Validation Of An Endoscope Drying Cabinet For Extended 7 Day Storage Of Non-Channelled Endoscopes - A Clinical Perspective.

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About Us
Use of Non-channelled Scopes in CUH

- ENT OPD attendance /4000 annually.
- National Paediatric Airways Surgical Clinic.
- Nasenoscopes- diagnostic and evaluation.
- Tracheostomy/Craniofacial/ Plastics
- Speech and Language Therapy
- 60% Decontamination activity.
Studies /standards focus on complex multi-channelled endoscopes.

- Non-channelled nasendoscopes are less complex devices.
- No biopsy or working channels.
- Not passed into highly contaminated areas of the body.

(Swift, 2010).
Risks Associated with Channelled Endoscopes

The “presence, during storage, of potentially contaminated water in endoscope channels may promote bacterial proliferation and bio film formation” (Pineau et al., 2007)
Endoscopy Standards
Standards/ Guidance for Storage?

- pr EN ISO 16442 (2012)
- NFS 98-03 : 2008
- CFPP 01-06:2012
- Guidance BSG 2008
- Guidance ENT UK 2010
Advisory time limits of 72 hours set by manufacturers.

Where appropriate quality assurance data is available, this repeat endoscope reprocessing at the start of each list not necessary.

Reprocess after a 72 hours even if the scope has not been used on a patient (ENT UK 2010).
Is 72 hour Storage Enough?

NON CHANNELLED ENDOSCOPE USE ENT AND ASSOCIATED PROCESSING 2011, 2012 Using 72 hour Storage time

NUMBER OF NON CHANNELLED ENDO SCOPES

USE 2011 PRO 2011 USE 2012 PRO 2012
Our Experience

ENT Non Channelled Nasendoscope Processing and Usage Data @ maximum 72 hours storage

<table>
<thead>
<tr>
<th>4 Month Period</th>
<th>Processed</th>
<th>Used</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>n=1393</td>
<td>n=477</td>
<td>3:1</td>
</tr>
<tr>
<td>2012</td>
<td>n=1390</td>
<td>n=455</td>
<td>3:1</td>
</tr>
</tbody>
</table>

25% of scopes were reprocessed to meet out of hours/ weekend needs i.e. clean scopes are reprocessed on Friday afternoon so they are available for clinician use over the weekend/ BH (72 hour storage)
New Developments - 31day Storage

Studies
- extending the storage period of channelled endoscopes from the accepted norm of 72 hours (Pineau et al., 2007) to 30 days (Smart et al., 2011; Rogers & Stapleton, 2011; Walters, 2012).

Results
- Surrogate devices which had been stored in a SCHE for 72 hours had the same status as those which had been stored for up to 31 days.

Note
- Findings from the study were based on storage of scopes under controlled (ideal) laboratory test conditions. Should be validated in the clinical environment (CFPP 01-06:2012)
Recommendations -31 Days

- AORN and Association for Professionals in Infection Control and Epidemiology (2010) - “In the interests of utmost caution espouse a maximum storage time of 5 and 7 days”.

- ASGE (2011) - “Although reuse of endoscopes within 10 to 14 days of high-level disinfection appears to be safe, the data are insufficient. This interval remains poorly defined and warrants further study”.

AORN Inc; (2010) Recommended practices for cleaning and processing endoscopes and endoscope accessories. Perioperative standards and recommended practices; p. 405-19.
Drivers for Change

- Availability for clinician use. (Swift 2010).
- Appearance of Scopes - Visual Quality
  “harsh chemicals have a negative effect on the appearance and clarity of the optics of the endoscopes” (Swift 2010).
- Time Labour cost - reduced staffing/ lean working ethos/ efficiencies.
- Repairs (Anquilo, 2011; Saxelby, 2012).
- (Pineau, 2011). Significant savings, relating to costs for repairs, labour, chemicals, energy usage and equipment upkeep, can be made if the storage time for non-channelled endoscopes is increased.
Study

- Approval?
- Ethical Do you take SCHE and scopes out of service?
- Choose locations/ risk points
- Minimum of 3 scopes
- Document Scope Size/ Serial Number/ Hanger
- Label scopes
- Use Aseptic Technique
- Over period of year assess all locations & scopes.
Performance Requirements

- Microbiological Testing
  - Swabs - surface contamination on scopes
  - Contact Plates - contamination on the inside surfaces of the SCHE
  - Settle Plates - airborne microbial contamination

- Additional Requirements
  - Particle Count/ air changes - air quality and cabinet recovery time.
  - Pressure differential – maintaining clean environment.
  - Relative Humidity and Temperature Control
Contact Plates

Methods:

- Each internal side of the cabinet - samples 1 & 2
- The back of the cabinet - sample 3
- The top of the cabinet - sample 4
- The floor of the cabinet - sample 5
Settle Plates

**Methods:**
- Lay on the floor of the cabinet.
- Expose for a minimum of 1 hour.
Analysis

- Incubated for 5 days at 30\(^\circ\)C.
- Plates were analysed on day 3 and 5 for the presence of bacterial (TSA) and fungal (SAB) colonies.
- The number of colonies (CFU/contact, settle plate or swab)
- Where applicable, identification to species level were reported.
Results

Table 12. Performance Requirements of SCHE (NS = Not Specified) Colour Code

<table>
<thead>
<tr>
<th>Performance</th>
<th>pr EN 16442 Requirements</th>
<th>CFPF 0106 Requirements</th>
<th>Cabinet Specification</th>
<th>Actual onsite Cabinet Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air Changes/ Hour</td>
<td>10</td>
<td>NS</td>
<td>NS</td>
<td>20</td>
</tr>
<tr>
<td>Particle Count</td>
<td>Class 3 in operation</td>
<td>NS</td>
<td>NS</td>
<td>Class 6 in operation</td>
</tr>
<tr>
<td>Temperature Control</td>
<td>&lt;60°C</td>
<td>NS</td>
<td>&lt;40°C</td>
<td>28°C</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>Within Manufacturer Specification or &lt;1-30%</td>
<td>NS</td>
<td>20-85%</td>
<td>34%</td>
</tr>
<tr>
<td>Pressure within the Cabinet</td>
<td>10 Pa</td>
<td>5Pa</td>
<td>NS</td>
<td>2 Pa</td>
</tr>
<tr>
<td>Surface Contamination SCHE</td>
<td>&lt;25 CFU/25cm²</td>
<td>NS</td>
<td>NS</td>
<td>0 cfu/0 Fungi</td>
</tr>
<tr>
<td>Contact Plates</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Airborne Microbial Contamination Within SCHE</td>
<td>&lt;23 cfu / plate with no pathogenic organisms no Aspergillus or filamentous fungi</td>
<td>NS</td>
<td>NS</td>
<td>&lt;6cfu/ 1 Fungi Penicillium</td>
</tr>
<tr>
<td>Settle Plates</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endoscope Drying</td>
<td>&lt;3 Hours</td>
<td>NS</td>
<td>NS</td>
<td>Scopes Dried in EDU Visual Inspection</td>
</tr>
<tr>
<td>Microbial Contamination of the endoscope</td>
<td>&lt;10cfu / endoscope and no Aspergillus or filamentous fungi</td>
<td>NS</td>
<td>NS</td>
<td>&lt;2 cfu/0 fungi</td>
</tr>
</tbody>
</table>

When the doors are open the air flow through the HEPA filter is still present resulting in a clean air stream in the upper part of the storage compartment.

This air movement is not that strong it will reduce the risk of contamination for the whole cabinet, but is reduces the entrance of contaminated air for the period in which the door is opened.
<table>
<thead>
<tr>
<th>Cabinet Details</th>
<th>Doors Closed after 3 minutes</th>
<th>Doors Closed after 1 minutes</th>
<th>Doors Closed after 10 seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recovery Time Minutes</td>
<td>Class 5 07</td>
<td>Class 5 05</td>
<td>Class 5 05</td>
</tr>
</tbody>
</table>

The lowest class drop when the doors were opened was to a class 8
Outcomes

<table>
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<td>3:1</td>
</tr>
<tr>
<td>2013</td>
<td>n=599</td>
<td>n=390</td>
<td>1.5:1</td>
</tr>
</tbody>
</table>

Processing and Usage Data @ maximum 168 hours storage

Previous Ratio  3:1
New Ratio 1.5:1
>50% Decrease Processing: Use
The Good News

• 2012 Repairs
• 12 Repairs = €15,896 ex VAT

• 2013 Repairs
• 6 Repairs = €7,839 ex VAT

• Saving
• €8,000
Factors Influencing Performance

- Type of scope.
- The location of the cabinet may influence the cabinets HEPA filter efficacy (Kerry & Kear 2012) may increase risk of environmental contamin.
- Environmental control, are there cleaning schedules in place?
- Validated decontamination process prior to storage in the SCHE.
- Reduce transfer time.
- SOP’s standardise practice for the handling of scopes—Sterile or non sterile gloves? Have staff been trained?
- SCHE cleaning practices/ sign off?
- Traceability
- IMS
Recommendations

Quality Assurance

- Validate in situ-
- Define Validation Parameters
- Ensure reproducibility of findings -controlling the decontamination life cycle.
- Investigate non conformance to parameters.
- Ensure test persons are appropriately attired and trained to take samples.
- Revalidate 1/4ly initially.
- Audit Practice.
Recommendations

Reports
- Calibration Certificates
- Certificate of Training
- Microbiological Testing Results
- Air Quality & Recovery Rate - Air changes
- Others
- Document parameters of each test.
- Servicing History
Thank You for Listening
Any Questions?