Protecting our patients – assessing and managing risks to ensure effective reprocessing of bronchoscopes

Presented by

Terry McAuley

STEAM Consulting Pty Ltd

terry@steamconsulting.com.au

In this presentation

- Review the areas in health care facilities where bronchoscopes may be used
- Examine the methods by which bronchoscopes may be reprocessed
- Describe the risks associated with inadequate bronchoscope reprocessing
- Discuss best practices in bronchoscope reprocessing

Where are bronchoscopes used?

- Accident and Emergency
- Intensive Care
- Outpatients clinics
- Operating Room

Why are bronchoscopes used?

As an aid to intubation

To remove foreign bodies causing airway obstruction

As a diagnostic tool

As part of interventional procedures

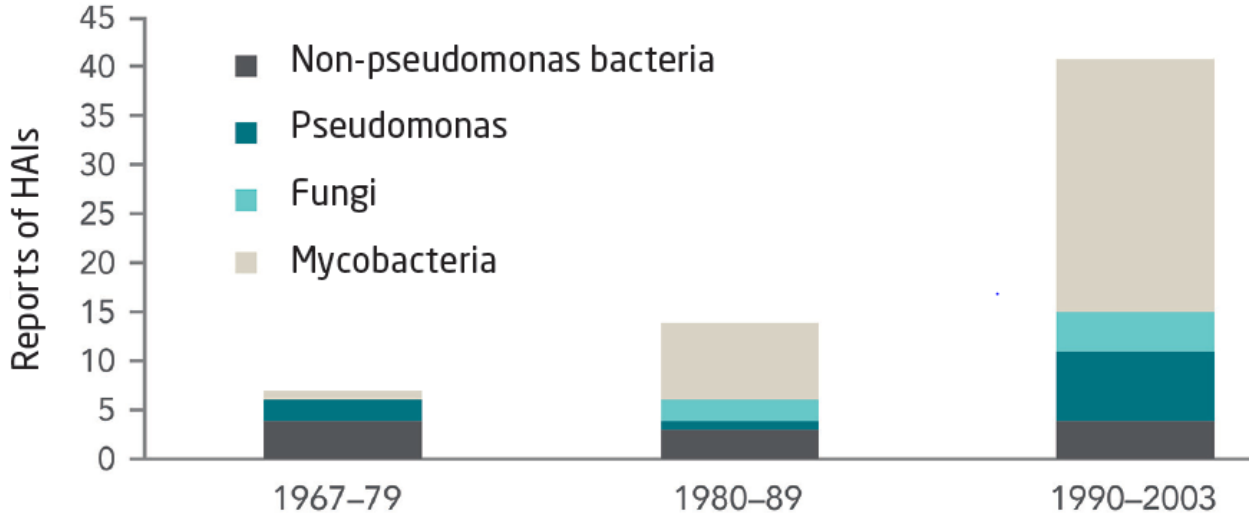


Figure 1: Reports of HAIs associated with contaminated bronchoscopes |

Do bronchoscopes transmit infectious agents?

Bach, E. (2019) *Reprocessing bronchoscopes – is it time for a change?* Steri World Vol 2 pp114-117

In 2015, the FDA received 109 reports of microbial transmission and infection associated with the use of bronchoscopes

A safety notice was released and advised that adverse events may still occur despite reprocessing being consistent with the manufacturer's Instructions for Use [IFU]

Some bronchoscopes showed persistent contamination despite correct reprocessing procedures being followed

Pseudo-outbreaks

- Pseudo-outbreaks of infection associated with bronchoscopy procedures are frequently reported in the literature
- Causes are sometimes related to a bronchoscope and / or an automated endoscope reprocessor being contaminated with an organisms and subsequent pathology findings report the organism is present in patient specimens

Glutaraldehyde resistance

- In Brazil 3,000 patients were infected with a bacteria resistant to glutaraldehyde
- Organisms resistant to glutaraldehyde include atypical *Mycobacterium spp; Cryptosporidium parvum* and *Pseudomonas aeruginosa*

- Bach 2019; Kovaleva, J. *et al.* (2013) *Transmission of Infection by Flexible Gastrointestinal Endoscopy and Bronchoscopy.* Clinical Microbiology Reviews Vol. 26 No. 2 pp231-254

After manual cleaning, 100% of bronchoscopes still had residual contamination

Protein residues

100% of bronchoscopes showed irregularities upon visual inspection

After processing 58% of bronchoscopes grew microorganisms

Organisms cultured included mould, oral flora, *P. aeruginosa* and also gut organisms such as *E. coli* and *Shigella*

A brand new bronchoscopes was tested for protein and microorganisms before and after manual cleaning

The manual cleaning process increased protein levels 4-fold and a small number of microorganisms were cultured [8 cfu]

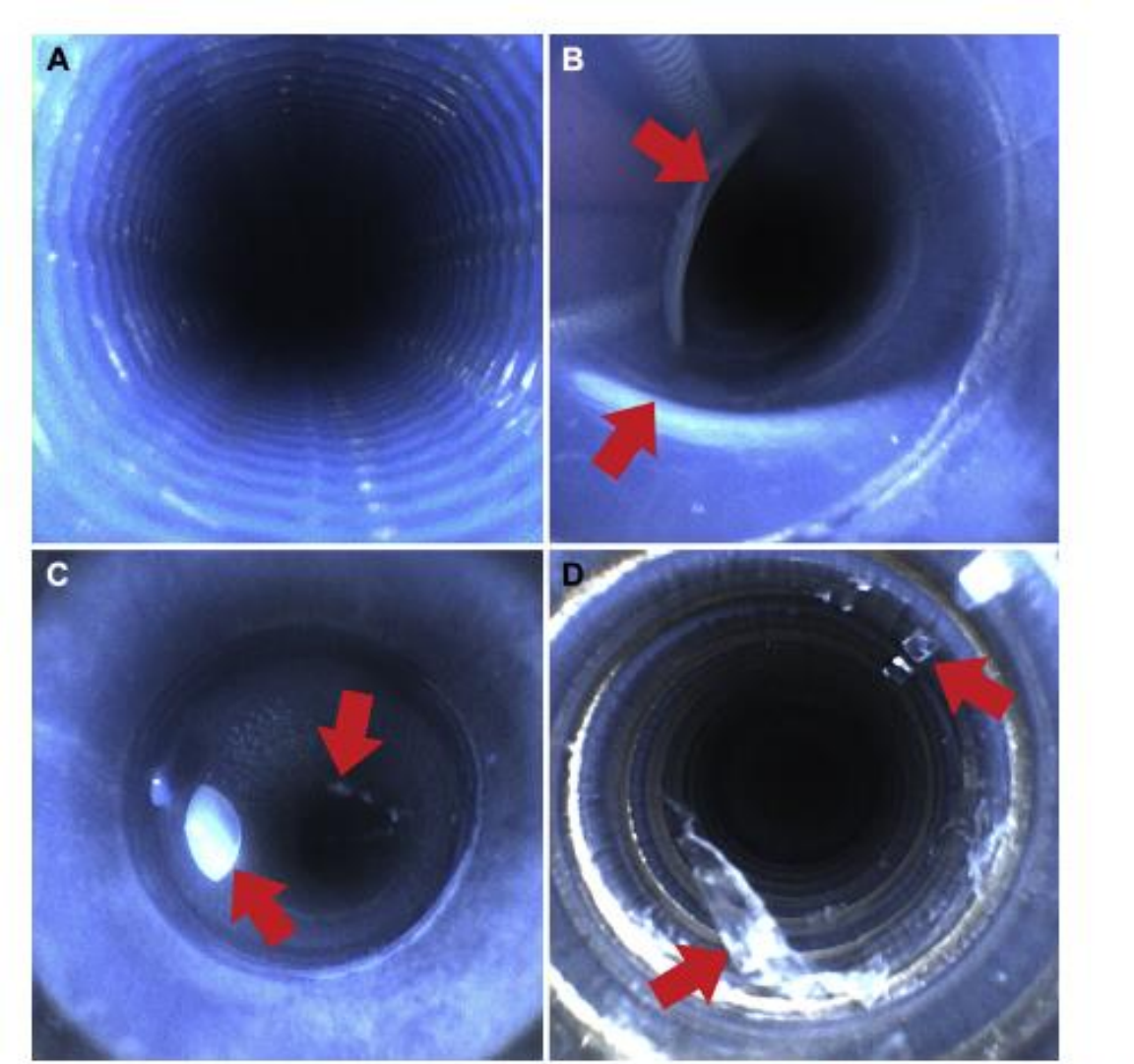
Ofstead *et al.* (2018) *Effectiveness of Reprocessing for Flexible Bronchoscopes and Endobronchial Ultrasound Bronchoscopes* Vol. 154 No. 55 pp 1024-1034

In the study by Ofstead…

- Three hospitals participated
  - One facility exceeded national guidelines in bronchoscope reprocessing yet the bronchoscopes were culture positive
  - The two other hospitals had multiple breaches in reprocessing
    - One skipped leak testing and most manual cleaning because the AER had this in the cycle
    - One disabled the AER cleaning stage to save time
    - Filters banks on the AERs were not monitored and may not have been changed as per the IFU
    - Staff reused cloths for wiping down / drying bronchoscopes prior to storage
    - Channels were not dried correctly prior to storage
    - Gloves were not changed between dirty and clean tasks in the reprocessing area
    - No physical separation of soiled and clean in two hospitals
    - The drying cabinets weren't clean and in one the drying fans were not operational
    - Staff handled processed bronchoscopes with bare hands

Visual inspection by borescope

- Risks for biofilm development were significant
- Defects in channels
- Debris and residues in channels
- Discolouration in channels
- Oily residues noted
  - Use of silicone based sprays / lubricants
  - Use of antifoaming agents



A, New bronchoscope channel compared with patient-ready bronchoscope channels with (B) dents, (C) residual fluid, and (D) flame
rows in (B), (C), and (D) indicate the location of the irregularities observed.

Ofstead 2018

What level of reprocessing for bronchoscopes?

Semi-critical

- Cleaning followed by high level chemical disinfection

Critical

- Cleaning followed by sterilisation
  - Bronchoscopes require a low temperature sterilisation method

In a recent survey conducted in Germany…

Bach (2019)

- The survey conducted by Bach showed that 97% of hospitals sterilised their flexible cystoscopes but only 42% of the hospitals sterilised their flexible bronchoscopes despite having a low temperature sterilisation system available
  - The rationale was that the cystoscopes were entering a "sterile body cavity"
  - I was taught that the lungs were considered a "sterile body cavity"
  - Recently published literature now indicates that both bladder and lungs may have their own microbiome
    - Thomas-White *et al.* 2016; Dickson & Huffnagle 2015

Table 1: International Guidelines	
Country	**Recommended guideline**
USA (FDA) [7]	Endoscopes used in sterile body cavities as well as all endoscopic accessories should be sterilized. Devices intended for semi-critical use should also be sterilized if their constructional design permits that.
Australia [8]	Semi-critical flexible endoscopes should preferably be sterilized.
Japan [9]	Semi-critical flexible endoscopes should preferably be sterilized but closely monitored HLD is currently permitted.
Canada [10]	Sterilization of semi-critical devices is deemed optimal.
Germany [2]	Bronchoscopes are advanced into normally sterile areas of the bronchial system. That implies more stringent requirements to assure a low microbial count (sterility).

Bach (2019) *Reprocessing bronchoscopes – is it time for a change?* Steri World Vol 2 pp114-117

Reasons why hospitals don't sterilise bronchoscopes

- Lack of inventory / cost of increasing inventory
- Decentralised reprocessing at point of use
- Logistics of centralization of reprocessing
- Low volume usage
- No low temperature sterilisation system

Managing risks

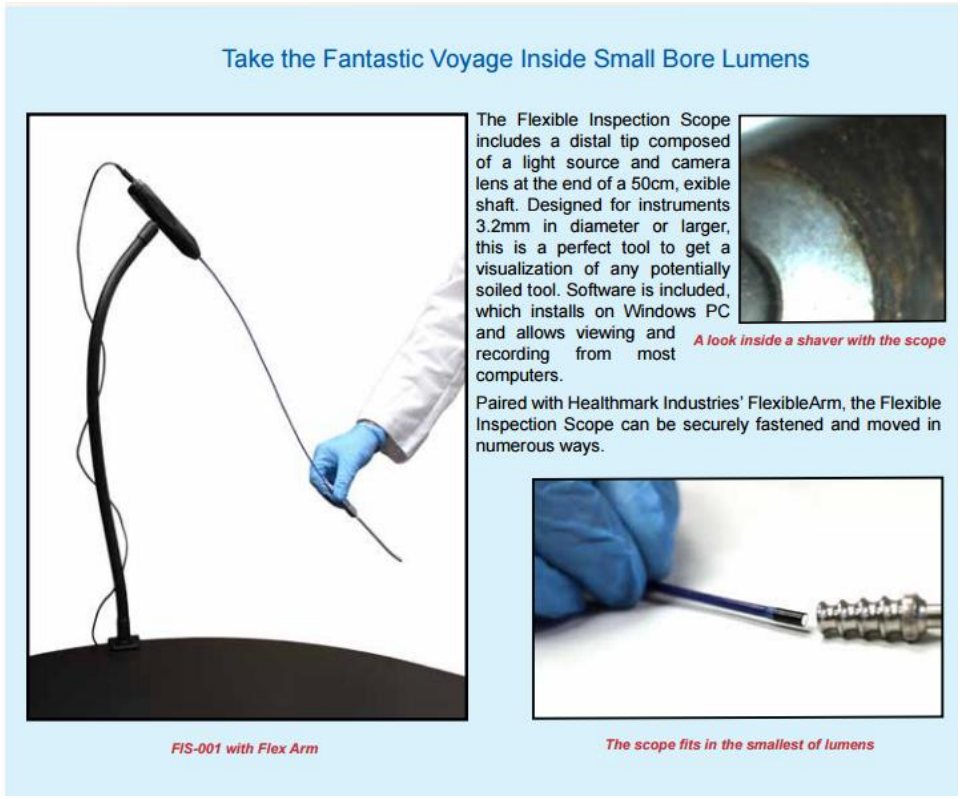
The evolution of the patient safety movement has changed the way we approach health care delivery

Health care is now more patient focussed

The goal is to prevent adverse events / avoidable harm occurring to patients during their care

Risk assessment is crucial to identifying and effectively managing the risks that exist in our healthcare system

Cleaning verification strategies



www.healthmark.info/

Enhanced visual inspection

www.ruhof.com

ATP test systems

www.hygiena.com/

www.invitro.com.au/

www.solutions.3m.com.au/

Protein / Haemoglobin / carbohydrate test systems

Current thinking

- Endoscopes undergoing high level disinfection should be processed in an automated cleaning and disinfection system
  - A washer-disinfector complying with ISO15883-1 and ISO15883-4
- Endoscopes undergoing low temperature sterilisation should be processed in an automated cleaning and disinfection system* prior to sterilisation

  * A washer-disinfector complying with ISO15883-1 and ISO15883-4

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

www.spypach.com

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

www.gallay.com.au/

www.medivators.com/

New endoscopy reprocessing facilities should be designed to eliminate risks of cross-contamination

Lessons to be learned

- Don't forget the bedside clean
- Don't forget the wet and dry leak test
- Manually clean the bronchoscope before processing in the AER
- Do not turn off the cleaning stage in the AER to save time
- Check filter pressures on the AER and change filters when required
- Dry bronchoscopes properly prior to storage or preferably use an EN16442 compliant storage cabinet
- Handle processed bronchoscopes with clean gloves
- Undertake microbiological surveillance of bronchoscopes and AERs
  - In Australia we conduct this monthly for AERs and HLD bronchoscopes
  - If a scope has been terminally sterilised frequency of scope surveillance is reduced
- Validate the processes delivered by equipment and monitor on an ongoing basis

What else can you do?

- Make sure that manufacturer's reprocessing instructions are obtained and followed
  - Especially for loan bronchoscopes!
- Ensure all your staff are trained and assessed as competent prior to working unsupervised
- Ensure competence is maintained over time and periodically reassessed
- 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

Thank you