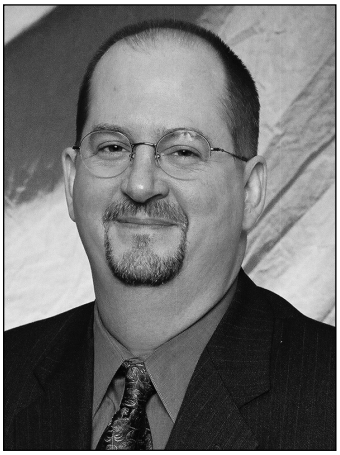
Infection control during gastrointestinal endoscopy

Douglas B Nelson MD FASGE[1], Paul C Adams MD[2], *Editor-in-Chief*

Dr Douglas Nelson is a staff physician in the department of gastroenterology at the Minneapolis VA Medical Center (Minnesota, USA) and a Professor of Medicine at the University of Minnesota (USA). He has written numerous articles on the subject of infection control during gastrointestinal endoscopy, and was the lead author of the "Multi-society guideline for reprocessing flexible gastrointestinal endoscopes" (1).



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PA: How common is a proven transmission of an infective agent during an endoscopy?

DN: Given the tremendous volume of gastrointestinal endoscopic procedures performed in the United States (and worldwide), the rate of transmission of infection is vanishingly small. There have been 35 documented cases of transmission of infection during endoscopy over the past decade (2), occurring over the course of approximately 34 million procedures per year in the United States alone, a rate of roughly one in 10 million procedures, which is an extraordinary safety record. Furthermore, in each of these cases, a breach in currently accepted endoscope reprocessing protocols has been identified, suggesting that when current guidelines are adhered to, the risk of transmission of infection is virtually eliminated.

PA: Some have argued that asymptomatic infections may be going undetected. How would you respond to these critics?

DN: While it is possible that some infections may not be recognized and go unreported, there is no evidence that this occurs with any significant frequency. Furthermore, when this has been rigorously studied, 'occult' infections have not been found. In a recent Italian landmark study (3), in an area with a relatively high endemic rate of hepatitis C virus (HCV) infection, 8260 HCV-negative patients undergoing endoscopy were tested for the virus six months after the procedure, but not a single case of HCV seroconversion was found (3).

PA: Are the current disinfectant solutions equally effective against bacteria and viruses?

DN: Different classes of microorganisms have variable resistance to liquid chemical germicides (LCGs) such as glutaraldehyde and peracetic acid. In general, spores are harder to kill than vegetative bacteria, which are in turn more resistant than most viruses. Perhaps ironically, the viruses that patients are most concerned with (HIV, HCV and hepatitis B virus) are among the most easily destroyed by commonly used LCGs. While there may be some variation among the different LCGs in terms of physical characteristics (irritant vapour, endoscope damage and/or degradation, cost and exposure time), there is no evidence that any particular LCG provides a superior outcome for the destruction of microorganisms during endoscope reprocessing. Although one LCG manufacturer has implied that their products may be more effective against antibiotic-resistant bacteria, there are no published data to support this claim, and in fact several studies (4,5) have shown that increased resistance to antibiotics does not correlate with an increased resistance to disinfectants.

The recent emergence of new pathogens, such as the severe acute respiratory syndrome (SARS) virus (SARS-coronavirus) and the avian influenza A virus (H5N1) raises the question about the efficacy of current endoscope reprocessing. Although there are few studies that directly address this issue, these are both fragile, lipid-enveloped viruses like HCV and HIV which, as discussed earlier, are easily destroyed by currently used LCGs. In fact, the SARS virus is completely eradicated by even low-level disinfection (much less potent chemicals than those used for endoscope reprocessing) (6).

PA: Should endoscopic channels be sterile after cleaning?

DN: This is a common misconception. Endoscopes undergo high-level disinfection between uses, which results in the destruction of all mycobacteria, vegetative bacteria, viruses, fungal spores and some (but not all) bacterial spores (these residual spores are not pathogenic in humans). It is important to note that the spores encountered during endoscopy, namely those of *Clostridium difficile*, are particularly susceptible to disinfection and are eliminated with relatively short exposure times to conventional LCGs (7-9). There are no published data demonstrating that sterilization of endoscopes provides a superior patient outcome over conventional high-level disinfection (or according to the Food and Drug Administration [FDA] that sterilization can even be reliably achieved with liquid chemical sterilants [10]).

PA: How do you determine if an infection pre-existed or was caused by endoscopy?

DN: There are several aspects to this question. It is important to remember that infections can occur after endoscopy for a variety of reasons that are not related to endoscope reprocessing. We know that every endoscopic procedure is associated with a degree of endogenous bacteremia (eg, the patient's own

[1]*Minneapolis VA Medical Center and University of Minnesota, Minneapolis, Minnesota, USA;* [2]*Department of Medicine, London Health Sciences Centre, London, Ontario*

Correspondence: Dr Douglas B Nelson, Minneapolis VA Medical Center, Room 111-D, One Veterans Drive, Minneapolis, Minnesota 55417, USA. Telephone 612-467-4106, fax 612-725-2248, e-mail Douglas.nelson@med.va.gov

bacteria entering the bloodstream) that may cause subsequent infection (11). For this reason, depending on the degree of bacteremia associated with the procedure and the patient's risk of developing an infectious complication, antibiotic prophylaxis may be recommended. The endoscopic procedure itself may be performed to treat an infection (such as an endoscopic retrograde cholangiopancreatography for cholangitis). Infectious complications that occur after the procedure may result from bacterial seeding that occurred before the procedure, or from an unsuccessful procedure (in other words, failure to treat or resolve the infection), but the endoscopy did not 'cause' the infection.

This question is particularly relevant because it pertains to patient notifications after a reprocessing failure. While it is estimated that approximately 2.3% of adults in the United States are HCV-positive, only a minority (in one report as low as 5%) of these individuals are actually aware that they harbour the virus (12). Thus, if 1000 patients are exposed to a reprocessing failure (whether or not there is a significant risk of infection), one could expect that approximately 23 patients that already had HCV before the procedure (most of whom will be unaware of their status) will receive notification that they were exposed to a potential infection. In the absence of baseline serologic testing after the reprocessing incident to demonstrate the presence of antecedent infection, these patients may otherwise mistakenly assume that they had acquired the virus from the reprocessing failure. Because it takes approximately five to six weeks for an acute HCV infection to result in seroconversion, it is prudent to establish, as quickly as possible, whether a pre-existing infection is present.

PA: Many endoscopic devices are disposable now. Is this because of the risk of transmitting infections or difficulty in sterilization?

DN: Single-use disposable (SUD) endoscopic accessories were introduced in the 1980s, and rapidly gained widespread acceptance in the gastroenterology community. The putative advantages were ease of use, increased unit efficiency by eliminating reprocessing and 'first use' performance. There have been few studies critically comparing SUDs with equivalent FDA-labelled reusable devices (not to be confused with reprocessing devices labelled as single-use), and there remains some controversy whether there are any demonstrable advantages (or disadvantages) with regard to performance characteristics or overall cost. Many devices, because of their design and complexity (such as hydrophilic coatings and multiple small lumens), are available only as single-use devices because these features would be difficult (if not impossible) to incorporate into a device that could withstand rigorous reprocessing. From purely an infection control stand point, both disposable and reusable endoscopic accessories are safe and effective when used as labelled by the FDA. The few cases of transmission of infection that have implicated a reusable endoscopic accessory have involved failure to appropriately reprocess the device. Because SUDs are never subject to reuse, there can be no possibility of user error during reprocessing and this may offer a theoretical systems advantage to their use.

PA: Should endoscopy units have periodic surveillance to determine safety of their endoscopes?

DN: The difficulty with environmental surveillance cultures of endoscopes is that there are no generally accepted, standardized methods to perform or interpret them. While the obvious extremes are not difficult to interpret (a surveillance culture with over 100,000 cfu/mL of enteric bacteria in a presumably patient-ready device would suggest a reprocessing failure, while a negative culture is reassuring), the middle ground is problematic. How to interpret a positive surveillance culture with a low number of organisms? If the organisms are common skin flora, this would seem straightforward because this likely represents environmental contamination of the culture rather than a problem with reprocessing. However, if a culture returned with a low number of coliform bacteria, does this mean there is a reprocessing failure? Two interesting abstracts (13,14) from Digestive Disease Week in May 2006 presented data that air contamination of endoscopic procedure rooms with enteric bacteria is common (suggesting that these culture results could also represent environmental contamination rather than reprocessing failure). Because the utility of routine environmental surveillance cultures has not been established, it is not yet recommended in the United States multisociety guideline (1).

PA: What are the new developments in this area?

DN: There are several new products that have recently been cleared for use in the United States. CIDEX OPA Concentrate (Advanced Sterilization Products – Johnson & Johnson Medical Ltd, United Kingdom) contains 5.75% *ortho*-phthaldehyde (OPA), which is mixed with tap water to achieve a diluted, single-use solution of 0.05% OPA for use in the EvoTech Integrated Endoscope Disinfection System marketed by the same company (it is contraindicated for manual reprocessing). Because its active ingredient is OPA, which has not been reported to cause endoscope damage, CIDEX OPA Concentrate is likely to be compatible with gastrointestinal endoscopes; however, for that same reason its use may be limited in the urology setting due to reports of anaphylaxis-like reactions in patients with cancer of the bladder after contact with cystoscopes that have been reprocessed using CIDEX OPA.

Aldahol III (Healthpoint Ltd, USA) contains a novel mixture of 3.4% glutaraldehyde and 26% isopropanol to achieve high-level disinfection in 10 min at 20°C, suggesting that isopropanol enhances the tuberculocidal properties of glutaraldehyde, reducing the time and temperature required to achieve high-level disinfection. The compatibility of gastrointestinal endoscopes with prolonged immersion in isopropanol (as opposed to a brief exposure of the internal channels to facilitate drying) has not been established.

Acecide (Minntech Corporation, USA) is a mixture of 8.3% hydrogen peroxide and 7% peracetic acid that is labelled to achieve high-level disinfection of flexible endoscopes in 5 min at 25°C (with a maximum reuse life of five days). The two components are supplied in separate containers and are mixed when ready to use. As with any LCG that requires an elevated immersion temperature to be effective, Acecide may require the use of an automated endoscope reprocessor.

The STERRAD NX System (Advanced Sterilization Products – Johnson & Johnson Medical Ltd, United Kingdom) uses an electrical field in a low-temperature, negative-pressure chamber to convert a solution of hydrogen peroxide and water to a hydrogen peroxide plasma cloud that contains ultraviolet light and free radicals with sporicidal properties. The device has been cleared to sterilize flexible endoscopes that feature a single working channel (no air, water or accessory channels) with an inner diameter of at least 1 mm and a length of 850 mm or shorter; thus, it is contraindicated for reprocessing gastrointestinal endoscopes.

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