High Level Disinfection

Who you gonna call?.... Bug Busters!

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Disclaimers: Dr. M. Alfa

- Sponsored to give invited presentations at various National and International conferences by: STERIS, 3M, J&J, Healthmark, Virox, MediSafe, Ontario Hospital Association, CHICA, and multiple conference associations.
- The University of Manitoba has licensed my patent for Artificial Test Soil to Healthmark.
- Research projects for STERIS, 3M, J&J, Novaflux, Virox, Olympus, MediSafe, Case Medical (no funds from these research projects comes to me personally - it is all handled by the St. Boniface Research Centre).
- Three day educational workshop on Microbiology for 3M
- On advisory panels and/or provided consulting advice for STERIS, Getinge, 3M, J&J, and Novaflux.

Overview:

- Spaulding classification
- High Level Disinfection:
  - flexible endoscopes
  - Respiratory equipment
  - Instruments: safe to handle
- What are some problem areas?
Spaulding Classification

- Proposed in 1968 by E.H. Spaulding
- The nature of disinfection needed for instruments → risk of infection related to the use of the items

Basic Recommendation

- Steam sterilization preferred for any instrument regardless of category as it is robust and cost-effective
- If steam sterilization is not feasible, then select appropriate disinfection method based on device classification

Note: Pre-vacuum steam sterilizers are much more efficient compared to gravity displacement steam sterilizers

SPAULDING Classification

Three Device Categories:

- **Critical**: Device enters sterile tissue or vasculature, therefore pose a high risk of infection if contaminated with microorganisms: *Require Sterilization*
- **Semi-critical**: Device comes in contact with mucous membranes or skin that is not intact, therefore pose a moderate risk of infection if contaminated with microorganisms: *Require High Level Disinfection*
- **Non-critical**: Device comes in contact with intact skin but not with mucous membranes, therefore, pose little to no risk of infection if contaminated with microorganisms: *Require Disinfection*
Where is High Level Disinfection used??

- **Terminal process: Semi-critical devices**
  - Flexible endoscopes
  - Respiratory equipment

How to Achieve:
Disinfection of Semi-critical Devices

- **Liquid chemical HLD**
  - > 2% Glutaraldehyde
  - OPA
  - 7% H₂O₂
  - Peracetic/ H₂O₂

- **Thermal disinfection**:  
  - Pasteurization (65-70°C for 30 mins)
  - Washer-disinfectors (Ao concept)

High Level Disinfection

- What thermal conditions provide the equivalent to Liquid chemical HLD??
- Cannot really equate thermal to liquid chemical killing
  - **Thermal killing is linear at high temp but not at < 80°C**
  - **LC killing is not a linear process and is affected by temperature, organic load and dilution (if reused)**
Examples of Reprocessing of Semi-critical devices

- Flexible endoscopes (HLD)
  - Bacteria-free final rinse
  - Storage: overgrowth due to moisture
- Ward Bedpan washers
  - C. difficile vs the Ao
- Respiratory equipment
  - Pasteurization vs Washers

Flexible endoscopes: High Level Disinfection

- Liquid chemical HLD: Immersed in specific liquid chemical for defined period of time
- Need to rinse off the liquid chemical AFTER HLD**
- Achilles Heel #1: water quality for rinsing
- Achilles Heel #2: storage of device

Flexible endoscopes:

- Periodic assessment of the AER final rinse water: should be bacteria-free (< 1 organism/50 - 100 mLs)
- Periodic assessment of the scope channels for microbial overgrowth (< 200 cfu/mL), and for cleaning efficacy
Data over 8 month period: Flexible GI Endoscopes

All scopes sampled on Monday after weekend storage

Maximum cfu/mL:
Wk 7:  S = 170
       A/W = 10
       Aux = 10
       Elev = 0
Wk 8:  S = 10
       A/W = 110
       Aux = 10
       Elev = 60

% samples with growth:
Month samples collected:

Scopes tested/month:
19 suction
19 Air/water
8 Auxiliary air/water
5 Elevator wire

New Storage Cabinets:
Dry channels → prevent overgrowth

- Stores up to 8 flexible endoscopes
- HEPA filtered air flow (1 hr); channels and exterior
- UV light (exterior)

This unit manufactured by Lancer UK

Thermal Disinfection

- How do we determine what thermal conditions to use if Pasteurization is not used??
**What is \( A_o \)?**

- \( A_o \) = equivalent time (seconds) at 80°C
- Fancy equation to calculate it - but basic concept is:

> Equal microbe killing may be achieved by various combinations of time and temp:

- \( A_o = 60 \) can be achieved: 60 secs @ 80°C
- \( A_o = 60 \) can be achieved: 6 secs @ 90°C

**Range of \( A_o \) used in ISO 15883-1:**

- \( A_o = 60 \) (60 secs at 80°C) **Bedpan washer**
  Devices that contact intact skin, unlikely to contain high numbers of heat resistant pathogenic organisms
- \( A_o = 600 \) (100 min at 70°C or 10 min at 80°C) **Surgical instrument Washer/dischefector**
  Devices that will ultimately be packaged and steam sterilized.
- \( A_o > 3000 \) : **WDs must be capable of this**
- \( A_o \) not applicable to steam sterilizers as temperature is > 100°C

**Ward Bedpan Washers**

- \( A_o = 80°C \) for 1 min
  ISO guidance document for bedpan washers
- Inadequate for **C.difficile** spores
Thermal killing of bacteria

A) Gram Positive vegetative

B) Gram Negative vegetative

C) Spores: C. difficile

Even an $A_0 = 600$ (i.e. 1 min at 90°C) could not eradicate *C. difficile* spores.

Ward Bedpan Washer: Extended testing

- Alkaline Detergent, 2 wash cycles, Thermal: 95°C for 10 mins, Water vol/cycle: ~ 60 L

- Alk Detergent, routine bedpan cycle, Thermal: 85°C for 1 min, Water vol/cycle: ~ 30 L

Cycle ~ 30 min/bedpan, 60 L water

What is the $A_0$ that would equate to achieving Pasteurization?

- $A_0 = \sim 227$ (30 min at 71°C) *Pasteurizer*
  - Respiratory equipment that cannot withstand steam sterilization

- *Washer/disinfector*:
  - Special cycles that can be used to replace Pasteurizers for Respiratory equipment.
  - Ensure they have $A_0 > 227$, but meet the lower temp restrictions of the respiratory equipment.
Why do Canadians need to understand $A_o$?

- WD manufacturers in Europe comply with ISO 15883 and Canadians need to understand what to request when WDs with $A_o$ specifications are purchased.
- CSA had adopted ISO 15883 series with Canadian deviations.
- The $A_o$ allows ability to have WDs with various settings that can still achieve the desired degree of lethality (more flexibility).

If the Device was used on a patient who has a “Nasty Bug”?

- Bronchoscope: Pulmonary TB HLD adequate
- Colonoscopy: $C.\text{difficile}$ associated diarrhea HLD adequate
- Bedpans used for patients with $C.\text{difficile}$ Need validated process for bedpan washer disinfectors
- Surgery: patient with Hepatitis B, or HIV Routine thermal conditions make instruments safe to handle

Disinfection/Sterilization

Cleaning of device prior to disinfection is crucial REGARDLESS of device category.

Staff training to ensure adequate re-processing is crucial REGARDLESS of device category.
Conclusions:

- **Spaulding classification** is still widely used and remains a valuable approach
- **Semi-critical devices:**
  - HLD using LC: least margin of safety
  - Thermal: Respiratory equipment → Ao ≈ 300
- **Critical:**
  - Washer-disinfector → Safe to handle → Ao 600
- Ao: Measure of thermal kill ability for temperatures from 65°C to 100°C

We need to take the “Eh?” out of Ao.