Concern about cross-contamination from reusable bronchoscopes

In its March 9, 2015 issue the Los Angeles Times reported that four patients at the Cedars-Sinai hospital had been infected with a multi-resistant microbe linked to a contaminated medical scope. 67 others may have been exposed. A similar outbreak was being investigated at UCLA's Ronald Reagan Medical Center where seven patients had been infected, two of whom died and up to 179 patients may have been exposed.[2, 3, 13]

The story received significant attention worldwide.

An accident waiting to happen?

Federal lawmakers, consumer advocates and patients' families have criticized both the regulators and manufacturers for failing to act sooner.

FDA intervention

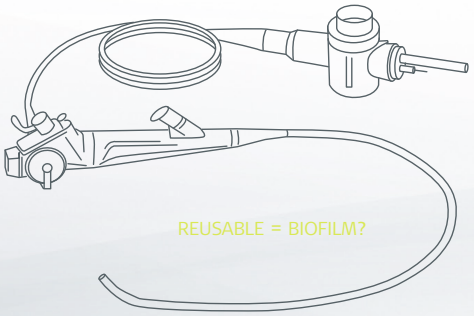
On March 12, 2015 the U.S. Food and Drug Administration announced new actions to enhance the safety of reusable medical devices and address the possible spread of infectious agents between usages.[4, 5, 15]

Since then the FDA has issued a new guidance on reprocessing of medical devices, hosted a 2-day seminar discussing the transmission of infection associated with endoscopes, issued warnings to duodenoscope manufacturers for lack of filing MDR reports, as well as issued a safety communication on the risk of infection associated with reprocessed flexible bronchoscopes.[15]

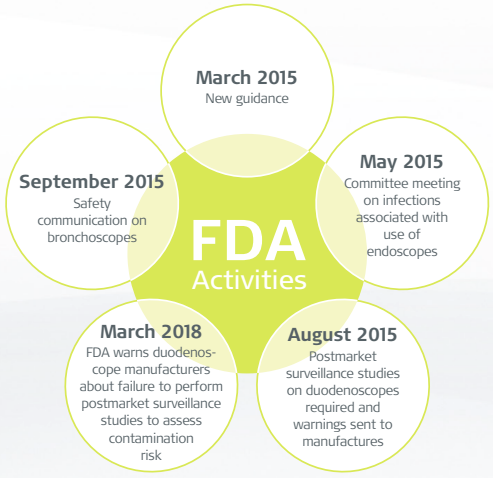
Furthermore, in March 2018 FDA warned duodenoscope manufacturers about failure to perform postmarket surveillance studies to assess contamination risk.[17]

Biofilm risk in reusable endoscopes

Implementation of microbiological surveillance of endoscope reprocessing is appropriate to detect early colonization and biofilm formation in the endoscope and to prevent contamination and infection in patients after endoscopic procedures.[1]



Significant health risk



Multi-resistance ups the stakes

More nosocomial infection and pseudo-infection outbreaks have been linked to contaminated endoscopes than to any other medical device.[6]

New challenges

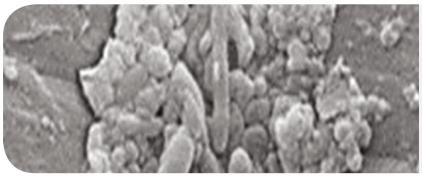
Intensivists, hygiene nurses and others involved in infection control have been aware of the risk of contamination and infection of patients under medical care for many years. The arrival of Multi-Drug Resistant Organisms (MDRO) such as Carbapenem-resistant Enterobacteriaceae (CRE) or multidrug resistant *Pseudomonas aeruginosa* constitutes a new challenge when it come to the risks involved for patients, physicians, hospitals and clinics.

Bronchoscopes pose a particular challenge

Flexible bronchoscopes are difficult to clean and disinfect due to the long and narrow channel. The question is whether it is possible to ensure 100% disinfection of each scope. Despite following cleaning instructions persistent device contamination has been seen, and failure to meticulously follow cleaning instructions is likely to lead to contaminated scopes.[1, 15]

Routine cleaning does not effectively remove biofilm from endoscope channels. Biofilm was present in 13 out of 13 endoscopes despite appropriate cleaning procedures being followed in the channels of 12/13 instruments.[8]

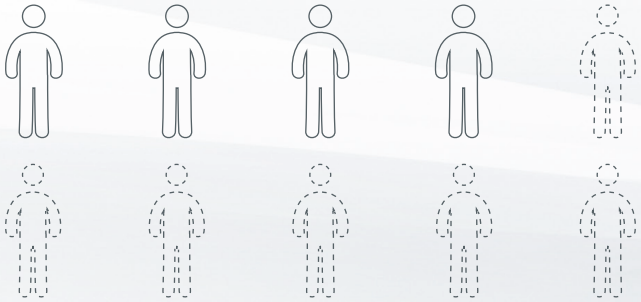
Accordingly, another study found microbial growth in 71% of ready to use endoscopes. The continues rate of contamination incidences make experts call for a shift to sterilization or single-use endoscopes.[18-20]



"Routine cleaning does not effectively remove biofilm from endoscope channels."[8]

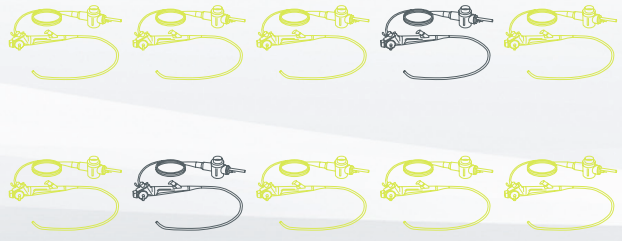
Hidden threat

CRE contributes to the cause of death in up to 44% of infected patients.[10]



Disinfection challenged

Flexible bronchoscopes are difficult to clean and disinfect due to the long narrow channel.



True incidence is likely under-recognized

The true incidence of cross-contamination and infection during flexible bronchoscopy is likely under-recognized due to underreporting and inadequate or no surveillance.[1, 7]

In an overview of infections associated with flexible bronchoscopy from 2013[1] 50 studies were identified. In 30 out of the 50 studies published the same contaminant was found in the patient as well as in the bronchoscope. A total of 569 contaminated patients and 115 infected patients (20.21%) could be directly related to contaminated bronchoscopes.[1]

Financial impact

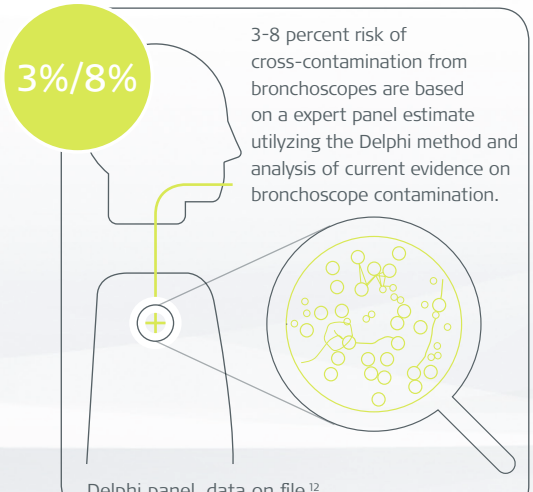
An independent expert panel, using the Delphi method, revealed a 3% mean risk of cross-contamination from bronchoscopes.[12] This is a conservative estimate since a systematic literature review of 13 studies including 1664 samples finds a weighted risk of cross-contamination of 8.7%(*). [21-33]

As the majority of patients contaminated from bronchoscopes suffer from pneumonia[1, 11] costs linked to ventilator associated pneumonia (£15.000) are used as the clinical impact in the calculation of costs. Combining the 3% or 8% risk of cross-contamination with the 20,21% infection risk, the overall costs associated with cross-contamination can be calculated. See calculations in figure below.

In a recent Pseudomonas outbreak, the health-care costs directly related to the diagnosis, treatment, and hospitalization of the six affected patients were estimated to be £215.000 or £35.800 per patient.[16]

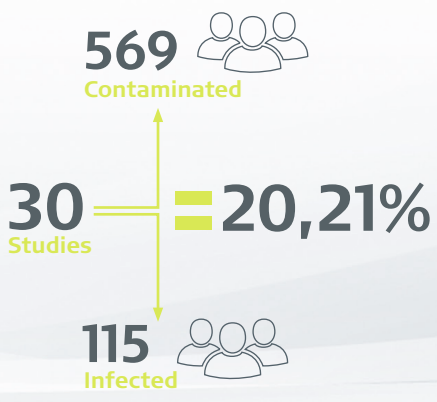
(*) "Search query: "Endoscope contamination" in PubMed. Inclusion criterion: published in or after 2008; have conducted tests for microbiological growth on bronchoscopes; the papers state the amount of positive or negative samples or bronchoscopes included".

Bronchoscope contamination investigated



Delphi panel, data on file [12]

Risk of infection



Kovaleva et al. Review 2013[1]

Bottom line

Cross-contamination costs per use associated with reusable bronchoscopy

1*0.03 OR 0.08*0.2021*£15.000

=

£91 (£243)

One bronchoscopy times the 3% or 8% risk of cross-contamination times the 20,21% risk of infection (calculation based on Kovaleva et al.[1]) times the cost of a ventilator-associated pneumonia (VAP) $25.149.[11]

Sterility straight from the pack

Outbreaks have led physicians to question the safety of bronchoscopy. Endoscopes, including bronchoscopes, are the medical devices most frequently associated with outbreaks of nosocomial infections.[9]

The risk of cross-infection with multi-resistant microbes in the ICU during bedside bronchoscopy procedures can be significantly reduced by using a sterile single-use bronchoscope.

Ambu's single-use aScope™ 4 Broncho minimizes the risk of cross-contamination in the ICU by ensuring sterility straight from the pack, thus avoiding residual biofilm caused by inadequate automatic endoscope reprocessing.

Read more about Ambu® aScope™ 4 Broncho at **visualisation.ambu.com**

1 Kovaleva J1, Peters FT, van der Mei HC, Degener JE. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clin Microbiol Rev. 2013 Apr;26(2):231-54. doi: 10.1128/CMR.00085-12.

2 Los Angeles Times. March 9, 2015.

3 Fierce Medical Devices. March 5, 2015. New superbug outbreak tied to endoscope devices surfaces amid FDA scrutiny. March 5, 2015.

4 FDA News Release. FDA releases final guidance on reprocessing of reusable medical devices. March 12, 2015.

5 Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff. FDA. March 17, 2015.

6 Seoane-Vazquez E et al. Exogenous endoscopy-related infections, pseudo-infections, and toxic reactions: clinical and economic burden. Current Medical Research and Opinions, Vol 22, No. 10, 2006, 2007-2012.

7 Mughai MM et al. Reprocessing the Bronchoscope: The Challenges, Seminars in Respiratory and Critical Care Medicine/volume 25, number 4, p. 443-449, 2004.

8 Pajkos et al. Is biofilm accumulation on endoscope tubing a contributor to the failure of cleaning and decontamination? Journal of Hospital Infection 2004, 58:224-229.

9 Srinivasan A, Wolfenden LL, Song X, Mackie K, Hartsell TL, Jones HD, et al. An Outbreak of Pseudomonas aeruginosa Infections Associated with Flexible Bronchoscopes. The New England Journal of Medicine, 2003; 348;221-7.

10 Falaga ME, Tansarli GS, Karageorgopoulos DE et al. Deaths attributable to carbapenem-resistant Enterobacteriaceae infections. EmergInfect Dis. 2014 Jul;20(7);1170-5.

11 NHS England 2018 "2017/2018 and 2018/2019 National Tariff Payment System"

12 C.J. Terhesen J. Kovaleva L. Ehlers Early Assessment of the Likely Cost Effectiveness of Single-Use Flexible Video Bronchoscopes.

13 New lawsuits filed against scope maker in deadly UCLA superbug outbreak, Los Angeles Times, March 17, 2015.

14 Michelle Alfa Ph.D., Endoscope Reprocessing Verification Testing, Presentation, Meeting Materials Non-FDA Generated, FDA Committee Meeting, May 14-15, 2015 http://www.fda.gov/advisorycommittees/committeesmeetingmaterials/medicaldevices/medicaldevicesadvisorycommittee/gastroenterology-urologydevicespanel/ucm445590.htm.

15 http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm462949.htm.

16 Kovaleva J Buss A, Usefulness of Bacteriological Monitoring of Endoscope Reprocessing, Therapeutic Gastrointestinal Endoscopy, www.intechopen.com, Chp 9, pp 141-162, 2011.

17 FDA, warning letters, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm600388.htm

18 Rutala WA and Weber DJ. Gastrointestinal endoscopes: a need to shift from disinfection to sterilization? JAMA 2014;312:1405-6

19 Association for the Advancement of Medical Instrumentation. Strong evidence for sterilization of endoscopes presented at stakeholder meeting. AAMI Articles and Press Releases; 2017.

20 Cori Ofstead. A multi-site study evaluating contamination and visual irregularities on flexible bronchoscopes. Presented at APIC 2018 Minneapolis, Mn

21 N. Shimono et al. An outbreak of Pseudomonas aeruginosa infections following thoracic surgeries occurring via the contamination of bronchoscopes and an automatic endoscope reprocessor; Journal of infection and chemotherapy: official journal of the Japan Society of Chemotherapy; 2008

22 M. Botana-Rial et al. A Pseudo-Outbreak of Pseudomonas putida and Stenotrophomonas maltophilia in a Bronchoscopy Unit; Respiration; 2016

23 T. Waite et al. Pseudo-outbreaks of Stenotrophomonas maltophilia on an intensive care unit in England; The Journal of hospital infection; 2016

24 D. Rosengarten et al. Cluster of Pseudoinfections with Burkholderia cepacia Associated with a Contaminated Washer - Disinfector in a Bronchoscopy Unit Published by: Cambridge University Press on behalf of The Society for Healthcare Epidemiology of America Stable; 2010

25 T. Guimarães et al. Pseudooutbreak of rapidly growing mycobacteria due to Mycobacterium abscessus subsp bolletii in a digestive and respiratory endoscopy unit caused by the same clone as that of a countrywide outbreak; American Journal of Infection Control; 2016

26 C. Ofstead et al. Practical toolkit for monitoring endoscope reprocessing effectiveness: Identification of viable bacteria on gastroscopes, colonoscopes, and bronchoscopes; American journal of infection control; 2016

27 M. Guy et al. Outbreak of pulmonary Pseudomonas aeruginosa and Stenotrophomonas maltophilia infections related to contaminated bronchoscope suction valves, Lyon, France, 2014; Eurosurveillance; 2016

28 C. Ofstead et al. Residual moisture and waterborne pathogens inside flexible ndoscopes: Evidence from a multisite study of endoscope drying effectiveness; American Journal of Infection Control; 2018

29 L. Gavaldà et al. Microbiological monitoring of flexible bronchoscopes after high-level disinfection and flushing channels with alcohol: Results and costs; Respiratory Medicine 2015

30 C. DiazGranados et al 2009; Outbreak of Pseudomonas aeruginosa Infection Associated With Contamination of a Flexible Bronchoscope; Infection Control & Hospital Epidemiology; 2009

31 M. Marino et al. Is reprocessing after disuse a safety procedure for bronchoscopy?: A cross-sectional study in a teaching hospital in Rome; Gastroenterology Nursing; 2012

32 S. Vincenti et al. Non-fermentative gram-negative bacteria in hospital tap water and water used for haemodialysis and bronchoscope flushing: Prevalence and distribution of antibiotic resistant strains; Science of the Total Environment; 2014

33 P. Batailler et al. Usefulness of Adenosinetriphosphate Bioluminescence Assay (ATPmetry) for Monitoring the Reprocessing of Endoscopes; Infection control and hospital epidemiology; 2015

Ambu Ltd • Burrel Road • St. Ives Cambridgeshire PE27 3LE • Phone +44 1480 498 403 • Ambu.co.uk

Ambu
Ideas that work for life

Is clean really clean?

"Most contemporary flexible endoscopes cannot be heat sterilized and are designed with multiple channels, which are difficult to clean and disinfect."[1]