World Gastroenterology Organisation Global Guidelines

Endoscope disinfection update: a guide to resource-sensitive reprocessing

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WGO Review Team

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1 Introduction

This World Gastroenterology Organisation (WGO) guideline on 'Endoscope Disinfection' is intended for use by health providers and professionals who are involved in the use, cleaning, and maintenance of endoscopes, and it aims to support national societies, official bodies, and individual endoscopy departments in developing local standards and protocols for reprocessing endoscopes.

These WGO Guidelines are the result of a systematic development process for expert consensus based on the medical and scientific literature, existing practice guidelines, and (regional) best-practice standards. The update addresses the recent outbreaks of multidrug-resistant organisms after endoscopy and proposes measures to reduce the risks of these outbreaks occurring. The recommendations are based on the consensus findings of an international multidisciplinary working group with expertise in microbiology, including biofilms, endoscope reprocessing, nursing, and gastroenterology, and with broad experience in developing national and international reprocessing guidelines.

1.1 Guidelines or standards

The delivery of safe and effective endoscopic services is governed by overlapping national and international standards, including those for the design and staffing of the facilities, automatic flexible endoscope reprocessors, disinfectants, water quality, and drying cabinets.

The implementation of the appropriate standards for reprocessing should follow the general principles of good manufacturing practice (GMP). GMP is a set of regulations, codes, and guidelines for a manufacturing process — in this case, reprocessing an endoscope — to produce high-level disinfection, which covers both the process and quality control. GMP is recognized worldwide for the control and management of manufacturing and quality control testing of pharmaceutical products and has evolved over the last 60 years in response to multiple well-publicized problems in the pharmaceutical industry [1].

Reprocessing instructions are often called "guidelines," but are in fact a technical standard that sets out the minimum acceptable practice for reprocessing to deliver high-level disinfection of endoscopes. Medical guidelines usually address a narrow clinical question using population-based data — often the results of randomized trials — to guide the care of an individual patient. Randomized trials are performed in specific populations, and clinicians must decide if the guidelines are applicable to their individual patient [2].

Standards are broader in application and set out specifications and procedures that are designed to ensure that products, services, and systems are safe, reliable, and consistently perform in the way they were intended. The supporting evidence for a standard is based on science, technology, and experience. Randomized trials in a specific population are rarely performed. The standards governing reprocessing are based on science and are often validated by measurements of efficiency in models with artificial soils or a known inoculum of bacteria. The science of cleaning, disinfection, drying, and microbiology forms the basis of reprocessing standards relevant in all countries.

Standards set out the minimum acceptable practice.

The terms "guidelines" and "standards" are both used to describe instructions for endoscope reprocessing [3,4].

1.2 General principles in endoscope reprocessing

The most important step in endoscope reprocessing is scrupulous manual cleaning prior to disinfection. Disinfection will fail if cleaning has been inadequate [5–7].

Manual cleaning must be undertaken by a person familiar with the structure of the endoscope and trained in cleaning technique. Cleaning should begin immediately after the endoscope is used, so that biological material does not dry and harden. Appropriate detergents and cleaning equipment should be used, and in particular brushes with the appropriate diameter should be used for each channel. Cleaning should be followed by thorough rinsing to ensure that all debris and detergents are removed prior to disinfection.

1.2.1 Manual cleaning

Precleaning: immediately after each procedure, with the endoscope still attached to the light source, wipe the insertion tube with a lint-free disposable cloth. Place the distal tip in a low-foaming medical-grade detergent solution and aspirate detergent through all the channels, including the suction/biopsy channel. Flush the air/water channels with detergent. Flush all channels, including the jet channel if present, with water, then air, as per the manufacturer's instructions. Flushing of the air/water channels with detergent may require the use of a specific valve.

Remove the endoscope from the light source and transport it to the cleaning area in a closed container that avoids environmental contamination from dripping or spillage and that clearly indicates that the endoscope within is contaminated.

It is essential that the endoscope is not allowed to dry prior to further cleaning, as this will make removal of organic matter difficult or impossible. Endoscopes should be processed without delay, within 30 minutes.

Leak testing should be performed to check the integrity of all channels before further processing. Remove all the valves and buttons and leak-test the instrument as per the manufacturer's instructions.

Brush and clean buttons and valves, paying particular attention to internal surfaces, and carry out high-level disinfection or sterilization according to the original equipment manufacturer's instructions.

Place the endoscope in a detergent solution in a sink in the "dirty" section of the decontamination area and wash its outer surface. A low-foaming medical-grade detergent should be used at the appropriate dilution according to the manufacturer's instructions. Brush all accessible sections of the suction biopsy channel according to the manufacturers' instructions for use. Each channel should be brushed until all debris is removed. Brush the tip and handles and clean valve seats. Fit cleaning adaptors and flush channels with fresh detergent for the product-specified time.

The endoscope should be rinsed by draining the detergent from the sink, rinsing the outer surface with cold running tap water, and then filling the sink with tap water and purging the channels with tap water, using the cleaning adapters following the manufacturer's instructions. Purge the channels with air to remove rinse water.

1.2.2 Disinfection

High-level disinfection is performed in an automatic flexible endoscope reprocessor (AFER), which should comply with the relevant national standard or be approved by the U.S. Food and Drug Administration (FDA). The AFER may or may not have an automated cleaning cycle as well as the disinfection cycle. All connectors should be specifically designed for each endoscope model. Ensure that all channels are connected at the start and end of a cycle. The detachable components, including the air/water and suction valves, can be steam-sterilized or reprocessed with the endoscope if the ability of the AFER to clean and/or disinfect these detachable components is validated by the AFER manufacturer.

After high-level disinfection, the endoscope is rinsed in the AFER with bacteria-free water produced by submicron filters. Water quality should be checked regularly.

Manual high-level disinfection is another option that is effective when performed by well-trained, dedicated reprocessing staff supplied with the appropriate personal protective equipment. The endoscope is immersed in disinfectant, and all channels are filled with disinfectant solution. Immerse the buttons and valves in the disinfectant. Soak the instrument for the required time at the required temperature and concentration as specified by the disinfectant manufacturer.

Purge the disinfectant from all channels with air and rinse the exterior of the endoscope and flush the channels with bacteria-free water, with the volume required for the specific disinfectant used, to remove any traces of disinfectant.

1.2.3 Drying

Endoscopes should be dried after each procedure by purging the water from the channels with compressed air, then flushing the channels with alcohol, followed by forced-air drying. Alcohol flushing facilitates drying and is a useful adjunct to disinfection, due to its bactericidal effects [8].

The use of alcohol may not be permitted in some countries (France, UK) due to concerns about variant Creutzfeldt–Jakob disease (CJD).

The endoscope is then stored in a forced-air drying cabinet to supplement drying.

If an endoscope is used infrequently, it is reasonable to store it separately, hanging vertically in a purpose-built cabinet, as opposed to a forced-air storage/drying cabinet, and to reprocess the endoscope prior to the next patient use. Endoscopes should be dried completely prior to hanging.

1.2.4 Accessories

The water bottle should be changed after each endoscopy session and steam-sterilized. The water bottle should be filled with sterile water immediately prior to use.

1.2.5 Documentation

All essential steps of endoscope reprocessing should be documented for quality assurance and for patient tracing if necessary.

2 Outbreaks

The recent reports of outbreaks of multidrug-resistant organisms (MDROs) after endoscopy, particularly carbapenem-producing Enterobacteriaceae (CPEs), have focused critical attention on the efficacy and safety of reprocessing protocols.

CPEs have become established in the hospital environment and may cause clinical infections with substantial morbidity and mortality due to their antibiotic resistance. Outbreaks of CPE after endoscopy have been reported in several countries, often after endoscopic retrograde cholangiopancreatography (ERCP) [9] but also following bronchoscopy [10], gastroscopy [11–13], and flexible cystoscopy [14]. Often microbiological surveillance identifies a single source for an outbreak of MDROs that can be traced to a culprit endoscope that has transmitted genetically similar bacteria on multiple occasions despite reprocessing.

MDROs may also be transmitted sporadically by endoscopes without a single source being identified by genetic studies. In case–control studies of hospital in-patients, a recent endoscopy — including gastroscopy, bronchoscopy, and ERCP — has been found to be a significant risk factor for acquiring MDRO colonization/infection [13,15–17].

Before these outbreaks, published reports of clinical infections after endoscopy were infrequent. However, cultures of patient-ready endoscopes and reviews of surveillance cultures suggest that at least 2–4% of endoscopes — including gastroscopes, colonoscopes, and duodenoscopes — are transmitting bacteria [18–21]. Transmission of antibiotic-sensitive enteric bacteria at gastroscopy and colonoscopy rarely causes clinical illness, but the transmitted bacteria may colonize the patient [22,23].

In the past, it was not possible to identify transmission and subsequent colonization with antibiotic-sensitive enteric bacteria, but CPEs are now acting as a marker of transmission [24]. The emergence of CPEs has exposed long-standing flaws in reprocessing.

Many of the problems associated with recent outbreaks are well-recognized problems from the past, including breaches of cleaning and disinfection protocols, often failure to dry before storage, and occult endoscope defects that compromise cleanability. However, there are also outbreaks in which cleaning and disinfection were performed in accordance with the guidelines and the manufacturer can find no fault in the endoscope.

Recent publications have found that current reprocessing standards do not provide a reasonable level of safety and effectiveness [25–27].

In response to outbreaks, the FDA convened an advisory panel in May 2015 [28] that encouraged facilities to consider supplemental measures including double reprocessing between patients, ethylene oxide sterilization, or the use of a liquid sterilant processing system. About 15 months after these recommendations were made, a survey of providers performing ERCP in the United States found that 63% of the centers were performing double disinfection and 12% ethylene oxide sterilization [29]. However, these additional measures are expensive and time-consuming, and ethylene oxide sterilization is not readily available [27].

Subsequent to this advice, a randomized trial comparing the three reprocessing protocols — standard high-level disinfection, double high-level disinfection, and ethylene oxide sterilization — concluded that these enhanced disinfection methods did not provide additional protection against contamination [27]. Another randomized trial found that double high-level disinfection was no better than standard high-level disinfection [30].

It is increasingly recognized that biofilms on endoscopes compromise cleaning and disinfection [31–33]. The conditions reported as causes of outbreaks facilitate biofilm formation and growth; these include inadequate cleaning, inadequate drying, occult endoscope defects including channel damage, and breaches of reprocessing protocols.

Biofilm prevention and control are core problems in reprocessing that are addressed in these guidelines.

The changes proposed can be broadly summarized as follows:

- *Cleaning* — carefully follow the manufacturers' updated reprocessing instructions specific for each model of endoscope.
- *Drying* — improved drying with an alcohol flush and 10 minutes' forced air after each procedure. Endoscopes should be stored in a forced-air drying cabinet.
- *Occult endoscope defects* — routine endoscope maintenance, to identify and repair defects. Routine channel replacement, to reduce the prevalence of occult defects and maintain a smooth, cleanable channel surface.
- *Breaches of reprocessing protocols* — establish a multidisciplinary committee to develop and implement reprocessing protocols and to perform quality control of training, the process, and outcomes.

3 New recommendations

3.1 Recommended changes to reprocessing and storage

Prompt attention to cleaning, disinfection, and complete drying reduces the growth of established biofilm and prevents bacteria from forming new biofilm.

Table 1 Specific recommendations for reprocessing and storage

Activity	Recommendations
Precleaning	— Precleaning must be carried out *immediately* after use.
Cleaning	— Cleaning (manual or using an AFER with an FDA or nationally approved cleaning cycle) must be carried out *promptly** within 30 minutes after precleaning. — Always follow the most up-to-date specific instructions from the manufacturer for cleaning for each model of endoscope.
Disinfection	— After manual cleaning of the endoscope, machine or manual high-level disinfection must be undertaken promptly. — Endoscopes should be thoroughly rinsed with bacteria-free water after disinfection.
Alcohol flush and forced-air drying	— After disinfection by any means, the endoscope must have a prompt initial alcohol flush and forced-air drying† for 10 minutes and storage in an approved forced-air storage/drying cabinet.‡
Drying cabinet storage	— Endoscopes must remain in approved forced-air drying cabinets until the next use in a patient.
Bacteriological surveillance	— Perform regular bacteriological surveillance of endoscopes and AFERs at intervals appropriate to local conditions and resources.
Maintenance	— Send endoscopes for regular yearly maintenance and consider replacing the instrument channel every 2 years or according to workload (or more frequently, as recommended by the endoscope manufacturer).

AFER, automatic flexible endoscope reprocessor; FDA, Food and Drug Administration.

Notes: Duodenoscopes are considered separately (see sections 3.2 and 5.2 below).

* "Promptly" in these guidelines means within 30 minutes.

† The endoscope may be used on another patient after the initial forced-air drying, but it must be placed in the storage cabinet if not immediately used for another patient procedure.

‡ See section 3.3 below on drying cabinets.

3.2 Recommended changes for duodenoscopes

Table 2 Specific recommendations for duodenoscopes

Endoscopy units performing ERCP should…	
Volume of procedures	— Consider if the number of ERCP procedures performed is sufficient to continue offering this clinical service.
Dedicated staff and training	— Have dedicated staff to reprocess duodenoscopes who are aware of, and have undertaken specific training in, the particular problems associated with cleaning and

	disinfecting the instruments and obtaining endoscope samples for bacteriological surveillance.
Bacteriological surveillance	— Perform *monthly* bacteriological surveillance cultures of duodenoscopes, using sample collection protocols that include samples from the distal lever cavity.*
	— Duodenoscopes with positive surveillance bacterial cultures in which organisms of concern are detected should be sent for service (unless there is an alternative explanation — e.g., staff error).
	— Include appropriate risk notification of possible MDRO transmission in the informed consent information.
Maintenance	— Regardless of culture results, send duodenoscopes for regular yearly maintenance.
	— Have instrument channels and "O-rings" replaced at least on a yearly basis (or more frequently, as recommended by the endoscope manufacturer).

ERCP, endoscopic retrograde cholangiopancreatography; MDRO, multidrug-resistant organism.

* Consideration should be given to using the recently published FDA/CDC/ASM duodenoscope sample collection and culture protocol, which has been validated by duodenoscope manufacturers [34].

3.3 Endoscope drying

It is critical that drying is performed after manual or AFER reprocessing — regardless of AFER manufacturer claims.

- *Initial drying* — All endoscopes should have a preliminary alcohol flush and forced-air channel drying for 10 minutes.
- *Storing/drying cabinet* — After initial drying, endoscopes should be promptly transferred to an approved endoscope forced-air storage/drying cabinet and channel-purge air drying should be started.
  — This should continue until the endoscope is used again, or the safe storage period has elapsed.
  — Storage/drying cabinets should comply with the relevant national standard or with European Standard EN 16442, "Controlled Environment Storage Cabinet for Processed Thermolabile Endoscopes."

Note: If needed, the duodenoscope can be used for another patient procedure after the initial forced-air drying, or before the drying cycle in the cabinet is completed.

3.4 Interventions to control CPE transmission in the facility

CPEs are spread via the fecal–oral route; the mode of transmission is often via contaminated hands of health-care workers or contaminated fomites. Carbapenemase-producing bacteria are commonly found in hospital waste water, and they are also found in sinks and faucets/taps [35]. Investigations during an outbreak of an MDRO after ERCP found the culprit MDRO in sinks and in the water used to rinse the duodenoscope prior to disinfection [36]. Guidelines for prevention and control of CPE emphasize hand hygiene, active surveillance and contact precautions, and environmental cleaning. Endoscopy units should implement national and local guidelines on infection control for multidrug-resistant organisms. Training that improves compliance with hand hygiene reduces the transmission of infection [37].

Table 3 Recommendations to control CPE transmission

Recommendations	
CPE status	— Be aware of the CPE status of your hospital.
CPE-infected patients	— Ensure that known CPE-positive patients are notified to the endoscopy unit *before* they arrive at the unit. — CPE-infected patients, or those at high risk who have yet to have cultures taken, should be examined last on the list and managed in isolation from other patients, with use of a separate toilet or a commode. — Clean and decontaminate the procedure room after the endoscopy procedure as per specific protocols for terminal cleaning of contaminated areas.
Plumbing standards	— Sinks, taps, and plumbing should comply with the national standards to minimize the risks of spray from drains in sinks or overflow of waste water from blocked pipes.
Infection control procedures	— The emergence of CPE is another compelling reason to meticulously follow standard infection control procedures including hand hygiene and the use of appropriate personal protective equipment (i.e., gloves and impervious gowns for each procedure). — Endoscopy units should provide regular education and should assess compliance with hand hygiene and environmental cleaning and decontamination.

CPE, carbapenem-producing Enterobacteriaceae.

3.5 AFER maintenance

- Ensure that the water quality is appropriate for the AFER.
- Ensure that a schedule of replacement for external water filters is established and that the internal submicron filters are replaced in accordance with the manufacturer's instructions for use.

4 Application of guidelines

Detailed recommendations for reprocessing are set out in international and national guidelines/standards. Recent guidelines from the USA, Europe, China, South-East Asia and the Middle East have been updated to reflect the latest research and manufacturers' recommendations [3,4,26,38–41]. These guidelines will inform the development of other national and regional guidelines.

In all countries, health resources are allocated in accordance with cost–benefit analyses. Prioritizing resources in low-income and middle-income countries has increasingly focused on cost-effectiveness [42]. The cost-effectiveness of endoscopy can be estimated from the cost of delivering the services, the outcomes achieved, and the costs of complications [43]. The emergence of CPE has increased the risk of serious infections occurring after endoscopy and has thus increased the costs of inadequate reprocessing. The costs of managing an infection with CPE are substantial in both developed and low- and middle-income countries [44,45].

The risk of transmitting CPE depends on:

- The prevalence of CPE in patients referred for endoscopy
- The quality of reprocessing

- The age and state of repair of the endoscopes

Each country and hospital should know the local prevalence of CPE in order to implement appropriate risk management.

Endoscopists must understand the principles of reprocessing and be aware of the risk to patients when there is a failure of endoscope reprocessing.

When purchasing second-hand equipment, hospitals should ask to see an endoscope's previous history of maintenance and repairs. Channels and O-rings that are old or have had a previous heavy workload should be replaced.

Endoscope reprocessing should be managed by a multidisciplinary committee.

Successful reprocessing is dependent on many interrelated processes, governed by overlapping standards. The delivery of endoscopic services is best managed by a multidisciplinary committee including nurses, endoscopists, infection control and engineering personnel, and most importantly management [26,46,47].

- The committee should use a process approach to develop, implement, and improve the effectiveness of a quality management system for both the people and the process itself, informed by the ISO 9001 and ISO 13458:2016 standards [48–50].
- The recent position statement of the European Society of Gastrointestinal Endoscopy and European Society of Gastrointestinal Nurses and Associates lists quality criteria for endoscope reprocessing [51].
- Policies, procedures, and strategies should be developed in consultation with relevant stakeholders [46].
- The committee must be up-to-date with recent publications and undertake internal audits to ensure that reprocessing complies with recent recommendations from manufacturers, guidance bodies, and regulatory departments.

In low-income and middle-income countries, there may be a lack of infrastructure and a shortage of trained personnel [45].

- Local guidelines should be tailored to specific needs, and quality control should start with simple, cost-effective measures such as education programs. Surveillance of the process and compliance with guidelines should be prioritized over outcome surveillance, which is more expensive and time-consuming [45].

If resources are limited, a local multidisciplinary committee should review the options available and make a decision based on a risk assessment informed by local conditions.

- Options that may be considered include referral to a center with more resources and reassessing the need for endoscopy — is a trial of treatment a safer option?

5 Science of reprocessing

During outbreaks of MDROs after endoscopy, patients may become colonized with bacteria and initially show no clinical symptoms, only to develop serious systemic infections weeks to months later, with mortality rates reported to be as high as 40% [36,52].

Often, a single species of CPE is transmitted from one endoscope on multiple occasions, despite reprocessing. This epidemiology is best explained by a biofilm on the endoscope that protects bacteria from cleaning and disinfection and acts as a reservoir for the transmission of infection.

5.1 Biofilm

In the 1999 Centers for Disease Control and Prevention (CDC) report of an outbreak of a carbapenemase-producing *Pseudomonas aeruginosa* following bronchoscopy, it was considered that biofilm formation in difficult-to-clean narrow endoscopy channels contributed to the outbreak [53]. A subsequent research investigation examined the surfaces of endoscope channels using scanning electron microscopy and confirmed the presence of biofilm, often lodged in surface defects [32]. Other studies have also found biofilm on endoscope channels [54–56] and on culprit endoscopes in reports of outbreaks [57–59].

Biofilm is a community of bacteria that are attached to a surface and to each other by an extracellular polysaccharide matrix. Bacteria living in a biofilm have properties different from those of free-floating (planktonic) bacteria of the same species. Bacteria incorporated into biofilms are resistant to disinfectants used at recommended reprocessing concentrations [60]. Planktonic CPEs are killed in under 1 minute by standard disinfectants, providing a wide safety margin for these planktonic bacteria [61]. However, the biofilm matrix limits the diffusion of the disinfectant, and multiple layers of cells and biofilm matrix are difficult for the disinfectant to penetrate [62]. Standard concentrations of disinfectants do not reliably kill the same bacteria within biofilms [63]. Bacteria in build-up biofilm (BBF) that accumulates in defects on endoscope channel surfaces are also protected by organic debris and cross-linked protein, making them more difficult to kill with standard reprocessing [31,55]. Current reprocessing parameters are based on data from models that use artificial soils and planktonic bacteria rather than models incorporating bacteria in biofilm or BBF.

Biofilm acts as a reservoir of bacteria attached to the surface of an endoscope channel, and given favorable conditions, bacteria in biofilms can multiply, detach, resume their planktonic state, and be transmitted to patients during endoscopy [31]. Moisture and a supply of nutrients facilitate biofilm growth and the release of planktonic bacteria.

The role of moisture in facilitating biofilm growth during storage and the importance of complete drying after reprocessing have been underestimated in the past. Current evidence indicates that 95% of endoscopes still had visible moisture in channels after AFER alcohol flush, a 3-minute drying cycle, and overnight storage in a regular cabinet [64]. Keeping the endoscope free of moisture — particularly the channels during storage — must be a priority.

Biofilm readily forms on endoscope defects, often longitudinal wear marks on biopsy channels, and is difficult or impossible to remove with standard reprocessing [31,32,55,65]. A multicenter study of patient-ready endoscopes found defects in all 45 endoscopes examined [66]. Channel inspection with a borescope commonly identifies occult surface defects [66–68]. Endoscopes should have regular maintenance to identify and repair macroscopic defects and routine channel replacement to reduce the prevalence of occult defects and help maintain smooth, cleanable channel surfaces [6,37]. The investigation by Verfallie et al. of the culprit duodenoscope in an outbreak found that duodenoscope O-rings were an important area of concern; these should be replaced annually together with the channels [36]. Other endoscopes may require less frequent replacement of channels, perhaps 1–2-yearly depending on the workload.

5.2 Duodenoscopes

Duodenoscopes are difficult to clean and disinfect. In addition to their complex design, factors such as the characteristics of patients referred for ERCP and the interventions performed also contribute to the risk of colonization and subsequent infection from bacteria transmitted during the procedure.

The rate of contamination of duodenoscopes, as judged by positive surveillance cultures, is similar to the rates of contamination of gastroscopes and colonoscopes [18–21]. Thus, patient characteristics and the interventions performed are dominant factors in the higher incidence of outbreaks after ERCP.

The risks of outbreaks are best addressed by specific changes to improve cleaning and disinfection of duodenoscopes, as well as improvements to reprocessing for all endoscopes. The manufacturers' updated cleaning protocols are an important improvement in duodenoscope reprocessing. A review of a quality-assurance database of 4307 duodenoscope cultures found that implementation of the new cleaning protocols significantly reduced the rate of positive cultures [69].

5.3 Drying

The reprocessing step of drying has often been ignored or carried out incompletely, and it is prone to human error [37]. A survey in the United States of reprocessing in 249 endoscopy units performing ERCPs found that 52% of the centers did not comply with the multisociety guidelines and did not use forced air to dry endoscopes [70]. Guidelines are inconsistent with one another and do not always specify the parameters for adequate drying [71]. Recent studies have found residual fluid in up to 95% of endoscope channels after reprocessing and drying, suggesting that drying guidelines need improvement [55,64].

Biofilms need moisture to grow. Alfa and Sitter, in a pivotal paper, demonstrated that if duodenoscopes were left damp after reprocessing, there was rapid growth of *Pseudomonas* and *Acinetobacter* species [72]. Drying for 10 minutes with forced air prevented this overgrowth in all duodenoscopes studied. Implementation of an alcohol flush followed by forced-air drying ended outbreaks of *Pseudomonas* infections following ERCP in the 1980s [73]. More recent studies have confirmed that alcohol flushing followed by 10 minutes of forced-air drying was more effective than alcohol flushing followed by a shorter, variable time of forced-air drying [66,74].

The Association for periOperative Registered Nurses (AORN) guidelines [4] recommend that endoscopes should be stored in a drying cabinet and state "The collective evidence shows that optimal storage of flexible endoscopes facilitates drying, decreases the potential for contamination, and provides protection from environmental contaminants."

This recommendation is supported by a review of surveillance cultures of patient-ready endoscopes, including duodenoscopes, gastroscopes, colonoscopes and echoendoscopes, which found that the introduction of drying cabinets significantly reduced the risk of endoscope contamination [75]. In a direct comparison, a forced-air drying cabinet dried endoscopes more rapidly and significantly reduced microbial growth in comparison with a standard storage cabinet [76].

5.4 Simethicone

Simethicone is a silicone-based polymer used in endoscopy to improve visibility. Randomized trials confirm a decrease in the number of bubbles and improved visibility. However, simethicone is not water-soluble, and in 2009 Olympus warned that simethicone was difficult to remove with standard reprocessing [77]. In 2016, van Stiphout et al. reported that if simethicone was added to water injected via the colonoscope's water-jet channel, crystal deposits formed in the water-jet connector and channel [78]. A more recent study has confirmed that various concentrations of simethicone flushed down the biopsy/suction channel form a residue that is not completely removed by standard reprocessing [79]. Residual simethicone may interfere with drying and increase the risk of biofilm formation, which may result in microbes surviving high-level disinfection and sterilization. In June 2018, Olympus recommended against the use of simethicone and other non–water-soluble substances [80]. A recent editorial notes that both Pentax and FujiFilm also recommend against using simethicone with their endoscopes, and the authors advise that endoscope manufacturers' instructions should be followed [81].

5.5 Tropical infections

There is very little evidence available on the risk of transmission of parasitic infections by gastrointestinal endoscopy. To become infective, most parasitic agents require progression in a life cycle that takes time, so that they are not immediately infective. Most potentially infective parasites would not survive endoscope reprocessing.

There is generally considered to be no risk with respect to helminths, nematodes, platyhelminths, *Anisakis*, or liver flukes such as *Fasciola hepatica*, but there is one report of four cases of *Strongyloides* esophagitis related to a single gastroscope [82]. However, concerns have been raised with regard to the risk of transmission of *Giardia lamblia*, *Cryptosporidium* species, and amebas.

5.6 Conclusion

The science of reprocessing is evolving. New research — including basic research, clinical research, and randomized trials that have been undertaken in response to published reports of outbreaks of CPE — is now being published. Endoscope manufacturers are continuing to improve endoscope design and validate new reprocessing instructions. New drying and cleaning technologies are emerging into the marketplace. Professional societies are producing updated versions of reprocessing guidelines in response to the flood of information.

This guideline, along with other recent guidelines, recommends that hospitals appoint a multidisciplinary committee with a diversity of interests and expertise to assess new information as it is published and to develop, implement, and — importantly — regularly update reprocessing guidelines that are appropriate to the hospital's resources and patient mix.

Effective reprocessing is key to patient safety in endoscopy.

6 Appendix

6.1 Funding and conflicts of interest statement

All of the authors of this update were requested to provide information on any conflicts of interest they may have had in relation to authorship:

- Any payments received for work on the guidelines
- Conflicts of interest with relevant companies — i.e., declarations with respect to this work, consulting with any related company, speaker at symposia, being a shareholder
- Any unrelated declarations that should be reported

Table 4 Authors' conflict of interest statements

First name	Surname	Country	Conflicts of interest
Tony	Speer (chair)	Australia	None to report.
Michelle	Alfa	Canada	Consultant for 3M, Olympus, J&J ASP, Novaflux, Ofstead & Associates. Royalties related to patent licensed to Healthmark through University of Manitoba. Honoraria from Olympus and J&J ASP for invited presentations.
Alistair	Cowen	Australia	No conflicts of interest.

Helen	Griffiths	UK	Speaker at education workshops sponsored by Cantel medical and Intercept medical
Di	Jones	Australia	No payment for work on these or any other guidelines. Have participated in focus group meetings with several AFER manufacturers. Have been a speaker at symposia/conferences supported by disinfectant and AFER manufacturers. All have been non-paid. I have shares in an Australian company involved in reprocessing technologies (not currently for endoscopy).
Douglas	Nelson	USA	No conflicts of interest.
Roque	Sáenz	Chile	No conflicts of interest.
Karen	Vickery	Australia	No conflicts of interest. Received no payment. Have been a non-paid, invited symposia speaker sponsored by Whiteley Corporation, a manufacturer of detergents and disinfectants.
Anton	LeMair	Netherlands	Acting as guideline development consultant for WGO.

6.2 Documents of interest

6.2.1 ISO standards

- ISO 9001:2015, Quality management systems — Requirements
- ISO 13485:2016, Medical devices — Quality management systems — Requirements for regulatory purposes
- ISO 15883:2008, Washer-disinfectors

6.2.2 Reprocessing guidelines

- American Society for Gastrointestinal Endoscopy (ASGE)
  Calderwood AH, Day LW, Muthusamy VR, Collins J, Hambrick RD, Brock AS, et al. ASGE guideline for infection control during GI endoscopy. Gastrointest Endosc 2018;87(5):1167–79.
- Asia Pacific Society of Infection Control (APSIC)
  Ling ML, Ching P, Widitaputra A, Stewart A, Sirijindadirat N, Thu LTA. APSIC guidelines for disinfection and sterilization of instruments in health care facilities. Antimicrob Resist Infect Control 2018;7:25:
  http://apsic-apac.org/wp-content/uploads/2017/01/APSIC-Sterilization-guidelines-2017.pdf
- Association for the Advancement of Medical Instrumentation (AAMI)
  Preventing device-related healthcare-associated infections (2016):
  https://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/Summits/161227_AAMI_HAI_Forum_Report.pdf
- Association for the Advancement of Medical Instrumentation (AAMI)
  ANSI/AAMI ST91: Comprehensive guide to flexible and semi-rigid endoscope processing in health care facilities (2015):
  http://www.aami.org/productspublications/ProductDetail.aspx?ItemNumber=2477

- Association of periOperative Registered Nurses (AORN)
  Guidelines for perioperative practice (2019):
  https://www.aorn.org/guidelines

- Australasian Health Infrastructure Alliance (AHIA)
  Australasian guidelines for design of health facilities (2016):
  https://www.healthfacilityguidelines.com.au/full-guidelines

- British Society of Gastroenterology (BSG)
  BSG guidance for decontamination of equipment for gastrointestinal endoscopy (2016):
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- Public Health Ontario
  Canadian environmental cleaning guidelines (2018):
  https://www.publichealthontario.ca/en/eRepository/Best_Practices_Environmental_Cleaning.pdf
- Society of Gastroenterology Nurses and Associates (SGNA)
  Standards of infection prevention in reprocessing flexible gastrointestinal endoscopes (2016)
  https://guidelines.sgna.org/Portals/0/Standards_for_reprocessing_endoscopes_FINAL.pdf
- Society of Gastroenterology Nurses and Associates (SGNA), and other societies
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6.2.3 Training in reprocessing

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- American Society for Gastrointestinal Endoscopy (ASGE)
  Website on transmission of CPE via ERCP:
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  Infections associated with reprocessed endoscopes (2018). Useful links to previous FDA announcements and manufacturers' updates to reprocessing instructions:
  http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454630.htm

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  https://wayback.archive-it.org/7993/20170112002249/http:/www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/ucm445590.htm

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  Supplemental measures to enhance duodenoscope reprocessing: FDA safety communication. Recommendations following May meeting (2015):
  http://wayback.archive-it.org/7993/20170722150658/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm

6.2.5 CPE general

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  Core infection prevention and control practices for safe healthcare delivery in all settings — recommendations of the Healthcare Infection Control Practices Advisory Committee (2017):
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6.3 Abbreviations

Table 5 Abbreviations used in this document

AFER	automatic flexible endoscope reprocessor
AORN	Association for periOperative Registered Nurses
BBF	build-up biofilm
CDC	Centers for Disease Control and Prevention
CJD	Creutzfeldt–Jakob disease
CPE	carbapenem-producing Enterobacteriaceae
ERCP	endoscopic retrograde cholangiopancreatography
FDA	Food and Drug Administration
GMP	good manufacturing practice
ISO	International Standards Organization
MDRO	multidrug-resistant organism
WGO	World Gastroenterology Organisation

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