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GUIDANCE FOR PRACTICE

ASGE American Society for Gastrointestinal Endoscopy

GI endoscope reprocessing: a comparative review of organizational guidelines and guide for endoscopy units and regulatory agencies

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GI endoscopy is performed to prevent, diagnose, and treat a host of digestive diseases and conditions. Throughout an endoscopic examination, the external surface and internal channels of flexible endoscopes are exposed to body fluids and contaminants. Consequently, reprocessing of these reusable, complex instruments is imperative to infection prevention. Reprocessing is typically achieved by mechanical and detergent cleaning, followed by high-level disinfection (HLD), rinsing, and drying[1]; strict compliance with following established reprocessing guidelines can significantly reduce or eliminate pathogen transmission to patients undergoing endoscopy.[2-4]

Reprocessing guidelines have become a cornerstone for endoscopy units across the United States seeking initial certification and subsequent maintenance of accreditation. To help prevent the transmission of infection and to protect patients, the Centers for Medicare & Medicaid Services standards require that ambulatory surgery centers and hospitals must have a formal infection control program. The infection control program must be based on nationally recognized infection control guidelines, directed by a designated healthcare professional with training in infection control, be ongoing, and include actions to prevent, identify, and manage infections and communicable diseases. The infection control and prevention program must include documentation that the ambulatory surgery center or hospital has considered, selected, and implemented nationally recognized infection control guidelines; however, no specific infection control guideline is endorsed by the Centers for Medicare & Medicaid Services, and this decision is left to the discretion of endoscopy units. To comply with Centers for Medicare & Medicaid Services standards, endoscopy units must cite references from nationally recognized specialty societies in developing their policies and procedures on endoscope reprocessing.

Multiple reprocessing guidelines exist to provide endoscopy units with specific recommendations on how to safely reprocess endoscopes and comply with governmental regulations. These reprocessing guidelines have been formulated by several national and international medical societies that include a variety of stakeholders such as physicians, nurses, infection control and medical instrumentation experts, and various government agencies. However, based on the setting of and leadership within the endoscopy unit, there is likely heterogeneity in which reprocessing recommendations are followed. Thus, it is imperative that endoscopy units review their infection control policies and reconcile any differences between reprocessing recommendations so that contradictory policies are not developed or followed. As part of the infection control guideline adoption process, endoscopy units should be aware of areas of consensus and differences as they relate to available reprocessing guidelines. Moreover, endoscopy units must undergo surveys and may be held accountable to national guidelines that are not necessarily applicable. In addition, endoscopy units and hospitals may adopt policies from national organizations that are neither recognized nor accepted by surveyors. Unless specifically stated otherwise in the federal requirements, facilities do have the latitude to adopt nationally recognized policies most suitable to their setting.[5]

Given the multitude of organizational reprocessing guidelines and varying surveying organizations, endoscopy units may find it challenging to be compliant with federal or state requirements based on the adoption of a particular organizational guideline. Regulators who use one guideline may penalize an endoscopy unit based on those guidelines, simply because the endoscopy unit is following another guideline for reprocessing. Therefore, it is imperative to provide endoscopy units with a comparative review of all major reprocessing guidelines to assist them in responding to regulators when both applying for and

maintaining accreditation. This document specifically examines the similarities and differences among various organizations as it pertains to endoscope reprocessing and provides a framework to reconcile the recommendations made by various organizations surrounding this topic. By providing a comparative review of multiple national societal reprocessing guidelines, this document puts each guideline in context with each other, provides endoscopy units with a risk assessment tool before site surveys, and allows better communication between regulators and endoscopy unit directors and managers undergoing review.

ENDOSCOPE REPROCESSING GUIDELINES EXAMINED IN THIS REVIEW

This document focuses on the recommendations enumerated by the following organizations given their high level of national expertise, experience in medical device infection prevention, and comprehensive standards set forth:

- Multi-Society Reprocessing Guideline spearheaded by the American Society for Gastrointestinal Endoscopy
- Association for the Advancement of Medical Instrumentation (AAMI)
- Association of Perioperative Registered Nurses (AORN)
- Association for Professionals in Infection Control and Epidemiology (APIC)
- Society of Gastroenterology Nurses and Associates (SGNA)
- Healthcare Infection Control Practices Advisory Committee (HICPAC)
- European Society of Gastrointestinal Endoscopy (ESGE)

Each organization listed above has used criteria to evaluate the level of evidence and provide specific recommendations. The most recent update on the Multi-Society Guideline on reprocessing endoscopes spearheaded by the American Society for Gastrointestinal Endoscopy uses the Grading of Recommendations Assessment, Development and Evaluation framework (Supplementary Tables 1 and 2, available online at www.giejournal.org).[6] In 2015 AAMI produced a guidance document for flexible and semirigid endoscope processing in healthcare facilities in which verbiage was used to provide a strength of recommendations for each aspect of endoscope reprocessing (Supplementary Table 3, available online at www.giejournal.org)[7]; this was updated in 2021.[8] In 2016 AORN produced guidelines on processing flexible endoscopes by reviewing the literature and critically appraising each article using the AORN Research or Non-Research Evidence Appraisal Tools.[9] The literature was independently evaluated, appraised, and rated according to the strength and quality of the evidence using the AORN Evidence Rating Model. The original APIC guideline for infection prevention and control in flexible endoscopy was published in 1994 and revised in 2000 to reflect updates by other organizations.[10] APIC has since commented on a number of documents and resources related to endoscope reprocessing. The Society of Gastroenterology Nurses and Associates originally published a document on the standards of infection prevention and reprocessing flexible GI endoscopes in 1996 that was most recently revised in 2018.[11] These guidelines were based on a comprehensive review of the current published data but did not provide any strength of recommendation or rating for the quality of evidence. HICPAC, a federal advisory committee chartered to provide advice and guidance to the Centers for Disease Control and Prevention (CDC), produced an updated document in 2017 on the essential elements of a reprocessing program for flexible endoscopes.[12] The HICPAC workgroup contained multiple stakeholder organizations including all U.S. organizations discussed in this document. The most recent update to the ESGE recommendations on endoscope reprocessing guidelines in 2018 was completed in conjunction with the European Society of Gastroenterology Nurses and Associates.[13] The quality of the evidence and strength of recommendations were not formally graded because they were generally low.

In this guideline we focus on the aforementioned organizations. In addition, the U.S. Food and Drug Administration (FDA), World Health Organization, and several national and international organizations have also lent guidance on various aspects of endoscope reprocessing, and their recommendations are also included as deemed appropriate.

AIMS AND OBJECTIVES

The aim of this document is to provide a comparative review of multiple societal reprocessing guidelines, outline a framework of best practices, and create a risk assessment tool that endoscopy units and regulatory bodies can use during the accreditation process. Several aspects of endoscope reprocessing are imperative to infection prevention and are examined in this document. These core principles of infection control include staff training and competency, endoscopy unit layout, precleaning, leak testing, manual cleaning, HLD, rinsing and drying, storage protocol and cabinet design, microbiologic surveillance, cleaning of accessories, and maintenance of endoscopes.

AREAS OF CONSENSUS AND VARIATION AMONG REPROCESSING GUIDELINES

Areas in which there is near complete agreement among guidelines in reprocessing endoscopes are enumerated in Table 1. Recommendations summarizing the areas in which there is a lack of consensus among guidelines in

TABLE 1. Uniform consensus among endoscope reprocessing guidelines

Staff training and competency
• All staff should undergo reprocessing training and competency should be verified[6,8-13]
Endoscopy unit layout
• Reprocessing of endoscopes should not be performed in the patient care area and should instead be performed in a designated room physically separated from the procedure room[6-13]
Precleaning
• Precleaning should begin immediately after a procedure is completed[6,8-13] • During precleaning, the endoscope needs to be cleaned with a cleaning solution on both the exterior and interior of the endoscope[6,8-13] • Cleaning solution should be aspirated through the endoscope during precleaning[6,8,11] • Endoscopes should be transported in a separate, closed, clearly labeled, and adequately sized container that protects staff from direct contact with the endoscope[6,8,9,11,13]
Leak testing
• Reprocessing staff should perform leak testing according to manufacturers' IFU[6,8-13] • Endoscopes failing a leak test should be removed from service and repaired or replaced[6,8-13]
Manual cleaning
• The manufacturers' IFU should be followed for manual cleaning[6,8-13]
High-level disinfection
• HLD should be performed as an integral component of reprocessing of endoscopes[6,8-13] • High-level disinfectant solutions should be tested for minimum effective concentration[6,8-13]
Rinsing
• Rinse endoscopes and flush channels for disinfectant solution removal after HLD[6,8,11,13]
Drying
• Air drying is recommended after HLD and rinsing of endoscopes[6,8,11,13]
Endoscope storage
• All endoscopes should be stored per manufacturers' IFU, and storage cabinets must be of sufficient height, depth, and width to allow endoscopes to be securely stored[6,11,13,15] • If stored vertically, endoscopes should hang freely and should not touch the bottom of the cabinet or other endoscopes in the storage cabinet[8,9,12,15]
Endoscope accessories storage
• Accessories should be disconnected or removed from the endoscope before HLD[6,11,13]
Verification of reprocessing
• Endoscopy units should develop a program for cleaning verification of endoscopes[6,8,9,11] • Endoscopy units should maintain documentation regarding endoscope reprocessing[6,8-13]
Reprocessing of endoscopic accessories
• Reusable water bottles and their tubing should undergo daily HLD or sterilization[6,8,11,13]
Maintenance of endoscopes
• Manufacturers' IFU should be followed for maintenance, repair, and replacement of endoscopes and regarding equipment used for reprocessing[6,8,9,11,13]
Endoscopy unit leadership
• Endoscopy units should have a leadership team with a multidisciplinary approach[6,8,11,12]

HLD, High-level disinfection; *IFU,* instructions for use.

reprocessing endoscopes can be found in Table 2. To see a more comprehensive summary of the recommendations of each organization, refer to Supplementary Table 3.

STAFF TRAINING AND COMPETENCY

Reprocessing of endoscopes requires specialized knowledge and skills. Any deviation from the reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection transmission within endoscopy units.[14] There is universal agreement that staff should undergo complete reprocessing training and that their competency be verified,[8,13,15] yet varying levels of detail are provided by each reprocessing guideline. For example, the Multi-Society Reprocessing guideline by American Society for Gastrointestinal

TABLE 2. Lack of consensus and variation among endoscope reprocessing guidelines

Staff training and competency
• Content of training and the frequency of competency evaluations
Precleaning
• Volume of solution to be aspirated during manual cleaning • Acceptable time interval within which precleaning should be performed
Manual cleaning
• Acceptability of reusable brushes in performing manual cleaning • Type and quality of rinsing water used at the end of manual cleaning
Borescope
• Frequency and indications for borescope use and findings requiring intervention
High-level disinfection
• Need for disinfectant solution used to be a U.S. Food and Drug Administration–cleared product • Use of automated endoscope reprocessors for HLD • Appropriate timing and frequency of testing the disinfectant solution for minimum effective concentration • Appropriate manner to discard the disinfecting solution used during HLD
Rinsing
• Quality of the water used in rinsing after HLD
Sterilization
• Type of devices that should undergo sterilization and methods that should be used
Drying
• Role of the alcohol flush in the drying process • Type and quality of air to be used during drying and the minimum drying time • Amount of drying a scope must undergo if it is to be returned to use immediately after HLD
Endoscope storage
• Type of cabinet (conventional, ventilated, or drying) needed and level of maintenance • Need for endoscopes to be stored vertically or horizontally • Storage interval for reprocessed endoscopes before repeat reprocessing before patient use
Endoscope accessories storage
• Accessories to be stored with a designated endoscope or separate from endoscopes
Role of endoscopic surveillance and verification of reprocessing
• Frequency and modality of testing for surveillance and verification of adequate reprocessing • Benchmarks for cleaning verification • Proper reprocessing steps and the types of endoscopes requiring cleaning verification • System identifying endoscope reprocessing and their readiness for patient use • Documentation of necessary information for endoscope reprocessing
Reprocessing of endoscopic accessories
• Method for reprocessing critical accessories and need for sterilization • Circumstances when single-use devices can be reprocessed
Endoscopy unit leadership
• Composition of the unit leadership team and their roles and responsibilities • Duties of the leadership team during an outbreak or breach in reprocessing protocol

HLD, High-level disinfection.

Endoscopy further specifies that all staff receive the same training and competency evaluation. Principles for reprocessing training programs include staff feedback, training checklists, competency-based, and a process for routine auditing by direct observation.[6] Other differences include personnel following a formally recognized reprocessing training program without specifying any particular program[13] and that trainers are competent to reprocess endoscopes while also training and verifying the competency of staff.[8,12]

Competency evaluation of personnel should be performed regularly, with most organizations explicitly stating that competency should be documented, verified, or certified.[8,10,12,15] Some guidelines recommend that competency should be documented by close observation[10] or that personnel complete a reprocessing certification examination.[7,8] The CDC and HICPAC provide the most comprehensive

instructions for completing reprocessing certification.[12] There is no uniform agreement as to the interval of competency evaluation. Specific instances when competency assessment should be performed include commencement of employment,[8,12,15] annually,[8] when introducing a new endoscope or reprocessing equipment,[8,11,12,15] after an update to the manufacturer's instructions for use (IFU),[12] after a breach in protocol, and in the context of local quality control efforts.[15] For device-specific reprocessing instructions, most guidelines recommend demonstration of model-specific competency for all steps of endoscope reprocessing as outlined by the manufacturer[11,12,15] and to consider extending this to proper use of validated automatic endoscope reprocessing systems and other equipment.[11] Additionally, temporary personnel should not be allowed to reprocess endoscopes until competency has been established.[11,16]

ENDOSCOPY UNIT LAYOUT

There is complete consensus that the entirety of reprocessing of endoscopes should be performed in a designated room physically separated from the procedure room and not performed in patient care areas.[7,13,15] Most guidelines recommend that reprocessing rooms are designed to ensure adequate space to permit a "1-way" pattern of flow from the contaminated area of the room toward the clean area of the room to prevent potential cross-contamination.[7,9,12] If possible, facilities should have 2 separate rooms for processing endoscopes with a wall separating the manual cleaning area from the disinfection area.[8] AAMI provides the most exhaustive recommendations on endoscopy unit layout such as maintaining the suggested environmental parameters of the room(s) (ie, lighting, ergonomics of work surfaces, and heating, ventilation, and air-conditioning parameters).[7,8] A pass-through window at counter height between the decontamination area and clean processing area has been recommended.[8] Importantly, consideration should be given to the review of local, state, and federal regulations as they pertain to the physical plant of the endoscopy unit.[11]

REPROCESSING

Precleaning

Precleaning of endoscopes is the initial step of reprocessing and is critical in removing debris and fluid from the interior and exterior of an endoscope after it has been used. The uniform consensus about performing precleaning focuses on 3 specific areas: timing, volume of cleaning solution aspirated, and transportation of the endoscope after precleaning is finished. First, there is agreement that precleaning begins immediately after a procedure is completed. Second, the endoscope needs to be cleaned with a cleaning solution on both the exterior and interior of the endoscope. Although there is uniform agreement about aspirating cleaning solution through the endoscope, there are differences in the volume of solution to aspirate; some guidelines recommend following the manufacturers' IFU,[7,10,12] whereas others recommend aspirating a large volume of cleaning solution until it appears clear[8,11] or aspirating a minimum volume (eg, 200-250 mL for at least 20 seconds).[13] There is agreement that transport of endoscopes occur in a separate container that protects staff from direct contact with the endoscope. These containers need to be closed, clearly labeled, and of adequate size to hold an endoscope, and prevent the spillage of contents from within it.

Leak testing

Leak testing is intended to safeguard against defects in an endoscope by ensuring there are no unintended openings in the endoscope where fluid or material could invade and damage the endoscope. Leak testing can be either automated or manual, with a movement toward using automated leak testing. All guidelines direct that reprocessing staff perform leak testing according to manufacturers' IFU, with a few recommending that leak testing is performed immediately when an endoscope arrives in the reprocessing area[7] or that manual leak testing is used in addition to automated leak testing.[13] All agree that if an endoscope fails a leak test, it should be removed from service and either repaired or replaced.

Manual cleaning

Manual cleaning is a crucial part of the reprocessing pathway, and when precleaning and manual cleaning are followed, the number of pathogens detected on endoscopes can be decreased by 99.9%.[17-20] Manual cleaning steps include detaching all devices from the endoscope with submersion of the endoscope in an enzymatic cleaning solution, exterior cleaning of the endoscope, brushing of all channels until they are clean of debris, flushing of channels with enzymatic cleaning solution, and rinsing the endoscope. Agreement is unanimous that manufacturers' IFU should be followed for manual cleaning. Manual cleaning should follow the manufacturers' recommended time frame and commence once precleaning is finished. Most highlight that if a time delay occurs for manual cleaning, then reprocessing personnel should follow manufacturers' delayed cleaning protocol.[7,11,12] If no timeframe is provided, manual cleaning should begin within 60 minutes of finishing a procedure.[7] Enzymatic cleaning solutions and brushes used in manual cleaning need to follow manufacturers' recommendations. Enzymatic cleaning solutions should not be reused during reprocessing.

More recently, most guidelines have paid particular attention to the complex design of duodenoscopes and curvilinear echoendoscopes. Reprocessing staff need to clean and brush the elevator mechanism of duodenoscopes and the recessed grooves of echoendoscopes.[7,9,11,13]

One area of debate is the use of single-use brushes and cleaning devices: Whereas most reprocessing guidelines favor single-use brushes,[7,10,11,13] others accept reusable devices if they undergo HLD or sterilization.[9,11,21] Another area of controversy is the quality of rinsing water used at the end of manual cleaning. Types of rinsing water include fresh water, which is drinking water of defined quality[13]; water recommended by the manufacturer[9]; utility water[7,9]; tap water[10]; or potable water.[21] No research exists on the quality of rinsing water, but at a minimum, reprocessing staff should follow the manufacturers' recommendations.

Borescopes

A borescope is a slim optical instrument that can be inserted into the lumen of another instrument to inspect or examine the inside of it. The use of borescopes during the endoscope reprocessing pathway can detect damage and retained fluid within the endoscope working channels.[22-24] However, many questions around the use of borescopes remain unanswered, such as variation in visual interpretations, a lack of standardization regarding the interpretation of noted findings, and the short- and long-term management of borescopic findings, none of which have been defined. At a minimum, most reprocessing guidelines advocate staff visually inspect endoscopes with an unaided eye, usually during the manual cleaning process, to identify damage or debris. Most guidelines do not make recommendations with respect to using borescopes,[10-12] although they be can be considered in examining the internal working channels of endoscopes as part of additional and enhanced visual inspection of endoscopes.[7,9,11] Recently, one guideline advocated the use of borescopes to inspect specific areas of endoscopes and provided examples of what should be examined when a borescope is used. However, the frequency and during what phases of the reprocessing process borescopes should be used was not stated specifically.[8] Although a novel technology, the benefits and role of borescopes in the reprocessing process remain unanswered, and more research is undoubtedly warranted.

High-level disinfection

Per recommendations of multiple governmental agencies and professional organizations, flexible GI endoscopes must be subjected to at least HLD, and there is uniform consensus that HLD should be performed as an integral component of reprocessing of flexible GI endoscopes.[12,25] Most reprocessing guidelines recommend following manufacturers' IFU for the performance of HLD and to consider specific instructions for the use of multiple individual disinfecting agents.[21] Ambiguity exists around disinfectants used in HLD, with some guidelines reporting that an FDA-cleared disinfectant should be used in HLD[7,10,11,15] and others not requiring a cleared disinfecting agent.[9,12,21] The ESGE reprocessing guideline is more proscriptive on this topic and specifies use of disinfecting agents designed, tested, and manufactured according to the European Medical Device Directive and in which claimed activity has been demonstrated.[13]

There is no consensus among the guidelines with respect to recommendations for the use of automated endoscope reprocessors (AERs). Although most recommend the use of AERs over manual disinfection,[8,10,13,15] there has not been unanimous preference for one option,[11] and their use is not specifically recommended over manual disinfection.[21] HICPAC does not specifically mention the use of AERs or manual disinfection, instead stating only to perform HLD or sterilization per the manufacturers' IFU for reprocessing.[12]

Reprocessing guidelines further explore how to enact quality control and discard disinfectants used in HLD. There is consensus that high-level disinfectant solutions should be tested for minimum effective concentration (MEC). Yet, there is significant variation regarding the timing and frequency of testing the disinfectant solution for MEC. Differences among guidelines include testing before each use,[7] testing at the beginning of each day,[15] and testing according to the manufacturers' IFU.[11] AORN is the only guideline that does not make any specific recommendation of testing for MEC.[9] A consensus on the process of discarding the disinfecting solution also does not exist. Most recommend discarding disinfecting solution at the end of its reuse life or when it fails to meet MEC, whichever comes first, noting that some disinfectants are single use,[7,11,15,21] whereas others make no comment.[9,10,12] Use of a disinfecting solution for a longer period risks lowering the MEC.[9] Additionally, reusable HLD solutions should be visually inspected before each use and discarded if precipitates or particulates are observed, even if within its use life.[8]

Rinsing

Rinsing and flushing of endoscope channels to remove disinfectant solution after HLD is collectively recommended. As with guidelines on water quality used for rinsing in manual cleaning, there is no consensus on the quality of water used in rinsing. Most guidelines prefer rinsing with sterile water.[9,13,15] If tap water is used, it should be followed by an alcohol rinse followed by complete drying.[10] Regarding the use of water in AERs, there is agreement that water used for rinsing should undergo filtration.[7,11] Filtration should be done with a bacterial-retentive filter as per manufacturers' IFU; water handling systems should be disinfected regularly and water filters changed per the manufacturers' IFU.[7] Periodic microbial assessment of the water used in the terminal rinse portion of the AER cycle may be considered.[8] Water used in endoscope reprocessing should meet specifications of the device and reprocessing equipment manufacturers. Also, following society guidelines recommending more

stringent water specifications should be considered.[12] For example, the Society of Gastroenterology Nurses and Associates states that filtered or sterile water should be used for duodenoscopes but does specifically mention water quality for rinsing other types of endoscopes.[11]

Sterilization of duodenoscopes

Because of reports of infectious outbreaks with multidrug-resistant organisms and carbapenem-resistant Enterobacteriaceae associated with duodenoscopes,[26-28] enhanced reprocessing of duodenoscopes has received considerable attention. The FDA recommended that endoscopy units use at least 1 supplemental measure to HLD in duodenoscope reprocessing: liquid chemical or ethylene oxide sterilization, microbial culturing, or repeat HLD.[26] Most guidelines comment on the potential utility of enhanced reprocessing of duodenoscopes, but there is no consensus on specific recommendations. Although most agree that the elevator wire channel of duodenoscopes must be cleaned and disinfected manually,[7,11,15] evidence is insufficient regarding sterilization of duodenoscopes.[12] Differences include performing sterilization for critical devices,[7,10] using FDA-suggested modalities in duodenoscope reprocessing,[11,15] and low-temperature sterilization if medical indications are appropriate, without specific recommendations beyond standard HLD for duodenoscopes.[13] A multidisciplinary team can conduct a risk assessment to determine if enhanced duodenoscope processing methods are warranted in specific endoscopy units, including use of ethylene oxide sterilization.[9]

Alcohol flushing

Alcohol flushing with 70% to 90% ethyl or isopropyl alcohol is used as a preliminary step in the endoscope drying process. Using alcohol in the drying process enhances water purging, evaporates more easily than water, facilitates drying of residual water from endoscope channels, and has intrinsic antimicrobial properties.[11] There is, however, some concern around the protein-fixation properties of alcohol and that its use may actually increase the bioburden within endoscope channels.[13] Although the use of alcohol in the drying process is controversial and is neither clearly supported nor contraindicated by available data, most guidelines agree that alcohol should be used as a preliminary step in the endoscopy drying process.[11,15,21] Differences include using alcohol only if channels are flushed with tap water instead of sterile water,[10] using alcohol if recommended by the endoscope manufacturer,[8] and using a multidisciplinary team to determine whether alcohol flushing should be used in individual endoscopy units.[8,9] Alcohol should not be used in countries with endemic prion disease (ie, United Kingdom) because of the fixative properties of alcohol.[21] ESGE is the only guideline that explicitly recommends not using alcohol in the drying process.[13]

Drying

Drying plays a crucial role in the endoscope reprocessing cycle given multiple reports of outbreaks of waterborne organisms tied to inadequate endoscope drying.[29-31] Previous studies have shown that hanging endoscopes alone leads to insufficient drying.[23,32,33] Agreement is near unanimous that air drying should be performed after HLD and rinsing of endoscopes. There are multiple modalities for delivering forced air into endoscope channels, including as part of the AER cycle or manual air introduction, yet there is no consensus with respect to the type and quality of air used or the drying modality to use. Variations on this topic across guidelines include the use of filtered forced air,[11,15] instrument air,[9,15] compressed air,[10,11,13] the drying function in automated reprocessors,[13] a mechanical processor drying system,[9] instrument air as part of the AER followed by manual drying outside the AER with instrument or high efficiency particulate air (HEPA)-filtered air,[8] and medical-quality air.[11] HICPAC does not explicitly recommend a drying protocol, only stating that storage of endoscopes shuold be performed in a manner that promotes drying.[12] Finally, there is no consensus recommendation on minimum drying times, although a minimum of 10 minutes should be considered.[8] If an endoscope will be used within a short period after reprocessing, most guidelines recommend complete drying of the endoscope after each reprocessing cycle, regardless of whether the endoscope will be reused immediately.[7,9,11,15,21]

Storage cabinets

After the endoscope has been reprocessed, the endoscope is stored in a fashion to promote drying and protect the instrument from environmental contamination, damage, and theft. Optimal storage cabinet features have yet to be determined[12,15]; however, there is consensus that endoscopes should be stored per manufacturers' IFU and cabinets must be of sufficient height, depth, and width to allow endoscopes to be securely stored. Endoscope storage cabinets should be placed in a secure location[9,15] and not within the endoscopy procedure room.[9] Although there is agreement that endoscopes must be dry before use, there is no consensus on whether a conventional, ventilated, or drying cabinet is necessary for storing endoscopes.

Endoscope position within the storage cabinet

Endoscopes may be stored in either 1 of 2 fashions, hung vertically or horizontally, depending on the storage cabinet furnished within the unit. There is no consensus among guidelines on whether endoscopes should be stored vertically or horizontally. When endoscopes are stored vertically, most recommend that the endoscope hang freely and be as straight as possible,[8] without

touching the bottom of the cabinet[9,12,15] or other endoscopes within the storage cabinet.[7] When the horizontal endoscope storage technique is used, care must be taken to ensure the endoscopes are not tightly coiled or in a position that promotes acute angles.[15] Regardless of the storage technique used, the endoscope's angulation locks must be in the free position and, if so equipped, the varying stiffness control placed in the neutral position.

Storage of endoscope accessories

After the procedure, reusable endoscope accessories (air–water valves, suction valves, etc) must be properly decontaminated and either be sterilized or undergo HLD before storage per manufacturers' IFU. Accessories must not to be reinserted into the instrument during the storage period. There is unanimous agreement that accessories are disconnected or removed from the endoscope. However, there is no agreement on whether accessories should be stored with a designated endoscope[7,9,13] or not.[10,12,15] In addition, tip protectors should not cover the opening of the tip because they are meant to be single use, unless otherwise specified by the manufacturers' IFU.[8] A system should be used to clearly identify that the endoscope has been reprocessed and is ready for patient use.[9,11]

Storage time

Often referred to as the "scope hang time" or "shelf life," this is better known as the storage interval for reprocessed endoscopes before repeat reprocessing. Overall, most guidelines do not propose a maximum storage time because of the lack of data that prolonged storage time is a risk factor for adverse patient outcomes.[7,9,12,15] Differences include an endoscopic storage time for a maximum of 7 days after proper reprocessing[11] and microbiologic surveillance when maximum storage time has elapsed.[13] The facility may convene a multidisciplinary team to formulate a storage time policy based on a comprehensive risk assessment of the various components of endoscope reprocessing and storage.[7,9,12]

Microbiologic surveillance and verification of reprocessing

Microbiologic surveillance involves the detection of pathogenic and nonpathogenic organisms common to the GI tract that may serve as an indicator of inadequate reprocessing or defective devices. Most U.S. reprocessing guidelines do not recommend routine endoscope microbiologic surveillance using culturing,[9-11] although some have not yet developed a position on the issue.[7,12] Microbiologic surveillance may be recommended in suspected or documented infectious outbreak within an endoscopy unit,[10] and surveillance culturing is almost exclusively focused on duodenoscopes. Moreover, because there is variability in duodenoscope surveillance sampling culturing protocols, the FDA, CDC, and the American Society for Microbiology have enumerated steps for performing microbiologic culturing of endoscopes.[27] When microbiologic surveillance is implemented, however, guidance on modalities, frequency, location(s) of the endoscope in which to obtain the culture, the level of colony-forming units that define a "positive culture," and the actions to be taken when a culture is positive is lacking. Most guidelines suggest a "culture and quarantine" approach in which an endoscope should be removed from service if a "positive culture" was detected. In contrast, international reprocessing guidelines recommend conducting microbiologic surveillance at defined intervals and sampling all parts and available channels of the duodenoscope.[13,34]

Most guidelines endorse endoscopy units developing a program for cleaning verification of endoscopes. However, reprocessing guidelines defer to endoscopy units to determine the frequency of testing, modality of testing, endoscope designs to test, steps to conduct cleaning verification, and benchmarks for the cleaning verification test(s) used.[7,9,11] In addition, using adenosine triphosphate testing as a substitute for bacterial culture in surveillance programs has not been supported by the literature or U.S. regulatory agencies[35]; however, this modality has been suggested as an appropriate tool to assess the adequacy of manual cleaning.[36] Presently, because there are no data on the validation of test strips and the FDA has not provided clearance for adenosine triphosphate test strips, the FDA has advised against the use of adenosine triphosphate testing for assessing the adequacy of cleaning during duodenoscope surveillance.[35] Finally, newer tests have been developed to assess the adequacy of endoscope drying (eg, use of cobalt chloride or copper sulfate–impregnated paper).[32,37] These tests have not been validated, and their implementation has not been addressed in reprocessing guidelines. Overall, bioburden assessment may be useful for training, competency testing and spot surveillance of the cleaning steps before and after HLD.[38-40]

Documentation of reprocessing

Documentation of endoscope reprocessing has been suggested to ensure quality endoscope reprocessing and allow adequate traceability in the event of an infectious outbreak. This also enables the identification of damaged equipment and allows the removal of defective equipment successfully. All guidelines recommend maintaining some form of documentation regarding endoscope reprocessing. Most guidelines recommend documenting the patient's name or medical record number, an identifier for the endoscope,[8,13,15] procedure date, and the name of the person performing cleaning or HLD.[7,9,11,13,15] The requirement for documentation of the endoscopist

performing the procedure is not uniform, and most do not require documentation of the types of methods or solutions used for endoscope reprocessing. In contrast, AAMI guidelines do recommend detailed documentation of HLD and sterilization information, including the type and concentration of the disinfectant solution, date the solution was opened, the use life of the open container, the reuse life of the solution, and shelf-life date of the solution. In addition, the date and time of the cycle and results of MEC or microbial contamination testing should be reported.[7,8] The CDC and HICPAC are unique in recommending documentation of procedure end time and start time of manual cleaning and the effectiveness of products used for cleaning and disinfection.[12]

ENDOSCOPE ACCESSORIES

Endoscope accessories must also be properly cleaned because the risk of infection transmission has been linked to improper reprocessing because of unfamiliarity with endoscope channels, accessories, and the specific steps required for reprocessing of attachments.[41] The endoscope accessories of concern include water bottles, tubing for insufflation of air, lens/irrigation wash water, waste vacuum canisters, and suction tubing. No data exist pertaining to the safety or potential risk of per-procedure versus per-day exchange of these attachments.[15] The FDA has released nonbinding draft guidelines regarding the reprocessing of backflow valves to prevent contamination of more distal tubing and devices near the patient.[42] Thus, for endoscope air and water channels, this means the air and water valves need to be replaced per procedure but the water bottle feeding this channel can be changed daily.

The reprocessing of reusable endoscopic accessories depends on whether the particular accessory breaks the mucosal barrier or not. Reusable accessories that penetrate the mucosal barrier are classified as critical and include biopsy forceps, cytology brushes, or cutting devices such as polypectomy snares and sphincterotomes.[10] Most reprocessing guidelines recommend that any reusable accessory devices that penetrate the mucosal barrier should be mechanically cleaned and then sterilized between each patient.[6,8,10,11,13,15] Ultrasonic cleaning of reusable devices can be performed before sterilization to remove soil and organic material from hard to clean areas.[10,13,15] APIC differs slightly in that reusable parts, accessories, and cleaning implements (eg, brushes) should be cleaned, brushed, and rinsed but gives endoscopy units the option of whether to perform HLD or sterilization.[9] HICPAC does not provide any specific statements on reprocessing of reusable critical accessories.[12]

Reusable endoscopic accessories that do not penetrate the mucosal barrier but come into contact with mucous membranes are classified as semicritical. These accessories include water bottles, tubing, valves, and buttons. Most guidelines recommend that endoscope accessories that come into contact with mucous membranes should receive at least HLD after each patient use.[8,11,13,15] Specifically to water bottles, there is uniform agreement that reusable water bottles and their tubing should undergo daily HLD or sterilization as per manufacturers' IFU and near-unanimous recommendation that these bottles should be filled with sterile water.[9,11,13,15] The ESGE makes an additional recommendation that water bottles should be included in regular microbiologic surveillance.[13] The CDC and HICPAC do not make any specific recommendations regarding the reprocessing of water bottles. To mitigate cost and waste, some endoscopy units have entertained the possibility of reprocessing single-use devices. This approach remains controversial, and implementing such a strategy requires a major institutional commitment, including a monitoring committee with clearly defined protocols.[43] Overall, the reprocessing of single-use items should not be performed except according to FDA guidance.[6,10,12,15]

MAINTENANCE OF ENDOSCOPES

Endoscopes eventually require servicing to remain in optimal working order. Equipment that is not properly functioning may compromise patient or operator safety and result in more severe equipment damage.[6] Most guidelines agree that the manufacturers' IFU should be followed regarding maintenance, repair, and replacement of endoscopes and equipment used for reprocessing.[6,8,9,11,13] Endoscopy units should also consider maintaining records of preventive maintenance and repair of endoscopes and reprocessing equipment.[8,12] The latest Multi-Society Guideline on Reprocessing Flexible Gastrointestinal Endoscopes and Accessories and AAMI guidelines both provide several more recommendations: having polices that track repairs and maintenance of equipment and having equipment that is sent out and returned to undergo reprocessing as directed by a receiving facility and device manufacturers' IFU.[6,8] There is also more granular detail on following reprocessing instructions that accompany loaned devices.[6,8] Specifically, loaned endoscopes should be inspected for damage and consistency with the original endoscope, processed according to manufacturers' IFU before use, and processed before return.[8] Currently, no other guidelines have specific recommendations regarding loaner devices.

ENDOSCOPY UNIT LEADERSHIP

The leadership of an endoscopy unit plays a key role in focusing on infection control during reprocessing to ensure patient and staff safety. Most guidelines agree that an endoscopy unit should have a defined leadership

team using a multidisciplinary approach.[6,8,11,12] However, agreement in defining the responsibility of the endoscopy unit leadership is lacking. Some guidelines outline that leadership teams are involved in policy development for safe infection control standards[6] and collaboration with infection prevention specialists, particularly when considering modifications to the reprocessing protocol, purchasing new reprocessing equipment, or assessing disease transmission risk in the reprocessing environment.[11] Other responsibilities include allocating sufficient human and material resources to minimize infection risk during endoscope reprocessing and ensuring that the essential elements of an endoscope reprocessing program are followed according to manufacturers' IFU.[12] Finally, endoscopy units should follow a continuous quality improvement program for reprocessing.[7] Facilities with limited personnel where formation of a multidisciplinary team is not possible should consider seeking external expertise to obtain multidisciplinary input.[12]

An aspect where endoscopy unit leadership is critical is in the event of an outbreak or breach in reprocessing protocol. In such cases, policies should be in place detailing the facility's response to a reprocessing breach or failure.[11] Most guidelines recommend management by a multidisciplinary team[9,12,13] or a designated, qualified individual (ie, infection control champion) who directs infection prevention plans and addresses infection outbreaks.[6] In the event of an outbreak there is agreement that the endoscopy unit leadership team should consider reporting the bacterial contamination to individuals responsible for infection control at the institution and the FDA's MedWatch, which is the FDA's Safety and Adverse Event Reporting Program.[6,10,12] The patient who underwent the procedure, referring physician(s), potentially affected patients, public health agencies, and manufacturer of the endoscope or disinfectant should also be notified.[6]

CONCLUSION

Proper reprocessing of endoscopes and their accessories is imperative in ensuring patient safety while also complying with federal and state regulatory bodies. Recent infectious outbreaks attributed to endoscopes has brought an increased awareness of infection control programs to mitigate future risk. Although several guidelines have been published, significant variation and heterogeneity in their implementation in endoscopy units across the country remain. This variation in reprocessing endoscopic equipment may be because of differences noted among various reprocessing guidelines and a lack of uniformity among aspects of endoscope reprocessing. In addition, depending on the regulatory body performing a site survey, different organizational guidelines may be applied to the endoscopy unit, which may or may not be appropriate. As noted in this article, there are several areas of agreement among national organizations, and care should be taken to implement these measures to minimize infection risk for patients and prepare endoscopy units for the accreditation process. At the same time, some guidelines offer more granularity on several aspects of endoscope reprocessing, and review of these recommendations may offer further clarity to endoscopy units. Endoscopy units can use this document to perform a risk assessment of their reprocessing policies and practices before a site survey by accrediting agencies. In instances where a surveyor holds endoscopy units accountable to a guideline that may not be applicable, endoscopy units can also respond to the surveyor by showing documentation of compliance with a nationally recognized organizational guideline that is more relevant to their practice and setting. Despite this comparative review that will enhance communication with regulators, aspects of endoscope reprocessing do not have sufficient data to derive evidence-based conclusions. In the future, it is important not only for national organizations to solidify further areas of consensus on endoscope reprocessing, but also for these organizations and regulators to collaborate on delineating best practices.

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REFERENCES

1. Calderwood AH, Muthusamy VR, Collins J, et al. ASGE guideline for infection control during GI endoscopy. Gastrointest Endosc 2018;87:1167-79.

2. Kovaleva J, Peters FTM, van der Mei HC, et al. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clin Microbiol Rev 2013;26:231-54.
3. Spach DH, Silverstein FR, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. Ann Intern Med 1993;118:117-28.
4. Nelson DB, Muscarella LF. Current issues in endoscope reprocessing and infection control during gastrointestinal endoscopy. World J Gastroenterol 2006;12:3953-64.
5. ASGE policy and procedure reference guide. Available at: https://www.asge.org/home/practice-support/practice-resources/asge-policy-procedure-reference-guide. Accessed April 4, 2021.
6. Day LW, Collins J, Kushnir VM, et al. Multi-Society Guideline on reprocessing flexible gastrointestinal endoscopes and accessories. Gastrointest Endosc 2021;93:11-33.
7. Brotherton SE, Etzel SI. Graduate medical education, 2014-2015. JAMA 2015;314:2436-54.
8. ANSI/AAMI ST91: 2021. Flexible and semi-rigid endoscope processing in health care facilities. Arlington, VA: AAMI; 2021.
9. Guideline for processing flexible endoscopes. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc; 2016. p. 675-758.
10. Alvarado C, Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. Am J Infect Control 2000;28:138-55.
11. Loyola M, Bocian S, Diskey A, et al. SGNA: standards of infection prevention in reprocessing flexible gastrointestinal endoscopes. 2018. Available at: https://www.sgna.org/Portals/0/SGNA%20Standards%20of%20infection%20prevention%20in%20reprocessing_FINAL.pdf?ver=2018-11-16-084835-387. Accessed July 7, 2021.
12. HICPAC Workgroup. Essential elements of a reprocessing program for flexible endoscopes—recommendations of the Healthcare Infection Control Practices Advisory Committee. 2017:1-12. Available at https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html. Accessed March 3, 2021.
13. Beilenhoff U, Blum R, Brljak J, et al. Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: position statement of the European Society of Gastrointestinal Endoscope (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA)—update 2018. Endoscopy 2018;50:1205-34.
14. Rutala WA. Healthcare Infection Control Practices Advisory committee (HICPAC), guideline for disinfection and sterilization in healthcare facilities. Available at: http://www.cdc.gov/hicpac/Disinfection_Sterilization/3_0disinfectEquipment.html. 2008. Accessed April 15, 2021.
15. Petersen BT, Hambrick D, Buttar N, et al. Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update. Gastrointest Endosc 2017;85:282-94.
16. Petersen BT, Cohen J, Cotton PB, et al. Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011. Gastrointest Endosc 2011;73:1075-84.
17. Bajolet O, Ciocan D, Vallet C, et al. Gastroscopy-associated transmission of extended-spectrum beta-lactamase-producing *Pseudomonas aeruginosa*. J Hosp Infect 2013;83:341-3.
18. Chu NS, Favero M. The microbial flora of the gastrointestinal tract and the cleaning of flexible endoscopes. Gastrointest Endosc Clin North Am 2000;10:233-44.
19. Kampf G, Fliss PM, Martiny H. Is peracetic acid suitable for the cleaning step of reprocessing flexible endoscopes? World J Gastrointest Endosc 2014;6:390-406.
20. Kovaleva J. Infectious complications in gastrointestinal endoscopy and their prevention. Best Pract Res Clin Gastroenterol 2016;30:689-704.
21. Decontamination and reprocessing of medical devices for health-care facilities. World Health Organization. Available at: https://apps.who.int/iris/handle/10665/250232. Accessed April 15, 2021.
22. Ofstead CL, Heymann OL, Johnson EA, et al. Longitudinal assessment of reprocessing effectiveness for colonoscopes and gastroscopes: results of visual inspections, biochemical markers, and microbial cultures. Am J Infect Control 2017;45:e26-33.
23. Thaker AM, Sedarat A, Watson RR, et al. Inspection of endoscope instrument channels after reprocessing using a prototype borescope. Gastrointest Endosc 2018;88:612-9.
24. Barakat MT, Huang RJ, Banerjee S. Scoping the scope: endoscopic evaluation of endoscope working channels with a new high-resolution inspection endoscope (with video). Gastrointest Endosc 2018;88:601-11.
25. Food and Drug Administration. Reprocessing medical devices in health care settings: validation methods and labeling, guidance for industry and Food and Drug Administration staff. March 17, 2015. Available at: https://www.fda.gov/media/80265/download. Accessed March 5, 2021.
26. Food and Drug Administration. Supplemental measures to enhance duodenoscope reprocessing: FDA safety communication. August 4, 2015. Available at: https://www.fdanews.com/ext/resources/files/08-15/081015-duodenoscopes-fda.pdf?1520541508. Accessed March 3, 2021.
27. The FDA provides interim results of duodenoscope reprocessing studies conducted in real-world settings: FDA safety communication. December 10, 2018. Available at: https://www.fda.gov/medical-devices/safety-communications/fda-provides-interim-results-duodenoscope-reprocessing-studies-conducted-real-world-settings-fda. Accessed June 17, 2021.
28. The FDA continues to remind facilities of the importance of following duodenoscope reprocessing instructions: FDA safety communication. April 12, 2019. Available at: https://www.fda.gov/medical-devices/safety-communications/fda-continues-remind-facilities-importance-following-duodenoscope-reprocessing-instructions-fda. Accessed May 10, 2021.
29. Alfa MJ. Monitoring and improving the effectiveness of cleaning medical and surgical devices. Am J Infect Control 2013;4:556-9.
30. Kovaleva J, van der Mei HC, Degener JE. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clin Microbiol Rev 2013;26:231-54.
31. Carbonne A, Fournier S, Fortineau N, et al. Control of a multi-hospital outbreak of KPC-producing *Klebsiella pneumoniae* type 2 in France, September to October 2009. Euro Surveill 2010;15:19734.
32. Perumpail RB, McGinty BL, Muthusamy VR. Endoscope reprocessing: comparison of drying effectiveness and microbial levels with an automated drying and storage cabinet with forced filtered air and a standard storage cabinet. Am J Infect Control 2019;47:1083-9.
33. Barakat MT, Banerjee S. Comparison of automated and manual drying in the elimination of residual endoscope working channel fluid after reprocessing (with video). Gastrointest Endosc 2019;89:124-32.
34. Devereaux D, Athan E, Brown R, et al. Australian infection control in endoscopy consensus statements on carbapenemase-producing Enterobacteriaceae. J Gastroenterology and Hepatology 2019;34:650-8.
35. FDA recommends health care facilities and manufacturers begin transitioning to duodenoscopes with disposable components to reduce risk of patient infection. August 29, 2019. Available at: https://www.fda.gov/news-events/press-announcements/fda-recommends-health-care-facilities-and-manufacturers-begin-transitioning-duodenoscopes-disposable. Accessed November 28, 2020.
36. Olafsdottir LB, Whelan J, Snyder GM. A systematic review of adenosine triphosphate as a surrogate for bacterial contamination of duodenoscopes used for endoscopic retrograde cholangiopancreatography. Am J Infect Control 2018;46:697-705.
37. Nerandzic M, Antlonga K, Litto C, et al. Efficcacy of flexible endoscope drying using novel endoscope test articles that allow direct visualization of the internal channel systems. Am J Infect Control 2021;49:614-21.
38. Quan E, Mahmood R, Naik A, et al. Use of adenosine triphosphate to audit reprocessing of flexible endoscopes with an elevator mechanism. Am J Infect Control 2018;46:1272-7.
39. Gillespie E, Wievert W, Swan M, et al. Adenosine triphosphate bioluminescence to validate decontamination of endoscopes. J Hosp Infect 2017;97:353-6.

40. Sethi S, Huang R, Barakat M, et al. Adenosine triphosphate bioluminescence for bacteriologic surveillance and reprocessing strategies for minimizing risk of infection transmission by duodenoscopes. Gastrointest Endosc 2017;85:1180-7.
41. Department of Veterans Affair. Office of Inspector General. Healthcare inspection. Use and reprocessing of flexible fiberoptic endoscopes at VA medical facilities; 2009. Report No. 09-01784-146:1-45. Available at: https://www.va.gov/oig/54/reports/VAOIG-09-01784-146.pdf. Accessed April 4, 2021.
42. Carethers JM, Quezada SM, Carr RM, et al. Diversity within US gastroenterology physician practices: the pipeline, cultural competencies, and gastroenterology societies approaches. Gastroenterology 2019;156:829-33.
43. Kozarek R. Coming clean on the reuse of endoscopic equipment. Gut 1998;42:155-6.

Abbreviations: AAMI, Association for the Advancement of Medical Instrumentation; AER, automated endoscope reprocessor; AORN, Association of Perioperative Registered Nurses; APIC, Association for Professionals in Infection Control and Epidemiology; CDC, Centers for Disease Control and Prevention; ESGE, European Society of Gastrointestinal Endoscopy; FDA, U.S. Food and Drug Administration; HICPAC, Healthcare Infection Control Practices Advisory Committee; HLD, high-level disinfection; IFU, instructions for use; MEC, minimum effective concentration.

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APPENDIX

SUPPLEMENTARY TABLE 1. Grading of Recommendations Assessment, Development and Evaluation categories of quality of evidence

Categories	Symbols	Meaning	Interpretation
High	⊕⊕⊕⊕	We are confident that the true effect lies close to that of the estimate of the effect.	Further research is very unlikely to change our confidence in the estimate of the effect.
Moderate	⊕⊕⊕	We are moderately confident in the estimate of the effect; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.	Further research is likely to impact our confidence in the estimate of the effect and may change the estimate.
Low	⊕⊕	Our confidence in the estimate of the effect is limited; the true effect may be substantially different from the estimate of the effect.	Further research is very likely to impact our confidence in the estimate of the effect and is likely to change the estimate.
Very low	⊕	We have very little confidence in the estimate of the effect; the true effect is likely to be substantially different from the estimate of the effect.	Any estimate of the effect is very uncertain.

SUPPLEMENTARY TABLE 2. Interpretation of definitions of strength of recommendations using Grading of Recommendations Assessment, Development and Evaluation framework

Implications for	Strong recommendation	Conditional recommendation
Patients	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	Most individuals in this situation would want the suggested course of action, but many would not.
Clinicians	Most individuals should receive the intervention. Formal decision aids are not likely to be needed to help individual patients make decisions consistent with their values and preferences.	Recognize that different choices will be appropriate for individual patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may be useful in helping individuals to make decisions consistent with their values and preferences.
Policymakers	The recommendation can be adopted as policy in most situations. Compliance with this recommendation according to the guideline could be used as a quality criterion or performance indicator.	Policymaking will require substantial debate and involvement of various stakeholders.

SUPPLEMENTARY TABLE 3. Categories of recommendations within the Association for the Advancement of Medical Instrumentation document

Recommendations	Definition
Must	Only to describe "unavoidable" situations, including those mandated by government regulation
Shall	Indicates requirements strictly to be followed to conform to the standard
Should	Indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or used to indicate that a course of action should be avoided but is not prohibited
May	Indicates that a course of action is permissible within the limits of the standard
Can	Used as a statement of a possibility and capability