Minimising the Risk of Transmission from Endoscopes

Presented by
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STEAM Consulting Pty Ltd
Declarations

- Opinion Leader Panel Participation, Consulting Services, Invited Speaker Conference Sponsorships
  - Halyard Health, 3M, Johnson and Johnson Medical, Sentry Medical, Thermofisher Scientific, Cantel Medical, Device Technologies, Majac Medical, Draeger Medical, Biomedical Solutions

- No Conflicts to Declare
Learning Outcomes

At the end of this session you should be able to:

- Discuss instances of infection control breaches in endoscopy settings
- Examine the root causes of these reported breaches
- Apply the lessons learned in your workplace
Inadequate cleaning of endoscopes is not ‘news’...

- Researchers for the study analysed 275 flexible duodenoscopes, gastroscopes and colonoscopes.
- They found a cleanliness failure rate of 30 percent, 24 percent and 3 percents for each type of those endoscopes respectively.
Reported EAI rates

According to GENCA (2010) the reported rate of endoscopy associated infection attributable to ‘exogenous’ sources is 1 per 1.8 million procedures.

- Figures quoted from American Society for Gastrointestinal Endoscopy (ASGE)
- More recent estimates published by the ASGE indicate a rate of 1 per 10 million procedures
How accurate are these statistics?

- A paper by Ofstead et al. debunked the widely quoted risk of 1 infection in every 1.8 million procedures by analysing the origin of the data used for this calculation
  - Data was inaccurate
    - Reported number of endoscopy procedures performed per annum not verifiable and was different according to different sources
  - Reporting bias
    - Instances of infection not always reported in the literature
- Unsound methodology

Post endoscopy complications

- A study conducted at Beth Israel Deaconess Medical Centre and Harvard Medical School showed 1% of 18,015 patients that had undergone endoscopy procedures visited the emergency room or hospital within 14 days of their procedure.

- At least 10 of these patients had signs and symptoms indicative of infection:
  - Fever [8], cellulitis of IV site [2] = 0.05% infection rate
  - Abdominal pain [63], back pain [2], nausea & vomiting [3], diarrhoea [2], pneumonia [7] = 0.48% infection rate

Are breaches actually happening?

- Dirlam Langlay et al. (2013) investigated reprocessing lapses in the USA and Canada reported in sources other than peer reviewed literature between January 2005 – June 2012
  - Discovered over 33 separate reported lapses
  - Some lapses covered more than one facility within a larger group
    - 74 Veterans Affairs facilities investigated - had a total of 20 lapses
    - 107 facilities investigated in Pennsylvania – reported a total of 62 lapses

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<table>
<thead>
<tr>
<th>Where &amp; When</th>
<th>Breach type</th>
<th>Duration</th>
<th>Number of patients exposed</th>
<th>Organisms identified / tested +ve</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado 2012</td>
<td>Improper cleaning</td>
<td>1 month</td>
<td>71</td>
<td>Not reported</td>
</tr>
<tr>
<td>North Carolina 2012</td>
<td>No cleaning / sterilization of a channel</td>
<td>5 months</td>
<td>10</td>
<td>Not reported</td>
</tr>
<tr>
<td>Ontario 2011-2012</td>
<td>Multiple cleaning and disinfection errors</td>
<td>9 years</td>
<td>6,800</td>
<td>408 tested positive for Hep B &amp; Hep C % newly diagnosed</td>
</tr>
<tr>
<td>Louisiana 2011</td>
<td>No disinfection</td>
<td>8 months</td>
<td>222</td>
<td>Not reported</td>
</tr>
<tr>
<td>Louisiana 2011</td>
<td>Wrong HLD temperature</td>
<td>8 weeks</td>
<td>360</td>
<td>Not reported</td>
</tr>
<tr>
<td>New Jersey</td>
<td>Unchanged water / cleaning solution</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td>British Columbia 2010-2011</td>
<td>Bioburden allowed to dry prior to cleaning</td>
<td>20 months</td>
<td>536</td>
<td>Pseudomonas infection in 11 patients</td>
</tr>
<tr>
<td>Minnesota 2010</td>
<td>No disinfection of one channel</td>
<td>3 years</td>
<td>2,600</td>
<td>Not reported</td>
</tr>
<tr>
<td>Georgia 2009</td>
<td>Wrong exposure time</td>
<td>17 months</td>
<td>1,300</td>
<td>Not reported</td>
</tr>
<tr>
<td>Florida 2009-2010</td>
<td>Improper cleaning elevator channel</td>
<td>&gt;8 months</td>
<td>191</td>
<td>13 patients including a death K. pneumoniae, E.coli, P. aeruginosa, P. mirabilis, Serratia</td>
</tr>
</tbody>
</table>

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Dirlam Langlay et al. (2013) & Ofstead et al. (2013)
But wait, there’s more...

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<tr>
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<th>Duration</th>
<th>Number of patients exposed</th>
<th>Organisms identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>California 2010</td>
<td>Expired disinfectant / improper disinfection</td>
<td>16 months</td>
<td>3,400</td>
<td>Not reported</td>
</tr>
<tr>
<td>Pennsylvania 2010</td>
<td>No disinfection of one channel</td>
<td>5 years</td>
<td>75</td>
<td>Not reported</td>
</tr>
<tr>
<td>Veteran’s Affairs Hospitals 2003</td>
<td>Contaminated instruments</td>
<td>6 years</td>
<td>10,000</td>
<td>Not reported</td>
</tr>
<tr>
<td>San Diego 2010</td>
<td>Contaminated instruments</td>
<td></td>
<td>3,400</td>
<td>Not reported</td>
</tr>
<tr>
<td>Atlanta 2013</td>
<td>Contaminated instruments</td>
<td></td>
<td>456</td>
<td>Not reported</td>
</tr>
<tr>
<td>Alberta 2007-2008</td>
<td>Improper cleaning, no disassembly, no HLD</td>
<td>4 years</td>
<td>300</td>
<td>MRSA</td>
</tr>
<tr>
<td>Quebec 2013</td>
<td>Improper reprocessing</td>
<td></td>
<td>1,000</td>
<td>Not reported</td>
</tr>
<tr>
<td>Minnesota across multiple sites</td>
<td>7 breaches reported: Improper cleaning, disinfection, reuse of single use devices</td>
<td></td>
<td>6 – 2,600 per incident</td>
<td>Not reported</td>
</tr>
</tbody>
</table>
Other findings  Dirlam Langlay et al. (2013)

- Incorrect programming of AER / AER malfunction
- Incorrect adaptors for AERS or cleaning adaptors resulting in inadequate cleaning and / or disinfection
  - One channel was not HLD for over three years because of manufacturer misinformation!
- Water used instead of a disinfectant
- Expired disinfectant used
- 25% of required amount of disinfectant used
- Chemical colitis due to inadequate rinsing
Other findings  Dirlam Langlay et al. (2013)

- 9 patients acquired C. difficile in infection post endoscopy with a scope that had retained debris
- 3 reports of staff knowingly using an inadequately reprocessed scope
- Storage of contaminated damaged scope amongst processed scopes

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We know that the most common causes of infection control breaches are associated with:

- Reprocessing failures – human and/or equipment factors
  - Non-compliance with reprocessing instructions
    - Delay in reprocessing, failure to clean or connect a channel, not allowing sufficient dwell time, not reprocessing cleaning adaptors, incorrect reprocessing of accessory items, inadequate drying procedures, inadequate training, lack of time, lack of staff
  - Inappropriate use of cleaning agents/high level disinfectant
    - Failure to activate, incorrect temperature, incorrect concentration, exceeded expiry dates
  - Equipment malfunction
    - Water quality, flush pumps, connectors

- Endoscope design flaws or defects
  - Different models, different brushes, different cleaning techniques
  - Undetected damage
Notes from the field...
Thankfully times are changing...

- The recent breaches involving duodenoscopes have highlighted that the risks of transmission of infection via endoscopes continues to exist despite:
  - robust endoscope reprocessing guidelines
  - pressure on endoscope manufacturers to VALIDATE their reprocessing instructions

- The studies conducted by Ofstead, Dirlam-Langley, Alfa and others are contributing to an increasing body of evidence that confirms endoscope reprocessing is an area requiring specialist knowledge and skills in order to ensure patient safety

- Recent US reprocessing standards and guidelines now calling for some form of cleaning verification tests prior to endoscopes undergoing HLD

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Some recent publications…

- **Control Group**
  - Standard reprocessing procedure
  - HLD using 2.5% Glutaraldehyde
    - $A = \text{initial inspection}$
    - $B = \text{2 months later}$

- **Intervention Group**
  - Standard reprocessing procedure, ATP test, re-cleaned if test above acceptance criteria
  - HLD using Peracetic Acid
    - $C = \text{initial inspection}$
    - $D = \text{2 months later}$

- Ofstead et al., “Assessing residual contamination and damage inside flexible endoscopes over time.” AJIC 2016 Article in Press
Ofstead et al. “Assessing residual contamination and damage inside flexible endoscopes over time.” AJIC 2016 Article in Press
Use of anti-foaming agents in endoscopy

- **Simethicone:**
  - contains silicone
  - is not soluble in water or alcohol
  - is hydrophobic
  - is not sterile and there have been recalls of these products due to contamination with moulds and other microorganisms such as *Burkholderia cepacia*

- Endoscope manufacturers advise against its routine use.

Ofstead et al. (2016) “Simethicone residue remains inside gastrointestinal endoscopes despite reprocessing.” (44) 1237-40
Simethicone residues

Residual fluid observed inside patient-ready endoscopes that had been reprocessed and alcohol / air purged

Simethicone products also contain carbohydrates and in some cases xanthan gum and these residuals pose a risk of contribution to biofilm formation

Ofstead et al. (2016) “Simethicone residue remains inside gastrointestinal endoscopes despite reprocessing.” (44) 1237-40

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Some other factors for consideration

- Biofilm formation is influenced by the presence of residual organic material and moisture
  - Multiple papers published by Vickery et al., Pajkos et al., Alfa et al., Ren-Pei et al.

- The age of the endoscope impacts on the efficacy of reprocessing
  - Ofstead et al. (2016) Residual contamination found on endoscopes in an ambulatory surgery center. Poster AORN Conference

Pajkos et al. (2004) “Is biofilm accumulation on endoscope tubing a contributor to the failure of cleaning and decontamination?” JHI (58) 224-229
What isn’t being done properly?

Direct observation found guideline nonadherence with manual cleaning of GI endoscopes (69 total):

- 57% did not brush all channels & components
- 55% did not dry with forced air
- 22% leak tested with sudsy water
- 16% skipped air purge after detergent flush
- 14% did not flush with alcohol
- 10% skipped final wipe down

Multiple steps skipped 45% of the time

99%

1% or more steps skipped or done incorrectly

Where to from here?
Cleaning verification strategies

Enhanced visual inspection

ATP test systems

Protein / Haemoglobin / carbohydrate test systems

www.healthmark.info/

www.ruho.com

www.hygiiena.com/

www.solutions.3m.com.au/

Validation of AERs – ISO15883-4

- Channel blockage / obstruction tests
- Channel non-connected tests
- Leak test failure / non-connection tests
- Cleaning efficacy – Artificial test soils
- Cleaning efficacy – patient soiled endoscopes
- Disinfection efficacy – Operational and performance
- Temperature throughout process
- Self-disinfection tests
Forced air drying / storage cabinets

- Dry endoscopes discourage biofilm formation
- Now a European Standard exists for forced air storage cabinets EN16442
- Horizontal or vertical designs

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State of the art endoscopy reprocessing design

New endoscopy reprocessing facilities should be designed to eliminate risks of cross-contamination
What else can you do?

- Ensure all your staff are trained and assessed as competent prior to working unsupervised
  - Even casual and agency staff must undergo competency assessment
- Ensure competence is maintained over time and periodically reassessed
  - Recommended annual assessment [SGNA 2016]
- Ensure you have documented policies and procedures and these are reviewed and updated on a regular basis
- Conduct random ‘spot checks’ or audits to make sure staff are following policies / instructions for use
- Make sure that manufacturer’s reprocessing instructions are obtained and followed
  - Especially for loan endoscopes!
Or in other words...

- Follow the GENCA / GESA Guidelines
- Recognise your professional accountability
- Make sure you keep up to date with the latest trends
Thank you

“One’s mind, once stretched by a new idea, never regains its original dimensions.”

— Oliver Wendell Holmes