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Inconsistencies in Endoscope-Reprocessing and Infection-Control Guidelines: The Importance of Endoscope Drying

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INTRODUCTION: Endoscope reprocessing is a multi-stepped process that renders a contaminated endoscope safe for reuse. Its steps include meticulous cleaning, complete immersion in a liquid chemical sterilant (LCS) or disinfectant to achieve high-level disinfection (or "liquid sterilization"), water rinsing, and proper handling and storage. Surveys and reports indicate that not all health-care facilities dry their endoscopes after reprocessing. Endoscope drying can be easily, quickly, and inexpensively achieved by flushing the endoscope's internal channels, and wiping its external surfaces, with 70–90% ethyl or isopropyl alcohol, to facilitate drying after reprocessing, followed by compressed or forced air.

METHODS: The medical literature was reviewed to evaluate the importance of endoscope drying to the prevention of disease transmission. Several national and international endoscope-reprocessing and infection-control guidelines and a public health advisory were also reviewed and compared for consistency and to evaluate the emphasis each places on endoscope drying. If a guideline recommends endoscope drying, this study clarified whether this step is recommended after reprocessing throughout the day (*i.e.*, between patient procedures), before storage, or both. These guidelines were also reviewed to determine whether any of them recommend reprocessing endoscopes before the first patient of the day.

RESULTS: This review identified several published reports and clinical studies that demonstrate the significant contribution of endoscope drying to the prevention of disease transmission. This review also identified significant differences and inconsistencies regarding the emphasis different published guidelines and a public health advisory place on endoscope drying. Some guidelines recommend drying the endoscope after completion of *every* reprocessing cycle, both throughout the day and before storage, while others deemphasize its importance and recommend endoscope drying only before storage, if at all. Instead of recommending endoscope drying before storage, some guidelines recommend reprocessing endoscopes before the first patient of the day.

DISCUSSION AND CONCLUSION: The finding that several guidelines are inconsistent with one another and that some are remiss and fail to recommend endoscope drying is of concern. Endoscope drying is as important to the prevention of nosocomial infection as cleaning and high-level disinfection (or "liquid sterilization"). Whereas wet or inadequately dried endoscopes pose an increased risk of contamination and have been associated with transmission of waterborne microorganisms and nosocomial infection, thoroughly dried (and properly cleaned and high-level disinfected) endoscopes have not been linked to nosocomial infection. Moreover, inconsistent guidelines can confuse reprocessing staff members and result in noncompliance, variations in the standard of care, and ineffective reprocessing. To minimize the risk of disease transmission and nosocomial infection, modification and revision of guidelines are recommended as required to be consistent with one another and to unconditionally recommend endoscope drying after completion of *every* reprocessing cycle, both between patient procedures *and* before storage, no matter the label claim of the LCS or disinfectant, the label claim of the automated reprocessing system, or the microbial quality of the rinse water. According to the medical literature, adoption of this recommendation may reduce the importance of not only monitoring the microbial quality of the rinse water, but also reprocessing endoscopes before the first patient of the day, both of which can be costly practices that a few guidelines recommend.

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INTRODUCTION

Endoscope reprocessing is a multi-stepped process that renders a contaminated endoscope safe for reuse. Several published endoscope-reprocessing and infection-control guidelines provide recommendations and step-by-step instructions for reprocessing endoscopes (1–17). Health-care facilities routinely use these guidelines to develop policies and procedures for reprocessing flexible (and rigid) endoscopes and their accessories. Endoscope reprocessing includes meticulous cleaning, complete immersion in a liquid chemical sterilant (LCS) or disinfectant to achieve high-level disinfection (or "liquid sterilization"), water rinsing, and proper handling and storage. The successful completion of each of these reprocessing steps is necessary to prevent disease transmission and nosocomial, or health-care-acquired, infection during flexible (and rigid) endoscopy. Surveys and reports indicate that not all health-care facilities dry their endoscopes after reprocessing (18). Endoscope drying can be easily, quickly, and inexpensively achieved by flushing the endoscope's internal channels, and wiping its external surfaces, with 70–90% ethyl or isopropyl alcohol, to facilitate drying after reprocessing, followed by compressed or forced air (7, 8, 11–13).

METHODS

The medical literature was reviewed to evaluate the importance of endoscope drying to the prevention of disease transmission. Several national and international endoscope-reprocessing and infection-control guidelines and a public health advisory jointly authored by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) were also reviewed and compared for consistency and to evaluate the emphasis each places on endoscope drying. If a guideline recommends endoscope drying, this study clarified whether this step is recommended after reprocessing throughout the day (*i.e.*, between patient procedures), before storage, or both. These guidelines were also reviewed to determine whether any of them recommend reprocessing endoscopes before the first patient of the day.

RESULTS

This review identified several published reports and clinical studies that demonstrate the significant contribution of endoscope drying to the prevention of disease transmission (7, 8, 11–13, 19–35). This review also identified significant differences and inconsistencies regarding the emphasis different endoscope-reprocessing and infection-control guidelines and a FDA-CDC public health advisory place on endoscope drying (Table 1). Some guidelines laud its significance and recommend endoscope drying after completion of *every* reprocessing cycle, both throughout the day and before storage (7, 8, 11–13, 33–35), while other guidelines deemphasize its importance and recommend endoscope drying only before storage, if at all (1–4, 14, 16, 17, 34, 36, 37). Instead of recommending endoscope drying before storage, some guidelines recommend reprocessing endoscopes before the first patient of the day.

For instance, although they recommend endoscope drying before storage after high-level disinfection (or after a tap-water rinse), guidelines published by the Association of periOperative Registered Nurses (AORN) do not recommend endoscope drying before storage after "liquid sterilization"[†] (or after a sterile-water rinse) (Table 1) (1–4, 34, 36, 37). Nor do AORN's guidelines recommend endoscope drying between patient procedures, after either high-level disinfection or "liquid sterilization." Instead of recommending endoscope drying, AORN's guidelines instruct reprocessing staff members to use the endoscope "immediately" after the terminal water rinse that follows chemical immersion. In addition, AORN's guidelines recommend that all endoscopes be reprocessed immediately before their first use of the day (Table 1) (2, 3, 34, 36, 37). Unlike the guidelines published by AORN, the guidelines published by the *Association for Professionals in Infection Control and Epidemiology* (APIC) and others recommend endoscope drying before storage (Table 1), no matter the label claim of the LCS, the label claim of the automated endoscope reprocessor (AER) or automated reprocessing system, or the microbial quality of the rinse water (*e.g.*, tap water, sterile water, or bacteria-free water) (6, 38). APIC's guidelines also recommend drying flexible endoscopes between patient procedures whenever tap water is used for rinsing, but not, however, if sterile water is used for rinsing (Table 1) (6, 38). (After high-level disinfection of rigid endoscopes, both between patient procedures and before storage, APIC's guidelines recommend rinsing the endoscope with sterile water followed by a drying method that will not result in recontamination (6, 38)).

In contrast to the guidelines published by AORN and APIC, guidelines published by *The Society of Gastroenterology Nurses and Associates* (SGNA) are clear, unconditional, and provide an all-inclusive standard that recommends endoscope drying after completion of *every* reprocessing cycle—that is, both between patient procedures and before storage, no matter the label claim of the LCS, the label claim of the AER or automated reprocessing system, or the microbial quality of the rinse water (Table 1) (7, 34, 35). And, unlike AORN's guidelines (2, 3), the guidelines published by SGNA (and APIC) do not recommend reprocessing every endoscope immediately before its first use of the day (Table 1), because of the lack of clinical data supporting the benefits of this time-consuming and expensive practice (6, 7, 38). Finally, an FDA-CDC public health advisory suggests

[†]During the past two decades, only one reprocessing "system" that uses a liquid chemical sterilant (*i.e.*, 0.2% peracetic acid) has been cleared by the FDA for marketing. Also labeled to provide rapid "liquid sterilization," two other similar types of endoscope reprocessing systems have been submitted to the FDA for a 510(k) clearance. Both of these devices, one developed by the Minntech Corporation and the other by Advanced Sterilization Products (61, 62), reportedly use a proprietary companion sterilant and a 0.2-μ bacterial water filtration system.

Table 1. The Positions, as Expressed in Published Guidelines, of Several Organizations Regarding Drying Flexible Endoscopes Using 70% Alcohol Followed by Forced or Compressed Air

	After High-Level Disinfection, a Tap-Water Rinse		After "Liquid Sterilization," a Sterile-Water Rinse		Reprocessing the endoscope before the first patient of the day
	Between-Patient Procedures	Before Storage	Between-Patient Procedures	Before storage	
ACCP, AAB (60)	*Unclear*	*Recommended*	*Unclear*	*Recommended*	*Not Recommended*
AORN (1–4,37,40)	*Not recommended*	*Recommended*	*Not recommended*	*Not Recommended*	*Recommended*
APIC (6,38)	*Recommended*	*Recommended*	*Not recommended*	*Recommended*	*Not Recommended*
ASGE (57)	*Recommended*	*Recommended*	*Recommended*	*Recommended*	*Not Recommended*
ASTM (11)	*Recommended*	*Recommended*	*Not applicable*	*Not applicable*	*Not Recommended*
BSG (17)	*Not recommended*	*Recommended*	*Not recommended*	*Recommended*	*Recommended*
CSGNA (9)	*Recommended*	*Recommended*	*Not recommended*[+]	*Recommended*	*Not Recommended*
ESGE (12)	*Recommended*	*Recommended*	*Not applicable*	*Not applicable*	*Recommended*
FDA-CDC (10,28,41,44,50–52,59)	*Unclear*	*To be "considered"*	*Unclear*	*Unclear*	*Not Recommended*
FSDE (14)	*Not recommended*	*Recommended*	*Not recommended*	*Recommended*	*Recommended*[*]
GSA (16)	*Not recommended*[†]	*Recommended*	*Not recommended*	*Recommended*	*Recommended* [***]
MACID (15)	*Recommended*	*Recommended*	*Not recommended*	*Recommended*	*Not Recommended* [****]
Multi-society Guideline (5,58)	*Recommended*	*Recommended*	*Unclear*[‡]	*Unclear*[‡]	*Not Recommended*
Muscarella (33,35)	*Recommended*	*Recommended*	*Recommended*	*Recommended*	*Not Recommended* [++]
Queensland Government (Australia) (13)	*Recommended*	*Recommended*	*Recommended*	*Recommended*	*Not Recommended*
SGNA (7,8,35)	*Recommended*	*Recommended*	*Recommended*	*Recommended*	*Not Recommended*

[*]Only if an automated endoscope reprocessor (AER) is used.
[†]In small units or isolated areas where neither water filtration nor regular bacteriological water monitoring is practical, then alcohol flushing and air drying between each case is recommended for routine endoscopy and colonoscopy.
[‡]This multi-society guideline will be updated in the near future to be in agreement with SGNA's guidelines (personal communication with lead author; 05-03-06).
[***]Recommended, especially for duodenoscopes.
[****]Only recommended if surveillance cultures of the endoscope are taken in the morning before the first patient and bacterial overgrowth is identified.
[+]CSGNA intends to revise its guidelines to be in agreement with SGNA's guidelines (personal communication with CSGNA; 01-09-05).
[++]Only under a few circumstances is drying the endoscope before the first patient of the day recommended (34).
AORN = Association of periOperative Registered Nurses; ASGE = American Society for Gastrointestinal Endoscopy; APIC = Association for Professionals in Infection Control and Epidemiology; SGNA = Society of Gastroenterology Nurses and Associates; CSGNA = Canadian Society of Gastroenterology Nurses and Associates; ASTM = American Society for Testing and Materials; ESGE = European Society of Gastrointestinal Endoscopy; FSDE = French Society of Digestive Endoscopy; MACID = Manitoba Advisory Committee on Infectious Disease; GSA = Gastroenterological Society of Australia; CDC = Centers for Disease Control and Prevention; FDA = Food and Drug Administration; BSG = British Society of Gastroenterology.

that reprocessing staff members use discretion and "consider" endoscope drying. This advisory's stance on endoscope drying, like some of the reviewed guidelines, is unclear (Table 1), if not incomplete and equivocal. In addition to not emphasizing the importance of endoscope drying, this advisory fails to clarify whether endoscope drying might be prudent between patient procedures after either high-level disinfection or "liquid sterilization," as well as before storage after "liquid sterilization" (or a sterile-water rinse) (10).

DISCUSSION

A finding with significant clinical implications, this study and review of several important infection-control and endoscope-reprocessing guidelines, as well as an FDA-CDC public health advisory, found significant differences and inconsistencies with one another regarding endoscope drying (Table 1). These results are of concern and suggest some arbitrariness, confusion, or misunderstanding about endoscope reprocessing. Failure by published guidelines to provide consistent reprocessing and infection-control recommendations and to recommend endoscope drying may explain, in part, published variations in endoscope-reprocessing practices and the results of surveys that indicate that some health-care facilities do not dry their endoscopes after reprocessing (18), notwithstanding the well-documented contribution and importance of endoscope drying to the prevention of nosocomial infection (6, 7, 11–13, 16, 18, 21–34, 38). In addition, inconsistent guidelines can confuse reprocessing staff members and result in noncompliance, variations in the standard of care, ineffective reprocessing, and an increased risk of nosocomial infection during flexible (and rigid) endoscopy. Whereas some guidelines provide an all-inclusive standard and recommend endoscope drying after completion of *every* reprocessing cycle (7, 35), other guidelines instead may be unclear, not recommend endoscope drying, or base their conditional recommendation to dry the endoscope on one or more of the following three factors (Table 2): (a) *time*, whether the endoscope will be used between patient procedures promptly after reprocessing, or stored for use at a later time; (b) *label claims*, whether the LCS or disinfectant, AER, or automated reprocessing system is labeled to achieve a high-level disinfection or "liquid sterilization;" and (c) *the microbial quality of the rinse water*, whether the endoscope is rinsed after chemical immersion with tap water, bacteria-free water, sterile water, "sterile" filtered water, or another type or quality of water. The importance to patient safety of published endoscope-reprocessing and infection-control guidelines being clear, descriptive, evidence-based, and consistent with the medical literature and with one another cannot be overstated.

Just-Reprocessed-and-Wet-With-Rinse-Water Endoscopes

Instead of recommending endoscope drying, some guidelines, including AORN's, recommend using the endoscope "immediately" after the terminal water rinse that follows chemical immersion (1–4, 12, 14, 16, 17, 33, 34, 36, 37, 39).

Table 2. Factors Used by Professional Organizations to Determine Whether to Recommend Endoscope Drying After Reprocessing

Time during the day when the endoscope is reprocessed:
• Between-patient-procedures
• Before storage
Label claims of the LCS, AER or automated system used to reprocess the endoscope:
• High-level disinfection
• "Liquid sterilization"
Microbial quality of the water used to rinse the endoscope:
• Sterile water or "sterile" filtered water
• Bacteria-free water
• Tap water

The safety of this dubious recommendation is questioned, however, because it virtually ensures that complying health-care facilities will treat patients using endoscopes whose external surfaces and internal channels are wet with rinse water. Many reports of true and pseudo outbreaks of waterborne microorganisms—specifically, Gram-negative bacteria and atypical mycobacteria—associated with wet or inadequately dried endoscopes have been published (10, 21–30, 32, 40–51). In fact, in some of these reports, the water used to rinse the endoscope after chemical immersion, despite being labeled as "bacteria-free" or "sterile" was identified as the source of the microorganisms (10, 21–30, 40–43, 48, 50, 51). In contrast, reports linking thoroughly dried (and properly cleaned and high-level disinfected) endoscopes to nosocomial infection have not been documented (with the possible exception of reports of true and pseudo outbreaks linked to several recalled bronchoscope models, the design of which was flawed and supported bacterial colonization and transmission despite apparent proper reprocessing, drying, and handling) (52).

Moreover, some published policies emphasize that because wet, moist, or damp instruments are associated with an increased risk of disease transmission and nosocomial infection, they are to be considered contaminated and require resterilization before reuse (53–55). Few practices would appear to pose as significant an increased risk of contamination, transmission of waterborne microorganisms, and nosocomial infection as the "immediate" use and introduction of just-reprocessed-and-wet-with-rinse-water (and, therefore, potentially contaminated) bronchoscopes, side-viewing duodenoscopes used during ERCP (or, *endoscopic retrograde cholangio-pancreatography*), and rigid arthroscopes and laparoscopes into patients' lungs, biliary tracts, knees, and peritoneal cavities, respectively. Even if provided insufficient time to multiply in the instruments' internal lumens and channels during storage or idle time during the day, small numbers of waterborne microorganisms that might have recontaminated the endoscope during water rinsing (or during direct or indirect contact with another environmental surface) could pose a significant risk of nosocomial infection, particularly if the patient is critically ill, young (*i.e.*, pediatric), or immunosuppressed (16). Understanding both the risk of transmission of waterborne microorganisms associated with wet or inadequately dried endoscopes and the contribution of

endoscope drying to the abrupt termination and prevention of true and pseudo outbreaks of waterborne microorganisms, it is puzzling why some of the published guidelines listed in Table 1 provide unclear, if not equivocal and incomplete, recommendations and do not unconditionally recommend endoscope drying after the completion of *every* reprocessing cycle, both between patient procedures and before storage, no matter the label claim of the LCS, the label claim of the AER or automated reprocessing system, or the microbial quality of the rinse water.

Determination of the Rinse Water's Microbial Quality

Microbiological monitoring of the rinse water used during endoscope reprocessing is required to determine and evaluate its microbial content and level of contamination. Nevertheless, this practice, which includes sampling, culturing, and analysis, is generally not recommended (except, for example, during an outbreak investigation) and, therefore, is not typically performed. As a consequence, the rinse water's microbial quality (and its endotoxin level, if the rinse water is claimed to be "sterile") is typically unknown (44, 45). Although overlooked in the medical literature, failure by a health-care facility to determine the rinse water's microbial quality and content by microbiologically monitoring it renders invalid any advertised claim, guarantee, or assurance that the endoscope was successfully high-level disinfected or "sterilized" (33), because the possibility exists that the endoscope was recontaminated with microorganisms during terminal water rinsing, posing an increased risk of nosocomial infection (14, 33, 44, 46, 49). The rinse water contacts the endoscope *after* chemical immersion, and, therefore, contaminated rinse water yields contaminated endoscopes irrespective of the potency, strength, or effectiveness of the LCS, AER, or automated reprocessing system. To be sure, the success of any endoscope reprocessing protocol that uses an LCS or disinfectant to achieve high-level disinfection or "liquid sterilization" is limited by, and dependent on, the microbial quality of the rinse water—the *Achilles'* heel of endoscope reprocessing. Assertions that the rinse water is "sterile" based, not on microbiologically monitoring the rinse water to evaluate its sterility, but solely on its manufacturer's label claim provide little assurance of safety, because, as previously mentioned, reports associating true and pseudo outbreaks following endoscopy to rinse water labeled as "bacteria-free" or "sterile" have been published (10, 21–30, 40–43, 48, 50, 51). Endoscope drying after completion of every reprocessing cycle may all but eliminate the need to monitor the rinse water, however, because endoscope drying virtually eliminates the risk of transmission of waterborne microorganisms during endoscopy (even if the rinse water might be contaminated) (16, 21–30).

Reprocessing the Endoscope Before the First Patient of the Day

A few guidelines recommend reprocessing endoscopes in the morning immediately before their first use of the day (Table 1) (1–4, 12, 14, 16, 17, 33, 34, 36, 37). This practice, however, can be time-consuming, onerous, and expensive, especially for a busy gastrointestinal endoscopy center with a large inventory of endoscopes to be used throughout the day. Most important, clinical data that substantiate this practice's benefit have not been published (7, 8, 34). In lieu of this practice, most guidelines recommend endoscope drying before storage (Table 1). Cases of transmission of waterborne microorganisms that, as a consequence of improper storage of a wet or inadequately dried endoscope, colonized and multiplied in the endoscope's moist internal channels to the first patient of the day undergoing endoscopy have been reported (30, 34, 42). The recommendations of a few guidelines notwithstanding (Table 1), reprocessing the endoscope immediately before its first use of the day may only be necessary under a few limited circumstances, including the removal of a moist or wet endoscope from storage (7, 34, 56). While the risk of nosocomial infection would seem to increase the longer the endoscope remains in storage and unmonitored, the threshold, or critical, number of days a particular type or model of endoscope can remain in storage without posing an infection risk and requiring reprocessing before reuse is unclear, as research on this topic is lacking. One report suggests that properly reprocessed and dried colonoscopes may remain in storage for as long as a week without requiring reprocessing before reuse (56). But, the validity of policies and procedures for storing endoscopes that are based on this one report's conclusion may be questioned, because, although extended by endoscope drying, the number of days an endoscope can remain safely in storage without likely posing an increased risk of nosocomial infection and requiring reprocessing before reuse depends, in part, on several variables, including the type of endoscope and the effectiveness of the entire reprocessing procedure, several steps of which are manual (*e.g.*, precleaning, terminal drying) and, therefore, may vary from one facility to another. Because of their design and the invasiveness of the procedure, reprocessing side-viewing duodenoscopes used during ERCP (as well as, possibly, bronchoscopes) before reuse if stored for only a few days may be advisable (22, 42).

CONCLUSION

Endoscope drying is as important to the prevention of disease transmission and nosocomial infection as cleaning and high-level disinfection (or " liquid sterilization"). Modification and revision of endoscope-reprocessing and infection-control guidelines as required to ensure each is clear, complete, and consistent and unconditionally recommends endoscope drying after completion of *every* reprocessing cycle—both between patient procedures and before storage, no matter the label claim of the LCS, the label claim of the AER or automated reprocessing system, or the microbial quality of the rinse water—are therefore recommended (7, 8, 33). (Use of a drying method that will not recontaminate the flexible [or rigid] endoscope is recommended

whenever possible (38)). Adherence to this recommendation may eliminate the need not only to monitor the rinse water used during endoscope reprocessing, but also to reprocess each endoscope before its first use of the day. Because few practices would arguably appear to pose as significant an increased risk of contamination, transmission of waterborne microorganisms, and nosocomial infection as the immediate use, and introduction into patients' viscera, of just-reprocessed-and-wet-with-rinse-water (and potentially contaminated) flexible (and rigid) endoscopes, several questions may be asked, including whether this practice, despite being recommended by some guidelines (Table 1), might be negligent and tantamount to medical malpractice, and why the clinical implications and increased risk of nosocomial infection associated with this practice are routinely overlooked by public health and accrediting agencies. In addition to thorough drying, proper storage of flexible endoscopes in a dry and well-ventilated environment is necessary, to prevent during endoscopy the transmission of waterborne microorganisms that may have colonized and multiplied in the endoscope's internal channels (5, 8, 57).

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