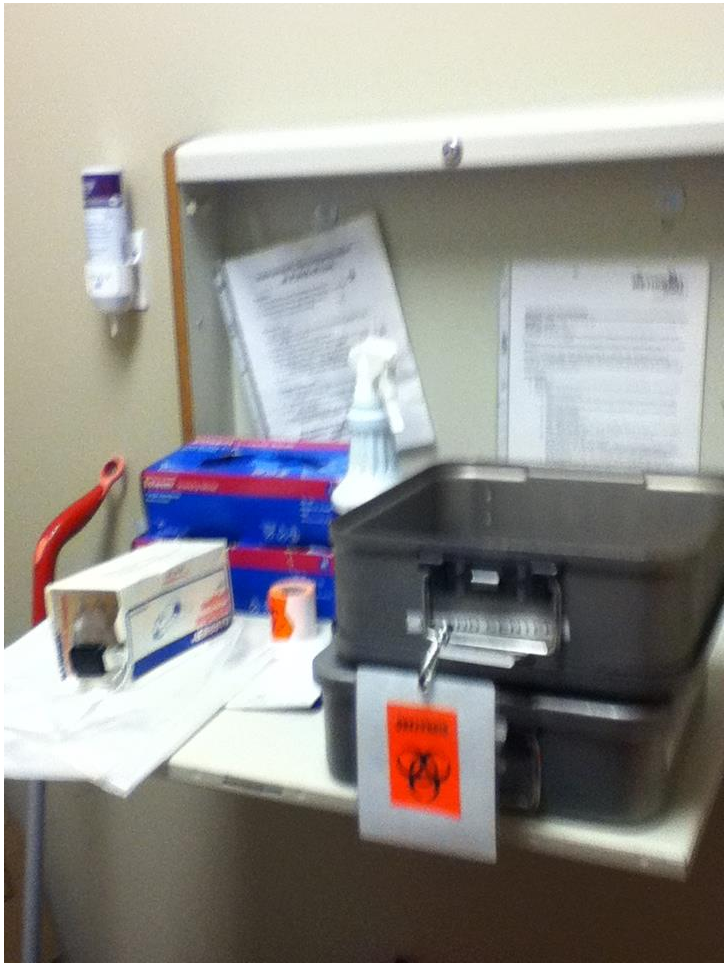
ENZYMATIC

Place instruments in open position in biohazard bin.
Spray with **Enzymatic** spray ~15 squirts (saturate)

L

LABEL

Cover **container**, **Label** with biohazard tag



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TJC – HLD-IC.02.02.01EP2

- No endorsement of any specific brand, product, process or device for performing HLD or sterilization
- Expect organizations to follow manufacturer recommendations to ensure, safe, effective use
- Organization minimizes risks associated with selecting, handling, sorting, transporting, using & disposing of hazardous gases, vapors
- Organizational leadership decision
  - Scope of services provided
  - Patient population served
  - EBP guidelines – AAMI, CDC
  - Laws and regulations

http://www.jointcommission.org/standards

Breaches in Disinfection/Sterilization

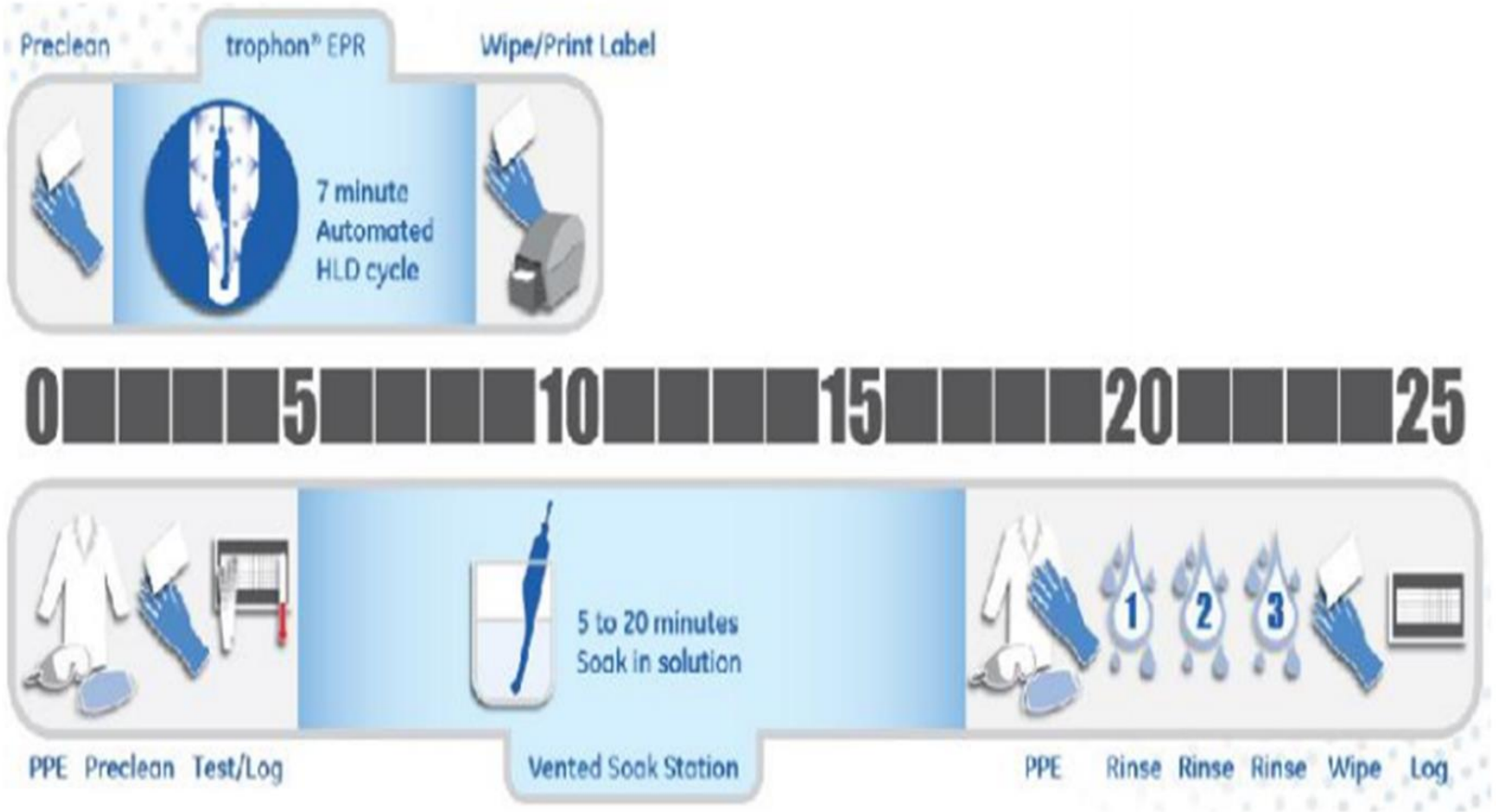
2014 Joint Commission surveys found 39% of office-based surgery practices had breaches in HLD pertaining to scope and US probe reprocessing & instrument sterilization process

- Lack of knowledge of/adherence to EBP guidelines
- Not following manufacturer instructions for use
- Lack of or incomplete documentation of competency, training and oversight
- Failure to adhere to & document physical/mechanical, chemical and biological monitoring of instruments
- Failure to maintain equipment to ensure HLD & sterilization efficacy
- Lapses in room pressure, temperature & humidity monitoring lapses

Three Commonly Used High Level Disinfectants

- OPA (Ortho-Phthalaldehyde:
  - Introduced to market 1999
  - Mostly odorless
  - 12 minute soak time at ≥68°F
  - Requires 3 large volume rinses – 1 minute each
  - PPE and ventilation requirements
- Glutaraldehyde:
  - Numerous brands with varying shelf-life, activation
  - Soak times vary – 20-45 minutes at 77°F
  - OSHA – exposure level limit .2ppm, ACGIH lower exposure limit .05ppm
  - PPE and ventilation requirements
- Hydrogen Peroxide:
  - Soak time 8 minutes at 68°F
  - Requires one low volume rinse
  - Resert SDS – ACGIH & OSHA exposure limit is 1ppm
  - Requires 6-15 minimum air exchanges per hours depending on area
  - PPE

Process Comparison



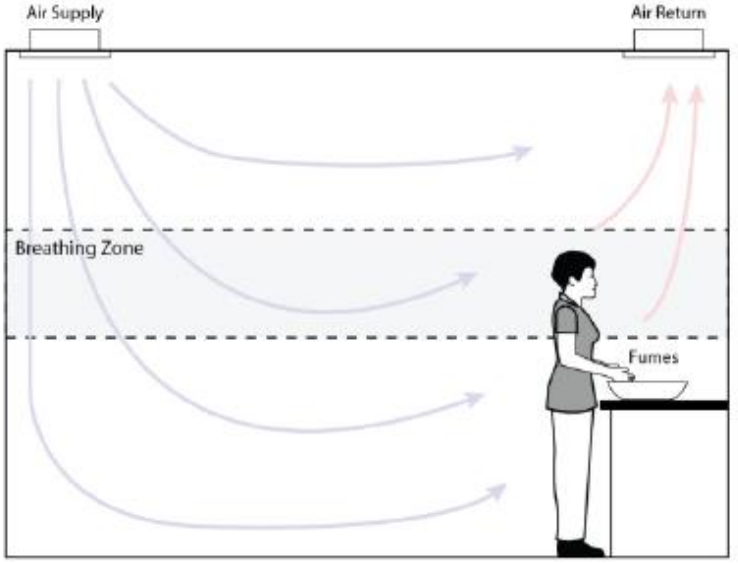
High-level Disinfection (HLD)

- Semi-critical items HLD or sterilized?
- Pre-cleaned first by manufacturer's instructions or evidence-based guidelines
- Visually inspect for residual soil & reclean as needed
- Transport device to Processing in enclosed container or biohazard bag
- Chemicals prepared/used per manufacturer's instructions for use
- Chemical tested for appropriate concentration per IFU
- Solution replaced per IFU?
- Documentation of above per IFU?

HLD

- Appropriate length of time?
- Appropriate temperature?
- Rinsed appropriately
- Items allowed to dry?
- Transported and stored in a clean area in a manner to prevent contamination
- Neutralize solution prior to discarding

- Follow manufacturer's recommendation to ensure safe, effective use
- Environmental requirements where HDL products are used
- Protect healthcare workers from risk
  - HDL disinfectants are toxic, fumes are known irritants
  - Use EBP – national guidelines – ANSI AAMI ST58:2013
  - Eye wash station available



- Use chemicals in an area that is properly ventilated
- If outside exhaust system not available, install a ductless fume hood (disinfection soaking station)
- Replace system filters per manufacturer instructions

Common Mistakes in Probe Disinfection

What's wrong with these methods?

Just put the probe straight into the bottle.

Topical Spray

No issue – as long as the tray is inside a vapor control system

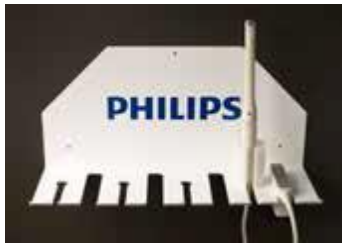
Don't laugh! This is a common method for disinfecting probes.

*Wipes are a widely used disinfectant for external ultrasound probes.**

http://www.pcimedical.com/ultrasound -soak-stations/disinfecting-probes-wrong-way?

Storage of Vaginal Probes

Ultrasound Probe Storage Rack



Ultrasound Probe Storage Cabinet

New Technology - High-level Disinfection

- Hydrogen Peroxide
- FDA Approved – Feb. 2011
- Seven minute process
- In-process chemical indicator
- Water & oxygen by-products
- No exposure to harmful chemicals
- Quick & easy cartridge replacement

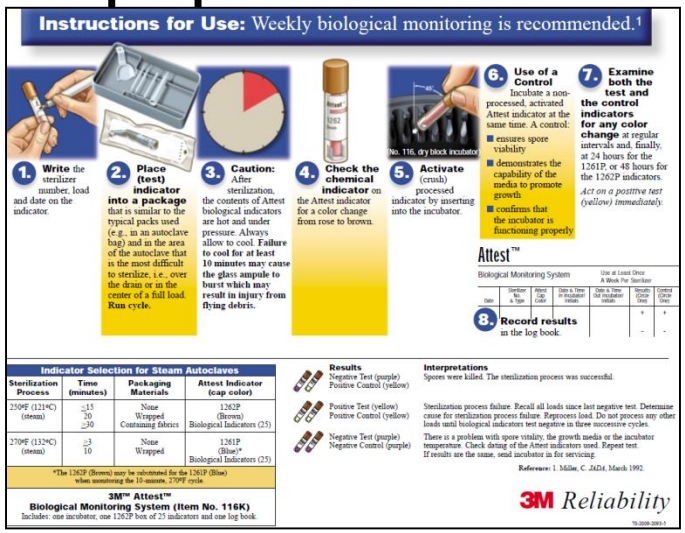
Sterile Supply Storage

Store in a manner that reduces potential for contamination:

- Closed or covered cabinets
- Storage rooms – temp (75°F), 4 air exchanges, ≤70% humidity
- Storage carts – 8-10 inches from floor; 18" from ceiling, at least 2" from outside walls
- Solid bottom shelves
- Positioned so pack is not crushed, bent, compressed, punctured or sterility compromised
- No outside shipping cartons or corrugated boxes

Suggestions for Sterilization & HLD

- Centralize
- Training –company reps, on-line, posters
- Competencies
- Assign accountability
- Model-specific protocols are current and posted
- Observe staff who perform equipment reprocessing



Cleaning / Disinfection Device and Environmental Surfaces– Clinic Setting

- Designated trained personnel
- Products used per manufacturer instructions
  - Compatibility of cleaning product / surface or device
  - Use EPA-registered product with appropriate germicidal claim
  - Follow manufacturer's safety precautions & instructions – dilution, safe use, storage, disposal – render safe for next user
- Staff can state contact times and meaning
- Scheduled cleaning / checklists

Cleaning/Disinfecting

- Frequency of cleaning
  - At least daily – patient care areas, medication prep areas (outside of pharmacy), bathrooms
  - Exceptions: Clean immediately
    - BBF spills
    - Medication prep areas when visibly soiled
    - Bathrooms after use by patient with infectious diarrhea
    - All environmental surfaces & devices when visibly soiled
    - Patient care device involves blood glucose meter or other point of care testing device

Exam Rooms

- Change exam table paper between patients
- Place used linens in designated container
- Clean med prep area after each patient encounter
- Focus on cleaning high touch surfaces (at least daily) – exam table, blood pressure cuff, door knob, ophthalmoscope
- High touch surfaces

Measuring Environmental Cleanliness

- ATP

Adenosine triphosphate (ATP) is an enzyme that is present in all living cells, and an ATP monitoring system can detect the amount of organic matter that remains after cleaning an environmental surface, a medical device or a surgical instrument. Hospitals are using ATP-based sanitation monitoring systems to detect and measure ATP on surfaces as a method of ensuring the effectiveness of their facilities' sanitation efforts. The amount of ATP detected, and where this ATP was detected, indicates areas and items in the healthcare setting that may need to be recleaned, and the possible need for improvement in a healthcare facility's cleaning protocols

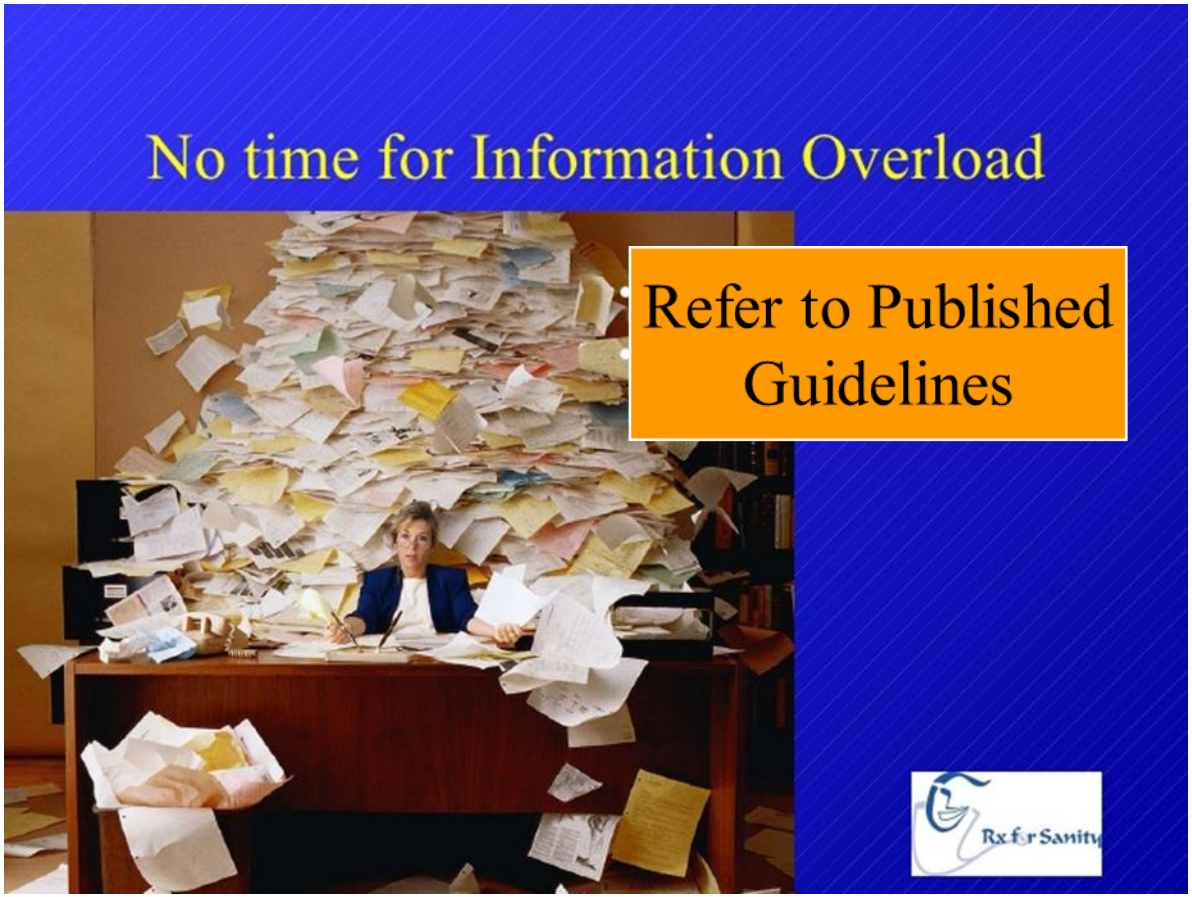
Review – Cleaning, Disinfection, Sterilization of Medical Equipment

- Ensure that reusable medical equipment is:
  - cleaned/reprocessed appropriately prior to use on another patient
  - Clean, reprocessed & maintained according to manufacturer instructions
- Assign responsibility to HCP with appropriate training
  - Maintain copies of manufacturer IFU
  - Observe procedure to document competencies
- Assure HCP have access to & wear appropriate PPE

Summary

- IP Program
  - Written infection prevention program
  - Assigned Infection Preventionist with training
  - Program based on national standards
  - Surveillance for infections
  - Education and Training
  - Policies and Procedures
  - Performance Improvement
  - Documentation
  - Know your state laws

Questions???


No time for Information Overload
Refer to Published Guidelines
Rx for Sanity

References:

CDC/HICPAC 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.
CDC Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care.
CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care.
CDC /HICPAC Guidelines for Environmental Infection Control in Healthcare Facilities (2003).
CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.
OSHA Bloodborne Pathogen Standard (29CFR 1910.1030)
CDC Basic Infection Control and Prevention Plan for Outpatient Oncology Settings
2014 Guidelines for Design and Construction in Health Care Facilities
2011 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST79:2010 & A1 & A2: 2011
2014 The Association for Medical Ultrasound: Guidelines for Cleaning & Preparing External and Internal Use Ultrasound Probes Between Patients