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.

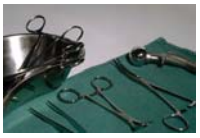
Overview:

- ***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

Kills all microorganisms except high levels of spores

- ***Liquid chemical HLD***
  - ≥ 2% Glutaraldehyde
  - OPA
  - 7% H_2O_2
  - Peracetic/ H_2O_2

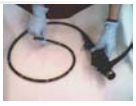
- ***Thermal disinfection:***
  - Pasteurization (65-70ºC for 30 mins)
  - Washer-disinfectors (Ao concept)

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 < 80ºC***
  - ***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

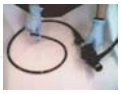


- Flexible endoscopes (HLD)
  - Bacteria-free final rinse
  - Storage: overgrowth due to moisture
- Ward Bedpan washers
  - *C.difficile* vs the Ao
- Respiratory equipment
  Pasteurization vs Washers

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

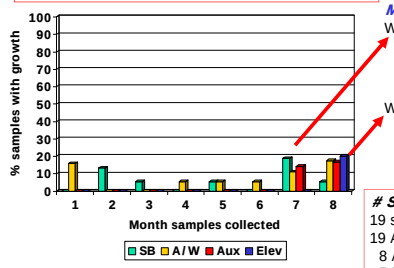
Flexible endoscopes:



- 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

 # Scopes tested/month:

19 suction
19 Air/water
8 Auxillary 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:

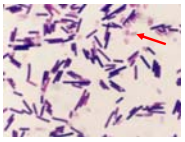
- ***A_o = 60 can be achieved: 60 secs @ 80°C***
  A_o = 60 can be achieved: 6 secs @ 90°C

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/disinfector***
  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

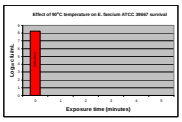
Ward Bedpan Washers

- Ao = 80°C for 1 min
  ISO guidance document for bedpan washers
- Inadequate for *C.difficile* spores

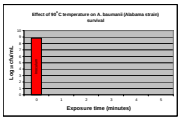


Thermal killing of bacteria

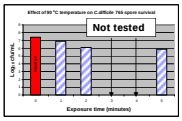
A) Gram Positive vegetative



B) Gram Negative vegetative



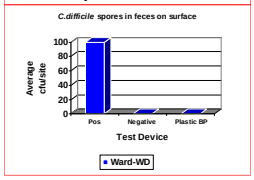
C) Spores: *C.difficile*



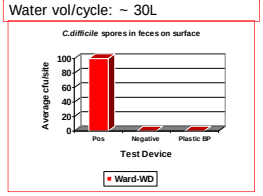
Even an A_o = 600 (i.e. 1 min at 90ºC) could not eradicate *C.difficile* spores

Ward Bedpan Washer: Extended testing

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



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



Cycle ~ 30 min/bedpan, 60 L water

What is the A_o that would equate to achieving Pasteurization?

- ***A_o = ~227*** *(30 min at 71ºC)* ***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 $A_o \geq 227$, 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.difficile* associated diarrhea	**HLD adequate**
Bedpans used for patients with *C.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 A_o