Sterilization of Endoscopes

And Why We Chose a Low Temperature Reprocessing Method

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About....

- Vancouver Coastal Health for 24 years
- Manager of MDRD at Vancouver General Hospital (VGH) and UBC Hospital since 2009/2013
- Economics, Urban Planning and Healthcare Administration
- President Elect & Vendor Director for CAMDR
- VCC MDRT Program, Regional Reprocessing standards, Regional MDR Committee, MoH Provincial Working Group
The Reason Why....

- Sterilization of Endoscopes and Why We Chose a Low-Temperature Reprocessing Method
  - Duodenoscopes and the challenge of reprocessing
  - Current standards
  - Recent CRE outbreaks
  - FDA recommendations
  - VGH incident & actions taken
  - Need for Provincial solution
  - Trial and evaluation of new technology
  - Conclusions/Future Expectations
What are Duodenoscopes?

- Multi-channeled flexible scopes that enter through the mouth and travel down into the top of the small intestine or duodenum.
- Endoscopic Retrograde Cholangiopancreatography – ERCP
- 650,000 in the US – 2016
The Challenge of Reprocessing

Why are duodenoscopes so difficult to reprocess?

- Complex design – forceps elevator channel
- Lengthy vendor IFU on reprocessing
- Delicate and expensive medical device
- Multi-channeled endoscope
- Material compatibility issues
Current Standards

Spaulding’s Classification

Table 1: Spaulding’s Classification of Medical Devices and Required Level of Processing/Reprocessing

<table>
<thead>
<tr>
<th>Classification</th>
<th>Definition</th>
<th>Level of Processing/Reprocessing</th>
<th>Examples</th>
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<tbody>
<tr>
<td>Critical Device</td>
<td>Device that enters sterile tissues, including the vascular system</td>
<td>Cleaning followed by Sterilization</td>
<td>• Surgical instruments</td>
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<td>• Biopsy instruments</td>
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<td></td>
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<td>• Foot care equipment</td>
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<td>• Cystoscopes*</td>
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<td>Semi-critical Device</td>
<td>Device that comes in contact with non-intact skin or mucous membranes but do not penetrate them</td>
<td>Cleaning followed by High-Level Disinfection (as a minimum) Sterilization is preferred</td>
<td>• Respiratory therapy equipment</td>
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<td>• Anaesthesia equipment</td>
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<td>• Cystoscopes*</td>
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<tr>
<td>Noncritical Device</td>
<td>Device that touches only intact skin and not mucous membranes, or does not directly touch the client/patient/resident</td>
<td>Cleaning followed by Low-Level Disinfection (in some cases, cleaning alone is acceptable)</td>
<td>• ECG machines</td>
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<td>• Oximeters</td>
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<td>• Bedpans, urinals, commodes</td>
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</tbody>
</table>

*Cystoscopes – 2012 appear in Critical and Semi-critical classification section. The preferred level of reprocessing is sterilization.

“You can clean without disinfecting, but you cannot disinfect without cleaning”
Dr. Earle Spaulding
Outbreaks of Deadly Bacteria

- Despite following the IFU cases of infection occurred
- Carbapenem-Resistant Enterobacteriaceae (CRE)
- Over 350 cases reported worldwide 2010-2015
- Superbug with 40 - 50% mortality rate
- Outbreaks in Los Angeles, Seattle, Chicago, Philadelphia and Pittsburgh
FDA Response & Recommendations

- Ensure strict adherence to IFU
- Competency testing of staff
- Device design
- Routine/periodic microbiological culturing
- Repeat high-level disinfection
- Use of a liquid chemical sterilant processing system
- ETO sterilization
A small cluster of 3 patients was identified in 2016
- Carbapenemase Producing Organism (CPO)
- ERCP’s completed in 2016
- Source of the infection unclear
- Duodenoscopes, Valves, buttons?
Actions Taken

VGH immediately put in place a number of measures to mitigate the transmission of CPO infections in the Endoscopy Clinic

- Complete environmental clean of the Endo Clinic
- External audit performed – 100% compliance
- Complete ETO sterilization of all endoscopes
- Steam sterilized of all reusable adapters
- New protocol for adapters HLD to Sterilization
- Vendor in-servicing of all staff
- Developed audit tool for ongoing staff competencies
- New informed consent procedures as per PICNet
- Duodenoscopes HLD – ETO Sterilization
The Provincial Solution

Challenge:
- ETO sterilization requires increase of scope inventories at VGH – capital investment
- Scope compatibility issues with ETO
- Infrastructure costs of ETO sterilizers
- Logistics of sending to VGH

Required:
- Sterilizer(s) for each site performing ERCP’s
- Materials compatibility with LTS
- Maintain scope inventory levels – quick cycle times
- Cost effective
New Technology Trial

- New low-temperature sterilizer which uses vaporized hydrogen peroxide and ozone in a multiphase process
- Validated in Canada – TJFQ180V Duodenoscope
- Requires an Oxygen source i.e. O2 tanks, concentrator, direct line.
- No special HVAC requirements/renovations
Trial Parameters

- 6 month trial period
- 8 TJFQ180V duodenoscopes - approx. 5 years old
- 2 sterilizing units
- O2 Bank used as Oxygen source
- Identify super users and train specific core group
- One scope per cycle, placed in compatible bin and wrapped
- Sterivent caps used on all scopes
- Continue with current process of manual clean, HLD in AER and then sterilize
- 4 scopes not in trial sterilized in ETO sterilizer
Trial Parameters

- Scopes randomly placed into 1 of 2 sterilizers
- Inspection of scope pre and post sterilization (both methods)
- Monitor cycle times and aborted cycles
- Monitor Hydrogen Peroxide Injection Times
- Record oxygen tank consumption
- Sterilant consumption
- Droplets inside container post sterilization
- User feedback
Initial Clinical Trial Results (Sep 1- Oct 2/17)

- 71 cycles logged
- Zero aborted cycles
- Average cycle times of 58:56
- 9 scopes per oxygen tank
- 9 scopes per sterilant bottle
- No droplets found in container after 71 cycles
- Positive user feedback
Pre & Post Scope Inspections

- **Scope D301** - 10 cycles
  - No issues reported

- **Scope D302**
  - Not used in trial

- **Scope D303** – 15 cycles
  - Sep 12/17 Slight discoloration noted after HLD, prior to sterilization. Removed when rinsed with sterile water.
  - Sep 28/17 Image brightness issue. Sent for repair
Pre & Post Scope Inspections

- Scope D304 – 3 cycles
  - Issue with previous repair and sent back to vendor to correct.
- Scope D305 – 13 cycles
  - Sep 12/17 discoloration noted after HLD, prior to sterilization. Discoloration rinsed off with sterile water
Pre & Post Scope Inspections

- Scope D306 – 2 cycles
  - No issues reported

- Scope D316 – 14 cycles
  - Sep 12/17 discoloration noted after HLD, prior to sterilization. Discoloration rinsed off with sterile water. Sep 20/17 discoloration reappeared after HLD and removed with sterile water.
Pre & Post Scope Inspections

- Scope D317 – 9 cycles
  - Black build up noticed post sterilization. Removed with swab and sample sent to lab. Scope remained in use.
Conclusion

- Average cycle times of < 1 hour on target with Provincial requirements
- Staff found the process to be user friendly
- Discoloration found on scopes post HLD also noted on scopes not in trial (ETO sterilized). Therefore, seems to be residue from HLD and not the sterilization process.
- Lab results from black deposit found on one scope returned as non-organic. Speculation this is excess adhesive from a previous repair. Scope returned to circulation.
- No noticeable degradation of scopes compared to those being ETO sterilized
Future Considerations

- After reviewing IFU’s and in consultation with vendor, the discoloration seems to be a result of both processes (HLD & Sterilization). The recommendation is to use just one process. Going forward all duodenoscopes will be manually cleaned and sterilized, not HLD.

- Will review consumable costs to get an accurate comparison of per cycle costs associated with both sterilization methods. Some costs may be offset by reduced HLD costs.

- Continue to monitor condition of scopes and to log specific repairs associated with reprocessing.

- Compare scope degradation from both ETO and VHP & Ozone
Questions?
References

- Centers for Disease Control and Prevention https://www.cdc.gov/hai/settings/lab/lab-duodenoscope-sampling.html
- CRE Superbug Org http://www.cresuperbug.org/duodenoscope-cre-infection/
- Fibertech Medical http://fibertechmedical.com/support/how-it-works/how-it-works-the-ercp-elevator-channel/