Improving duodenoscope safety: a work in progress

A recent safety communication from the US Food and Drug Administration (FDA) has highlighted higher than expected contamination rates in duodenoscopes used in clinical practice that had been disinfected (reprocessed) in compliance with manufacturer instructions. These conclusions were drawn from surveillance studies that the FDA had requested of manufacturers of duodenoscopes sold in the US to assess the effectiveness of duodenoscope reprocessing in clinical settings. Specifically, one (1%) of 104 samples from reprocessed Fujifilm duodenoscopes (analysed from two health-care facilities) tested positive for viable organisms not associated with disease ("low-concern"), and two (1·9%) were positive for organisms generally associated with disease ("high-concern") such as *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, beta-haemolytic *Streptococcus*, and yeasts. Further, 15 (3·7%) of 406 samples from reprocessed Pentax duodenoscopes (five facilities) and five (0·5%) of 1082 samples from reprocessed Olympus duodenoscopes (17 facilities), were positive for low-to-moderate concern organisms; 22 (5·4%) of 406 and 52 (4·8%) of 1082, respectively, were positive for high-concern organisms. The FDA has requested all three manufacturers to investigate the causes of duodenoscope contamination.

The FDA also recently reported an increase in medical device reports associated with patient infections and reprocessed duodenoscopes between Oct 15, 2018, and March 31, 2019; these reports described patient infection (n=45), patient exposure to infectious residue (n=1), and device contamination (n=159). Furthermore, three duodenoscope-related deaths were reported in the USA in 2018.

Reprocessing duodenoscopes between uses is critical to prevent carry-over of potentially infectious tissue or fluid from one patient to the next via the interior channels and the exterior surface of the instrument. This procedure can be challenging due, in part, to the complicated design of the duodenoscope, a side-viewing endoscope with an elevator channel for positioning instruments at the distal end, which is itself complex. As a result, there are small external crevices and an elevator mechanism where microbes and biofilm can become established and difficult to eradicate during reprocessing.

The FDA continues to urge health-care providers to follow manufacturer's instructions for reprocessing duodenoscopes. After manually cleaning the distal end and elevator mechanism with a brush and rinsing internal and external surfaces of the scope with filtered water, reprocessing can be done manually or in an automated endoscope reprocessor using the cycles and germicide recommended by the duodenoscope manufacturer. The FDA recommends that, to reduce the risk of contamination further, the reprocessing step be repeated or followed by at least one extra step such as culturing for microbes, liquid chemical sterilisation, or ethylene oxide sterilisation.

The FDA is considering extra measures should contamination rates of reprocessed duodenoscopes not drop below 1%. Under consideration are adding a sterilisation step after reprocessing, working with manufacturers to design new duodenoscopes less prone to contamination, or designing disposable scopes to eliminate the need for reprocessing.

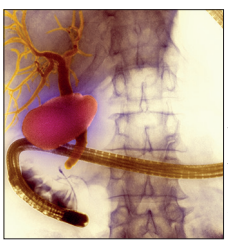
V Raman Muthusamy (David Geffen School of Medicine at University of California, Los Angeles, CA, USA) said that, while the FDA study results are still preliminary, "they show that contamination of reprocessed duodenoscopes occurs significantly more often than initially estimated". He added that the report also shows that while medical device reports have reduced significantly, they still occur, and patient infections have continued.

Jack Brandabur (Providence St Joseph Health, Renton, WA, and Swedish Medical Center, Seattle, WA, USA) said that while it is important to remember that "a risk of infection is part of informed consent for procedures involving duodenoscopes", the FDA's recent safety communication "highlights the need for continued vigilance". Brandabur noted that vigilance requires dedicated technicians routinely undergoing review and certification, culturing to provide early warnings of any needed servicing of equipment, frequent review and checking of institutional processes, and maintenance of the endoscopic fleet. "A dedicated team is needed to manage these processes, including endoscopists, nurse managers, endoscopic technicians, infection prevention, and infectious diseases."

Muthusamy believes that these results will continue to drive the substantial efforts already underway to address this issue. "These include improvements in training, evaluation, and monitoring of reprocessing personnel, and advances in products used in standard high-level disinfection. Much research and development is occurring in duodenoscope redesign, development of practical sterilisation techniques, technologies and equipment to monitor the adequacy of reprocessing, and even the development of disposable duodenoscopes."

Brandabur commented that all three duodenoscope manufacturers have new prototypes with disposable tips; the Pentax and Fujifilm instruments have been approved by the FDA, and the Olympus version is currently under submission at FDA. Further, a multicentre clinical study (NCT03701958) began on April 15 for a single-use, disposable duodenoscope.

Judith A Gilbert



CNRI/Science Photo Library

Lancet Gastroenterol Hepatol 2019

Published **Online** May 7, 2019 http://dx.doi.org/10.1016/S2468-1253(19)30143-8

For the **FDA safety communication** see https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm635828.htm

For more on **extra steps being considered by the FDA** see https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm635889.htm

For more on **safe duodenoscope reprocessing** see **Review** *Lancet Gastroenterol Hepatol* 2018; **3:** 499–508