

FEATURE

FEATURE

A 21st century nosocomial issue with endoscopes

Endoscopic procedures provide lifesaving diagnostic information, but do they put patients at unnecessary risk of deadly infection from cross contamination?

Anne Marie Noronha *senior associate*, Steve Brozak *president*

WBB Securities, 67 Walnut Avenue, Clark, NJ 07066, USA

On 3 January 2014 the results of a year long investigation by the US Centers for Disease Control (CDC) into an outbreak of New Delhi metallo- β -lactamase (NDM)-producing carbapenem resistant Enterobacteriaceae (CRE) were released. Of 69 patients with confirmed CRE infections, 29 went to Advocate Lutheran General Hospital (ALGH) for the same procedure—an endoscopy.¹ The endoscopy itself is not dangerous, but the current cleaning process used between procedures leaves patients susceptible to infection and troubles many healthcare practitioners.

With more than 18.6 million gastrointestinal endoscopies and at least a half million bronchoscopies every year in the US alone,² medical practitioners must take the utmost care during the cleaning process between patients, especially with the emergence of superbugs such as CRE. But the safety profiles of the cleaning protocols are less than acceptable in preventing life threatening outbreaks. The endoscopes are frequently the means for facilitating pathogenic cross contamination between patients—making the case at ALGH far from unique.

The threat of cross contamination may not be visible to a clinician from personal experience alone, but broader and more comprehensive studies show that the cleanliness of endoscopes varies greatly. A mid 2013 study reported that about 15% of endoscopes in US hospitals failed to achieve an accepted standard of cleanliness after liquid reprocessing (the prevailing disinfection process used between patient procedures).³ In this study, duodenoscopes were the dirtiest at a 30% contamination rate, and colonoscopes were the cleanest at a 3% contamination rate.³

All in all, reprocessing is time consuming, labor intensive, expensive and, most importantly, susceptible to failure. Among the most problematic features of an endoscope are the luminal channels, which often become contaminated by endoscope accessories.⁴ The lumen is difficult to access and can easily harbor pathogens through multiple reprocessing procedures, even when the protocol is followed correctly.⁴ Not only must the cleaning protocol be followed strictly, but the equipment

and reprocessing environment also must be well maintained.⁵ Disinfectants and cleaning materials for endoscopes are often contaminated themselves in these incidents.⁶

Ironically, the commonly used liquid reprocessing procedure is sometimes called “liquid sterilization” even though it does not sterilize the instrument. According to guidelines from the Society of Gastroenterology Nurses and Associates, Inc. (SGNA) the protocol requires up to 43 steps and, according to another study, over half an hour of labor.^{5,7} To begin, debris is removed during pre-cleaning. Next, leak testing makes sure that all internal channels are intact and that no holes contribute to instrument contamination. The scope then must be taken apart to allow access for manual cleaning, which removes any foreign material that may interfere with disinfection. The endoscope is then immersed in a high level disinfectant.⁵ The disinfectant must be potent enough to remove contaminants, yet gentle enough to preserve the integrity of the instrument, since a disinfectant that is too concentrated may decrease the life span of the instrument.⁸ The scope is then rinsed, dried, and stored.⁵ The SGNA also offers several guidelines for maintaining the cleaning reprocessing environment to help make reprocessing as effective as possible.⁵

Regrettably, endoscope contamination is not a new phenomenon. In 2006 Seoane-Vazquez and colleagues reported meta-data analysis on all available contamination incidents in the US during the 30 year period between 1974 and 2004.⁶ Research showed that 10 989 patients were exposed to a contaminated instrument and 740 patients were contaminated (although not all reports stated how many were exposed).⁶ The implicated types of endoscopy varied. Bronchoscopy and gastrointestinal endoscopy contributed the highest numbers of incidents (see table 1); and upper GI endoscopy infected the most patients per patients exposed (see table 2).⁶ The infectious agents identified the most were *Mycobacterium tuberculosis* and *Pseudomonas aeruginosa*, both of which are life threatening and have associated antibiotic resistant strains.⁶

Owing to limited surveillance, limited reporting, and lack of immediate clinical symptoms of patients, experts agree that the endoscopic cross contamination is significantly under-reported and its incidence cannot be accurately determined.⁶ Outbreaks that are recognized usually involve severe or unusual pathogens, which then prompt thorough investigations.⁶ If an older patient contracts tuberculosis, a doctor is not likely to suspect that the patient's latest endoscopy is implicated, even though *M tuberculosis* transmission represents a significant proportion of recent outbreaks.⁶ Even so, since 2000, several outbreaks of life threatening pathogens have been traced to contaminated endoscopes in facilities throughout the US and Europe.⁹⁻¹⁷

In 2009, 11 000 patients were notified of possible infection after the US Department of Veterans Affairs (VA) learned through an internal investigation that only 42.5% of its endoscope reprocessing units were adequately cleaning endoscopes.¹⁸ Because US government agencies are generally required to publicly divulge their findings, the VA's information may provide better representation of all endoscope facilities, including those that are not subject to the same mandated reporting.

Infections resulting from scope contamination break the trust between patients and doctors and place a financial burden on healthcare institutions. Two VA patients (one with hepatitis C and the other with HIV) successfully sued the federal government.^{19 20} The statute of limitations meant an unfortunate veteran who was infected with hepatitis B could not seek compensation because the time limit had expired before he learned that he had been infected.²⁰

Following an outbreak last year at the Neosho Memorial Regional Medical Center, substandard scope cleaning was detected and 244 patients were notified of possible exposure to HIV, hepatitis B, and hepatitis C.¹⁷ In 2002, an outbreak of *P aeruginosa* infected at least 32 of 414 exposed patients at Johns Hopkins Hospital and may have played a role in three deaths.¹⁰ At an unnamed Texas hospital in 2009, an arthroscope transmitted the same bacteria to seven patients.¹¹

Among those healthcare organizations that were able to determine the exact cause of their disease outbreaks, the lumen of the endoscope was most often found to be the chief culprit.⁴ The lumen, through which auxiliary equipment such as biopsy forceps can be threaded, is difficult to clean and inspect, making it an easy place for bacteria to hide.⁴ In 2001, three consecutive outbreaks in one French hospital were caused by a loose port at the entrance of one luminal channel.¹² The resulting infection rates were 117 out of 418 scoped patients.¹² In 2003, two implicated bronchoscopes in a different French hospital had damaged lumens, which were promptly replaced. In this incident, 4 of 16 scoped patients were infected.¹³

Despite the high rate of endoscope contamination and published outbreaks resulting from such contamination, the medical community tends to attribute mishaps to negligent cleaning and human error. The Emergency Care Research Institute, which lists inadequate reprocessing of endoscopes as one of its "2014 Top 10 Technology Health Hazards," asserted that guidelines should be continuously reviewed and technicians should be better trained.²¹ However, this advice is over two decades old and the problem still persists. The CDC has also been warning about cross contamination since 1991²² and other medical organizations have concurrently tightened procedural guidelines.^{23 24} Meanwhile, the proportion of incidents caused by equipment defects and cleaning equipment contamination (not human error) has since risen, according to the 30 year US based study.⁶ Additionally, not all incidents covered in the study

were reported to have had an in-depth investigation into the causality of events; thus, human error could be an assumption in many of the cases.⁶

As past experience demonstrates, even the most stringent liquid reprocessing guidelines do not prevent outbreaks. The complexity of reprocessing protocols and the intricacy of endoscope design are inherent flaws, because they foster statistically predictable failures that allow pathogens to persist on the endoscope, particularly in the luminal channels^{4 12 13} and in the cleaning equipment and detergent.⁶

One of the very few positive outcomes of a contamination incident is the change of disinfection practices that follows. After its superbug outbreak, the ALGH switched to ethylene oxide gas sterilization.¹ Alternatively, several other facilities in the US and the UK have begun using sterile disposable sheaths on scopes and have reported improvements in safety.^{7 25 26 27}

The sheath provides a single use sterile barrier between the scope and the patient without hindering functions such as visualization and biopsies. The device incorporates a sterile "working channel" that allows equipment such as biopsy forceps to pass through unhindered.²⁷ Studies show that using the sheath, along with a simple alcohol wipe down between uses, guarantees sterility, offering a vast improvement over current decontamination procedures.^{26 28} Even if there is a defect in the integrity of a single sheath, research confirms that the second sheath prevents contaminants from infecting the next patient.²⁵ The central idea behind the sheath is that a pathogen cannot overcome it. Because each sheath is used only once, pathogens cannot hide on the outside of sheaths or become resistant to disinfecting liquids. One added benefit to using sheaths, which no other decontamination protocol offers, is protection against prions, such as that which causes Creutzfeldt-Jakob disease.²⁸

By using sheathed endoscopes, healthcare facilities will spend less on labor and equipment^{7 27} and avoid exposure to noxious chemicals.^{7 26} Although acquiring new endoscopes that accommodate sheaths may require an initial investment, the scopes are less expensive than unsheathed models and better in terms of long term benefits in patient care, efficiency, and lower operating costs.²⁷ The sheath eliminates unreliable and cumbersome reprocessing, condensing the protocol into just a few steps, and reduces reprocessing time by up to 31 minutes.⁷ It also is more cost effective, reduces repair costs, and decreases investment in multiple scopes that are out of operation while being cleaned.^{7 26 27}

Other sterilization methods exist for endoscopes, but each has its drawbacks in terms of safety, efficiency, and cost. Ethylene oxide gas sterilization is a toxic and carcinogenic process, requiring additional time for a post-sterilization aeration period.⁸ Hydrogen peroxide gas plasma sterilization also has a long processing time, is expensive, and can be corrosive to certain materials. Neither of these methods protects against prions.⁸

The advent of antibiotic resistant bacteria such as CRE and deadly viruses requires that cleaning standards be continuously improved. Just about every invasive instrument we use is sterilized better than the endoscope. Syringes and needles are almost universally disposable and many surgical instruments are subjected to intense heat and pressure between uses. Endoscopy demands the same standards, because the instruments come into contact with or break the delicate mucosal membranes.

In 2013, the UK Department of Health (DH) recommended a "tracking, traceability and audit trail" designed to systematically expose instances of cross contamination before becoming widespread.²¹ US outbreaks between 2000 and 2004 lasted an

average of 84 days,⁶ and the recent CRE outbreak at ALGH lasted the full year,¹ highlighting the importance of a vigilant surveillance system. The system proposed by the DH will provide the medical community with a more accurate and active survey of epidemiology, and hopefully push its constituents to replace liquid decontamination with a more effective alternative.

The *BMJ* is an appropriate venue for this discussion because of its undeterred criticism of conformist practices with the intent of improving healthcare. In 2012, the *BMJ* addressed nosocomial infection in an article titled “Dirty, deluded and dangerous” by Gary L French,²⁹ which exposed the recent trend of doctors who wash their hands much less frequently than expected.³⁰

The issue of scope cross contamination and the growing incidence of negligence in hand washing have a common historical background. In the 1800s, most European physicians rejected the theories of Ignaz Semmelweis,³¹ who proposed that hand washing would lower the postpartum mortality rate.³² Since the advent of antibiotics, doctors have paid less attention to the value of meticulous sterilization.²⁹ However, with the recent appearance of superbugs, we need to be more mindful of careful sterilization.

We must not make the same mistake as Semmelweis’s contemporaries, who remained passive as their patients suffered the consequences of doctors with dirty hands while a simple, lifesaving alternative was sensible, affordable, and available. Like hand washing in Semmelweis’s day, better procedures for cleansing and even sterilizing scopes between uses are mandatory to prevent cross contamination, prevent infection, and potentially save lives.

Competing interests: I have read and understood the BMJ Group policy on declaration of interests and have no relevant interests to declare.

Provenance and peer review: Not commissioned; externally peer reviewed.

- Centers for Disease Control and Prevention (CDC). Notes from the field: New Delhi metallo-β-lactamase-producing *Escherichia coli* associated with endoscopic retrograde cholangiopancreatography. 3 Jan 2014. www.cdc.gov/mmwr/preview/mmwrhtml/mm6251a4.htm.
- Peery AF, Dellon ES, Lund J, Crockett SD, McGowan CE, Bulsiewicz WJ, et al. Burden of gastrointestinal disease in the United States: 2012 update. *Gastroenterology* 2012;143:1179-87.
- Bommarito M. A multi-site field study evaluating the effectiveness of manual cleaning of flexible endoscopes with an ATP detection system. Abstract #040 APIC 2013 annual conference, 9 June 2013.
- Hervé R, Keevil CW. Current limitations about the cleaning of luminal endoscopes. *J Hosp Infect* 2013;83:22-9.
- Society of Gastroenterology Nurses and Associates, Inc. Standards of infection control in reprocessing of flexible gastrointestinal endoscopes. 2012. www.sgna.org/Portals/0/sgna_stand_of_infection_control_0712_FINAL.pdf.
- Seoane-Vazquez E, Rodriguez-Monguio R, Visaria J, Carlson A. Exogenous endoscopy-related infections, pseudo-infections, and toxic reactions: clinical and economic burden. *Curr Med Res Opin* 2006;22:2007-21.
- Krebs A, Borin JF, Kim IY, Jackson DJ, McDougall EM, Clayman RV. Evaluation of practice efficiency with a novel sheathed flexible cystoscope: a randomized controlled trial. *Urology* 2007;70:883-7.

- Sabnis RB, Bhattu A, Vijaykumar M. Sterilization of endoscopic instruments. *Curr Opin Urol* 2014;24:195-202.
- Department of Veterans Affairs Office of Inspector General. Healthcare inspection: follow-up colonoscopy reprocessing at VA medical facilities. 17 Sept 2009. www.va.gov/oig/54/reports/VAOIG-09-02848-218.pdf.
- Srinivasan A, Wolfenden LL, Song X, Mackie K, Hartsell TL, Jones HD, et al. An outbreak of *Pseudomonas aeruginosa* infections associated with flexible bronchoscopes. *N Engl J Med* 2003;348:221-7.
- Tosh PK, Disbot M, Duffy JM, Boom ML, Heseltine G, Srinivasan A, et al. Outbreak of *Pseudomonas aeruginosa* surgical site infections after arthroscopic procedures: Texas, 2009. *Infect Control Hosp Epidemiol* 2011;32:1179-86.
- Cêtre JC, Nicolle MC, Salord H, Pérol M, Tigaud S, David G, et al. Outbreaks of contaminated broncho-alveolar lavage related to intrinsically defective bronchoscopes. *J Hosp Infect* 2005;61:39-45.
- Corne P, Godreuil S, Jean-Pierre H, Jonquet O, Campos J, Jumas-Bilak E, et al. Unusual implication of biopsy forceps in outbreaks of *Pseudomonas aeruginosa* infections and pseudo-infections related to bronchoscopy. *J Hosp Infect* 2005;61:20-6.
- Gonzalez-Candelas F, Guiral S, Carbo R, Valero A, Vanaclocha H, González F, et al. Patient-to-patient transmission of hepatitis C virus (HCV) during colonoscopy diagnosis. *Virol J* 2010;7:217.
- Larson JL, Lambert L, Stricof RL, Driscoll J, McGarry MA, Ridzon R. Potential nosocomial exposure to *Mycobacterium tuberculosis* from a bronchoscope. *Infect Control Hosp Epidemiol* 2003;24:825-30.
- Aumeran C, Poincloux L, Souweine B, Robin F, Laurichesse H, Baud O, et al. Multidrug-resistant *Klebsiella pneumoniae* outbreak after endoscopic retrograde cholangiopancreatography. *Endoscopy* 2010;42:895-9.
- Ryan K. Patients at Chanute hospital possibly exposed to hepatitis, HIV. *Wichita Eagle* 16 Jul 2013. www.kansas.com/2013/07/16/2890467/patients-at-chanute-hospital-possibly.html.
- U.S. Department of Veterans Affairs. VA continues notification process for veterans affected by reprocessing issues. Press release. 3 April 2009. www1.va.gov/opa/pressrel/pressrelease.cfm?id=1661.
- Smiley D. Vet who contracted Hep C wins malpractice suit against VA hospital. *Miami Herald* 21 November 2012. www.miamiherald.com/2012/11/21/3108483/vet-who-contracted-hep-c-wins.html.
- Hall KM. Court rules against Tenn. vet in colonoscopy case. *Associated Press* 1 June 2012. <http://bigstory.ap.org/article/court-rules-against-tenn-vet-colonoscopy-case>.
- Emergency Care Research Institute (ECRI). 2014 top 10 health technology hazards. Health Devices. 2013. www.ecri.org.
- From the Centers For Disease Control (CDC). Nosocomial infection and pseudoinfection from contaminated endoscopes and bronchoscopes—Wisconsin and Missouri. *JAMA* 1991;266:2197-8.
- ASGE Standards of Practice Committee, Banerjee S, Shen B, Nelson DB, Lichtenstein DR, Baron TH, et al. Infection control during GI endoscopy. *Gastrointest Endosc* 2008;67:781-90.
- U.K. Department of Health. Choice framework for local policy and procedures 01-06—decontamination of flexible endoscopes: operational management. 2013. www.gov.uk/government/uploads/system/uploads/attachment_data/file/192522/Decontamination_of_flexible_endoscopes.pdf.
- Baker KH, Chaput MP, Clavet CR, Varney GW, To TM, Lytle CD. Evaluation of endoscope sheaths as viral barriers. *Laryngoscope* 1999;109:636-9.
- Lawrentschuk N, Chamberlain M. Sterile disposable sheath system for flexible cystoscopes. *Urology* 2005;66:1310-3.
- Gupta D, Srirajakalindindi A, Wang H. Reduced turnover times make flexible optical reusable scope with EndoSheath® Technology significantly cost-effective. *J Biomed Res* 2012;26:241-7.
- Winter SC, Thirwell A, Jervis P. Flexible nasendoscope with a disposable-sheath system versus standard nasendoscopy: a prospective, randomized trial. *Clin Otolaryngol Allied Sci* 2002;27:81-3.
- French GL. Dirty, deluded, and dangerous. *BMJ* 2012;345:e8330.
- Boyce JM, Pittet D. Guideline for hand hygiene in health care settings. Recommendations of the Healthcare Infection Control Practice Advisory and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *Infect Control Hosp Epidemiol* 2002;23:S3-40.
- Carter KC, Carter BR. Childbed fever: a scientific biography of Ignaz Semmelweis. Transaction Publishers, 2005.
- Routh CH, Loud MD. On the causes of the endemic puerperal fever of Vienna. *Lancet* 1848;2:642-3.

Cite this as: *BMJ* 2014;348:g2047

© BMJ Publishing Group Ltd 2014

Tables

Table 1 | Table 1 Patients exposed to endoscope related contamination by type of intervention (1974-2004)

Intervention	Outbreaks reporting patients contaminated
Arthroscopy	1
Bronchoscopy	35
Cystoscopy	3
Endoscopic retrograde cholangiopancreatography	7
Lower gastrointestinal endoscopy	12
Upper gastrointestinal endoscopy	10
Gastrointestinal endoscopy*	1
Total	69

*Outbreaks not included in lower or upper GI endoscopy.

Data only include outbreaks that also report patients exposed.

Adapted from: Seoane-Vazquez E, Rodríguez-Monguio R, Visaría J, Carlson A. Exogenous endoscopy-related infections, pseudo-infections, and toxic reactions: clinical and economic burden. *Curr Med Res Opin* 2006;22:2007-21.

Table 2| Table 2 Ratio of patients exposed to patients contaminated by type of intervention

Intervention	Number of outbreaks	Number of patients exposed	Number of patients contaminated	% contaminated
Arthroscopy	1	352	7	2.0
Bronchoscopy	15	4001	270	6.7
Cystoscopy	2	773	25	3.2
Endoscopic retrograde cholangiopancreatography	4	554	38	6.9
Lower gastrointestinal endoscopy	4	4179	42	1.0
Upper gastrointestinal endoscopy	3	1130	107	9.5
Total	29	10<thin>989	489	4.4

Note: Data only include outbreaks that report patients exposed and patients contaminated.

Adapted from: Seoane-Vazquez E, Rodriguez-Monguio R, Visaria J, Carlson A. Exogenous endoscopy-related infections, pseudo-infections, and toxic reactions: clinical and economic burden. *Curr Med Res Opin* 2006;22:2007-21.