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CHILDREN'S UNIVERSITY HOSPITAL
140 YEARS
Caring for Sick Children

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

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About Us

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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.

Research

Studies /standards focus on complex multi-channelled endoscopes.

- Non-channelled nasendoscopes 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

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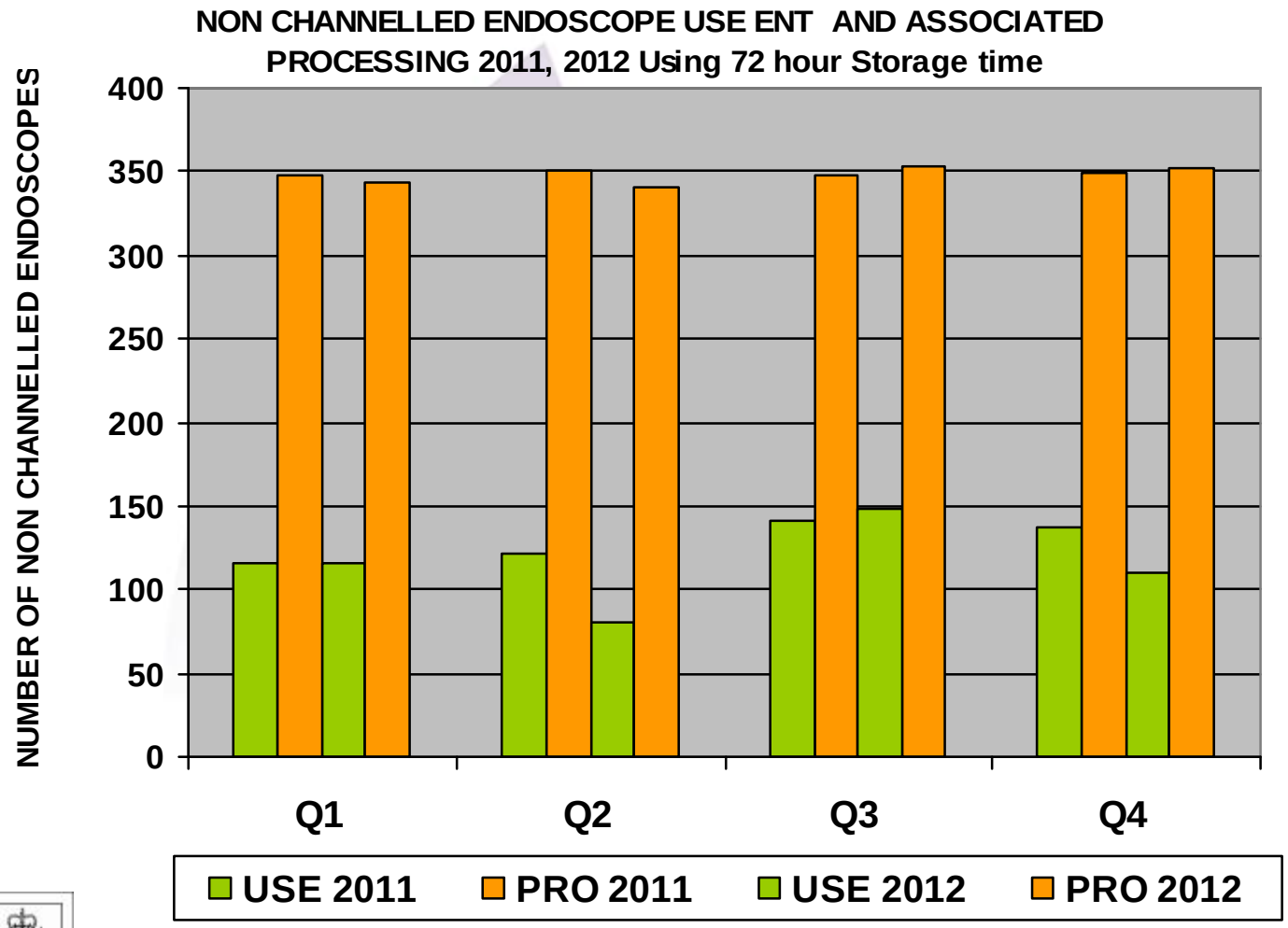
Standards/ Guidance for Storage?

- ? pr EN ISO 16442 (2012)
- ü NFS 98-03 : 2008
- ü CFPP 01-06:2012
- ü Guidance BSG 2008
- ü Guidance ENT UK 2010

Current Practice

- Advisory time limits of 72 hours set by manufacturers.
- (BSG 2008)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?



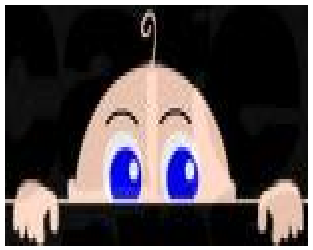
Our Experience

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

4 Month Period	Processed	Used	Ratio
2011	*n*=1393	*n*=477	3:1
2012	*n*=1390	*n*=455	3:1

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



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Studies

- Ø 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

- Ø 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

- Ø 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)

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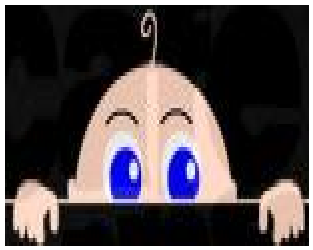
Recommendations -31 Days



- 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.

Alvarado CJ., Reichelderfer M. APIC (2000) guidelines for infection preventionand control in flexible endoscopy. *Am J Infect Control* ;28:138-55

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 serv
- 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

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

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

Contact Plates

Methods:

- Each internal side of the cabinet- samples1&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^{o}C.
- Plates were analysed on day 3 and 5 for the presence of bacterial (TSA) a 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 Key **Green** = Pass **Red** = Fail **Orange** = 5% Deviation from the Standards

Performance	pr EN 16442 Requirements	CFPP 0106 Requirements	Cabinet Specification	Actual onsite Cabinet Performance
Air Changes/ Hour	10	NS	NS	20
Particle Count	Class 8 in operation	NS	NS	Class 6 in operation
Temperature Control	<60°C	NS	<40°C	28°C
Relative Humidity	Within Manufacturer Specification or <=30%	NS	20-85%	34%
Pressure within the Cabinet	10 Pa	5Pa	NS	2 Pa
Surface Contamination SCHE Contact Plates	<25 CFU/25cm²	NS	NS	0 cfu/0 Fungi
Airborne Microbial Contamination Within SCHE Settle Plates	<25 cfu / plate with no pathogenic organisams no *Aspergillius* or filamentous fungi	NS	NS	<6cfu/ 1 Fungi Penicillium
Endoscope Drying	<3 Hours	NS	NS	Scopes Dried in EDU Visual Inspection
Microbial Contamination of the endoscope	<10cfu / endoscope and no *Aspergillius* or filamentous fungi	NS	NS	<2 cfu/0 fungi

Pressure Differential

- 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

Results- Recovery Rate

Cabinet Details	Doors Closed after 3 minutes	Doors Closed after 1 minutes	Doors Closed after 10 seconds
Recovery	Class 5	Class 5	Class 5
Time Minutes	07	05	05

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

Outcomes

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Processing and Usage Data @ maximum 168 hours storage

Period	Processed	Used	Ratio
2012	*n*=1390	*n*=455	3:1
2013	*n*=599	*n*=390	1.5:1

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

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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 contam.
- 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

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