

Special Report

WEO position statement on hygiene in digestive endoscopy: Focus on endoscopy units in Asia and the Middle East

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The aim of this position statement is to reinforce the key points of hygiene in digestive endoscopy. The present article details the minimum hygiene requirements for reprocessing of endoscopes and endoscopic devices, regardless of the reprocessing method (automated washer-disinfector or manual cleaning) and the endoscopy setting (endoscopy suite, operating room, elective or emergency procedures). These minimum requirements are mandatory for patient safety. Both advanced diagnostic and therapeutic endoscopies should be carried out in an environment that is safe for patients and staff. Particular attention is given to contaminants. Procedural errors in decontamination, defective equipment, and failure to follow disinfection guidelines are major factors contributing to transmission of infection during endoscopy. Other important risk factors include inadequate cleaning, use of older endoscopes with surface and working channel irregularities, and

contamination of water bottles or irrigating solutions. Infections by multidrug-resistant organisms have become an increasing problem in health-care systems worldwide. Since 2010, outbreaks of multidrug-resistant bacteria associated with endoscopic retrograde cholangiopancreatography have been reported from the USA, France, Germany, and The Netherlands. In many endoscopy units in Asia and the Middle East, reprocessing procedures have lagged behind those of Western countries for cultural reasons or lack of financial resources. This inconsistency in standards is now being addressed, and the World Endoscopy Organization has prepared this position statement to highlight key points for quality assurance in any endoscopy unit in any country.

Key words: Asia, endoscope reprocessing, hygiene, Middle East, patient safety

INTRODUCTION

IN MANY ENDOSCOPY units in Asia and the Middle East, reprocessing procedures have lagged behind those of Western countries for cultural reasons or lack of financial resources. This inconsistency in standards is now being addressed, and the World Endoscopy Organization

(WEO) has prepared this position statement to highlight key points for quality assurance in any endoscopy unit in any country.

Both advanced diagnostic and therapeutic endoscopies should be carried out in an environment that is safe for patients and staff. In daily practice, routine reprocessing of endoscopes and endoscopic devices must follow international standards, even in small endoscopy units. Use of reusable devices that have been cleaned manually should be as effective and safe as those reprocessed by automated washer-disinfectors (WD) or as single-use devices. Education and training of all endoscopy staff is

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mandatory. Recommendations for the effective reprocessing of endoscopes and endoscopic devices have been issued by the American Society for Gastrointestinal Endoscopy (ASGE), European Society of Gastrointestinal Endoscopy (ESGE), and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA). The cascade guideline published by the WEO with the World Gastroenterology Organization (WGO) is a good example of how to take into account local resource availability.¹⁻⁷

The aim of this position statement is to reinforce the key points of hygiene in digestive endoscopy. The present article details the minimum hygiene requirements for reprocessing of endoscopes and endoscopic devices, regardless of the reprocessing method (automated WD or manual cleaning) and the endoscopy setting (endoscopy suite, operating room, elective or emergency procedures). These minimum requirements are mandatory for patient safety. Particular attention is paid to variations in procedures according to the reprocessing method used, duodenoscopy-specific procedures, and the reprocessing of endoscope accessories. National guidelines and statements from individual countries of Asia and the Middle East have also been included. Details and literature are available in multiple guidelines as cited in the References.

HIGH-LEVEL DISINFECTION

HIGH-LEVEL DISINFECTION (HLD) of medical devices by peracetic acid (PPA), orthophthalaldehyde (OPA), and glutaraldehyde (GA) results in the reduction or destruction of all vegetative microorganisms, mycobacteria, small or non-lipid viruses, medium or lipid viruses, fungal spores, and some, but not all, bacterial spores to a level appropriate for safe use in patients.

Flexible endoscopes are exposed to body fluids and other contaminants. Procedural errors in decontamination, defective equipment, and failure to follow disinfection guidelines are major factors contributing to transmission of infection during endoscopy. Other important risk factors include inadequate cleaning, use of older endoscopes with surface and working channel irregularities, and contamination of water bottles or irrigating solutions.

Further risks are associated with the design or maintenance of automated endoscope WD, improper selection of disinfecting agents, inadequate drying and/or storage of endoscopes and, in particular, incorrect connectors.

In order to prevent transmission of infections, flexible gastrointestinal endoscopes (as well as other heat-sensitive endoscopes) require proper cleaning and, at a minimum, HLD following each use. However, some bacterial spores

may survive disinfection if present in high numbers, and therefore, pre-cleaning and a visual check for reduction of bioburden are important.

Effective disinfection of all parts of the endoscopic equipment is necessary to prevent transmission of infection during subsequent endoscopies. This includes the external surface of the scope, the internal channels for air, water, and accessory devices, and any accessories that were passed through the working channels, such as biopsy forceps.

Some pathogens are more difficult to eliminate during the endoscope disinfection process than others. These pathogens are (in decreasing order of resistance to disinfectants/sterilization):

- prions; e.g. Creutzfeldt–Jakob prion;
- bacterial spores; e.g. *Bacillus subtilis*;
- coccidia; e.g. *Cryptosporidium parvum*;
- mycobacteria; e.g. *Mycobacterium tuberculosis*, *Mycobacterium terrae*;
- non-lipid or small viruses; e.g. poliovirus, coxsackie viruses.
- fungi; e.g. *Aspergillus* spp., *Candida* spp.
- vegetative bacteria; e.g. *Staphylococcus aureus*, *Pseudomonas aeruginosa*;
- lipid or medium-sized viruses; e.g. HIV, herpes viruses, hepatitis B and C viruses.

Given the range of pathogens that can contaminate endoscopic equipment, and the difficulty in eliminating some of them, it is important that the hygiene protocols in endoscopy units are validated and that periodic microbiological sampling is conducted, as this is the only way to maintain quality of the hygiene procedures and ensure that any shortcomings are rectified swiftly and effectively before patients or staff become infected or suffer harm.

MINIMUM REQUIREMENTS

IN ALL ENDOSCOPY settings, the following procedures should be followed, regardless of whether manual or automated reprocessing is used.

Pre-cleaning

Pre-cleaning is necessary to prevent fixation of biomaterial in the endoscope channels and on the outer surfaces of the endoscope. Key points are as follows.

- Pre-cleaning must be carried out immediately after the procedure at the point of use prior to disconnecting the endoscope from the power source.

- The endoscope insertion tube must be wiped down using an appropriate detergent solution.
- The endoscope channels must be flushed through using an appropriate detergent solution.

Leak testing

The purpose of leak testing is to ensure that the endoscope has not been perforated. Leak testing is crucial to prevent fluid invasion into the working elements of the scope and damage to the scope, and is critically important to ensure that there are no areas in which microorganisms will be protected from contact with the high-level disinfectant.

Brushing, cleaning, and rinsing

Brushing, cleaning, and rinsing are necessary to remove biomaterial from the endoscope channels and the outer surfaces of the endoscope. Key points in this procedure are as follows.

- An appropriate brush/cleaning device should be used to clean the endoscope channels. A new brush should be used for each scope. (If cleaning brushes are to be reused, they should undergo the same treatment as the scope for cleaning and disinfection.)
- An appropriate low-foaming detergent should be used.
- Specified instructions, such as those relating to concentration, contact time, contact temperature, and rinse requirements, should be followed.

Disinfection

Key points for disinfection are as follows.

- An appropriate high-level disinfectant should be used (see Endoscope Reprocessing below for the properties of the ideal disinfectant).
- Specific instructions from the manufacturer relating to concentration, contact time, contact temperature, and rinse requirements should be followed.

Drying

Drying is an important step in the reprocessing of endoscopic equipment. Any moisture left within an endoscope may permit the growth of microbes.

- The outer surface of an endoscope should be patted dry with a clean lint-free cloth, and the channels should be purged with compressed air following guideline recommendations.

Storage

To prevent the growth of microbes as well as reduce the risk of cross-contamination, endoscopes should be stored in a controlled environment. Endoscopes can be stored either vertically (hanging), or horizontally (shelved). If horizontal storage is used, the cabinet should provide a means to continually purge the channel with high-efficiency particulate air.⁸

Transportation

Endoscopes should always be transported within a protected/enclosed environment to prevent users from being contaminated by dirty scopes or clean scopes from being contaminated by the operators and the environment.

Water quality for endoscope reprocessing

Water quality plays a fundamental role in endoscope reprocessing. It is important to ensure that water quality meets the minimum standards (potable water quality standards).

Microbiological sampling

Water should be tested periodically at the source, at the point of use, and inside the automated endoscope WD. Endoscopes should be randomly tested at routine intervals.⁹

Training and monitoring

Staff training and monitoring/auditing are also minimum requirements to ensure hygiene.

ENDOSCOPE REPROCESSING

ENDOSCOPE PRE-CLEANING SHOULD always be carried out immediately after finishing the procedure, independently of where the endoscopy procedure is done:

- in the endoscopy department or in a different department (in the operation room, intensive care ward) which requires time for transportation;
- as a planned procedure on the daily list or as an emergency case outside regular service time (e.g. during the night or at weekends).

Time between the end of the procedure to the meticulous pre-cleaning steps should not exceed 30 min (as a guide) in order to avoid any debris, fluid or other contaminant from drying and sticking firmly to the instruments.

The ideal disinfectant has the following properties:

- effective against a wide range of organisms, including blood-borne viruses and prion proteins;
- compatible with endoscopes, accessories, and endoscope reprocessors (PPA, OPA, GA);
- non-irritant and safe for users;
- permits environmentally friendly disposal.

Disinfectants must be used at the correct temperature and in accordance with the manufacturer's instructions and current recommendations in the literature. The disinfectants should be tested regularly with test strips and/or kits provided by manufacturers to ensure optimal activity of the products.

Factors influencing the choice of disinfectant include:

- dilution process;
- stability of the solution;
- number of reuses possible;
- direct cost;
- indirect costs (e.g. appropriate WD, storage space, conditions for use, staff protection measures).

Thorough drying of the entire endoscope channels and surfaces should always be carried out before storage in order to avoid any growth of microorganisms.

Automated washer-disinfectors

ESGE/ESGENA guidelines are available for reprocessing using WD.⁴

Before automated reprocessing, staff should ensure that all manual pre-cleaning steps have been carried out according to local standard operating procedures or the manufacturer's instructions for use.

Endoscopes and their components should be placed correctly in the WD. All channels should be connected according to the manufacturer's recommendations, even if they were not used during the procedure.

If other medical devices are planned to be reprocessed in the WD, details of the respective loads should be recorded for procedure validation. Regular audit and ongoing training are also mandatory.

Performance requirements for WD

The procedures involved in the reprocessing of flexible endoscopes in a WD aim to fulfill a number of basic performance requirements.

- Leak testing – assessing the integrity of the scope to be reprocessed by the WD process.
- Cleaning – a first rinsing phase may be required to remove any residual pre-cleaning chemicals from the outside of the WD. The cleaning phase should remove all visible dust and residue from the scope surfaces and interior of the scope channels using a specified detergent. Cleaning of the scope inside the WD is done by water, which must be pumped through the scope channel systems at specified temperatures for a specified time. The amount of detergent added during the cleaning phase must be monitored and should not go below the specified concentration range.
- Disinfection – removal of all contaminants and pathogens that have the potential to cause harm during subsequent endoscopies.
- Rinsing – a first rinse serves to remove any chemical residues remaining from the disinfection phase. This is followed by a second rinse phase for further removal of the chemical load from the instruments/scopes that have been disinfected. Recontamination of the disinfected scopes from the rinsing water, which is of inappropriate microbiological, chemical, and physical quality, must be prevented.
- Removal of rinse water and drying.

A summary of the advantages and disadvantages of WD is shown in Table 1.

Table 1 Advantages and disadvantages of automated endoscope washer-disinfectors

Advantages	Disadvantages
High grade of standardization in reprocessing	High cost
Low risk of either patient or staff infection	Dedicated user skills/knowledge required
Complete documentation	Additional validation costs covered by users
Full compatibility with latest European standards	More complexity and more training required
Economic use of chemicals and other resources	If not regularly maintained, there is a risk of infection
User friendly	
Reliable	
Regular validation of full process will increase reliability	

Table 2 Advantages and disadvantages of manual endoscope reprocessing

Advantage	Disadvantages
Easy to establish without any major investments	<p>Validation is not possible, but standardization for all reprocessing steps is possible</p> <p>Increased risk of human error (inconsistencies, mistakes etc.)</p> <p>Staff exposure to processing chemicals and potentially infectious material; additional precautions necessary</p> <p>Increased workload because staff required for each reprocessing step</p> <p>In case of reuse of disinfectant, efficacy problems to be expected</p> <p>Traceability and documentation is more time-consuming and more difficult</p> <p>Increased risk of recontamination, followed by increased risk of infection for patients</p> <p>Increased risk of health problems for staff (infection, injuries, allergies etc.)</p>

Manual cleaning

Manual reprocessing of endoscopes gives reliable results, provided that well-trained and competent staff carry out endoscope reprocessing conscientiously and according to defined standard operating procedures. However, there are several disadvantages to manual reprocessing of endoscopes, including potentially severe risks to patients and staff. Therefore, the same precautions as for automated WD are required. Regular audit and ongoing training are required to maintain the quality of manual cleaning procedures.

A summary of the advantages and disadvantages of manual endoscope reprocessing is shown in Table 2.

Duodenoscope-specific procedures

Since the late 1970s, there have been sporadic reports of nosocomial infections linked to endoscopic procedures. The majority of documented cases were caused by:

- non-compliance with national and international guidelines (including inadequate reprocessing, drying or storage of endoscopes, and endoscopic accessories);
- damage and design limitations of endoscopes and accessories;
- defective or contaminated endoscope WD;
- insufficient processing chemicals (wrong substances, temperature, dosage);
- contaminated rinsing water;
- recontamination caused by insufficient handling of reprocessed endoscopes and equipment, and insufficient hand hygiene.

Infections by multidrug-resistant organisms have become an increasing problem in health-care systems worldwide.

Since 2010, outbreaks of multidrug-resistant bacteria associated with endoscopic retrograde cholangiopancreatography (ERCP) have been reported from the USA, France, Germany, and The Netherlands.¹⁰

Duodenoscopes have a side-viewing distal tip with an elevator mechanism, which allows fine movements and controlled insertion of accessories into the biliopancreatic system. This complex design has been a challenge for reprocessing since the establishment of ERCP in the 1970s. Currently available duodenoscopes differ in the design of their distal tip and their elevator mechanism, depending on the manufacturer and the endoscope generation. The different designs must be taken into account during reprocessing.

In reported outbreaks, duodenoscopes with a fixed distal end and a sealed elevator wire channel were more often involved than other models. Discussion and actions taken have been focused on Olympus endoscopes, although it is important to stress that duodenoscopes from all major manufacturers (Olympus, Pentax, Fujifilm) have been affected in reported outbreaks. It is also important to emphasize the following points.

- Written reprocessing protocols, based on the manufacturer's instructions, should clearly explain the different reprocessing steps necessary for the different types of endoscope.
- Special cleaning equipment that strictly follows the manufacturer's recommendations should be used for duodenoscopes.
- Only purpose-designed single-use cleaning brushes should be used.
- Special emphasis should be placed on thorough cleaning and drying of duodenoscopes.

In addition to the leak test, visual inspection of the distal end as well as frequent maintenance of

duodenoscopes should be carried out according to manufacturer's recommendations in order to detect any damage at an early stage.

Reprocessing of endoscope accessories

Endoscope accessories include all removable parts of the endoscope and devices that are inserted into the endoscope channels. Major devices include biopsy forceps, hook wires, guidewires, and balloon dilators.

Endoscopic accessories that penetrate the mucosal barrier (e.g. biopsy forceps, guidewires, polypectomy snares, injection needles) are classified as critical devices and must be sterile at the point of use. Accessories that come into contact with the skin and intact mucosa only are defined as non-critical devices (e.g. mouth guards, blood pressure cuff, finger tips or electrodes) and do not need to be sterile, but must undergo disinfection. Due to the need for traceability, these accessories are often single-use items. Blood pressure cuffs and electronic cables which come in direct contact with the patient need to be cleaned and disinfected by surface disinfectants after each use.

Recommendations from the Korean Society of Gastrointestinal Endoscopy (KSGE) can be used as an example for the reprocessing of critical devices.

- Disinfect all reusable endoscopic accessories.
- Immerse dismantled endoscopic accessories in detergent solution, and use a brush and sponge to clean the internal surfaces.
- Clean accessories using an ultrasonic cleaner in detergent solution.
- After rinsing accessories with clean water, use a clean cloth and compressed air to dry the device.
- Reusable accessories such as suction, air water valve, and rubber biopsy valve caps should undergo HLD before reuse.
- Disposable needles or forceps should not be used more than once.
- The water bottle and its connecting tube should be sterilized once a day and should contain sterile water.

Proper reprocessing of endoscope accessories is vital but it is also important to consider that repeated sterilization and reuse can gradually reduce the effectiveness of accessories. In particular, repeated reprocessing of biopsy forceps may cause damage and render them more susceptible to contamination as they are not durable. Biopsy forceps can be reprocessed and reused in a cost-effective way. However, they are increasingly used only once in many countries, and a Korean study found that clinical efficacy of biopsy forceps

was greater when used once only. Single-use biopsy forceps can be economical if the reprocessing costs are high; however, disposable biopsy forceps must be used for patients who have infectious diseases in order to prevent the spread of infection. Guidelines recommending the use of disposable needles are increasing in Europe. Debate over the reuse of single-use devices continues in many countries. The issue of safety versus availability of financial resources has to be considered in individual jurisdictions. In some countries, reusing single-use devices is illegal.

To date, there has been no report of the optimal replacement frequency, safety, and potential risks associated with water bottles, lens wash water, tubing for air insufflations, waste vacuum containers, and suction tubes used in endoscopy. However, these accessories should be disinfected once a day and should contain sterile water.

For critical devices, the development of single-use accessories has obviated the risk of cross-contamination; however, the cost of such devices could be a limitation in some endoscopy units. Single-use devices are not designed for reuse either in terms of their ability to be disinfected or in endoscopic performance.

STAFF PROTECTION AND TRAINING

REPROCESSING PROCEDURES MUST ensure the protection of staff, including nurses, assistants, and those in continuing medical education. Training is therefore essential. Key points for staff protection and training are as follows.^{3,11,12}

- Endoscopy staff should be protected against infectious material during the endoscopy procedure as well as against direct contact with contaminated instruments or chemicals during the reprocessing procedures.
- Department-specific health and safety policy as well as appropriate equipment should be available for the management of spills, and the handling of sharps, chemicals, and body fluids.
- Staff involved in the reprocessing procedure should wear appropriate personal protective equipment including:
 - chemical-resistant single-use gloves;
 - protective glasses and face masks or protective full-face visors;
 - respiratory protective equipment in case of spillage of chemicals that are respiratory sensitizers;
 - special examination/protection coat (long-sleeved, moisture-resistant).
- Splashing should be avoided during the entire reprocessing procedure in order to avoid contact with infectious material and disinfectants or detergents.

Table 3 Details of endoscope reprocessing practices in countries of Asia and the Middle East

Country	Standards followed†	Pre-cleaning	Endoscope reprocessing	Endoscope disinfection	Accessories	Training	Monitoring and audit	Local cascade recommendations
China	China Health Human Resources. Technical specification for cleaning and disinfection of endoscope 2004 ¹³	Carried out in endoscopy room by nurse	Carried out immediately after the procedure. Manual pre-cleaning compulsory before automated reprocessing	Recommended disinfectants used, as per European and American guidelines	Disposable accessories used as recommended; however, as a result of high cost, some centers sterilize disposable accessories	No training programs on disinfection. At local level, training on disinfection for nurses and doctors in hospitals, mainly delivered by endoscopy companies	Biological monitoring of HLD of endoscopes carried out quarterly; sterilization of the endoscope carried out monthly	No local cascade recommendations
Egypt	No local standards. European and American guidelines	As per European and American guidelines	80% automated and 20% manual endoscope reprocessing	Recommended disinfectants used, as per European and American guidelines	Disposable accessories used as recommended; however, as a result of high cost, some centers sterilize disposable accessories	No training programs on disinfection. At local level, training on disinfection for nurses and doctors in hospitals, mainly delivered by endoscopy companies	Only done in big hospitals that are accredited or working toward accreditation	No local cascade recommendations
Hong Kong	Local standard follows the SGNA, BSG, ¹⁴ ESGENA, Hong Kong Hospital Authority	Carried out in the procedure room immediately after removal of insertion tube from the patient and prior to disconnecting the endoscope from the power source. Specific reprocessing area for endoscope reprocessing	Manual reprocessing and WD used	Manual disinfection: (Ethicon Inc., Cincinnati, Ohio, USA) Cidex® OPA (12-min contact time at 20°C, 20°C, 5-min contact time for standard disinfection, 10 min for mycobacteria and bacteria spores). Rinsing: bacteria filter 0.2 µm recommended for final rinse. Disinfected endoscope must be used within 3 h, otherwise, it must be pre-soaked again (flexible endoscopes for early sessions need to be pre-soaked and checked for leakage)	Single-use accessories are used for all procedures. Reusable water bottles are used and sent to Sterile Supply Unit for sterilization after 1 day session (and tracked appropriately). Autoclavable reusable devices (e.g. biopsy forceps) are washed, brushed and cleaned with detergent and then placed in the ultrasonic cleaner with detergent for 30 min	Nurses and endoscopy assistants responsible for handling endoscope reprocessing following formal training (post-registration clinical course endoscopy nurse training program, organized by Institute of Advanced Nursing Studies and conducted by designated cluster hospital). Further training available after 2 years' experience	Monitoring: Tracking system in place for all steps of reprocessing procedure. Automated WD and flexible endoscope are automatically tracked and tagged by radiofrequency identification. Daily, weekly, monthly routine checking of WD. Auditing: Staff audited every 6 months. Auditing of some public hospitals every 3 months for presence of mold and TVC of final rinse water. Mold is not acceptable. TVC <10 cfu is acceptable; 1–9 cfu on regular basis = acceptable; 10–100 cfu = risk assess for potential problem and	Testing of final rinse water for TVC and mold for validating effectiveness of WD. Tracking one set of endoscope, valves, suction button, and air-water button to avoid cross-contamination between devices. Validation of drying HEPA filtered cabinet. Validation of ATP=adenosine triphosphate to audit manual cleaning of flexible endoscope channels, especially for raising elevator channel. Considering separating bronchoscopy procedure room and patients from gastrointestinal endoscopy

Table 3 (Continued)

Country	Standards followed†	Pre-cleaning	Endoscope reprocessing	Endoscope disinfection	Accessories	Training	Monitoring and audit	Local cascade recommendations
India	Tandon 2000 ¹⁵ Ramakrishna 2002 ⁵	Manual cleaning carried out in endoscopy room or in a specified room	Majority of centers carry out manual cleaning. Automated WD used in high-volume centers		Kumar 2011. ¹⁶ Reusable accessories are used after strict adherence to cleaning, sterilization and quality control. Informed consent for reuse	Institution specific	superchlorinate or repeat WD self-disinfect; >100 cfu = risk assess/consider taking WD out of service Institution specific	
Indonesia	SGNA 2013 ¹⁷	Carried out in endoscopy room by nurse. Separate reprocessing room for manual cleaning	Leak test; manual cleaning; rinsing after manual cleaning; visual inspection; automated HLD for endoscopes (GA >2%, and OPA 0.55%); rinsing after HLD; drying; labeling; storage; documentation; waste disposals; using reverse osmosis water; duodenoscopes are brushed especially the elevator part, cleaned using HLD, and rinsed		Critical devices: reused, and sterilized in center for sterilization. Non-critical devices: HLD. Suction, air water valve, and rubber biopsy valve caps are cleaned using HLD	Training delivered by hospital education and training department	Monitoring done every 6 months (for scope swab and culture). HLD checked using test strips every day. Temperature and humidity are checked daily	As per Cipto Mangunkusumo National General Hospital SOP and SGNA 2013 ¹⁷ documents
Japan	Japanese guidelines, ¹⁸ WGO/WEO, 2011 ⁷	Carried out by endoscopy staff immediately after procedure: endoscope tube is wiped down, and endoscope channels are flushed through using appropriate detergent solution	Carried out immediately after procedure with automated WD	Pre-cleaning must be carried out. Automatic reprocessing is required	Endoscopic accessories that penetrate the mucosal barrier are used once only or cleaned ultrasonically/mechanically and then sterilized/autoclaved between each patient	Endoscopy staff receive training in maintaining hygiene standards	Efficacy of disinfection procedure for endoscopy unit, endoscopy channels, and accessories is monitored at regular intervals	JGES guidelines for endoscope disinfection is are development

Table 3 (Continued)

Country	Standards followed [†]	Pre-cleaning	Endoscope reprocessing	Endoscope disinfection	Accessories	Training	Monitoring and audit	Local cascade recommendations
Korea	KSGE 2015 ¹⁹	Carried out immediately after procedure in endoscopy room by endoscopy nurse or assistant nurse	Carried out immediately after procedure according to manufacturer and KSGE guidelines		Disposable accessories used as recommended. Reusable accessories are used after strict adherence to cleaning and sterilization	Training in maintenance by KSGE every 3 years	Accreditation of 'Excellent Endoscopy Unit' by KSGE	
Malaysia	SGNA 2013 ¹⁷ / GENCA ²¹	At bedside by assisting nurse. Endoscope leak testing and decontamination process are done in designated reprocessing room	Cleaning processes as per SGNA/GENCA recommendations in reprocessing room. Duodenoscope – SGNA latest update 2016 ²⁰	Majority of hospitals moving toward PAA base; however, GA is still most widely used	Reusable or single-use cleaning accessories are used for both government and private practice	Post basic training (MOH). Unit competency: every 2 years. Training delivered by vendor	Endoscope culture and sensitivity as per GENCA guidelines for some private hospitals. Air exchange monitored once to twice a year for some private hospitals. Government sector: too costly	Local guidelines are in progress for MOH approval
Singapore	SGNA ^{17,20} / GENCA 2011 ²¹	Pre-cleaning in endoscopy room by procedure nurse as per manufacturer's instructions	Most centers use WD. Leak test. Cleaning as per manufacturer's instructions. HLD prepared according to manufacturer's instructions for use	Only approved chemicals used and manufacturer's recommendations followed for contact time, number of rinses, and minimum effective concentration	Single use of accessories is generally practiced – determined by individual hospital. Cleaned and disinfected as per manufacturer's recommendations. Stored with the scope with which they were used to enhance traceability	Determined by individual hospital. Should be frequent and assessed for competency. 12 monthly according to GENCA	Determined by individual hospital. Infection control/ outside organization both planned at least annually and random visits/audits	No national recommendation
Thailand	SGNA 2016, ²⁰ ESGENA 2008, ¹¹ GESA 2006, ²² GENCA, 2010 ²¹	Carried out by nurse or assistant nurse in procedure room/at bedside. Separate reprocessing room for automated WD	WD use OPA. Manual cleaning: as per adaptation from SGNA and ESGENA recommendations. Duodenoscope-specific procedures: as recommended by the manufacturer and SGNA guidelines		Combination of SGNA, ESGENA, and GENCA	Annually	Monitoring of air exchange is done every 2 years	Combination of SGNA and ESGENA for scope reprocessing with addition of GENCA for accessory reprocessing

Table 3 (Continued)

Country	Standards followed†	Pre-cleaning	Endoscope reprocessing	Endoscope disinfection	Accessories	Training	Monitoring and audit	Local cascade recommendations
Taiwan	DEST guidelines ^{23,24}	Carried out immediately after endoscopy procedure in endoscopy room by endoscopy nurse. A purpose-designed reprocessing room is used for cleaning and disinfection to minimize patient and staff exposure to chemicals and contaminants	Estimated 95% WD and 5% manual cleaning: as per DEST recommendations. Duodenoscope-specific procedures: as recommended by the manufacturer and DEST guidelines	Disinfectants used in accordance with manufacturer's instructions. Disinfectants tested every day with test strips and kits provided by manufacturers to ensure optimal activity of the products. Hospital infection Control Unit and Taiwan Joint Commission on Hospital Accreditation regularly monitor documentation of disinfectants. Disinfection should occur immediately after cleaning, and according to specified instructions	All reusable endoscopic accessories such as suction, air water valve, and rubber biopsy valve caps should undergo HLD before reuse. Disposable needles, forceps, cutting knife, guidewire, basket etc. should not be used more than once. Water bottle and its connecting tube should be sterilized once a day and should contain sterile water	Endoscopic Nursing Association (DEST) plays a major role in developing guidelines, providing CME, establishing system for certification of junior endoscopy nurses and re-certification for senior endoscopy nurses every 6 years	Infection Control Unit monitors microbiological surveillance by monthly microbial sampling and culture. Labor Safety Unit routinely monitors cleaning room regarding air exchange (12 times/h) and chemical level such as GA every 6 months. DEST monitoring and audit every endoscopy room every 4 years. Taiwan Joint Commission on Hospital Accreditation: monitoring and audit of every hospital every 4 years	Taiwan national guidelines, and DEST statements were updated in 2016

† See References for published standards, statements, and guidelines.

BSG, British Society of Gastroenterology; cfu, colony forming units; CME, continuing medical education; DEST, Digestive Endoscopy Society of Taiwan; ESGENA, European Society of Gastroenterology and Endoscopy Nurses and Associates; GA, glutaraldehyde; GENCA, Gastroenterological Nurses College of Australia; GESA, Gastroenterological Society of Australia; HEPA, high-efficiency particulate air; HLD, high-level disinfection/disinfectant; JGES, Japan Gastroenterological Endoscopy Society; KSGE, Korean Society of Gastrointestinal Endoscopy; MOH, Ministry of Health Malaysia; OPA, orthophthalaldehyde; PAA, peracetic acid; SGNA, Society of Gastroenterology Nurses and Associates, Inc.; SOP, standard operating procedure; TVC, total viable count; WD, washer-disinfector; WEO, World Endoscopy Organization; WGO, World Gastroenterology Organization.

- Reprocessing rooms should be designed ergonomically to avoid musculoskeletal disorders and injuries.
- Injection needles as well as endoscopic/ultrasound needles should be used once only and should never be reprocessed.
- Regular health surveillance is recommended for all staff working with potentially sensitizing or allergy-inducing chemicals (e.g. related to allergic asthma, skin and/or mucosal sensitivity problems). Health surveillance should also cover problems of non-ergonomic workplaces (e.g. musculoskeletal disorders).
- It is recommended that all staff be offered appropriate vaccination against infectious agents (e.g. type B hepatitis). Staff known to be disease carriers should avoid duties that could transmit their disease to patients. Treatment should be offered if applicable (e.g. to carriers of methicillin-resistant *Staphylococcus aureus*).

Nurses with special training in digestive endoscopy are key players in maintaining hygiene standards. The endoscopy nursing associations (Society of Gastroenterology Nurses and Associates [SGNA], ESGENA) play a major role in developing guidelines and continuing medical education.

MONITORING AND AUDIT: PROCESS OF VALIDATION AND ROUTINE TESTING

The reprocessing room

MONITORING AND AUDIT of hygiene practices in digestive endoscopy encompass two areas of practice – the reprocessing room and the reprocessing procedures.

The endoscopy department or unit must fulfill technical and organizational prerequisites. A purpose-designed room for cleaning and disinfection that is separate from the procedure rooms is recommended in order to minimize patient and staff exposure to the chemicals used in cleaning and disinfection (e.g. toxic/allergic reactions, GA vapor, or PAA components), and to reduce the risk of infection and contamination with potentially infectious material, blood, and other body fluids.

The reprocessing procedures

Washer-disinfectors

The manufacturer must provide information about the structure and function of the WD. The validation can be carried out when the WD is installed according to the manufacturer's instructions and local safety regulations. Validation (periodic microbial sampling to demonstrate a quality standard in reprocessing) is an important quality-

assurance tool in hygiene and infection control, and patient safety, whether endoscopy procedures are carried out in hospitals, in private clinics, or in doctors' offices.

The clinical service provider relies on the correct functioning of automated WD according to the manufacturer's specifications. Current tools for regular quality control are routine maintenance and microbiological surveillance. Validation procedures have long been common practice in the monitoring of sterilization devices; for example, in central sterilization units.

The ESGE/ESGENA guidelines provide practical details on the role of different stakeholders in effective monitoring. These stakeholders include:

- clinical service providers who have the responsibility of meeting structural and organizational requirements and to provide educated staff for the safe use of WD;
- endoscopists, endoscopy nurses, and other users of WD who use flexible endoscopes and who are responsible for the safe reprocessing of endoscopy equipment;
- hospital hygienists, microbiological personnel, microbiologists, and authorized agencies that carry out regular microbiological quality control in endoscopy units;
- manufacturers, suppliers, and authorized third parties who sell, install, and maintain flexible endoscopes and WD for gastrointestinal endoscopy;
- institutions, companies, and other qualified agencies that are authorized to carry out validation of WD.

Routine checks of technical parameters (such as leak testing and channel obstruction testing, and testing of temperature, water quality etc.) can reduce the required number of microbiological tests on endoscopes, as the technical tests demonstrate that the WD is working within its specifications. In addition, paper print-outs document that the particular reprocessing cycle has been completed within the required process parameters. Daily checks of single machine parameters document that the WD is operating within its specifications. The manufacturer or the service provider may define these daily checks.

Regular maintenance of WD is part of quality management and is a prerequisite for their safe use. It ensures early detection of possible weaknesses and defects.

Manual cleaning

The same prerequisites for the reprocessing room and cleaning are mandatory for manual cleaning. The safety of staff is even more important in this setting because of exposure to chemical vapors in an enclosed space.

Regular monitoring of various protocols should be conducted and reviewed, as personnel change and manual cleaning is not as reliable as automated WD. Quality should be assessed at the same level for all endoscopy procedures and settings.

LOCAL CASCADE RECOMMENDATIONS: NATIONAL GUIDELINES AND STATEMENTS

TABLE 3 PROVIDES DETAILS of endoscope reprocessing practices in countries of Asia and the Middle East. Information on the guidelines followed has been included where appropriate.

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DISCLAIMER

THIS WEO POSITION statement represents a consensus of best practice based on the available evidence at the time of preparation and may not apply in all situations. The statement should be interpreted in the light of specific clinical situations and resource availability.

CONFLICTS OF INTEREST

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