Validation of the Cleaning and Sterilization Process used for Medical Instruments

Dr. Michelle J. Alfa Ph.D., FCCM
Medical Director Clinical Microbiology, DSM, Winnipeg, Canada
Overview:

- How to assess adequacy of instrument cleaning
- Process monitors for sterilization - steam
- What are the issues?
Reprocessing of Medical Devices: Who is responsible for What??

- **Manufacturers** _validate_ that an instrument can be reliably cleaned and sterilized/disinfected and is therefore reusable.

- **Users** _verify_ that cleaning/sterilization equipment is working and that in-hospital cleaning/sterilization protocols are consistently performed.
Cleaning verification: Users

- Visually inspect the instruments after cleaning
- Monitor the automated washer
Check Instruments after cleaning

- **Visual inspection:**
  - good lighting, magnifying conditions
  - Do routinely for all surgical instruments
  - Not adequate alone: lumens, hinged areas etc.

- **Take samples and test for residuals**
  - protein, hemoglobin, carbohydrate
  - cutoff for acceptable cleaning??
Taking Samples from Instruments

- Swab of surface
- Elute from instrument by immersion and sonication in sterile Reverse Osmosis water
Rapid User Tests: SURFACE TESTING in-hospital cleaning assessment

- **ProtTEST Check (unknown LD):**
  Protein (MediSafe, UK) swab device assess

- **Protec Swab test (unknown LD):**
  Protein or ATP (Biotrace) swab can be tested.
  (commercially available)

- **Ninhydrin Swab test (2.5 µg/swab):**
  Protein: ISO/CEN method evaluated for users; swab method (deBruin 2002)
**Study:** Assess Surgical Instruments Before and After Cleaning to determine level of organic material

- Swab same area (1 cm$^2$) on each instrument
- Elute swab
- Test fluid for protein, hemoglobin, carbohydrate and endotoxin

**Quantitative test**
Plastic surgery instruments: patient-used [Avg of 5 patient procedures]

Carbohydrate on instrument

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Before Cleaning</th>
<th>After Cleaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Curved forceps</td>
<td>100 ug/cm²</td>
<td>200 ug/cm²</td>
</tr>
<tr>
<td>Fine needle driver</td>
<td>150 ug/cm²</td>
<td>350 ug/cm²</td>
</tr>
<tr>
<td>Curved Iris scissors</td>
<td>200 ug/cm²</td>
<td>400 ug/cm²</td>
</tr>
</tbody>
</table>
Plastic surgery instruments: patient-used [Avg of 5 patient procedures]

Endotoxin on instrument

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Endotoxin EU/cm² Before Cleaning</th>
<th>Endotoxin EU/cm² After Cleaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Curved forcep</td>
<td>0</td>
<td>15000</td>
</tr>
<tr>
<td>Fine needle driver</td>
<td>0</td>
<td>25000</td>
</tr>
<tr>
<td>Curved Iris scissors</td>
<td>0</td>
<td>20000</td>
</tr>
</tbody>
</table>
Conclusions: Testing Instruments

- Level of Carbohydrate and Endotoxin increased AFTER cleaning
- Level of Protein and Hemoglobin reduced after cleaning
- Likely due to final rinse water contaminated with biofilm [has high carbohydrate and endotoxin]
- Water used for final rinse needs to be monitored periodically.
What are cutoffs for adequate cleaning??

**Stainless Steel Surgical Instruments: Protein**

- OPA method: 0.01 µg/device; (Verjat 1999)
- Ninhydrin method: 2.5 µg/swab; (deBruin 2002)
- Biuret method: 5.5 µg/cm²; (Kruger 1997)
- BCI method: 6.4 ug/cm²; (Alfa 2002)

Still controversial – No International Standard
What Cleaning monitors for Washers are available (Surface vs Lumen)?

- **TOSI:**
  - *HealthMark USA, Medisafe, UK*
  - TOSI; Washer
  - TOSI Lumcheck
  - Flexi check: Endoscope lumen
  - Medisafe Lumen check: Laparoscopic device lumen

- Browne’s Soil and washer monitor (dye)
Guidance documents: Cleaning of Surgical Instruments

- ISO15883-1: Washer-disinfectors – General requirements, terms and definitions and tests
- ISO15883-5: Test soils and methods for demonstrating cleaning efficacy
- AAMI TIR34:2007: Water for reprocessing of medical devices
Monitors for Sterilization of Surgical Instruments

- **Europe**: Parametric release; [Based on standardized loading of sterilizer]

- **North America**: Biological and Chemical Indicators [Not able to ensure standardized loading of sterilizer]
Steam Sterilization

- Gravity Displacement
- Dynamic Air-removal Steam sterilizer e.g. Pre-vacuum steam sterilizer

Amsco/Steris

Getinge
Pre-Vac Steam Sterilization: Routine Hospital cycles

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Exposure time at 132°C (270°F)</th>
<th>Exposure time at 135°C (275°F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped instruments</td>
<td>4 minutes</td>
<td>3 minutes</td>
</tr>
<tr>
<td>Unwrapped nonporous items (e.g. instruments)</td>
<td>3 minutes</td>
<td>3 minutes</td>
</tr>
<tr>
<td>Unwrapped nonporous &amp; porous items in a mixed load</td>
<td>4 minutes</td>
<td>3 minutes</td>
</tr>
</tbody>
</table>

Dry Times not indicated, as these vary widely.

AAMI ST79 Steam Sterilization Guidance document 2006
Extended Steam Sterilization Cycle

Instrument manufacturer recommended steam sterilization cycles that go beyond the times listed for routine hospital cycles.
Two main reasons for manufacturer recommended Extended-Steam cycles

- **Acetabular reamer system:**
  - 18 mins PreVac at 132°C

- **Orthopedic Set**
  - 132°C for 40 mins

"Prion" related cycle:
European instruments
- alternatives may be given my manufacturer

Large mass/density of medical device or instrument set
- steam penetration & heating issues
Medical Device Reprocessing: User’s Responsibilities

- Provide Appropriate Process Monitoring for Steam sterilization cycles used.
- Both CI and BI have a role in process monitoring if parametric release is not used.
Monitoring of Standard Pre-vac Steam sterilization cycles

- **Biological Indicator (BI)**
  - run 1/day (minimum 1/week) for every steam cycle used that day
  - required for every load with implant(s)
  - quarantine implant until results of BI known

- **Chemical Indicator (CI)**
  - Class I to VI (Canada)
  - external, internal and in PCD

**BI:** only used in Process Control Device (PCD)

**CI:** used in PCD or in/on actual instrument package
BI: Monitor Steam Cycle

- Spores
- Spores in self-contained BI
- Spores in BI in Process Challenge Device (PCD)

BI in PCD used for routine monitoring of steam and ETO cycles in Healthcare
Chemical Indicators:

- **Class 1: Process Indicators** (changes color when exposed to steam)
  - differentiate processed vs unprocessed products.
  - use on the *outside of ALL packages* sterilized (e.g. autoclave tape).

- **Class 2: Bowie-Dick**
  - *ONLY for pre-vacuum sterilizers* to show adequate air removal

- **Class 3: Single Parameter Indicator** (e.g. temp, or steam, or ETO)
  - monitors single variable
  - place *inside instrument package* or *in Process Challenge Device*

- **Class 4: Two or more critical variables** (e.g. temp & sterilant)
  - monitors multiple variables
  - place *inside instrument package* or *in Process Challenge Device*
Chemical Indicators:

Class 5 & 6: “Integrators”:
ALL critical variables for cycle
(e.g. correct temp, & sterilant for specified period of time)

- tightly controlled must achieve success for ALL variables evaluate
- place *inside instrument package* or *in Process Challenge Device*
- Loads can be released based on these CIs
  (except implants which still need result of BI prior to release)

- Class 5 correlate with BI characteristics,
- Class 6 “emulating” indicator correlate with stated values not necessarily with BI characteristics
Why are BIs needed when CIs are more tightly controlled?

- Can chemicals or enzymes repair damage to regain function? **NO**
- Can microorganisms repair damage to regain function (e.g. Potential for infection) **YES**
INAPPROPRIATE to use a BI (OR CI) in a test pack that has been validated for a standard hospital cycle (e.g. 4 min @ 135°C) to monitor an extended cycle (e.g. 18 min @ 132°C).

A self-contained BI in a “Test Pack” (i.e. PCD) is validated for a specific type of sterilization method and for a **specific set of cycle parameters**.
What can go wrong when manufacturer recommends extended steam cycle?

- **Routine BI & CI in extended cycle:**
  - not a proper challenge to ensure cycle parameters are adequate

- **Standard steam cycle using appropriate routine BI:**
  - inadequate sterilization instruments may not be sterile despite BI that passes
What can Users do??

- Ask medical device manufacturer if extended cycles have been validated
- Limited user-testing to ensure steam penetration:
  - test BEFORE set is used for first time
  - place 3 BIs inside each layer of set
  - if any BIs fail; break set down into smaller tray sets and re-test
Steam Sterilization:
Multi-layer Surgical Sets

- If failure of any BIs: report to medical device manufacturer
- Break down set to smaller tray sets and re-test
Issues that need Site specific attention:

- Ensure proper BIs and CIs used for steam cycles
- Ensure Device manufacturer cycle parameters (e.g. extended steam cycles) are followed unless written instructions otherwise
- Consolidate extended cycles to one sterilizer unit and ensure training and competency of staff
- May verify steam penetration using BI in tray-set as PCD
What is being done to address this issue?

- Manufacturers working with AMMI and CSA to harmonize to ONLY two extended cycles (10 and 20 minutes suggested).
- All instruments and sets will be validated for existing routine steam cycles or for one of the two extended cycles.
- Manufacturers to develop appropriate PCD for BI/CI monitoring of the two extended cycles (Note; there are CIs cleared for some extended steam cycles).
SUMMARY

- BIs or CIs recommended for routine cycle monitoring when parametric release not used.

- **Do NOT process devices/sets in routine cycles** if extended cycles recommended by manufacturer

- Heavy, complex instrument sets suggest limited pre-testing using instrument tray set as PCD until more appropriate ones available


