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## ADVANCES IN ENDOSCOPY

### Safety of technology: Infection control standards in endoscopy

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**Abstract** Transmission of infection related to gastrointestinal endoscopy continues to be a subject of much discussion. The principles of infection control during endoscopy are reviewed. Guidelines set forth by a number of gastrointestinal endoscopy associations have emphasized the need for meticulous cleaning of endoscopes immediately after use, followed by appropriate disinfection, rinsing and drying. Most, if not all, episodes of transmission of infection during endoscopy are associated with lapses in cleaning and disinfection protocols. The need for universal compliance with infection control standards, and for the development of strategies to achieve such compliance, is highlighted.

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**Key words:** chemical disinfection, clinical guidelines, endoscope reprocessors, endoscopic accessories, gastrointestinal endoscopy, infection control, manual cleansing, technology safety, total quality management.

### INTRODUCTION

Gastrointestinal endoscopes were developed about a half-century ago in order to gain access to cavities with minimal invasiveness and maximum effectiveness. As their use became widespread, and with further technological developments, concern arose over the possibility of transmitting infection through these instruments. Until the 1960s, cleaning of endoscopes consisted only of wiping the exterior surface with dilute soap solution, water and alcohol, and flushing the channels manually with soap solution and water. Flushing with disinfectants, usually quaternary ammonium compounds, was later introduced. In the mid-1970s liquid chemical germicides capable of sterilization or high-level disinfection became available, and were widely used for endoscope disinfection. Infection transmitted at endoscopic retrograde cholangiopancreatography (ERCP) was recognized in the early 1980s,<sup>1,2</sup> and was attributed to moisture left in the channels leading to proliferation of microorganisms. This led to alcohol flushing, forced air-drying, and vertical uncoiled storage of endoscopes. Automated endoscope reprocessing machines were developed alongside, and continue to be perfected. Endoscope design underwent further development to allow perfusion of channels through the universal cord instead of through the channel head, and to provide air and water channels that could be brushed, in addition to steam-autoclavable air and water valves. Guidelines

for cleaning and disinfection of gastrointestinal endoscopes were formulated by professional associations in the 1980s, and have been widely followed in the developed countries since the late 1980s.

Contaminated endoscopic equipment may cause infection in three ways. First, pathogenic organisms may be transmitted from one patient to another through the endoscope or accessories, the commonest example being salmonellosis. Second, opportunistic organisms that colonize endoscopic and ancillary equipment on storage may be introduced into sterile cavities in the patient, causing clinical infection in the presence of obstruction to drainage, or in immunocompromised individuals. Third, pathogenic organisms may also be transmitted from patient to staff (or less commonly, vice versa) during the process of endoscopy, usually through needle-stick injury. This review will consider only the first two possibilities, and will bear on the principles of infection control as applicable to gastrointestinal endoscopy.

### Theoretical considerations of infection risk management

In the 1960s, Spaulding evolved a classification system that combined the principles of microbial inactivation with risk assessment and management. It was applicable

to all medically used devices<sup>3</sup> and was based on the premise that it was neither practical nor warranted for every device or instrument to be sterile before use. According to this system (Table 1), any instrument that penetrated skin or mucosa or came into contact with normally sterile tissues or the vascular system was classified as critical. The probability that such an instrument could transmit infection if it was contaminated was high, and it was critical that these instruments should undergo sterilization before making this degree of contact.

Sterilization is a stringent process in which even resistant microbial organisms are likely to be destroyed. The process of sterilization can be verified by using highly resistant bacterial spores (commonly either *Bacillus subtilis* or *Bacillus stearothermophilus*). Sterilization should reduce the probability of contamination to one in a million. In the hospital environment, the gold standard of sterilization is achieved by using the steam autoclave. Heat-stable critical instruments can be sterilized using a steam autoclave or a forced-air dry heat oven. Heat-sensitive critical items can be sterilized using chemical gases (ethylene oxide) or vapor plasma methods and, less frequently, by liquid chemical germicides (e.g. glutaraldehyde, peracetic acid or hydrogen peroxide). Compared with heat sterilization, these chemical methods are likely to fail in the presence of residual material or moisture left on instruments being processed. Sterilization can also be achieved by using liquid chemical germicides, but exposure for hours is necessary to inactivate all bacterial spores. The use of liquid chemical germicides for sterilization should be at the point of use, as instruments cannot be wrapped to maintain sterility until use.

Intact mucus membranes are resistant to infection and instruments not designed to penetrate these require a process less rigorous than sterilization. If the instrument is heat sensitive and sterilization is not feasible or practical, then a process termed high-level disinfection, in which all major groups of pathogens are disinfected, is appropriate. These instruments are labeled semicritical. High-level disinfection is a less potent process than sterilization, but destroys all microorganisms with the exception of high numbers of bacterial spores. This process is usually achieved by employing any of the liquid

chemical germicides used for sterilization, except that exposure is only for minutes, compared to hours for sterilization. The necessary exposure time for high-level disinfection is determined by the time it takes to inactivate 10<sup>6</sup> resistant non-spore-forming test microorganisms, such as *Mycobacterium tuberculosis*, var. *bovis*. It should be noted that most aerobic bacterial spore formers are non-pathogenic. High-level disinfection inactivates all pathogens including hepatitis B virus (HBV), human immunodeficiency virus (HIV), *M. tuberculosis*, etc.

Instruments coming into contact only with intact skin have very little risk of transmitting infection even if they are contaminated with microorganisms. These are labeled as non-critical, and they need not be sterilized before use.

### Intrinsic resistance of various microbes to the process of sterilization

Germicides have varying degrees of potency against different organisms,<sup>4</sup> and it is necessary to factor this into considerations of endoscopic disinfection. Table 2 indicates the relative resistance of various microbial organisms to germicides. Bacterial spores, usually found in the genera *Bacillus* and *Clostridium*, have among the highest resistance in the microbial world, and are used as the benchmark to test the process of sterilization. Most of the infectious organisms relevant to gastrointestinal endoscopy are fairly sensitive to disinfectants. The sensitivity of hepatitis C virus (HCV) to germicides has not been tested using infectivity assays, but being a lipid-coated virus it is expected to be quite sensitive.

There has been recent concern about neurodegenerative diseases caused by prions, particularly Creutzfeldt-Jakob disease or its variants. Prions are resistant to most physical and chemical inactivation methods, and there is no safe way to guarantee their eradication from endoscopes or accessories. The brain, pituitary and cornea carry the highest risk of transmitting prion disease, but prion protein has also been detected in lymphoid tissue such as the tonsil and appendix.<sup>5,6</sup> The inability to eradicate these organisms,

**Table 1** The classification of risk posed by medical instruments or devices, and relation to intensity of decontamination (Spaulding<sup>3</sup>)

Classification	Description	Infection risk	Sterility level required	Examples
Critical	Penetrates skin or mucosa, or enters sterile tissue or vascular system	High	Sterilization	Biopsy forceps, sclerotherapy needles, ERCP cannulas, sphincterotomes
Semi-critical	Does not penetrate intact mucus membrane/skin	Low to poorly defined	High level disinfection	Gastrosopes, colonoscopes, duodenoscopes, grasping forceps
Non-critical	Only comes in contact with intact skin	Nil	Washing or mild disinfection	Cautery plates, electrodes

ERCP, endoscopic retrograde cholangiopancreatography.

**Table 2** Intrinsic resistance of microbial organisms to germicides

High
Prions
Spores ( <i>Bacillus</i> , <i>Clostridium</i> spp.)
Moderately high
Mycobacteria
Non-lipid viruses (poliovirus, hepatitis A virus)
Encysted forms of some parasites
Intermediate
Vegetative bacteria and fungi
Low
<i>Helicobacter pylori</i>
Very low
Hepatitis B virus, human immunodeficiency virus
Unknown
Hepatitis C virus

coupled with the invariably fatal nature of the diseases they cause, has led to the recommendation that endoscopy should be avoided wherever possible. If used on a patient with definite disease, it has been recommended that the endoscope be destroyed and incinerated.<sup>4,6</sup>

### Overview of the basic steps in endoscope cleaning and disinfection

The amount of organic material left on the endoscope at the time of disinfection or sterilization is the single most important factor affecting the outcome of any germicidal procedure. Other factors include the microbial load, type of germicidal agent, and temperature and time of exposure.<sup>7</sup> The organic debris left on the endoscope after use may protect imbedded microorganisms; it may also inactivate germicides before they have time to work and, it may, in itself, contain high numbers of microorganisms.

Bioburden is a term that has been used to describe the microbial load left on the surface and channels of endoscopes after clinical usage. Gastrointestinal flexible endoscopes have bioburden levels ranging from  $10^5$  to approximately  $10^{10}$  colony forming units/mL after clinical use.<sup>8,9</sup> The outer sheath and water channel of endoscopes generally show lesser levels of contamination (by approximately 2-logs) than the suction channel.<sup>10</sup> The nature of the microorganisms contaminating the endoscope depends on its site of use. Studies using material from suction channels of gastroscopes show that Gram-positive rods predominate, probably because of the higher load of diphtheroids in the gastrointestinal tract.<sup>8</sup> In contrast, Gram-negative bacilli commonly associated with the intestinal tract, including *Escherichia coli* and *Bacteroides*, predominate in the suction channels of colonoscopes.<sup>9</sup> In contrast to the suction channel, the surface of the insertion tube contains a large number of Gram-positive organisms, including *Corynebacterium*, *Staphylococcus* and *Streptococcus*. Thus, contamination of the suction channel appears to be mainly from the intes-

tinal lumen, while the process of handling in a non-sterile environment contaminates the surface.

### Cleaning

It is important to ensure that the endoscope and its channels are kept moist immediately after use in order to prevent any organic matter from drying. This would hinder cleaning and disinfection. The first important step of processing is manual cleaning. Manual cleaning improves the efficiency, reliability and effectiveness of the high-level disinfection process, and shortens the exposure time necessary for the germicide.<sup>11</sup> A neutral or enzymatic detergent should be used, the latter being a more effective cleanser.<sup>12</sup> Aldehydes, such as glutaraldehyde, harden the organic matter; exposure of endoscopes to these, before the endoscope surface and channels have been adequately cleaned, should be avoided.

The need for meticulous manual cleaning prior to any disinfection has been emphasized in all guidelines relating to endoscope reprocessing. Manual cleaning has been shown to markedly reduce levels of microbial contamination. In a study by Chu *et al.*,<sup>9</sup> manual cleaning reduced the microbial load by greater than 1-log on the surface, and by about 5.5-log within the channel. Another study demonstrated that manual cleaning of gastrointestinal endoscopes reduced the level of microbial contamination by 4–6 logs.<sup>10</sup>

### Disinfection

Following cleaning, the endoscope is exposed to a chemical germicide to destroy any microorganisms that remain. Activated glutaraldehyde (2%) is the most widely used of the liquid chemical germicides. It has a minimum killing time of 1 min for vegetative bacterial pathogens, while 2 min exposure inactivates HIV as well as enteroviruses; HBV is inactivated after 2.5–5 min. Low titers of *M. tuberculosis* are destroyed within 5–10 min, but it may take up to 20 min to inactivate high titers of this organism. *Mycobacterium avium intracellulare* requires 60–120 min of disinfection, and bacterial spores are killed only after 3–4 h. The postactivation use life of glutaraldehyde varies from 14 to 28 days, depending on the claims of the manufacturer. However, use life should be dictated by the concentration of the glutaraldehyde, and it is recommended that the concentration should not fall below 1–1.5% when used as high-level disinfectant.<sup>13</sup>

Glutaraldehyde may cause adverse reactions in endoscopy staff exposed to the fumes; therefore, unnecessary exposure to the germicide should be avoided. Peracetic acid (0.35%) is another widely used germicide. It is a strong oxidizing agent, and kills vegetative bacteria, viruses and mycobacteria within 5 min, and spores within 10 min. In addition, peracetic acid can remove glutaraldehyde-hardened organic material from biopsy channels; therefore, it may be superior to glutaraldehyde. It is, however, unstable, and there is concern that it may damage or discolor components of the endoscope. A recently introduced germicide is superoxidized

water. This is produced by electrolysis of dilute saline. This solution provides oxygen and hydroxyl radicals and exhibits high activity against most microbes. It is unstable, and should therefore be generated at point of use. It is likely that superoxidized water may find wider application in the future. Other disinfectants that are occasionally used include 7.5% hydrogen peroxide, a combination of 0.08% peracetic acid plus 1% hydrogen peroxide, and 0.5% orthophthalaldehyde.

Endoscopes should be immersed in the germicide at the beginning of the day's session, between use on patients, and again at the end of each day's session. Guidelines formulated by various professional associations<sup>14-18</sup> have minor differences in the recommended time of exposure to 2% glutaraldehyde, as shown in Table 3. The equivalent exposure time when using 0.35% peracetic acid is 5 min for decontamination of endoscopes in all situations not requiring sporicidal activity. Exposure may be extended to 10 min if sporicidal activity is required.<sup>6,15</sup>

#### Rinsing and drying

Rinsing with a large volume of water to remove all potentially toxic chemical residues follows the step of chemical disinfection. Tap water may contain organisms, and should not be used for the final rinse. Several societies have advised that, in the case of manual treatment of semicritical endoscopes, water of potable quality is adequate for final rinsing. Water that has been passed through bacterial filters (0.2 mm or 0.45 mm) is preferable. In the case of ERCP, the final rinsing after disinfection should be performed with sterile water to avoid possible recontamination.<sup>19</sup> Rinse water retained after cleaning may permit overnight proliferation of waterborne microorganisms. Hence, at the end of the day, and prior to instrument storage, all channels must be rinsed with 70% alcohol followed by forced air-drying. Endoscopes should be stored in the vertical uncoiled position after removing the valves and biopsy cap to permit proper ventilation.

The sequential performance of each of the above procedures is essential for the optimal disinfection of gas-

trointestinal endoscopes; due care should be paid to each step. Most cases of endoscopic transmission of infection result from inadequate attention to the process of cleaning or disinfection. In addition, the following study shows the value of alcohol rinse in decontaminating endoscopes. High-level disinfection was tested in 46 endoscopes after contamination with *M. chelonae*. It was observed that manual cleaning achieved a 4-log reduction, while bacteria persisted in a small number of endoscopes even after exposure to glutaraldehyde for 10, 20 or 45 min. In this particular instance, complete disinfection was obtained only after alcohol rinse and drying.<sup>20</sup>

#### Use of automated endoscope reprocessors

Automated endoscope reprocessors or washer-disinfectors are increasingly being used in endoscopic facilities. They have been recommended by most professional societies, particularly when the number of endoscopies exceeds 50 per week. Several designs are available, most of which use glutaraldehyde or peracetic acid as the disinfectant.

These machines offer several advantages:

1. They automate and standardize the disinfection and rinsing step.
2. Staff are not exposed to potentially toxic vapors from glutaraldehyde, as it operates in a closed system.
3. Reprocessing parameters are automatically recorded for quality assurance.
4. Filtered bacteria-free tap water is provided in most endoscope reprocessors.
5. The liquid germicide can be heated to provide optimal disinfection.
6. Alarms can be set to monitor the various steps in the process.

However, automated reprocessors also have significant limitations:

1. Manual cleaning is still necessary before the endoscope reprocessor can be used; it must not be neglected.

**Table 3** Recommendations of various professional organizations and societies regarding exposure time (in minutes) to 2% glutaraldehyde for endoscopic disinfection

Society	Beginning of day	Between patients	End of day	Special situations*
APCDE 2000 <sup>13</sup>	10	10	20	20
BSG 1998 <sup>14</sup>	10	10	10	20. 60-120 For <i>MAI</i>
ESGE 1995 <sup>15</sup>	10	10	10	20
WCOG 1998 <sup>16</sup>	10	10	10	20
ASGE-SGNA <sup>17</sup>	20	20	20	20
FSDE 2000 <sup>5</sup>	10	20	20	20

\*Applicable during endoscopic retrograde cholangiopancreatography, before use in immunocompromised patients, and after use in tuberculosis patients.

APCDE, Asia-Pacific Congress of Digestive Endoscopy; ASGE-SGNA, American Society for Gastrointestinal Endoscopy, Society of Gastroenterology Nurses and Associates; BSG, British Society of Gastroenterology; ESGE, European Society of Gastrointestinal Endoscopy; FSDE, French Society of Digestive Endoscopy; *MAI*, *Mycobacterium avium-intracellulare*; WCOG, World Congress of Gastroenterology.

2. Post-processing, (i.e. alcohol rinse and forced air-drying) is still necessary after passage through the reprocessor.
3. The machines available cannot process several different types of endoscopes; they are limited to specific types.
4. The overall reprocessing time may be longer than with manual processing.
5. These machines do not generally monitor concentration of the germicide.
6. Microbial contamination can occur, either through contamination of the bacterial filters, or through failure to maintain and replace the bacterial filters at the appropriate time.

The European Society of Gastrointestinal Endoscopy has recently published a checklist for prospective purchasers of endoscope reprocessors or washer-disinfectors.<sup>21</sup>

### Reprocessing of endoscopic accessories

The reprocessing of endoscopic accessories remains a contentious issue, essentially because the cost of these accessories is considerable, and economic forces dictate a need to reuse many of them.<sup>22</sup> Accessories are of different levels of complexity in terms of the presence of internal lumens, retractable components, and cutting wires. With each of these features, there is an additional risk of contamination with infectious organisms.

Because of the complexity of reprocessing, many of these devices have been designed for single use and are available only in this format. Biopsy forceps are considered critical because they breach normal mucosa; they therefore need to be sterilized. Current recommendations suggest that biopsy forceps should be either sterilized prior to each use, or that disposable sterile forceps should be used. Other accessories, particularly those used within the biliary tract or pancreatic ducts, are also considered critical by the Spaulding classification because they enter normally sterile body cavities.

Cleaning of accessories needs particular attention, particularly because infective and organic material can lodge in the various crevices and wire coils that characterize them. It is recommended that accessories are soaked immediately after use in enzymatic solution. This should be followed by flushing of any accessory lumen, scrubbing, rinsing, and then cleaning in an ultrasonic cleaner.<sup>23</sup> The latter is necessary to dislodge blood and mucus, particularly from the coil wire and tip present in many accessories.

Where possible, reusable critical accessories should be steam autoclaved. Heat-sensitive accessories such as ERCP cannulas can be treated with ethylene oxide. Sterilization can also be accomplished by treatment with liquid chemical germicide (60 min for 2% alkaline glutaraldehyde<sup>19</sup>) at point of use. However, the view has also been expressed that the level of disinfection of accessories need not exceed the standards for disinfection of the endoscope. Thus, it has been suggested that small centres that do not have a high endoscopy load

might reuse accessories after adequate cleaning followed by disinfection in glutaraldehyde for 10 min.<sup>23</sup>

### Infections reported to have been transmitted at endoscopy

In 1976, Bilbao *et al.* reported a 1.1% incidence of infectious complications in patients undergoing ERCP.<sup>24</sup> This study preceded the use of cleaning and disinfection protocols, particularly with regard to high-level disinfection or sterilization of catheters. In 1993, Spach *et al.* conducted a survey of all published reports relating to transmission of infection at endoscopy from the years 1966–1992. They found only 281 reports of transmission of infection related to gastrointestinal endoscopy during these 26 years.<sup>25</sup>

The American Society of Gastrointestinal Endoscopy surveyed all reports of infectious complications related to gastrointestinal endoscopy over a 5-year period from 1988 to 1993.<sup>26</sup> These complications were recorded following the adoption of good practice guidelines issued by various professional bodies. The group concluded that endoscopic procedures were extremely safe, with a chance of transmitting infection of one in 1.8 million procedures. Infectious complications that were recorded were all considered to be due to interruptions of the cleaning and disinfection protocols that had been in place since 1988. The authors identified several factors as being responsible for transmission of infection, including improper mechanical cleaning, the use of an ineffective chemical disinfectant, and improper drying and storage techniques. Lack of standardization of training and non-compliance of health personnel performing the reprocessing of endoscopes were also pinpointed as a cause of these failures.

Table 4 lists a number of infections that have been documented to have been transmitted at endoscopy. During the process of endoscopy, transmission of common pathogens may not be detected for several reasons. First, the background prevalence of infection in the community may be high, as in the case of *Helicobacter*

**Table 4** Infections documented to have been transmitted by gastrointestinal endoscopy

Bacteria
<i>Salmonella</i> species
<i>Pseudomonas aeruginosa</i>
<i>Enterobacter aerogenes</i>
<i>Staphylococcus epidermidis</i>
<i>Helicobacter pylori</i>
Viruses
Hepatitis B
Hepatitis C
Fungi
<i>Trichosporon beigeli</i>
<i>Trichosporon asahii</i>
Parasites
<i>Cryptosporidium</i>
<i>Strongyloides stercoralis</i>

*pylori*. Second, the incubation period for illness may be long, such as for *M. tuberculosis*, HIV, and *H. pylori*. Mycobacterial transmission has not been reported following gastrointestinal endoscopy, although transmission through bronchoscopy has been documented.<sup>25</sup> Evidence from experimental studies suggests that conventional cleaning and disinfection techniques should eliminate any chance of endoscopic transmission of *H. pylori*.<sup>27</sup> However, molecular techniques of investigation have clearly shown patient-to-patient transmission of *H. pylori* following endoscopy; the approximate frequency is 1.1%.<sup>28</sup> In the latter study, it appeared that, between use on patients, endoscopes were cleaned mechanically using detergent followed by treatment with 70% alcohol. Decontamination probably also requires adequate exposure to a germicidal agent following cleaning, as emphasized in all current guidelines.

Transmission of HCV infection by endoscopy has assumed importance recently. Epidemiologic studies of French HCV-positive patients suggested that the use of biopsies during endoscopy was the only factor linked to anti-HCV seropositivity.<sup>29</sup> The first documented case of HCV transmission related to gastrointestinal endoscopy was reported from France in 1997.<sup>30</sup> Here, infection was transmitted at colonoscopy from one patient who was HCV positive to two other patients who underwent colonoscopy on the same day in the same unit. Failure to use two currently recommended endoscope disinfection procedures could have resulted in HCV being transmitted: the biopsy-suction channel of the endoscope was not cleaned with a brush. The biopsy forceps and the diathermy loop were cleaned with detergent and exposed to glutaraldehyde but not autoclaved following each use. Inadequate procedures to avoid contamination via anesthesia equipment may also have led to HCV transmission.

Earlier this year, eight patients who underwent endoscopy at a single clinic were found to have developed acute hepatitis C.<sup>31</sup> The reasons for transmission of infection in the latter instance remain under investigation. Hepatitis B virus is inactivated by even intermediate-level disinfectants, and all current guidelines are sufficient for inactivating HBV. Human immunodeficiency virus is also very sensitive to cleaning (which produces a 4-log reduction in titer), and to disinfection (a 2-min exposure to glutaraldehyde causes a 4-log reduction in titer).

In samples of suction channel wash fluid taken after endoscopy in HCV-positive patients, viral nucleic acid was detectable immediately after endoscopy in 27%. Following detergent wash, only 2% were positive, and viral nucleic acid was not detectable at all following immersion for 20 min in 2% glutaraldehyde.<sup>32</sup> Six percent of biopsy forceps were contaminated after use, but none after detergent washing and glutaraldehyde immersion. Another study showed that manual cleaning followed by disinfection was very effective in eliminating HCV from experimentally contaminated endoscopes.<sup>33</sup> Ten percent of needles used for endoscopic sclerotherapy had detectable viral nucleic acid immediately after use in patients with HCV infection. The needles continued to remain positive for viral nucleic acid after immersion in 2% glutaraldehyde for 10 min,<sup>34</sup> although

immersion in glutaraldehyde was not preceded by rigorous cleaning, detergent use, or the use of ultrasonic cleaning. These studies suggest that rigorous attention should be paid to basic recommendations regarding cleaning and disinfection in order to prevent the transmission of infections such as hepatitis C.

Thus far, we have dealt with infections transmitted from one patient to another during endoscopy. The issue of infection being induced in a sterile tissue or cavity in a patient as a result of an opportunistic organism also needs to be considered. Transient bacteremia, usually lasting for minutes, is well known to occur following gastroscopy and colonoscopy.<sup>35</sup> The incidence of transient bacteremia following procedures such as dilatation and sclerotherapy is higher. Sterilization of dilators almost completely abolished the bacteremia associated with stricture dilatation, while the use of shorter needles and sterile water reduced that associated with sclerotherapy.<sup>36,37</sup> Endoscopic retrograde cholangiopancreatography is associated with bacteremia in up to 50% of cases.<sup>38</sup> Although bacteremia during endoscopy is transient, usually peaking at 5 min and then decreasing rapidly thereafter, it may be responsible for clinical infections in patients with obstructed biliary systems or in immunocompromised individuals. The American Society for Gastrointestinal Endoscopy recommends the use of antibiotic prophylaxis in patients with prosthetic valves, history of endocarditis, systemic-pulmonary shunt, or synthetic vascular graft (less than 1 year old) when undergoing procedures with a high rate of bacteremia. The latter include stricture dilatation, variceal sclerosis, or ERCP in the presence of an obstructed biliary tree.<sup>39</sup>

### Current concerns regarding cleaning and disinfection

Endoscopes and accessories are becoming more complex in design to accommodate new needs and developments. This introduces new dimensions to the cleaning and disinfection of accessories. In addition to the design complexity of endoscopes, there is a lack of uniformity in endoscopic cleaning techniques. Given the same guidelines, there is device-to-device, day-to-day, person-to-person, and site-to-site variation. Variability in rigor and duration of cleaning could be important. Challenges exist in the complete removal of all biological material, including mucus, blood, and other intestinal debris, from all areas of the flexible endoscope. All the evidence gathered to date by infection control studies suggests that endoscope cleaning, and not the specific disinfection or sterilization procedure, is of paramount importance. If cleaning is not adequate, then there can be failure of disinfection or sterilization that results in transmission of infection.

Instances of patient infection from contaminated gastrointestinal endoscopes can generally be attributed to failure to follow appropriate reprocessing guidelines. The need to follow a rigorous protocol for cleaning and disinfection was illustrated by a study from Australia, in which specimens were obtained from the internal chan-

nels of endoscopes from four endoscopy centers, before, during, and after decontamination.<sup>40</sup> In one center, vegetative bacteria were grown in broth culture after cleaning and disinfection in 2% glutaraldehyde for 20 min. From the same center, HBV and HCV nucleic acid were detected in three of four and four of six viremic patients undergoing endoscopy, respectively. Errors were found in the manual cleaning procedure. Once this was corrected, no bacteria were cultured, and no viral nucleic acid was found in nine patients with HCV infection. Human immunodeficiency virus RNA was detected in five of 14 samples taken immediately after endoscopy of HIV-positive individuals, but all samples were negative after adequate decontamination. In a second center, despite the use of peracetic acid, 15% of samples grew bacteria after decontamination. This study points to the importance of a rigorous standard protocol for cleaning and disinfection.

A number of studies have revealed that there is a varying gap between the recommended guidelines for endoscopic cleaning and disinfection, and the actual practice of these procedures.<sup>41-43</sup> A recent postal survey conducted in the USA demonstrated that approximately 10% of respondents did not follow adequate manual cleaning procedures prior to disinfection.<sup>44</sup> Additionally, 26% of respondents did not sterilize non-disposable forceps before use, and 29% reused disposable accessories, preferring high-level disinfection to sterilization of these. Glutaraldehyde was the most widely used disinfectant, with over 95% using a contact time of 20 min or more. Despite this level of non-compliance with guidelines, the overall impression was that of considerable improvement in reprocessing practices when compared to earlier surveys. Thus, actual observation of endoscopic facilities in the USA<sup>43</sup> showed that 78% of the facilities failed to sterilize biopsy forceps. In an Italian survey, 74.6% of respondents did not carry out any form of sterilization of the biopsy forceps.<sup>45</sup> In contrast, a survey from Spain recorded that there had been an overall improvement in cleaning and disinfection practices in recent years, and improved compliance with standard guidelines.<sup>46</sup> In the Asia-Pacific region, a postal survey established that one-third of the respondents did not practice disinfection at the start of the day, and that approximately one-third used a soak time of less than 10 min in glutaraldehyde.<sup>47</sup> Forced air-drying or alcohol was not used in 40% of centers at the end of the day, and reuse of accessories meant for single use was widely practised. Disposable biopsy forceps were recently reported to be associated with a high degree of operator satisfaction, and they may eventually prove to be cost-effective in comparison with reusable forceps.<sup>48</sup> The wide use of disposable forceps will eliminate one current source of infection transmission at endoscopy: improperly cleaned biopsy forceps.

Optimal control of infection related to gastrointestinal endoscopy requires total quality management, including the use of written protocols, availability of trained personnel, good record keeping, equipment monitoring, periodic microbiological testing, facility design, waste disposal, and accountability. Infectious complications of endoscopy can largely be avoided by following currently available guidelines for cleaning and

disinfection of endoscopes and endoscopic accessories. Attempts to further reduce transmission of infection at the time of gastrointestinal endoscopy will require operations research that is targeted at the reasons for non-compliance with current guidelines, and appropriate strategies to overcome this problem.

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