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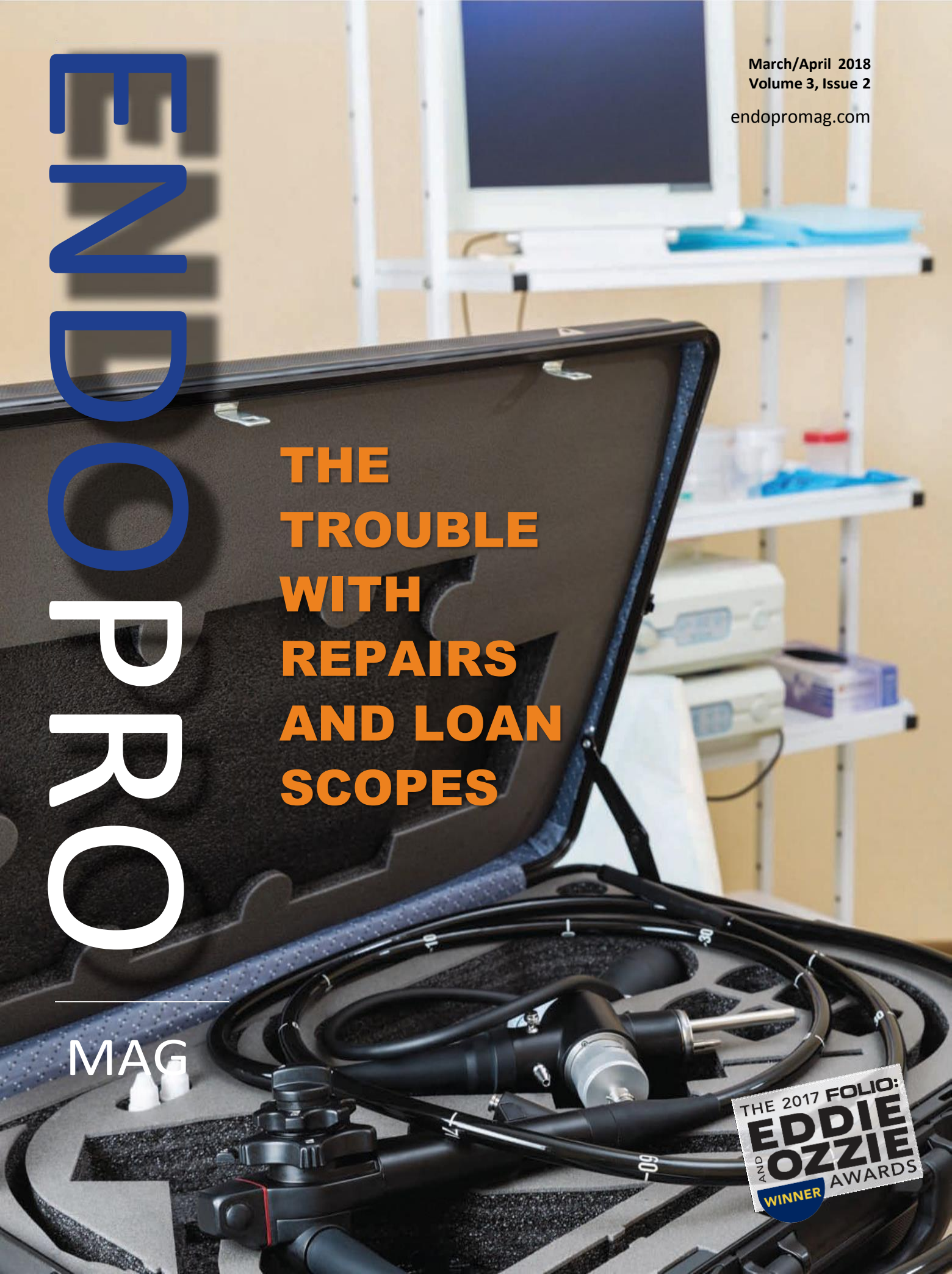
THE TROUBLE WITH REPAIRS AND LOAN SCOPES



THE 2017 FOLIO: EDDIE AND OZZIE AWARDS WINNER

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The trouble with

By Andy Eakins, DipM, MCIM

The topic of cross-contamination and endoscopy continues to make headline news.

Just recently, Buffalo Veterans Affairs Medical Center had to notify 526 patients that the use of an improperly cleaned medical scope might have put them at risk of infection.[1] During a review of the disinfection process, it was noted that steps in the manufacturer's instructions might not have been followed in some cases.

For some years now, there has been increasing concern about infections linked to endoscopes. Organic residue often remains after manual cleaning, research has indicated, and contamination can persist even in institutions with documented adherence to reprocessing guidelines.[2,3] Infections from inadequately reprocessed devices are not often recognized or reported to federal authorities, so the number of infections linked to improperly cleaned endoscopes remains unknown.

Staff must be familiar with the special design of each endoscope used in the respective endoscopy department; this also applies to endoscopes on loan. General reprocessing recommendations are not sufficient, and detailed reprocessing protocols for each individual endoscope are fundamental to safe reprocessing. For example, staff must have a detailed knowledge of the channels and specific components, such as the structure of the elevator system, to be able to conduct reprocessing correctly.

Nosocomial outbreaks where the cause was attributed to inadequate decontamination of on-loan endoscopes have been reported. This article highlights the risks of using on-loan and repaired endoscopes, particularly regarding their commissioning and adherence to disinfection protocols. In an era of increasing antibiotic resistance, bacterial cross-contamination by endoscopes remains a significant concern.

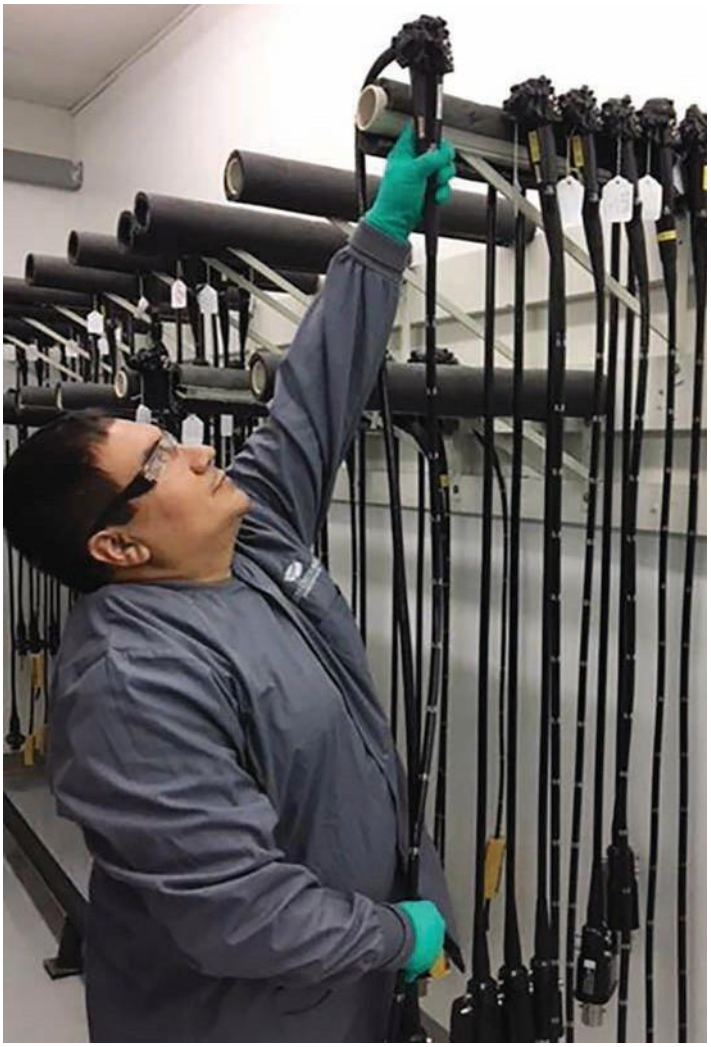
Damage to endoscopes

A recent abstract at the DDW found that video inspection of endoscopes after full reprocessing found scratches, shredding, moisture, debris, stains or discoloration that could jeopardize the cleanliness of the devices.[4]

While visual examination has been proposed as a quality assurance step during reprocessing, the range and severity of potential findings are unknown.

Adarsh M. Thaker, MD, and colleagues implemented a pilot inspection program using a digital video camera passed through the instrument channel of 59 duodenoscopes, gastroscopes, echoendoscopes and colonoscopes. Each inspection consisted of video recordings made by endoscopy technicians anterograde through the channel port, and retrograde through the channel from the distal tip.[5]

Five expert endoscopists reviewed 97 videos and scored each for moisture, debris, stains or discoloration, scratches and channel shredding. "The most common finding in all our devices was scratches, followed in equal amounts by shredding and discoloration," Thaker reported.



Courtesy Mobile Instrument Service and Repair

repairs and loan scopes

All types of scopes revealed scratches (86 percent), shredding (59 percent) and discoloration (59 percent). Debris was observed less often (24 percent) and was seen in none of the colonoscopes. Although moisture and fluid were observed infrequently overall (8 percent of inspections), it was not uncommon in gastroscopes (36 percent) and colonoscopes (33 percent) and was not visible in duodenoscopes or echoendoscopes. Nor was simethicone evident.

Whether the imperfections observed in this study present a risk for pathogens or infection remains unknown, he added. Bret Petersen, MD, a professor of medicine at Mayo Clinic, in Rochester, Minnesota, emphasized that the most important issue is whether the scratches, shredding, moisture and so forth correlate with the presence of bacteria and its potential transmission to patients. "Linking the findings with culture positivity would be very interesting," he said.

Recently evidence indicating that sterilization is a superior method to high-level disinfection (HLD) for the reprocessing of endoscopes was reported during a meeting held at AAMI headquarters in Arlington, Virginia.[6] Cori L. Ofstead, MSPH, president and CEO of Ofstead & Associates Inc., in Saint Paul, Minnesota, presented data from studies conducted during 2008 to 2017. Ofstead's research involves visiting healthcare facilities throughout the country and collecting real-world data on a large variety of endoscopes.

Theoretically, HLD should work, said Ofstead. However, the group's research revealed that amongst other things, one of the barriers to effective reprocessing include damaged scopes.

Many healthcare facilities investigated by Ofstead's team placed a high value on efficiency, to the point that patient safety was compromised. This emphasis on efficiency, coupled with human factors barriers (e.g., complex designs and instructions for use make it difficult for staff to adhere to all steps in endoscope reprocessing), means that "HLD is cutting it too close," said Ofstead.

Other than continued use of damaged endoscopes and the use of defoaming agents and lubricants that can't be removed, sterilization addresses all other barriers listed above, noted Ofstead.

Michelle Alfa, PhD, principal investigator at St. Boniface Research Centre in Winnipeg, Canada, presented findings showing that repeated use of endoscopes leads to gradual accumulation of debris, which can lead to microbial survival following disinfection.

The use of loan scopes

Damaged endoscopes will of course need to be retuned for repair. In addition, endoscopy service providers often cannot do without their endoscopes and rely of loan scopes to continue their provision of service.

And this isn't just for GI endoscopes. In fact, uretorenoscopes have recently been scrutinized in the United States.[3] A presentation a presentation given by its author[7] cited that high frequency of repairs related to functional failures occur:

- 5-60 uses before initial repair.
- 4-11 uses before more repairs are needed.

In addition, the high annual cost for repairs/refurbishment was between $4,181 to $10,833 per ureteroscope. Study of existing literature revealed this also led to procedural disruption and inefficiency due to repairs. There was a need to have two

While visual examination has been proposed as a quality assurance step during reprocessing, the range and severity of potential findings are unknown.

ureteroscopes in the procedure room and frustration by the physician when scopes fail during procedures. There was also interruption to reprocessing workflow when leak tests fail and there is also additional time required for paperwork.

Loan scopes have their own set of unique issues to deal with though. For example, what is the history of the loan scope, who has it been used on, what pathogens was it exposed to, who cleaned it, and how well was it cleaned?

In addition, if a like-for-like loan scope is not provided for the returned scope, does it have any unique features and cleaning regimens which you need to be made aware of? Does additional training need to be given?

According to the British Society of Gastroenterology (BSG),[8] a record should be kept of the serial number of each endoscope used in each patient. This log should include any loan endoscopes. This is important for any future contact tracing when possible endoscopic transmission of disease is being investigated. Details of each decontamination step, including the operator performing the leak test and manual clean, the endoscope washer disinfector and the cycle details, including cycle number, used in decontaminating that endoscope should also be kept. This should also include loan endoscopes.

BSG goes on to say that the handling of loan endoscopes requires special consideration. Loan scopes need to be reprocessed prior to first patient use and incorporated within the tracking and traceability process.

The Society for Gastroenterology Nurses and Associates (SGNA)[9] also takes a similar view. The organization states, "A system should be in place to track repairs and maintenance of endoscopes, loaner endoscopes, or other reusable endoscopic equipment."[10]

In the Association of periOperative Registered Nurses (AORN)[11] guideline for processing flexible endoscopes, the organization states that it is not possible to verify how all new, repaired, refurbished, or loaned equipment and devices have been handled, cleaned, inspected, or processed before receipt in the facility. Failure to correctly clean, inspect or process an item could lead to transmission of pathogenic microorganisms from a contaminated device and create a risk for patient injury or infection.

Policies and procedures for managing loaned endoscopes, accessories and equipment should be developed. The systematic management of loaned instrumentation reduces loss and helps ensure effective processing through increased collaboration, communication, and accountability.[12]

Repairing scopes

Hospitals increasingly are saving money by operating on patients with refurbished and repaired surgical instruments, but safety fears could prompt the government to intervene.

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Unregulated by either the state or federal government, medical device maintenance has quietly grown into a $50 billion industry. Now, as anecdotes circulate about injuries caused by faulty equipment, the U.S. Food and Drug Administration is exploring regulations to the industry that repairs everything from imaging systems and X-rays to ventilators and endoscopes.[13]

"First and foremost, this is an issue about patient safety, so it's important that the FDA gets it right," said Colin J. Ford, senior director of state and federal government relations at the Michigan State Medical Society, which has not taken a position on any regulations.

Hospitals and patient advocacy groups contend the practice saves money, reduces waste and is safe. Third-party shops charge 30 to 50 percent less than manufacturers to repair equipment and thousands of dollars less for replacing it, according to FDA documents.

"A robust marketplace drives out poor performers," said David Anbari, vice president of Mobile Instrument Service Repair Inc., an Ohio company, told an FDA panel.

Medical device manufacturers point to horror stories about rebuilt equipment that broke during surgery, increasing the risk of infection, septic shock or other complications. More than 100 pages of mishap incident reports were presented to the FDA by Karl Storz, one of the world's largest makers of endoscopes. In one case, kidney stone removal surgery went awry when the beak of a rebuilt rigid endoscope dislodged in a 68-year-old man, and the doctor couldn't retrieve the broken piece. In another, two hours were added to a surgery to fix an enlarged prostate when the sheath of a repaired scope broke off in a 69-year-old man's urethra.

Unlike repair shops, manufacturers are heavily regulated by the FDA. By law, they must report all injuries and deaths involving surgical instruments or medical devices to the FDA. No one keeps track of how many repair shops exist, but they range from multi-state operations to those with fewer than 10 employees.

Jim Schneiter, a Chicago-based instrument designer, said endoscopes degrade over time and need to be replaced. "Endoscopes are very complex, delicate, expensive instruments. I can understand manufacturers not wanting other people to fix them," he noted.

One Detroit Medical Center doctor disagreed, saying he often uses refurbished flexible scopes without problem. There's no issue as long as they are rebuilt by reputable firms, said the doctor.

"We have extensive experience with third-party service and repair and have experienced significant cost savings as a result," said Brian Taylor, spokesman for Ascension Michigan, which



owns St. John Providence in Detroit, Crittendon Hospital in Rochester, Genesys Health System in Grand Blanc and three other Michigan hospitals. "This has been possible without compromising patient safety and quality of care. We urge the FDA to exercise great care as it considers these issues." At Henry Ford, staffers "routinely inspect surgical instruments for safety," limit repairs to a "small number of tools and discard

Even with the correct processes in place, cross-contamination of loan scopes has been reported in the literature.

those that can't be repaired, said spokesman David Olejarz, who added that federal oversight would "ensure the highest standards of quality and safety."

When you take delivery of loan instrumentation, the items should be delivered to a designated receiving area. Under all circumstances, the instrumentation must be considered contaminated (March 2007 AORN journal – Walter Reed Army Medical Center "Processing the Unknown" – Biohazard Containers). You shouldn't use decontamination information from another hospital. You have to record of the sterilization process and quality assurance measures in your own establishment. You cannot be sure how the scope was package protected during handling and transportation — and your patient deserves to know you have monitored the process yourself.[14]

According to AORN,[11] "A formalized program between healthcare organizations and healthcare industry representatives should be established for the receipt and use of loaner instrumentation. Implementation of tracking and quality controls and procedures are necessary to manage instrumentation and implants brought in from outside organization and companies."

Cross-contamination and loan scopes

Even with the correct processes in place, cross-contamination of loan scopes has been reported in the literature. In the book Disinfection and Decontamination: Principles, Applications and Related Issues,"[15] the authors comment on 10 published articles that described suspected outbreaks related to GI endoscopy. One of these cases[16] conducted a case- control study following an outbreak of multidrug-resistant P aeruginosa sepsis in five patients who underwent ERCP procedures with the same duodenoscope.

The endoscope, which was on loan from the manufacturer, had been processed and cultured with negative results one month earlier before being put into clinical use. The investigators concluded that the organism that caused the outbreak had most likely been transmitted from patient to patient by the loaned endoscope.

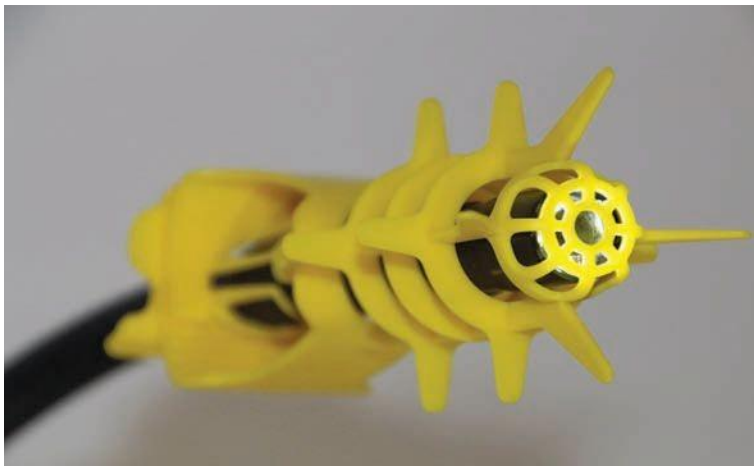

Figure 1. Use of this new tip protector resulted in a 66.7 percent reduction in loan scopes required.

There was not enough information to postulate why the loaner endoscope would harbor contamination. However, the book goes onto say that it is tempting to speculate that because the staff was unfamiliar with the endoscope, it was not effectively cleaned, or it was not properly connected to the automated reprocessing equipment.

More recently, in a paper published in the APIC journal,[17] the authors reported a historic nosocomial outbreak of Salmonella enteritidis affecting four inpatients who underwent endoscopic retrograde cholangiopancreatography. The cause was attributed to inadequate decontamination of an on-loan endoscope used over a weekend. This report highlights the risks of using on-loan endoscopes, particularly regarding their commissioning and adherence to disinfection protocols. The authors state, "In an era of increasing antibiotic resistance, transmission of Enterobacteriaceae by endoscopes remains a significant concern."

Reducing scope tip damage may reduce the reliance on loan scopes

Earlier this year the FDA[18] issued a safety communication to U.S. hospitals, discussing a particular model of duodenoscope. The FDA's notice stated that "cracks and gaps in the adhesive that seals the device's distal cap to its distal tip can occur, which can lead to microbial and fluid ingress. These areas

Users roles and responsibilities	Decontamination staff roles and responsibilities	Manufactures/suppliers roles and responsibilities
The overall responsibility for management of loan scopes resides with the endoscopy unit. This covers assessing the requirement for loan scopes to returning them to the supplier.	Prior to agreeing to process loan scopes, the decontamination staff should ensure that all loan scopes are compatible and can be processed with their existing decontamination processes.	Provide safe, fit-for-purpose and traceable reusable loan scopes to agreed timescales.
Ensure a full understanding of loan scope policies and procedures. For unfamiliar scopes recognise the additional time that may be required for reprocessing and provide information on them for training and processing. Coordinate with all interested parties to enable the supplier's trainer to deliver training and update as required.	Ensure full understanding of loan scope supplier's reprocessing procedures; inform users when unfamiliar loan scopes are received as these require longer training and processing time.	Ensure the cleanliness, functionality and completeness of loan scopes.
Establish service level agreements with suppliers. All scopes on loan from manufacturers should be subject to a written agreement that defines the loan scope management requirements, including the acquisition, deployment, maintenance, repair and disposal responsibilities and liabilities.	Confirm and check upon arrival that all loan scopes and documents are present. Disassemble complex loan scopes and inspect. Notify users if discrepancies occur. Quarantine if appropriate.	Package appropriately.
Ordering loan scopes and checking the indemnity agreement with supplier. Inform decontamination staff at least 24 hours before delivery.	Consider loan scopes as contaminated upon delivery and personal protective equipment should be worn throughout.	Ensure compliance with the facility's handling policy.
Acceptance checks of loan scopes and documents from supplier before forwarding for decontamination. Advise supplier of discrepancies immediately.	Enter details onto tracking system and prevent loan scope migration throughout process.	Include training and documentation on "new" devices.
Introduction of loan scopes onto the endoscopy register/IT system for traceability: identify and tag as "on loan." Endoscopy unit should track loan scope details to the patient and prevent loan scope migration.	Decontaminate using own procedures and in accordance with written manufacturer's processing instructions.	Ensure training in the handling, use and reprocessing of unfamiliar devices, is provided for clinical and cleaning staff.
Pre- and post-use checks of loan scopes and documents: ensure packaging is intact not compromised upon delivery. Ensure loan scope and documents are complete and in order.	Loan scopes should be cleaned and disinfected/ sterilized prior to returning to suppliers, accompanied with a decontamination certificate.	Provide full supporting documentation such as reprocessing instructions, a decontamination certificate, product codes and detailed ancillary lists for the loan scope.
Return loan scopes to supplier with decontamination certificates and traceability information.	Packaging should be appropriate to prevent damage on transport back to the supplier.	Ensure loan medical devices are controlled on a robust tracking system.
Check and package appropriately to prevent damage of loan scope on return to supplier. Sign off in the endoscopy tracking system.	Maintain and archive paper and electronic records.	Ensure an immediate supply of replacements is provided.
Reporting other non-conformances, complaints and incidents to the relevant parties; raise complaints directly to the relevant parties. In the event of an incident/defect, notify immediately the manufacturer/ supplier, decontamination unit and any local or national reporting system.		In the event of an incident/defect, notify immediately the endoscopy unit and any relevant authority, such as the FDA.
Additional responsibilities for "high risk" potential CJD/vCJD patients such as staff must identify patients who have been "notified that they are at increased risk of CJD/vCJD and the appropriate infection control procedures and guidelines are followed.		Maintain and archive paper and electronic records.

Table 1 shows the key roles and responsibilities of the users, decontamination staff and manufactures/suppliers which should be risk assessed against for loan scope provision. Adapted from the National Decontamination Guidance on Loan Medical Devices (Reusable): Roles & Responsibilities. NHS National Services Scotland July 2015.[23]

can be challenging to clean and high-level disinfect and may increase the risk of infection transmission among patients."

The FDA recommended that hospitals "immediately remove from service for assessment, and repair or replace any duodenoscope that shows visible signs of damage." The FDA wrote that "examples of (such) damage may include (among other cited issues) cracks and gaps in the adhesive that seals the device's distal cap or other signs of wear or damage."

A study published this year in the American Journal of Infection Control[2] examined 20 scopes over a seven-month period. The researchers found visual irregularities that could foster the growth of bacterial or fungi, discoloration and debris in channels. Samples from 12 of 20 endoscopes had microbial growth after cleaning, and the researchers reported in the journal that "this study demonstrated that more rigorous reprocessing practices may not be sufficient to ensure that patient-ready endoscopes are free from residual contamination, particularly when the endoscope has defects that could harbor organic debris and biofilm."

Of the 14 available repair reports of the 17 scopes returned for repair, 12 of the scopes had some kind of distal end damage which were categorized as:

- Distal end damage.
- Bending section dent.
- Degraded distal sheath.
- Worn distal sheath.
- Minor distal end scratches.
- Distal end build-up and dent; cracked lens.

Use of scope tip protectors for reducing damage to the delicate optics and bending section rubbers of endoscopes is well documents.[19,20] A brand new study[21] recently published on a next generation, fit-for-purpose (non-sponge) tip protector (see figure 1) was recently evaluated.

The paper discusses that protecting the tip of an endoscope can help maintain it and reduce damage. Scopes can suffer damage anywhere including transport and storage and the best way to avoid repair costs is to avoid damage. They investigated the causes and number of flexible scope repairs and loans required, in a five-month period since implementing the use of a new scope tip protector, compared to the same period the previous year without tip protection.

Six scopes required repair since using the new tip protector, compared to 13 scopes the previous year. There was only one tip damage since using the new protector, compared to eight the previous year. Four loan scopes were required since using the tip protector, compared to 12 before the use of the protector.

Therefore the authors concluded that use of the new ProTech device resulted in a 53.8 percent decrease in overall repairs and a 66.7 percent reduction in loan scopes required.

Training and risk assessment

Endoscopes are medical devices with a complex design, which require detailed specialist knowledge and special care during reprocessing. Guidelines and healthcare regulatory bodies require that only qualified personnel reprocess endoscopes. Special training programmes have been established in many countries to communicate the aspects of hygiene, infection prevention, reprocessing procedures and instrument technology.[22]

All devices on loan from manufacturers should be subject to a written agreement which defines the device management requirements, responsibilities and liabilities. Delivery receipt and pre-use procedures for loan scopes should be the same as those for purchased endoscopes, unless otherwise specified in this written agreement. For an effective management system, it is recommended that you should have robust procedures to deal with all scopes loaned within the organisation and are aware of the overall policy and systems for medical device management within the healthcare organisation.[23]

Clear national guidance is required to define roles and responsibilities required in the decontamination process of loan scopes. However, very little guidance currently exists, and therefore in the meantime, you should be looking to do as much as possible to reduce the risks yourselves.

Your loaner policy and procedure should address all such issues as information regarding the ordering, receipt, processing, inspection, inventorying, post-use processing, post-use inventorying, and return to the vendor or manufacturer.[24] The policy should specify who has the authority to order the scopes and the notification of the decontamination department of the arrival of the instruments, date of arrival and how the scope will arrive (e.g., by courier, sales representative, delivery service).

The decontamination unit should then track the scope to ensure it is processed in time for the scheduled case. If arrival information is not communicated to the decontamination unit, case delays can occur. The policy should also address the condition of the loan scope. Any scopes that are damaged, or in otherwise poor condition should not be used. The vendor and the endoscopy unit should be contacted regarding the problems so that they can be corrected before the scheduled case.

The Food and Drug Administration (FDA) requires that all manufacturers provide detailed instructions for use for their devices. It is the responsibility of Decontamination Unit management or designee to obtain manufacturers' IFU and to ensure that the most current IFU information is available for use. Manufacturers constantly update IFU therefore, it is important to continually update the information. The IFU should be dated when received.

The National decontamination guidance on loan medical devices[25] produced for NHS National Services Scotland produced guidance aimed to reduce risks associated with loan medical devices and deliver positive health impacts. This document relates only to surgical devices but is perhaps a good starting point for flexible endoscopes.

Contained within the guidance are roles and responsibilities for users, decontamination units and manufacturers/suppliers.

LOAN AND REPAIR SCOPE SUMMARY CHECKLIST

Considerations	Rationale
Protect your scopes	Prevention of damage will do much in reducing scope repairs and the reliance on loan scopes.
Are you familiar with the loan scope?	Is the scope a like-for-like replacement? If not, how do you decontaminate it? Do you have the right connectors, chemicals and other ancillary items needed to reprocess the scope?
Is a full traceability record available from the loan company?	If the scope has been contaminated, or becomes contaminated, will a definitive list of patients be available? Could they all be contacted?
Gauge staff training	Ensure all staff, including new staff, involved in the decontamination process are fully trained and that this training is regularly updated as appropriate.[26] Clinical guidelines and manufactures IFU should be fully understood, as should preventative care and maintenance to prevent scope damage.
Assess risks	Examine the roles and responsibilities for users, decontamination staff and manufacturers/ suppliers when bringing in a loan scope. Ensure everyone knows their responsibilities throughout the entire use of the scope to ensure there is no possibility of cross-contamination.

Table 2 –shows the minimum recommended action that should be implemented to reduce the risk of damaging your scopes and any consequential use of loan scopes

The guidance encompasses the entire loan cycle from the decision to order a loan medical device to the returning of the loan medical device to the supplier. The guidance ensures loan medical devices are delivered to theatre fit for purpose, in a timely manner and returned safely to the supplier.

Whenever a scope is brought in for loan, all these elements should be appropriately risk assessed. Such considerations are summarized in Table 1.

Key points and take-home message

Healthcare facilities are using reusable loan medical devices to provide needed inventory to perform procedures. An obligation of healthcare facilities is to ensure these loan medical devices have minimal contamination and are appropriately processed at time of use. Additionally, national initiatives exist to minimise Healthcare Associated Infections (HAIs) and harm to patients and staff. The effective control of loan medical device decontamination presents challenges to endoscopy units, clinics, decontamination departments, manufacturers and suppliers. Loan medical devices must be managed in a consistent way to ensure patient and staff safety. Table 2 describes the minimum recommended action that should be implemented to reduce the risk of damaging your scopes and any consequential use of loan scopes to ensure an uninterrupted provision of endoscopy services.

Conclusion

There are various endoscope models from different manufacturers on the market for the various endoscopic

interventions. This underlines not only the need for intensive training and instruction in use of the instrument but also makes the duty to report and notify clear. Staff training, adherence to guidelines and manufacturers' specifications and regular hygiene surveillance are important tools in the prevention of infections.[22]

Preventing damage to the distal end and protecting the delicate lens optics and internal chip will do much in helping to reduce repair and service contract costs and reduce the need for loan scopes. Having scopes in use for longer also yields benefits in maintaining procedure lists.

Loan scopes need to be tracked and traced like any other endoscope though extra care needs to be taken understanding reprocessing protocols of loan scopes, should it not be a like-for-like replacement. Ultimately, looking after your endoscopes will do much in mitigating the risk of damaging your scope, which will also have a positive impact in reducing the amount of loan scopes required. n

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