Module F

# Principles of Disinfection and Sterilization in the outpatient setting

## Objectives

- State the principles of disinfection and sterilization
- List the current methods for disinfection and sterilization per CDC guideline recommendations

## Spaulding Classification

Spaulding Classification of Surfaces:

1. **critical** – Objects which enter normally sterile tissue or the vascular system and require sterilization
2. **semi-critical** – Objects that contact mucous membranes or non-intact skin and require high-level disinfection, which kills all but high-levels of bacterial spores
3. **non-critical** – Objects that contact intact skin but not mucous membranes, and require low-level disinfection

## Order of resistance of microorganisms to disinfectants

Hardest to Kill

Easiest to Kill

Prions (Creutzfeldt-Jakob Disease (CJD), mad cow disease)
Spores (*C. difficile)*
Mycobacteria (Tb)
Non-enveloped viruses (norovirus)
Fungi (*Candida)*
Vegetative bacteria (MRSA, VRE)
Enveloped viruses (HIV, HBV)

## Factors influencing the efficacy of disinfection and sterilization processes

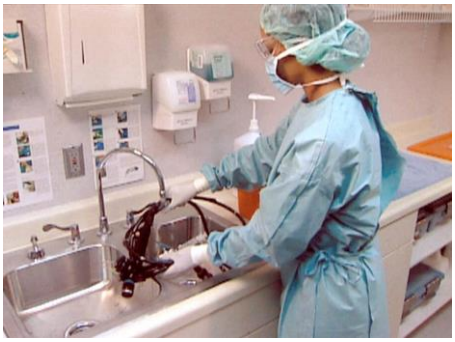
- Cleaning of the object
- Organic and inorganic load present
- Type and level of microbial contamination
- Concentration and exposure time to the disinfectant/sterilant
- Nature of the object
- Temperature, pH, and water hardness

## Processing Critical Instruments

## Processing Critical Instruments

- Penetrate or enter normally sterile tissue or spaces, including the vascular system
  - Surgical instruments, cardiac catheters, IV devices, urinary catheters
- Must be sterilized between uses or used as single-use disposable devices
- Goal: Sterility = devoid of all microbial life

## Processing Semi-critical instruments



## Processing Semi-critical objects

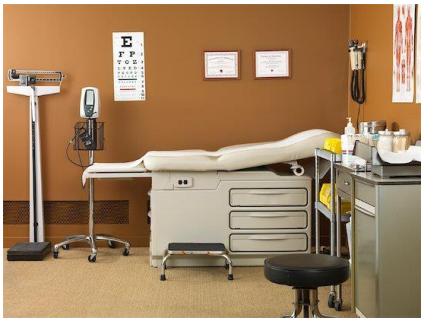
- Contact mucous membranes and non-intact skin
  - Endoscopes, Respiratory and Anesthesia equipment, endocavitary probes, tonometers, diaphragm fitting rings, vaginal speculums
- Must be sterilized or immersed in high-level disinfectant
- Goal: High-level disinfection = free of all microorganisms except low numbers of bacterial spores

## High-Level Disinfectants

| Germicide | Concentration |
|---|---|
| Glutaraldhyde (Cidex®) | ≥ 2.0% |
| Ortho-phthaladehyde (Cidex OPA®) | 0.55% |
| Hydrogen Peroxide* (Sporox™) | 7.5% |
| Hydrogen Peroxide and peracetic acid* (Peract™) | 1.0% / 0.08% |
| Hydrogen Peroxide and peracetic acid* (Endospor™ +) | 7.5% / 0.23% |
| Hypochlorite (free chlorine)* (Sterilox) | 650-675 ppm |
| Accelerated hydrogen peroxide (Resert™ XL) | 2.0% |
| Peracetic Acid (Steris 20™) | 0.2% |
| Glutaraldehyde and Isopropanol (Aldahol III®) | 3.4% / 26% |
| Glutaraldehyde and phenol/phenate (Sporicidin®) | 1.21% / 1.93% |

Exposure time ≥8 -45 min (US) and temperature 20-25°C;
*May cause cosmetic and functional damage

## Cleaning of non-critical surfaces or devices



## Non-critical instruments and devices

- Contact intact skin
  - BP cuffs, electrocardiogram (EKG) leads, stethoscopes
- Disinfect using a low level disinfectant
- Goal: Kill vegetative bacteria, fungi, viruses

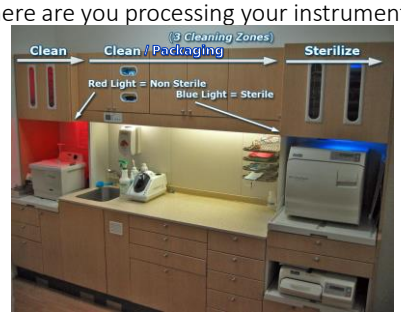
## Liquid Disinfectants

| Disinfectant Agent | Use Concentration |
|---|---|
| Ethyl or isopropyl alcohol | 70% - 90% |
| Chlorine (bleach) | 100ppm |
| Phenolic | UD |
| Iodophor | UD |
| Quaternary ammonium compound (QUAT) | UD |
| Improved hydrogen peroxide | 0.5%, 1.4% |

Exposure time ≥ 1 minute

UD = Manufacturer's recommended use dilution

## Where are you processing your instruments?




## Step 1 – Cleaning instruments

- Soak in enzymatic or non-enzymatic detergent
- Wear the appropriate PPE
- Keep instruments submerged in solution and scrub with brush

## Automated Cleaning

- Ultrasonic cleaner
- Instrument washer
- Washer-disinfector
- Regulated by FDA
- Household dishwasher NOT recommended


Fig. 3 Cleaning in an instrument washer (right) and an ultrasonic cleaner should be performed according to the manufacturer's directions.

## Sterilization

The complete elimination or destruction of all forms of microbial life by either physical or chemical processes.

## Methods of sterilization

Steam sterilization
Hydrogen peroxide gas plasma
Ethylene oxide
Ozone
Vaporized hydrogen peroxide
Steam formaldehyde

## Steam Sterilization

- Advantages
  - Non-toxic
  - Cycle easy to control and monitor
  - Inexpensive
  - Rapidly microbicidal
  - Rapid cycle time
  - Least affected by organic/inorganic soils
  - Penetrates medical packing, device lumens

## Steam Sterilization

- Disadvantages
  - Deleterious for heat labile instruments
  - Inappropriate for heat-sensitive instruments
  - Inappropriate for moisture-sensitive instruments
    - Dulling
    - Rusting
  - Potential for burns

## Steam Sterilization

- Steam under pressure (autoclaving)
  - Gravity displacement
  - Pre-vacuum

## Process times for packaged items

| Method | Time (minutes) Does not include drying time | Temperature Range |
|---|---|---|
| Steam autoclave | | |
| Gravity | 30 | 121°C |
| | 15 | 132°C |
| Prevacuum | 4 | 132°C |

## Dry Heat Sterilization

- Transfers heat energy from air inside the oven to the instruments
- Requires higher temperatures
- Good for items that are likely to dull or rust in the autoclave,
- Good for powders, cellulose and ink
- Packaging must be able to withstand high temperatures

## Liquid Chemical Sterilant/Disinfectants

- Only for heat-sensitive critical and semi-critical devices
- Powerful, toxic chemicals raise safety concerns

http://www.fda.gov/cdrh/ODE/germlab.html

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm133514.htm

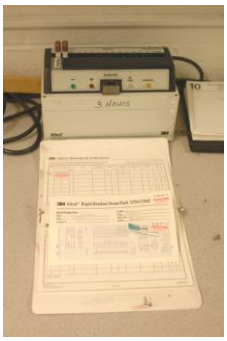
## Recommendations
## Methods of Sterilization

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Use immediately critical items that have been sterilized by liquid sterilants (e.g. peracetic acid) immersion process (no long term storage)

## Conclusions . . .

- All sterilization processes effective in killing spores.
- Cleaning removes salts and proteins and MUST precede sterilization.
- Failure to clean or ensure exposure of microorganisms to sterilant could interfere with the sterilization process.

## Monitoring



## Sterilization Monitoring

Sterilization monitored routinely by combination of physical, chemical, and biological parameters

- Physical - cycle time, temperature, pressure
- Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters reached
- Biological - *Bacillus* spores that directly measure sterilization

## Monitoring of Sterilizers

- Internal Chemical Indicator
  - Validates the sterilant penetrated the pack or tray
  - Detect local problem

## Biological Monitors

- Steam - *Geobacillus stearothermophilus*
- Dry heat - *B. atrophaeus (formerly B. subtilis)*
- Ethylene oxide (ETO) - *B. atrophaeus*

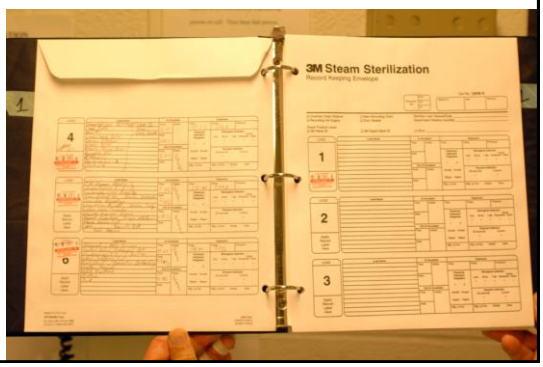

## Recommendations
## Monitoring of Sterilizers

- Monitor each load with physical and chemical (internal and external) indicators.
- Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer.
- Use biological indicators for every load containing implantable items

## Recommendations
## Monitoring of Sterilizers

**Following a single positive biological indicator from steam sterilization:**

- Remove the sterilizer from service and review sterilizer instructions
- Retest the sterilizer
- If spore test negative, put the sterilizer back in service
- If the spore test is positive: do not use until it has been inspected; and recall (to the extent possible) all items processed since the last negative spore test; challenge in three consecutive empty sterilization cycles.
- Single positive biological indicator (BI) from other than steam sterilization: treat as non-sterile all items back to last load tested with negative indicator




## Packaging

- Peel packs
- Rigid containers
- Self seal roll stock
- Sterile wraps woven and non-woven
- Must be FDA approved

## Loading

- Place items/packages correctly and loosely into the sterilizer so as not to impede penetration of the sterilant
- Peel packs and non-perforated containers (e.g., basins) should be placed on their edge

## Sterilzation Recommendations . . .

- Steam is preferred for critical (and semi-critical) items not damaged by heat
- Always follow manufacturer's operating instructions
- Use an "FDA cleared" container, wrapping or packaging system that is compatible with the type of sterilization process used
- Do not overload the chamber

## Recommendations
### Storage of Sterile Items

- Ensure the sterile storage area is a well-ventilated area that provides protection against dust, moisture, and temperature and humidity extremes.

8

head present
– 10 inches from floor

- Sterile items should be stored so that packaging is not compromised.
- Label sterilized items with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and if applicable the expiration date.

## Recommendations
### Storage of Sterile Items

- Event-related shelf life recognizes that the product remains sterile until an event causes it to become contaminated (e.g. moisture).
- Packages should be evaluated before use for loss of integrity. Repack and reprocess if compromised.
- If time related storage of sterile items is used, label the pack at the time of sterilization with an expiration date. Once this date expires, reprocess the pack.

## Endoscopes/Automatic endoscope reprocessors (aers)

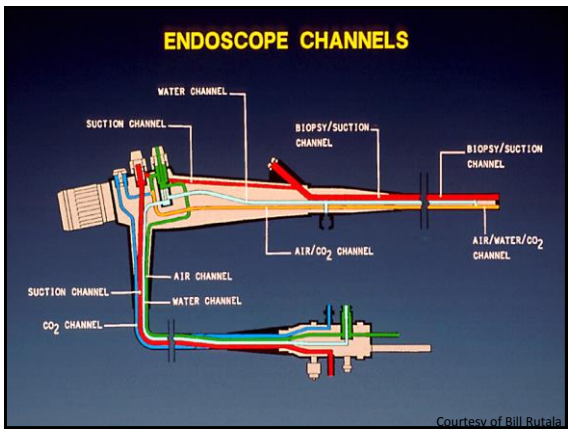
## Murphy Was an ICP!

**Murphy's Law:**

"Whatever can go wrong will go wrong"

**Corollary:**

"…in the worst possible way at the worst possible time"



## GI ENDOSCOPES AND BRONCHOSCOPES

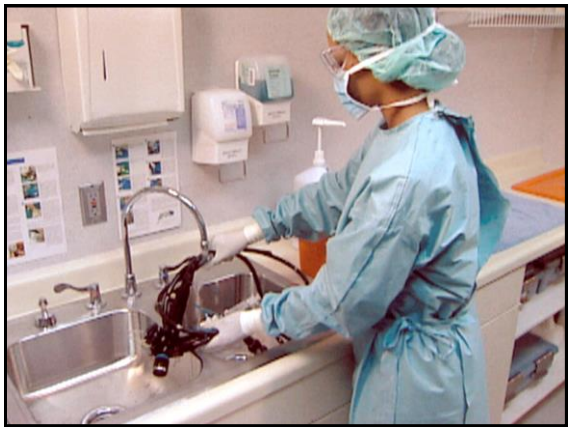
- Widely used diagnostic and therapeutic procedure
- Endoscope contamination during use (GI $10^9$ in/$10^5$ out)
- Semi-critical items require high-level disinfection at a minimum
- Inappropriate cleaning and disinfection has led to cross-transmission
- In the inanimate environment, although the incidence remains very low, endoscopes introduce risk of disease transmission

## TRANSMISSION OF INFECTION

- Gastrointestinal endoscopy
  - >300 infections transmitted
  - 70% agents *Salmonella sp.* and *P. aeruginosa*
  - Clinical spectrum ranged from colonization to death (~4%)
- Bronchoscopy
  - 90 infections transmitted
  - *M. tuberculosis*, atypical *Mycobacteria*, *P. aeruginosa*

## ENDOSCOPE INFECTIONS

- Infections traced to deficient practices
  - Inadequate cleaning (clean all channels)
  - Inappropriate/ineffective disinfection (time exposure, perfuse channels, test concentration)
  - Failure to follow recommended disinfection practices (tapwater rinse)
  - Flaws in design of endoscopes or automatic endoscope reprocessers (AERs).

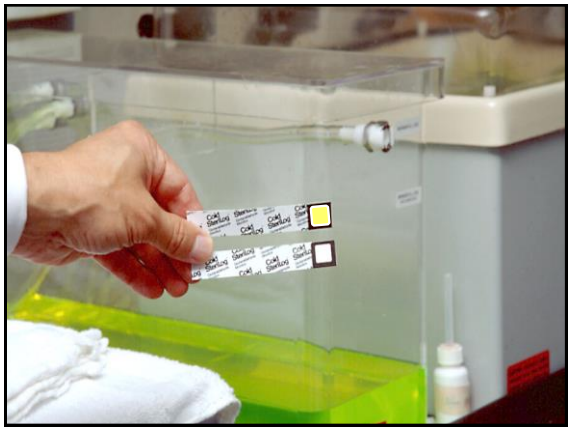


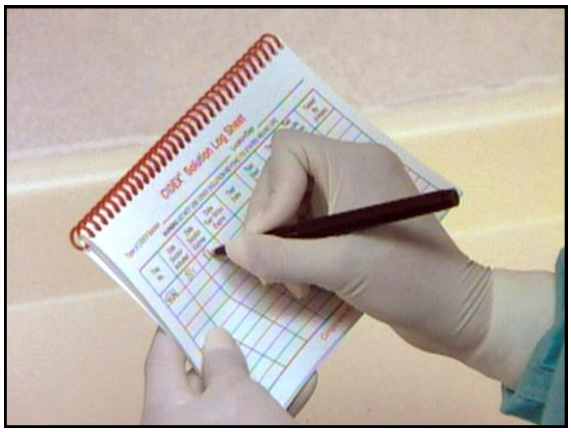
## Steps in ENDOSCOPE DISINFECTION

- CLEAN-mechanically clean with water and enzymatic or non-enzymatic cleaner
- HIGH LEVEL DISINFECT/STERILIZE-immerse scope and perfuse high level disinfectant/sterilant through all channels for the time recommended by the manufacturer
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water followed by alcohol
- DRY-use forced air to dry insertion tube and channels
- STORE-prevent recontamination

## Minimum Effective Concentration Chemical Sterilant

- Dilution of chemical sterilant occurs during use
- Test strips are available for monitoring minimum effective concentration (MEC)
- Test strips for glutaraldehyde monitor 1.5%
- Test strip not used to extend the use-life beyond the expiration date (date test strips when opened)
- Testing frequency based on how frequently the solutions are used (used daily, test at least daily)
- Record results





## Automated Endoscope Reprocessors (AERs)

- Advantages: automate and standardize reprocessing steps, reduce provider exposure to chemicals, filtered tap water
- Disadvantages: failure of AERs linked to outbreaks, does not eliminate precleaning, does not monitor high level disinfectant (HLD) concentration
- Problems: incompatible AER (side-viewing duodenoscope); biofilm buildup; contaminated AER; inadequate channel connectors
- MMWR 1999;48:557. Used wrong set-up or connector
- Must ensure exposure of internal surfaces with HLD/sterilant

## Failure to Follow Disinfection and Sterilization Principles

What Do You Do?

Scenario:

Hospital A discovered that for the past 3 days all surgical instruments were exposed to steam sterilization at 132°C for 0 minutes rather than the intended 4 minutes. A central processing technician turned the timer to 0 minutes in error.

## Steps in the event of Disinfection and Sterilization failure

1. Confirm failure of disinfection or sterilization reprocessing
2. Immediately embargo any possibly improperly disinfected/sterilized items
3. Do not use the questionable disinfection/sterilization unit (sterilizer, automated endoscope reprocessor) until proper functioning has been assured.
4. Inform key stake holders (risk management, management, lawyers)
5. Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6. Prepare a line listing of potentially exposed patients
7. Assess whether the disinfection/sterilization failure increases a patient's risk for infection
8. Inform an expanded list of stakeholders of the reprocessing issue
9. Develop a hypothesis for the failure and initiate corrective actions
10. Develop a method to assess potential adverse patient events
11. Consider notification of appropriate state and federal authorities (health department, FDA)
12. Consider patient notification
13. If patients are notified, consider whether such patients require medical evaluation for possible post exposure therapy with appropriate anti-infectives, as well as follow-up and detection of infections (HIV, Hepatitis B and C) if warranted.
14. Develop a detailed plan to prevent similar failures in the future
15. Write after-action report.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Original research article

Assessing the risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines

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## Recommendations
## Quality Control

- Provide comprehensive and intensive training for all staff assigned to reprocess medical/surgical instruments
- To achieve and maintain competency:
  - Staff receive hands-on training
  - Work with supervision until competency is documented
  - Competency testing should be conducted at commencement of employment and regularly
  - Review written reprocessing instructions to ensure compliance

## Recommendations
## for Quality Control

- Conduct infection control rounds periodically
- Establish a maintenance contract and record of service.
- Ensure protocols equivalent to guidelines from professional organizations
- Consult Association for the Advancement of Medical Instrumentation (AAMI) and/or manufacturer for preparation and packing of items

## Resources


**Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008**

William A. Rutala, Ph.D., M.P.H.[1,2], David J. Weber, M.D., M.P.H.[1,2], and the Healthca

Infection Control Practices Advisory Committee (HICPAC)[3]

GUIDELINE

reprocessing flexible gastrointestinal