

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, Novaflex, 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 Novaflex.

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**
 - $\geq 2\%$ Glutaraldehyde
 - OPA
 - $7\% \text{H}_2\text{O}_2$
 - Peracetic/ H_2O_2



- **Thermal disinfection:**
 - Pasteurization ($65\text{-}70^\circ\text{C}$ 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 $< 80^\circ\text{C}$*
 - *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

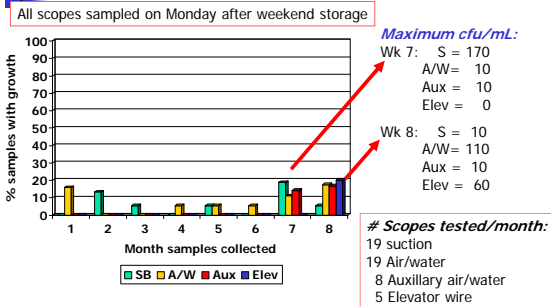
- Liquid chemical HLD: Immersed in specific liquid chemical for defined period of time
- Need to rinse off the liquid chemical AFTER HLD**
- Achilles Heel #1: water quality for rinsing
- Achilles Heel #2: storage of device

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



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_0 ?

- A_0 = 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:

- $A_0 = 60$ can be achieved: 60 secs @ 80°C
- $A_0 = 60$ can be achieved: 6 secs @ 90°C

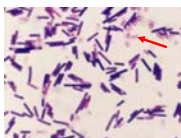
Range of A_0 used in ISO 15883-1:



- $A_0 = 60$ (60 secs at 80°C) **Bedpan washer**
Devices that contact intact skin, unlikely to contain high numbers of heat resistant pathogenic organisms
- $A_0 = 600$ (100 min at 70°C or 10 min at 80°C) **Surgical instrument Washer/disinfector**
Devices that will ultimately be packaged and steam sterilized.
- $A_0 3000$: **WDs must be capable of this**
- A_0 **not applicable to steam sterilizers** as temperature is > 100°C

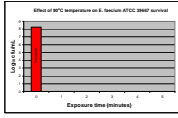
Ward Bedpan Washers

- $A_0 = 80^\circ\text{C}$ for 1 min
ISO guidance document for bedpan washers
- Inadequate for *C. difficile* spores

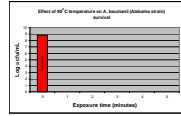


Thermal killing of bacteria

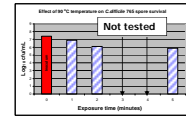
A) Gram Positive vegetative



B) Gram Negative vegetative



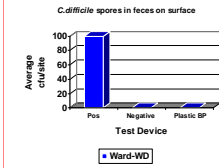
C) Spores: C. difficile



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

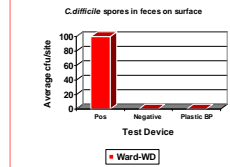
Ward Bedpan Washer: Extended testing

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



Cycle ~ 30 min/bedpan, 60 L water

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



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 $A_0 \geq 227$, but meet the lower temp restrictions of the respiratory equipment.

Why do Canadians need to understand A₀?

- WD manufacturers in Europe comply with ISO 15883 and Canadians need to understand what to request when WDs with A₀ specifications are purchased
- CSA had adopted ISO 15883 series → with Canadian deviations
- The A₀ 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: <i>C. difficile</i> associated diarrhea | HLD adequate |
| ■ Bedpans used for patients with <i>C. difficile</i> | 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 → $A_0 \sim 300$
- **Critical:**
 - Washer-disinfector → Safe to handle → $A_0 600$
- **A_0 :** Measure of thermal kill ability for temperatures from 65°C to 100°C



We need to take the "Eh?"
out of A_0