Infectious Disease Advisor

Hospital Infection Control

Endoscopy

Puneet Puri

What are the key issues surrounding gastrointestinal endoscopy related infection prevention and control?

Gastrointestinal endoscopy dates back to 1911 when the gastroscope was first developed. It was not until 1950 when the "gastro camera" was introduced, allowing physicians to take images of gastric ulcers. Since then the field of endoscopy has advanced tremendously with the first flexible fiberoptic endoscope in 1961. Awareness for infection transmission emerged and collaborative efforts to establish proper cleaning guidelines dates back to as early as 1979 when the first symposium on hazards of endoscopic procedures was held in England. Many disinfection guidelines have evolved over these 50 years to reflect changes in complexity of the endoscope and the endogenous microbial burden.

Endoscopy related infections occur endogenously or exogenously. Endogenous infections are a result of pathogen spread through a breach created after an endoscopic procedure. Exogenous infections are spread from patient to patient by contaminated equipment or from endoscopy personnel to patients. This section will focus on exogenous mechanisms of infection.

The longstanding issues with infection control pertain to the inherently complex nature of the endoscope and compliance with cleaning. With the advent of advanced non-autoclavable fiberoptic endoscope, it is technically not feasible to sterilize the endoscope and therefore must undergo high-level disinfection. In practical terms, endoscopes cannot be completely bacteria free. The success of "adequate" disinfection is thus dependent on the diligence with which tissues are physically removed from biopsy channels and other hard-to-access parts of the endoscope, and with the degree to which the chemical disinfectants have full contact with (adequate time of contact), characteristics of the specific and variable viruses, bacteria, and other infectious agents. The realistic aim of reprocessing protocols is to prevent transmission of pathogens from patient to patient.

What practices are necessary for endoscopy-related infection prevention and control?

Most infections predated the 1988 multisociety guidelines that emphasized effective manual cleaning in addition to the use of approved high-level disinfectants. It has been proven multiple times that regardless of soak time, type of disinfectant, or processor used, effective manual cleaning remains the most important step in reducing microbial burden.

Current U.S. guidelines prescribe the following features:

1. Pre-cleaning

2. Leak testing

3. Cleaning

4. Rinsing

5. Disinfection

6. Rinsing

7. Drying

8. Storage

What research regarding endoscopy procedures guides current infection control practices and policies?

Since the 1990's, healthcare facilities and manufacturers have been required to report to the FDA any information that reasonably suggests that a device (such as an endoscope, accessory, or automated endoscope washer-disinfector) has caused or contributed to a death, injury, or serious illness of a patient.

A total of 281 episodes of pathogen transmission were attributed to gastrointestinal endoscopy as reported in a review in 1993. The transmission of infectious organisms during gastrointestinal endoscopy was considered rare even at that time with rates of 1 in 1.8 million cases between 1993 and 2003; there were only 5 additional reported cases, all occurring outside the United States.

In a 2003 review by Nelson et al., only 35 cases of transmission of infection during GI endoscopy had been reported in the prior decade. An estimated 17 million lower GI endoscopies and about the same number of upper endoscopies are performed annually in the United States. If this procedure rate was constant during the past decade, the estimated infection rate approaches 1 in 10 million procedures. In the absence of defective equipment, every reported case of hospital acquired infection associated with a contaminated GI endoscope have been linked to a breech or violation of at least one of several requisite reprocessing steps. After the establishment of the 2003 multi-society guidelines for the reprocessing of flexible gastrointestinal endoscopes, there have been no reported cases of transmission of infection when these high-level disinfection (HLD) guidelines were followed.

It is important to note that these numbers are gross estimations and are likely an underestimation due to a combination of underreporting, unrecognized asymptomatic infections, or unrecognized association of infections with prior endoscopy where the incubation period of the organism is very long. Transmission of infection is difficult to distinguish between improperly processed scopes versus inadequate aseptic techniques.

What are the consequences of ignoring infection control recommendations regarding endoscopy procedures?

Compliance is a continuing dilemma.

Every patient must be considered a potential source of infection. Failure to comply with recommendations for cleaning will not only lead to pathogen transmission, but also to misdiagnosis from retained debris from prior studies and instrument malfunction and costly replacement/repair. In general, compliance with reprocessing guidelines can be improved.

In 1991, Gorse and Messner surveyed 2,030 members of the Society of Gastroenterology Nurses and Associates and found that compliance with various aspects of existing guidelines ranged from 67% to 93%. There was widespread lack of knowledge of the potential problems with contamination. A 1992 collaborative study by the FDA and 3 state health departments investigating endoscope reprocessing at 26 healthcare facilities reported that 24% of patient-ready endoscopes (GI endoscopes and bronchoscopes) were culture positive, and these were associated with a number of fundamental errors in the disinfection process. More concerning, in 1997 Jackson and Ball surveyed 19 family and internal medicine practices performing endoscopy and found that all were deficient in following reprocessing guidelines in at least one area.

Most recently in a 1998 and 1999 survey of healthcare professionals found that overall, compliance with infection guidelines has improved but a significant minority of centers still do not conform to guidelines. They have noted a trend towards reusing disposable items. Almost 50% of responders reported reusing disposable items.

The Veterans Affairs (VA) hospital system has reported incidences where reprocessing has deviated from guidelines. In 2008, the Tennessee Alvin York Campus reported blood in the auxiliary water tubing and found that a one way valve was absent during the procedure that prevents back flow of body fluid. The connector tubing was switched unknowingly and it was never determined how long the tubing was in use. Further investigations also found the two components of the auxiliary water tubing were not being disinfected or discarded accordingly. Nursing staff responsible for reprocessing did not receive proper training.

In 2009, the Bruce Carter Miami VA Campus inspection revealed that the auxiliary water tube and other accessories were not sterilized prior to initial use, was not reprocessed between patients, and none of the irrigation components had been changed or reprocessed since 2004 when the equipment arrived onsite. Further, debris was found in the auxiliary water channel while flushing multiple coloscopes that were presumed clean.

What other information supports the research on the prevention of endoscopy-related infections?

The post procedure endoscope has a bacterial burden estimated to be $10^{5\text{-}10}$ colony forming units (CFU) per mL, with the highest burden within suction channels. Appropriate manual cleaning of endoscopes reduces the number of microorganisms and organic load by 4-6 logs or 99.99%. In order of most resistant organisms in descending order are prions, bacterial spores, mycobacteria, non-lipid viruses, vegetative fungi and bacteria, and finally lipid containing viruses (HBV, HCV, and HIV).

Please see below sections for details on specific case reports on pathogen transmission.

What is the impact of endoscopy related infections relative to the impact of other infections?

Flexible endoscopes are currently the most common endoscopic instruments used in clinical practice. These are complex medical instruments having multiple long and narrow working channels that are subject to torque and angulation forces. These require special materials and advanced engineering including state of the art electronics, fiber optics and imaging technology. Thus, there is apprehension about proper cleaning of flexible scopes due to the inherently complex nature of the instrument and the procedure raising concerns about endoscopic transmission of infections. This is seen in light of an estimated 30-35 million flexible endoscopic procedures performed annually in the United States alone. More importantly, these procedures are performed in a variety of settings, from a doctor's office to a hospital surgical suite. The methods employed to clean and disinfect these flexible endoscopes are also very diverse. A key concern, no matter where these procedures are done, is how clean these scopes are after reprocessing.

Overview of important clinical trials, meta-analyses, case control studies, case series, and individual case reports related to infection control and endoscopy.

Bacterial transmission

Pseudomonas is the most common pathogen isolated in endoscope-associated infections. They flourish in biofilm within internal channels and have been associated with overwhelming sepsis. Immunocompromised patients in particular are susceptible to bacteremia post procedure. There have been approximately 216 reported cases of Pseudomonas aeruginosa transmission, the majority of which occurred early and were related to inadequate disinfectants. Other potential sources include unsterilized irrigation water bottles attached to the endoscope, lack of cleaning and air drying, and failure to disinfect the elevator channel of duodenoscopes.

An outbreak published in 1991 was attributed to an automated endoscope reprocessor (AER) that had biofilm contamination, and which resolved after flushing the channels with alcohol and forced air drying. Lubricating jelly has been shown to shield pseudomonas from high-level disinfection (HLD) in the case of dental equipment. One 1999 study found that manual cleaning with HLD failed to achieve 6-log reduction in bacterial burden. But when alcohol rinse was added to the drying step, all endoscopes achieved 6-log reduction.

There are no definitive reports of Clostrdium difficile transmission by GI endoscopy. Current guidelines have shown that spores are adequately inactivated.

Historically, salmonella infections have been associated with frequent transmission and outbreaks. Between 1974 and 1988, there were 48 cases of Salmonella transmission. There have been no reported cases since the publication of the 1988 recommendations for cleaning.

Helicobacter pylori transmission is typically related to inadequate reprocessing of endoscopes and forceps. Up to 61% of endoscopes are contaminated after use in infected patients. There have been 12 reported cases of H pylori infection that have been attributed to endoscopic transmission. Both manual and automated reprocessing protocols consistent with currently accepted guidelines have been shown to result in 100% eradication of the organism.

There are no reports of transmission of mycobacterim tuberculosis by gastrointestinal endoscopy, although there are reports of bronchoscopic transmission. In patients with active tuberculosis, Australian guidelines and the Centers for Disease Control for bronchoscopy specifically recommend avoiding this procedure unless absolutely necessary.

Early studies in the 1990's raised concern that 2% gluteraldehyde does not eliminate all atypical mycobacteria using standard contact time of 20 minutes and may require 45 minutes. Current reprocessing procedures that include cleaning have been shown to be adequate in eradicating mycobacteria.

Other bacteria that have been isolated include E. coli, Klebsiella, Enterobacter, Serratia, and Campylobacter, all of which occurred with insufficient cleaning and disinfection.

Viral Transmission

Due to longer incubation periods, documentation of transmission is difficult as patients may be asymptomatic. There are few documented cases of Hepatitis C virus transmission via gastrointestinal endoscopy. Cases were attributed to lack of manual cleaning of suction channels with a brush, failure to sterilize biopsy forceps, and reuse of IV tubing, syringes, or multidose vials. With appropriate cleaning following guidelines, HCV transmission is effectively removed.

There is a 1997 report of Hepatitis C transmission via upper endoscopy despite adequate cleaning techniques, although formal review of anesthesia and cleaning techniques were not reported. In 2001, New York officials closed a Brooklyn endoscopy unit after 9 patients were diagnosed with hepatitis C post endoscopy. In 2007, a Nevada unit documented a Hepatitis C outbreak and attributed this to aseptic techniques with a multidose vial. A landmark study in 2005 comprised of 8,260 patients undergoing endoscopy who were tested for HCV before and 6 months after the procedure found no cases of seroconversion.

Transmission of hepatitis B does not occur or is very rare. There have been few cases of HBV transmission. These were early as well and were related to failure to disinfect channels and removable parts. In 6 studies, a total of 223 patients in whom endoscopy was performed with an instrument previously used on a patient with HBV were followed for 3-6 months; there were no serocnversions. Three other studies conducted in patient populations with relatively high rates of HBV infection followed a total of 600 seronegative patients for up to one year after endoscopy and found no episodes of seroconversion attributable to endoscopy.

There are currently no reports of HIV transmission by gastrointestinal endoscopy. However, the long incubation period until clinical AIDS makes the detection of transmission difficult. The Centers for Disease Control and Prevention (CDC) are in agreement with the current guidelines. Manual cleaning of the endoscope eradicates >99% of the virus and subsequent disinfection with gluteraldehyde for as little as 2 minutes was shown to eliminate the virus from endoscopes. There is a report however, that lubricating jelly can shield HIV from HLD in the case of dental equipment.

Both SARS associated coronavirus and avian influenza viruses (H5N1) are readily inactivated. The H5N1 virus is lipid enveloped and is the easiest to inactivate by physical or chemical decontamination methods compared to all other types of microorganisms. There are no published reports of transmission.

Parasite Transmission

There are few documented reports of parasite transmission. There are 4 cases of strongyloides transmission via a contaminated endoscope. In this case, it was failure to follow recommended guidelines for cleaning and disinfection.

Cryptosporidium oocysts are more resistant to cleaning. One study comparing 3 types of disinfectants showed that even after 90 minutes of soaking in 2.5% gluteraldehyde solution, cryptosporidium oocysts were not inactivated. Current U.S. recommendations only require 20-45 minute of soaking time. There is evidence that hydrogen peroxide gas sterilization is an alternative that can be used with fragile medical equipment. It is unlikely that exposure should cause significant harm to the majority of patients, but can be fatal in an immunocompromised host.

Fungal Transmission

Trichosporon beigelli cross contamination of gastric aspirates occurred in 10 patients using the same endoscope. Despite following appropriate cleaning and disinfection guidelines established in 1989, there were fungal elements isolated within the biopsy channel. Another case of trichosporon transmission occurred in 2001; however this was due to inadequate sterilization of the biopsy forceps.

Candidal transmission is not well investigated. There is report of endogenous infection after variceal sclerotherapy with candida esophageal abscess and sepsis after upper endoscopy in an immunocompromised patient.

Prion Transmission

There are no reports of GI endoscopy related transmission of prions to date. Prions in particular are resistant to conventional disinfectants and sterilants and have recently been found in the spleen, skeletal muscle, and olfactory epithelium of individuals with sporadic Creutzfeldt-Jakob Disease (CJD). There is no evidence at this time of its presence in the GI mucosa. Because of low to no risk of exposure to contaminated tissue, current guidelines are adequate.

Variant Creutzfeldt-Jakob Disease (vCJD) is a condition caused by the consumption of contaminated beef by the bovine spongiform encephalopathy agent. Unlike CJD, the prions associated with vCJD have been detected in the lymphoid tissue, notably the tonsil and appendix, and possibly the ileum and rectum. It is very possible that endoscopic exposure to infected tissue could lead to transmission. At this time, as vCJD is virtually nonexistent in the United States, no changes to the current guidelines are warranted.

Summary of current controversies.

Automated, brushless washing versus manual cleaning and brushing

The U.S. Food and Drug Administration (FDA) approved new labeling for an automatic endoscope reprocessor in 2006 as a “washer-disinfector” for endoscopes without prior manual washing and channel brushing. At this time, there are no independent studies to confirm efficacy of this machine. Almost all Automated Endoscope Reprocessors (AER) designs are tested when they are new, negating the future development of biofilm within the connectors and tubing. There is no indepedent data currently available to

show that automated endoscope reprocessors are able to provide cleaning of endoscopes that is comparable to that of manual washing and brushing. Current guidelines recommend that regardless of manual HLD or automated HLD, manual cleaning is required prior to disinfection. Current guidelines however do not specify the amount of manual cycles needed, nor do they specify time needed for manual cleaning.

Automated Endoscope Reprocessors (AER)

American surveys in 1988 and 1999 showed around 70% of units employed AERs. There are many benefits to having AERs. They standardize the disinfection process and decrease personnel exposure to chemicals. Compared to manual washing, some individual reports argue that AERs have better disinfection results. One study raised the possibility that constant recirculation of germicide may be superior to static exposure in a totally manual system. A Japanese study detected H. pylori even after proper manual washing, but not after mechanical washing.

All systems have flaws, and in AERs, the machine itself can be a reservoir for infection. In 1996, a group conducted a study where endnoscopes were reprocessed using an AER. All scopes were manually cleaned prior to HLD. Group A was disinfected in standard fashion, Group B's AER connectors were soaked in gluteraldehyde prior to HLD and Group C's AER channels, connectors, and valves were sprayed prior to HLD. All groups were cultured and only Group C did not yield bacteria. Even more interesting was that the bacterial load in Group A was cumulative among the endoscopes. The water filtration system within newer models does not provide reliably bacteria free water. In a study of a bronchoscope AER in the UK, water sampled from the filter repeatedly grew mycobacteria. Another 1991 study showed a 36% increase in the number of bacteria isolated by survellance cultures 19 months into using AERs. It was not until after rinsing with alcohol did endoscopes achieve HLD.

An AER should have the following features:

1. The machine should circulate fluids through all endoscopic channels at an equal pressure without trapping air. Channel flow sensors provide an added measure of compliance.

2. The detergent and disinfectant cycles should be followed by thorough rinse cycles and forced air to remove all used solutions.

3. The disinfectant should not be dilute with any fluids.

4. The machine should be self disinfecting.

5. No residual water should remain in hoses and reservoirs.

6. Cycles for alcohol flushing and forced air drying are desirable.

7. The machine should also feature a self-contained or external water filtration system.

8. A method to automatically store or print data verification of cycle is desirable.

There is no international consensus on AER requirements.

Routine microbiological surveillance

There are no current recommendations regarding routine testing of endoscopes or water. Currently the CDC does not recommend routine water testing. At this time, it is okay to use potable tap water, bacteria free water, or sterile filtered water. Performing routine cultures of endoscopes is not currently recommended, but may be done in the event of an identified outbreak.

The ESGE-ESGENA guideline committee recommends routine testing for contaminated reprocessing procedures at intervals no longer than 3 months. For specific step by step guide to sampling and testing, refer to the 2007 ESGE-ESGENA guidelines.

Disinfection prior to the first procedure of the day

It is unclear how long endoscopes can hang before they need to be reprocessed again prior to use. Some studies indicate that it is okay to use within 5-7 days. There are no independent data that suggest reprocessing endoscopes on the morning before the first procedure reduces the risk of patient infection. The reprocessing of side viewing duodenoscopes used during ERCP is recommended before each use.

There are certain situations when it is recommended to reprocess an endoscope just prior to the first patient.

1. When there is uncertainty about whether or not the scope was reprocessed properly (i.e. observed dried organic material, fixed blood, etc.)

2. When the scope is observed to be improperly stored.

3. When there is a known burden of contamination of water within the facility with pseudomonas or mycobacterium.

The Duodenoscope

Of special note is the duodenoscope. Due in part to the anatomy, physiology, and sterile nature of the biliary tract, the design of the side-viewing duodenoscope (elevator channel), and the invasive nature if the procedure, ERCP is probably more vulnerable to endogenous infection than other endoscopic procedures. It is therefore of utmost importance that these scopes are adequately cleaned. The elevator channel of the duodenoscope has a very small lumen. Most AERs cannot generate the pressure required to force fluid through the lumen. A 2-5mL syringe must be used to manually reprocess the elevator channel in ALL steps unless the AER is validated to perfuse this channel. Current guidelines recommend that duodenoscopes must always undergo full disinfection prior to the first procedure of the day due to the residual dampness allowing proliferation of remaining organisms such as pseudomonas.

Special Patient Populations to consider

There are no separate guidelines for reprocessing in special patient populations such as HIV, immunocompromised, or Hepatitis C. Current guidelines, when followed, have been shown to be adequate in eliminating transmission. The only exception is when there is a suspicion for variant CJD as it is highly resistant to conventional reprocessing. When there is any suspicion, endoscopy should either be avoided or a dedicated endoscope should be used.

Sterilization

Due to the fragile nature of flexible endoscopes, they cannot be routinely sterilized. This does not mean that they absolutely cannot be sterilized. The only circumstance where sterilization is required is when it is used in a sterile operative field. There are sterilization systems available that are effective. The System 1 STERIS system was compared to manual cleaning and disinfection in a 1999 study and showed that regardless of manual pre-cleaning, the liquid peracetic acid process successfully removed bacteria.

Sheathed Flexible Endoscopes

Sheathed endoscopes were introduced in the 1990's and prospective trials have compared them to standard endoscopes. No clinical trials published show that these scopes reduce infection rates, or do they address cost effectiveness. They have however demonstrated a reduction in turnover time of endoscopes between procedures. Physicians in general still prefer the standard endoscope

What are the national endoscopy guidelines?

Key Definitions

Anionic detergents have an anionic group that fulfills the hydrophilic function. The molecules do not ionize in aqueous solutions. Some rely solely on mechanical action for removal of bioburden. Some are bactericidal. Enzymatic detergents are low foaming detergents that have enzymes capable of digesting organic material such as blood and mucous. They have negligible effect on surface tension while still suspending soil particles providing easy rinsibility. Some studies demonstrate that enzymatic detergents are superior to neutral detergents in reducing microbial burden.

Cleaning refers to the physical removal of organic material and or soil usually by water with detergents. These remove microorganisms rather than kill them.

High-Level Disinfectants are chemical germicides that have been cleared by the FDA as capable of destroying all viruses, vegetative bacteria, fungi, mycobacterium, and some but not all spores. Most high-level disinfectants are typically reused. There are many types with variations in advantages and disadvantages. For an updated list of approved disinfectants and sterilants, see the FDA website: http://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofsingle-usedevices/ucm133514. 2% Glutaraldehyde is the most commonly used high-level disinfectant. It is also used in cold sterilization and has been used for more than 30 years. The American Society for Gastrointestinal Endoscopy (ASGE) recommends using a surfactant free solution as the residue is difficult to remove during rinsing.

Disinfection kills most microorganisms and is commonly performed by using liquid chemical germicides (LCG). There are 3 levels, high, intermediate, and low. Low level disinfection is a process that can kill most bacterua, some viruses, and some fungi. It cannot be relied on to kill resistant organisms such as tubercle bacilli or bacterial spores. HLD destroys vegetative microorganisms, mycobacteria, fungi, small or nonlipid viruses, but not necessarily large numbers of bacterial spores. It is defined by the U.S. FDA as a 6-log

reduction of mycobacteria. This is recognized by organizations as the standard for reprocessing of endoscopes.

Sterilants are chemical germicides that have been cleared by the FDA as capable of destroying all microorganisms, including all bacterial spores. Sterilization is a process that will kill all microbial life, including the elimination of bacterial spores, and usually achieved with heat or ethylene oxide gas. The only circumstance where sterilization is required is when it is used in a sterile operative field.

Over 30 years ago, Dr. Earle Spaulding developed a classification system to determine what type of disinfection or sterilization is appropriate for medical devices. These 3 classes stratify the risk of infection associated with each device based on its use. Critical devices break the mucosal barrier and enter sterile tissue or vascular spaces. Examples include reusable biopsy needles, surgical instruments, biopsy forceps, rigid endoscopes, and papillotomes. These devices should be sterilized. Semi-critical devices come into contact with mucous membranes and non-intact skin. They do not ordinarily penetrate sterile tissue. Examples include endoscopes, thermometers, and anesthesia equipment. These devices should be sterilized or at least receive HLD. Non-critical devices come into contact with intact skin or do not touch the patient. Examples include blood pressure cuffs and stethoscopes. These devices can be cleaned with soap and water or disinfected with a germicide.

U.S. Guidelines for Endoscope Reprocessing

The majority of gastrointestinal procedures are performed with flexible endoscopes. In contrast to rigid endoscopes, flexible endoscopes are heat labile and cannot be routinely autoclaved. The use of non-immersible endoscopes is no longer acceptable because endoscopes that cannot be completely immersed in liquid cannot be adequately cleaned and undergo HLD. At all times, it is best to refer to the manufacturer's cleaning guide for the specific model used. The following guidelines are based on the 2007 standards set forth by the Society of Gastroenterology Nurses and Associates (SGNA), the American Society for Gastrointestinal Endoscopy (ASGE), and the Association for Professionals in Infection Control and epidemiology (APIC).

Current U.S. guidelines prescribe the following features:

1. Pre-cleaning

2. Leak testing

3. Cleaning

4. Rinsing

5. Disinfection

6. Rinsing

7. Drying

8. Storage

Precleaning is done immediately post procedure within the procedure room. It involves immediately wiping down the scope and alternating suction of fluid and air to remove debris from the internal lumen.

Step by step instructions are as follows:

- Wipe the tube with a wet cloth or sponge in freshly prepared detergent solution. The cloth should be disposed of, sterilized or subjected to HLD.
- Place the distal end of the endoscope into the detergent solution. Suction the solution through the biopsy/suction channel, alternating suctioning detergent solution and air several times.

  Alternating air and fluid suctioning is more effective than suctioning fluid alone in the removal of debris from internal lumen.

  Immediate flushing precludes drying of organic material and debris on lumen surfaces and may remove large numbers of microorganisms.
- Stop when solution is visibly clean. Finish by suctioning air.
- Flush or blow out air and water channels in accordance with the endoscope manufacturer's instructions.
- Flush the auxiliary water channel.
- Detach the endoscope from the light source and suction pump.
- Attach the protective video cap if using video endoscope
- Transport the endoscope to the reprocessing area in an enclosed container.

Leak testing is performed in the reprocessing area. This is done to detect damage to the interior or exterior of the endoscope. It is done before immersion in reprocessing solutions to minimize damage to parts of the endoscope not designed for fluid exposure. This is recommended by the Multisociety Guidelines of 2003. There are instructions for manual and computerized leak testing.

Manual leak testing steps are as follows:

1. Remove suction, air, water, and biopsy valves. Discard those designed as disposable.

2. Attach the leak tester and pressurize the scope before submerging it in water.

3. With the pressurized insertion tube completely submerged, flex the distal portion of the scope in all directions, observing for bubbles.

4. Submerge the endoscope, depress the freeze and release buttons observing the control head.

5. Check the insertion tube and distal bending section as well as the universal cord for bubbles coming from the interior of the scope.

Computerized leak testing steps are as follows:

1. Remove suction, air, water, and biopsy valves. Discard those designed as disposable.

2. Attach the leak tester to the computer

3. Input data including scope ID and user

4. Move knobs and depress the freeze and release buttons when indicated

5. Reprocess when test is complete

Manual cleaning is necessary immediately after removing the scope from the patient and prior to automated or manual disinfection. This step minimizes chances of biofilms development. It includes using a medical grade, low foaming, and neutral pH detergent formulated for endoscopes that may or may not contain enzymes. Low foaming detergents are such that the device can be clearly visualized during the cleaning process, preventing personnel injury and allowing for complete cleaning of lumen surfaces. Note that excessive foaming can inhibit good fluid contact with the device. Endoscopes exposed to synthetic lipids may require additional pre-cleaning with a detergent formulated to remove synthetic lipids. Freshly prepared detergents should be used for each endoscope to prevent cross contamination. Step by step instructions are as follows:

1. Fill the sink or basin with a freshly made solution of water and a medical grade, low-foaming, neutral pH detergent (that may or may not contain enzymes) formulated for endoscopes.

2. Dilute and use according to the detergent manufacturer's instructions.

3. Immerse the endoscope

4. Wash all debris from the exterior of the endoscope by brushing and wiping the instrument while submerged in the detergent solution. Whenever practical, leave scope submerged as this helps to prevent splashing of contaminated fluid and aerosolization of bioburden.

5. Use a small, soft brush to clean all removable parts, including inside and under the suction valve, air/water valve, and biopsy port cover and openings. Use nonabrasive and lint free cleaning tools to prevent damage to the endoscope.

6. Brush all accessible endoscope channels including the body, insertion tube and the umbilicus of the endoscope. Use a brush size compatible with each channel.

7. After each passage, rinse the brush in the detergent solution, removing any visible debris before retracting and reinserting it.

8. Continue brushing until there is no visible debris on the brush.

9. Attach the endoscope manufacturer's cleaning adapters for suction, biopsy, air, and water channels. Automated pumps are available for this step that eliminates the manual flush.

10. Attach the manufacturer's cleaning adapters for special endoscope channels (e.g. elevator channel, auxiliary channel, double-channel scopes).

11. Flush all channels with the detergent solution to remove debris.

12. Soak the endoscope and its internal channels for the period of time specified by the label, if using an enzymatic detergent. Follow the manufacturer's recommendations for the maximum liquid exposure time.

If it is not possible to complete the reprocessing immediately, the scope should be leak tested, flushed, brushed and allowed to soak in a detergent solution until it can be thoroughly reprocessed. Brushes should be cleaned and high-level disinfected between cases. Brushes should be inspected between cases and replaced when worn, bent, frayed, or otherwise damaged, as damaged brushes may damage endoscope channels.

Of note, because the elevator channel of a duodenoscope is a small lumen, this channel requires manual reprocessing in all steps using a 2-5mL syringe. The ASGE guidelines also include the option of using an ultrasonic device in addition to the above steps to help remove organic material from reusable endoscope accessories.

Rinse with bacteria free, potable tap water, or sterile filtered water. None of the aforementioned water types is necessarily bacteria free. However, the use of fresh tap water for rinsing has not been shown to pose an increased risk for infection, provided the endoscope is dried properly. Steps are as follows:

1. Thoroughly rinse the endoscope and all removable parts with clean water to remove residual debris and detergent.

2. Purge water from all channels using forced air.

3. Dry the exterior of the endoscope with a soft, lint free cloth. This step prevents dilution of the liquid chemical germicide used in subsequent steps.

High-Level Disinfection (HLD) is variable from institution to institution and determined by the specific disinfectant used and type of endoscope. Multiple studies and societies agree that HLD is achievable with a 20 minute soak time at room temperature (20 degrees Celsius) using a 2% glutaraldehyde solution which does not contain surfactant and which tests above its MEC (Minimum effective concentration). This differs from the actual chemical label which recommends a 45 minute soak at 25 degrees Celsius. The longer soaking time is based on testing done by the manufacturer without prior manual cleaning. To manually use the high-level disinfectants and sterilants:

1. Prepare the product according to the manufacturer's label instructions.

2. Test the product for the MEC according to the label on the test strip container. This should be done at least daily. The reuse half-life of a reusable high-level disinfectant or sterilant is related to dilution, time, temperature, and number of uses.

3. Completely immerse the endoscope and all removable parts in a basin of high-level disinfectant/sterilant. Do not soak with other sharp objects

4. Inject disinfectant into all channels of the endoscope until it can be seen exiting the opposite end of each channel. Purge until a steady flow of solution is observed. Take care that no air pockets remain. Complete microbial destruction cannot occur unless all surfaces are in complete contact.

5. Cover the soaking basin with a tight fitting lid to minimize chemical vapor exposure. The basin must have a tight fitting lid to contain the vapors.

6. Soak the endoscope in the high-level disinfectant/sterilant for the time, temperature required to achieve HLD. Use a timer.

7. Purge all channels completely with air before removing the endoscope from the high-level disinfectant/sterilant. Purging channels preserves the concentration and volume of the chemical, and prevents exposure from dripping and spilling.

An AER is available within this step depending on the manufacturer and facility. It is required to follow all steps of manual cleaning prior to automated reprocessing. Steps are as follows:

1. Prepare the endoscope reprocessor according to manufacturer's guidelines.

2. Place the endoscope in the reprocessor and attach all channel adapters according to the manufacturer's instructions. Note that the elevator channel of a duodenoscope has a very small lumen and AERs are unable to generate the pressure required to force fluid through the lumen. This channel must be cleaned manually.

3. Place valves and other removable parts into the soaking basin of the reprocessor. Unless the reprocessor has a dedicated space for accessories, reprocess these items separately.

4. Set machine for the appropriate time and temperature depending on the chemical used.

5. Start the machine and allow it to complete all cycles/phases. If cycles are interrupted, HLD cannot be ensured. Full cycles must be repeated.

For both manual and automatic processing, monitor the concentration of the re-used disinfectant at least once a day, or more often, in accordance with the manufacturer's instructions. The minimum effective concentration (MEC) may never be used to extend the reuse life claim of the product.

If the machine has a cycle that uses enzymatic detergent, it should be a product that is compatible with the reprocessor andendoscope. Improper amounts and dilution of the enzymatic detergent may allow detergent residue to remain on the internal external surfaces of the endoscope and on the sink surfaces of the reprocessor. The residue may interfere with the action of the high-level disinfectant or sterilant.

All surfaces and removable parts should be thoroughly rinsed and all channels flushed with clean water as high-level disinfectants have the potential to injure mucous membranes. Adverse reactions in patients from gluteraldehyde residuals after cleaning can cause colitis, abdominal cramps, and bloody diarrhea.

Drying after rinsing prevents the growth of bacteria such as pseudomonas. Steps are as follows:

1. Purge all channels with air until dry. Avoid the use of excessive high air pressure, which can damage the internal channels of scopes.

2. Flush all channels, including accessory channels; with alcohol until the alcohol can be seen exiting the opposite end of each channel. 70% Isopropyl alcohol can be used in this step.

3. Purge all channels with air. Alcohol mixes with the remaining water and promotes evaporation of residual water as air flows through the channels.

4. Remove all channel adapters.

5. Dry the exterior of the endoscope with a soft, clean, lint free towel. This step is required and is as important as cleaning and HLD.

6. Thoroughly rinse and dry all removable parts. Do not attach removable parts during storage as this may trap water during storage.

If the AER does not include a final alcohol rinse cycle, this step should be done manually.

The ERCP elevator channel must be manually flushed and dried.

When storing the endoscope, hang the endoscope vertically with the distal tip hanging freely in a clean, well-ventilated, dust-free area. This allows continued air-drying and prevents moisture buildup. Padding the lower portion of the storage area with non porous material may prevent damage to the distal end of the scope.

After cleaning the endoscope, perform HLD or sterilize the water bottle and its connecting tubes at least daily.

Institutional recommendations for prevention of transmission

An individual should be designated and assigned to monitor compliance with the reprocessing protocol. Quality measures need to be established include proper documentation of equipment use, person performing the procedure, and patient name. Only individuals who are able to read and understand the instructions on proper cleaning should be given the responsibility to reprocess such instruments. Temporary personnel should not be allowed to clean or disinfect instruments in either a manual or an automated reprocessing system. Personnel should complete the initial infection control orientation/reprocessing competency, subsequent annual competency review and infection control updates, and documentation should accompany each. There should be annual personnel review.

What international guidelines exist regarding endoscopy infection control?

For links to individual international societies, visit: http://www.worldendo.org/internet-links-societies.html

The European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) have established 2008 guidelines similar to U.S. standards. Significant differences include a strong recommendation for use of the automatic washer-disinfector in addition to manual cleaning. The rinse and dry cycles are optional when using the washer disinfector. In Europe, the use of detergents that have antimicrobial activity is common a recommended.

Ideally, detergents are to be changed for each endoscope, but if the detergent has antimicrobial activity and the solution is not visibly contaminated, then changing the detergent at least once daily in allowed.

Regarding brushes, they recommend single use brushes. All reusable brushes must be cleaned mar then undergo ultrasonic cleaning and decontamination. They also recommend a specific step for ultrasonic cleaning of reusable endoscope accessories. For manual drying, 70-90% alcohol or isopropyl alcohol is recommended but should be done only at the end of the day as residual fluid poses a fire risk during electrosurgical procedures. Single use injection needles are recommended and under no circumstances should they be reprocessed, as the narrow lumen is difficult to clean.

In 1996, the British Medical Devices Agency published a bulletin and recommended that HLD should follow the manufacturer's label of glutaraldehyde soak time at 45 minutes instead of the 20 minutes used in the U.S.

Due to the fixative nature of alcohol, its use is not recommended in some countries.

The World Gastroenterology Organization (WGO) and World Endoscopy Organization (WEO) 2011 guidelines regarding endoscope disinfection is a collaboration between representatives from 4 continents. It provides a comprehensive hierarchical approach to disinfection as resources vary between regions. Key differences are listed below:

1. Pre-cleaning: Specific steps are listed for checking for bite marks, blockages, external damage.

2. Cleaning: Ideally all cleaning supplies should be disposed. Since most enzymatic detergents require at least 15 minutes of contact time to be effective, nonenzymatic detergents are preferred. They also recommend using ultrasonic cleaning for endoscope accessories.

3. Drying: Similar to European guidelines, endoscope drying is not required in between procedures. Alcohol is used at the end of the day prior to storage. If tap water is used to rinse, then a flush with 70% isopropyl alcohol should be performed.

4. Endoscope use should be avoided in patients with confirmed or suspected vCJD.

Australian Guidelines

In Australia, the ability to provide bacteria free water, or its equivalent, continues to be highly complex and expensive. Therefore it is mandatory to perform bacteriological surveillance of water supplies. Routine bacterial surveillance of duodenoscopes and accessories should be performed monthly. All endoscopes must have full disinfection prior to use at the beginning of the day. Prior to storing at the end of the day, dry with alcohol.

For classic CJD, they recommend alternative diagnostic means, but if unavoidable, use a dedicated scope. Discard all accessories after use in this patient population. Regarding vCJD, there are no current recommendations as this has not been reported in Australia.

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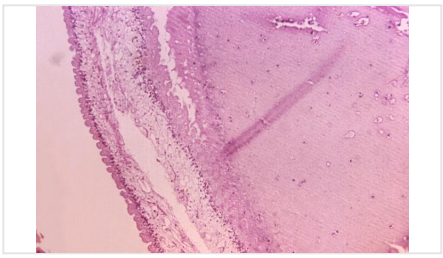

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