Common pitfalls in flexible endoscope processing

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Flexible endoscopes: types and procedures

Endoscopes are reusable devices that are used for a variety of minimally invasive medical, diagnostic and surgical procedures. They are often classified as being rigid or flexible in their design. As their name suggests, flexible endoscopes are made of predominantly flexible materials that facilitate their use in body orifices (see Table 1, below). They are also referred to generally as GI endoscopes (for use in the gastro-intestinal tract), upper GI (gastroscopes, duodenoscopes), lower GI (coloscopes and sigmoidoscopes), and respiratory endoscopes (e.g., bronchoscopes).

Flexible endoscopes range in design from simple to complex, but overall they are some of the most complicated and sensitive devices to handle for processing. They are typically made of a variety of materials and adhesives, as well as containing light/visualization systems (including lens, fiberoptics, etc). They are therefore predominantly heat sensitive, restricting them from being sterilized by steam. They also contain from one to as many as seven internal channels, often interconnected, for various functions during patient procedures. These channels or lumens can range in diameter (~0.7 to 6 mm) and length (~300 to 3000 mm). The internal channels require particular attention to detail during cleaning and final disinfection or sterilization. In addition to the flexible endoscope itself, various accessories and systems are used with the device during procedures including valves, caps and connections to a water bottle and air source (see Figures 1 and 2). These components are also important to consider during processing to ensure safe patient procedures.

Risks to patient safety: the pitfalls of inadequate processing

Given their complexity it may not be surprising that more adverse patient events such as infections and toxic reactions have been linked with the use of inadequately processed flexible endoscopes than to any other types of devices. Despite this and based on reviews of published reports, the Centers for Disease Control previously estimated the risks of infection following flexible endoscopy to be very low (~1 in 1.8 million procedures). Recent reports have suggested that such risks are underestimated and facility audits have found widespread lapses in processing guidelines and the ECRI Institute has also listed inadequate reprocessing of endoscopes and surgical instruments as one of the Top 10 Health Technology Hazards for 2013.
Patient risks due to inadequate processing can include:

- Cross contamination that may lead to patient colonization and infection. Flexible endoscopes have been frequently implicated as the source of cross-infection events and infection outbreaks.
- Toxicity, due to chemical residue or other toxic substances. This has been particularly associated with the use of certain types of disinfectants (aldehyde-based).
- Device damage. This can include a variety of physical or chemical damage to the device, which can lead to complications during patient procedures.

A review of the literature and of the Food and Drug Administration’s MAUDE medical device report system has highlighted the following concerns:

1. **Device damage to internal or external parts of the device.** Overall, repair statistics indicate that 60 percent of damage to devices is from normal use (wear and tear), while 40 percent is specifically due to care and handling issues such as cracked fibers, internal damage and fluid invasion. Such damage can allow patient material to enter into unintended parts of the device and pose a cross-contamination risk. Failure to adequately leak test, which can allow for contamination of internal device components, is an example of how this can happen. Repeated exposure to a plasma sterilization process that led to parts of the device being dislodged during a patient procedure is another example.

2. **Inadequate cleaning and/or rinsing following cleaning.** Cleaning of internal lumens requires close attention to detail. Investigations have shown that although the main biopsy-suction channel is often heavily soiled during patient use (in particular in lower GI devices like colonoscopes), the other accessory lumens (e.g., air-water, elevator guide-wire) are also soiled and require diligent cleaning. Infection outbreaks and potential toxic reactions due to inadequate cleaning have been reported, with visual soil being found in lumens.

3. **Inadequate disinfection or sterilization.** Reports of infection due to inadequate disinfection/sterilization have included inadequate preparation of the disinfectant, failure to connect device lumens to channel flow in automated endoscope reprocessors (AERs), and inefficient disinfection. A number of recently highlighted cases involving transmission include a group of bacteria known as CRE (carbapenem-resistant Enterobacteriaceae). CRE include bacteria such as Klebsiella and Escherichia coli, and are difficult to treat because they have high levels of resistance to antibiotics. Cases of transmission of these bacteria to patients through the use of a particular type of endoscope (duodenoscope) have been of particular concern in the U.S. within the last year. There remains much to learn regarding these reports, but investigations to date would suggest that causes will include lack of adequate disinfection and difficulty with the disinfection of these types of devices (particularly at the distal tip area). In one investigation, sterilization of devices was recommended as a precaution, despite the fact that these bacteria should be readily inactivated by disinfection. In contrast, one of the largest infection outbreaks to date was linked to the ability of another type of bacteria (Mycobacterium species) to survive the disinfection activity of glutaraldehyde. Other investigations have reported the identification of other bacteria that could resist the activity of glutaraldehyde and OPA-based disinfectants.

4. **Lack of adequate rinsing and drying following disinfection.** Two major concerns have been identified. The first is cross-contamination from bacteria in the rinse water. Bacteria like *Pseudomonas* are common in water and if water quality is not controlled correctly, these bacteria can be introduced into the device during rinsing of the device after the disinfection process. Sources can include the use of contaminated potable water being used for manual rinsing or in AERs. If moisture remains in device lumens, the bacteria can multiply and, over time, develop biofilms. High numbers of bacteria from biofilms can be transferred into patients during the subsequent use of the device. This can be prevented by the correct disinfection/sterilization and rinsing of the device with treated potable water, and drying of the device prior to storage. Other microbial risks in water can include the potential presence of viruses and protozoa. An additional concern is that patient toxicity can occur when disinfectants are not correctly rinsed away following disinfection. The most common causes have been reported in association with the use of glutaraldehyde and OPA disinfectants. These types of disinfectants can readily remain on the device in the event of inadequate rinsing, which may require up to five fresh water rinses under controlled conditions to ensure the lack of patient toxicity (in accordance with disinfectant manufacturer’s instructions).

5. **Improper device preparation for or during patient use.** Events have included cross-contamination from reused water bottles during the patient procedure.
procedures that may include contact with ‘sterile’ parts of the body or blood contact, but at a minimum should be high-level disinfected. Chemical sterilization, as defined by AAMI/ANSI 58°, can be achieved by using a liquid chemical or gaseous sterilization process (see Figure 3).

Examples include the SYSTEM 1E Liquid Chemical Sterilant Processing System that is cleared for liquid chemical sterilization and includes a controlled, extensively treated water rinsing phase. Others include ethylene oxide sterilization (when validated by the manufacturer) or, for certain types of flexible endoscopes in accordance with cleared label claims, hydrogen peroxide gas sterilization processes. Drying and ensuring venting caps are fitted are essential steps before gaseous sterilization. There are many types of AERs and high level disinfectants, with an increasing number of oxidizing agent-based disinfectants based on peracetic acid or hydrogen peroxide. Disinfectants vary in their label claims and instructions for correct use, so these should be carefully reviewed. Remember that disinfection is always a two step process, including disinfection and then rinsing. Rinsing may need to be done multiple times and the water quality should be controlled (e.g., in accordance with AAMI TIR 34). In selecting a disinfection or sterilization method, consider at least four safety risks: safety for the patient, for the staff, for the device (compatibility) and for the environment.

5. Adequate storage. For any device that is not sterilized in sterile packaging, it is important to make sure that the device (in particular the internal channels) are dried prior to storage. This typically includes purging the water and then drying with air. Devices packaged or not, must be stored correctly, if not used immediately after processing. It is impossible to recommend a minimum storage time for which a device will remain safe for use following disinfection and drying, as this will depend on the facility policy regarding how the devices are disinfected/sterilized, dried and stored. These factors should be considered to support any facility storage policy, to reduce patient risks.

6. Inspection. The device should be inspected for correct operation prior to patient use. Particular care should be taken in inspecting the lenses, adhesives, etc. for obvious signs of damage. Inspection also applies to other accessories or equipment used during a patient procedure with the device.

7. Quality control verification. These tests can include a variety of physical, chemical and even biological tests (AAMI ST58°) and are an important part of the facility policy as a verification of correct endoscope processing. These are considered in further detail in the final section.

The role of quality control
Quality control is essential in any circumstance or place where device processing takes place. This is as applicable to flexible endoscopes as to any other reusable device. As a starting point, it is essential that quality assurance and safety requirements are included in the processing policy. An important tool during the development of facility policies and specific work instructions is to perform a risk assessment for the entire process. This will allow management and staff to understand the multiple risks in endoscopy processing, from when a device is used on one patient to its safe delivery for the next procedure. Risk sources (hazards) to be considered will include maintenance of associated equipment such as visualization systems, water bottles, water lines, and air filters, the bedside procedure, transport, device/accessory disassembly, cleaning, rinsing, drying and packaging (when appropriate), inspection, disinfection or sterilization, post-disinfection drying, storage and/or transport to use, and finally reassembly/inspection for the following procedure.

Management should ensure that they have adequate, designated areas and supplies to follow the policy. Staff should be trained on and demonstrate competency with the policy and the specific work instructions. Detailed work instructions should not only be written, but periodically audited to ensure compliance.

With these controls in place, there are a number of verification points that can be considered, and may be required in compliance to manufacturers IFUs, standards and guidelines. These include physical and chemical monitoring, and can be supplemented by biological (bacterial (sterilization or testing) when appropriate). Examples include:

• Cleaning verification, such as verifying the dilution method for detergents, correct temperature and contact time for cleaning and sufficient rinsing. Visual inspection for the lack of patient soil is required, but it is also recommended that more sensitive cleaning indicators (such as those detecting protein or ATP) be used.

• High-level disinfection verification will also include physical indicators such as exposure time, temperature, number of rinses, etc. These should be verified for both manual and automated (e.g., AER) disinfection systems. Disinfectants are also provided with specific solution test strips or chemical monitoring devices that verify whether the correct disinfectant concentration is present. Facilities may also want to consider verification methods to ensure that the water quality is adequate for rinsing.

• Liquid chemical sterilant verification. This will include physical monitors/print-outs, diagnostic cycles, routine maintenance steps, and the use of chemical indicators and spore test strips.

• Gaseous chemical sterilization verification, also including physical monitors (pressure, time, etc.), sterilizer leak tests, calibration, chemical indicators, process challenge devices and biological indicators. There is some debate on proposals that facilities should consider routine or periodic microbiological sampling/monitoring of flexible endoscopes. At this time, in the U.S. there are no specific guidelines on a method to be employed or the interpretation of results, although there is existing guidance in some European countries and Australia. There are currently no known rapid methods that can be used for this specific purpose and traditional microbiology methods require specialized training, so it is important to work closely with an infection control practitioner or those with training in microbiology to ensure that samples are collected, analyzed and interpreted correctly.

Conclusion
Flexible endoscopes provide great medical benefits, but have been highlighted as being a potential hazard to patient safety when not processed carefully. Care to ensure the correct processing steps are conducted and close attention to quality control and assurance during processing can ensure that these devices are safe for patients, each and every time. HPN
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Circle the one correct answer:

1. The risks of inadequate endoscope processing are:
   A. Cross contamination and infection
   B. Toxicity
   C. Device damage
   D. All of the above
   E. A and B only

2. Flexible endoscopes are easy to clean and disinfect.
   A. True
   B. False

3. A duodenoscope is a device used for:
   A. Inspection and biopsy of the colon
   B. A specialized device to allow entry into the duodenum
   C. Inspection of the urinary tract

4. During processing, flexible endoscopes should be cleaned and then high-level disinfected or sterilized.
   A. True
   B. False

5. Processing should consider the flexible endoscope, any reusable accessories and the visualization system/accessories.
   A. True
   B. False

6. CRE (carbapenem-resistant Enterobacteriaceae) are types of:
   A. Bacteria
   B. Viruses
   C. Fungi

7. Rinsing following high level disinfection is required to:
   A. Ensure the device is clean
   B. Ensure water is present during the next patient procedure
   C. To remove any chemicals used on the device that may be toxic to the patient

8. After cleaning or disinfection, rinsing with the right quality of water should be done:
   A. Once
   B. Twice
   C. In accordance with cleaner or disinfectant manufacturer instructions

9. When considering disinfection, which type of product should be used for semi-critical flexible endoscopes?
   A. Low level disinfectant
   B. Intermediate level disinfectant
   C. High level disinfectant
   D. Liquid chemical or gaseous sterilant
   E. C or D

10. For quality control in the processing of flexible devices, it is only important to use chemical indicators or chemical test strips for the disinfectant, liquid chemical sterilant or gas sterilant.
    A. True
    B. False


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Dr. Gerald McDonnell is Vice President of Research and Clinical Affairs for STERIS Corporation. He holds a BSc in Medical Laboratory Sciences and a Ph.D. in Microbial Genetics. He has worked for 20 years in infection prevention and contamination control with over 170 publications and patents. He recently co-authored his second book entitled A Practical Guide to Decontamination (Wiley-Blackwell). Dr. McDonnell is actively involved in the development of national and international standards and guidelines, including AAMI sterilization standards.