GI SOCIETIES JOINT STATEMENT

GI Societies Joint Statement on ANSI/AAMI ST91: GI societies vote No on AAMI revisions on endoscopic processing

Changes to ST91 for flexible and semi-rigid endoscopes create obstacles to implement standards and offer impractical, inappropriate, or conflicting guidance.

EXECUTIVE SUMMARY

Our societies are committed to initiatives focused on eliminating healthcare-associated infections through improved education about evidence-based practices. Although the American Association for the Study of Liver Diseases (AASLD), American College of Gastroenterology (ACG), American Gastroenterological Association (AGA), American Society of Colon and Rectal Surgeons (ASCRS), American Society for Gastrointestinal Endoscopy (ASGE), Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), and Society of Gastroenterology Nurses and Associates (SGNA) appreciated the opportunity to engage in the discussion around the 2021 revision of ST91 flexible and semi-rigid endoscope processing in healthcare facilities, the joint GI societies remain concerned and do not support some of the finalized revisions to the standards and therefore voted negative on the vote for approval.

While the GI community awaits the availability of widespread, cost-effective, alternative endoscopes and novel reprocessing technologies, it is critical for our patients that the focus of the national dialogue continues for the more salient issues of training, oversight, and enhancement of cleaning practices and technologies.

Fundamentally, our societies remain concerned about the inability for healthcare teams to implement and operationalize this ST91 standard at the practice level because of its length, construction, internal redundancies, disparate definitions, and, at times, conflicting recommendations.

BACKGROUND

The Association for the Advancement of Medical Instrumentation (AAMI) is a private, membership-based organization of stakeholders with interests in medical instrumentation safety, care, and use. Members include device manufacturers, governmental agencies, healthcare delivery organizations, accrediting organizations, and independent consultants in the field.

AAMI standards often mirror guidelines of numerous other organizations and are available through membership, subscription, or purchase. Some AAMI standards are endorsed by the American National Standards Institute (ANSI). For endoscope reprocessing, the AAMI standard is 1 among several, including the "Multisociety guideline on reprocessing flexible GI endoscopes and accessories"[1] and those from the SGNA,[2] Association for Professionals in Infection Control and Epidemiology,[3] Association of periOperative Registered Nurses,[4] and Centers for Disease Control and Prevention's Healthcare Infection Control Practices Advisory Committee,[5] among others.

In the fall of 2017, the AAMI initiated an early, off-cycle revision of "ANSI/AAMI ST91:2015 Flexible and semi-rigid endoscope processing in health care facilities,"[6] an endoscope reprocessing standard document widely adopted by endoscopy units across the country. The revision was prompted by the belief that new evidence relative to achieving endoscopes free of residual contamination and viable microbes before patient use had come to the fore. Most concerning to our combined societies was discussion of a potential sterilization mandate that could generate significant risk aversion among both practitioners and consumers, thereby reducing both availability and willingness to employ endoscopy for screening, surveillance, and therapy while

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increasing liability before widespread, cost-effective, alternative endoscopes and novel reprocessing technologies would be available. With this, our societies engaged in the ST91 revision process by joining the AAMI and the workgroup tasked with the document's update.

The journey of updating ST91 was a long one. Our societies gained significant understanding of the tenor and process of the workgroup and believe we contributed significantly to improving the document. Nevertheless, throughout the development of this revision, GI society representatives voiced significant concerns that the drafting process was not driven by evidence, lacked transparency of editorial input, and was unduly cumbersome, with some issues arbitrated even after prior resolution and repeatedly polled for a sense of the majority.

To comply with standards set by the Centers for Medicare & Medicaid Services (CMS), individual institutions and practices must cite references to guidance from nationally recognized specialty societies in developing their policies and procedures on endoscope reprocessing and most probably adopt a mix of recommendations from available guidance. Generally speaking, endoscope reprocessing guidelines are similar, with some variation in their prescriptive detail, predominantly based on expert opinion and nuanced interpretation of data.

Each of our societies has endorsed the "Multisociety guideline on reprocessing flexible GI endoscopes and accessories," which provides evidence-based recommendations for the reprocessing of flexible GI endoscopes based on rigorous review and synthesis of the contemporary literature and application of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, included significant input from the endorsing organizations, and achieved consensus through redistribution. The process of revising ST91 and the final output varied significantly from the standards for guideline development expected by our societies, which led to our casting and maintaining negative votes on the final revised version of ANSI/AAMI ST91 "Flexible and semi-rigid endoscope processing in health care facilities."[7]

SUMMARY OF KEY CHALLENGES FACING GI ENDOSCOPY FROM AAMI REVISIONS TO ST91

The following outstanding issues prompted our societies to vote negative on the final version of the document:

- The standard begins atypically with an opening editorial containing statements lacking data to substantiate often inflammatory claims.
- There was a lack of transparency in the development process. The AAMI states on its website "A basic principle of all standards work is openness and transparency with due process afforded to all stakeholders and interested parties" (A.6.2.1 General information).[8] The revision process included representatives from for-profit companies and other entities advocating for standards language that would support use of their products or services, often with specificity but without substantive peer-reviewed supporting data. Transparency would have been achieved by using tent cards with names and affiliations. These were not used, making it impossible to determine the potential for conflict of interest during discussions and polls for majority opinion. The actual document with its listing of participants provided does not result in full public conflict of interest disclosure of employment and/or consultancies.
- There are statements unsubstantiated by evidence. The GI societies were successful in eliminating or mitigating many significant suggested changes to practice in this revision that were unsubstantiated by evidence; however, several examples such as the following remain within the document:
  - Questionable evidence on AAMI guidance for use of cleaning verification tests after each use for all high-risk endoscopes—not approved for such use by the U.S. Food and Drug Administration (FDA)[9] nor demonstrating clear outcome metrics.
  - Questionable evidence on AAMI guidance for segregation of buttons and biopsy caps with associated endoscopes and/or labeling the buttons, endoscopes, and biopsy caps to enable tracking of use per patient.
  - Questionable evidence on AAMI guidance on use of borescopes in evaluation of endoscopes. To date, no manufacturers have defined acceptable or unacceptable findings. Furthermore, not all channels are accessible for examination with a borescope.
- There are disparities in the normative and formative sections of the standard. The GI societies expressed our discomfort with the disparities between the normative (i.e., evaluated standards) and formative (i.e., implementation guidance) sections of the standard; however, they remain within the document. This is unacceptable because it leads to confusion and our inability as society representatives to make solid definitive recommendations. Reprocessing guidelines have become a cornerstone in formal infection control programs for endoscopy units across the United States seeking initial certification and subsequent maintenance of accreditation. To comply with CMS standards, endoscopy units must cite references from nationally recognized specialty societies in developing their policies and procedures on endoscope reprocessing. As noted earlier, AAMI ST91 is an endoscope reprocessing standards document widely

adopted by endoscopy units across the country. Inconsistent guidance in the standard could lead to unnecessary or inappropriate compliance with the formative rather than normative sections of the standard and further could lead to citations from accreditation bodies.
  - One example of inconsistency between the normative and formative sections of the standard relates to routine utilization of drying verification.
  - Another example is the inclusion of guidance relative to loaned endoscopes in the formative but not normative section of the standard. The process for tracking, exposure, and culture of loaner endoscopes is not universal and is a significant loophole in the system.
- There is impractical and inappropriate guidance. The GI societies made significant headway in eliminating much of the impractical and inappropriate guidance from early drafts; however, such guidance remains in the final draft of the revised standard. Following are 3 examples that were discussed in multiple workgroup meetings but remain in the document:
  - The section addressing detachable parts reads: "Detachable parts and valves pose unique concerns. To minimize risk of transmission from infection, any one of the following measures are recommended: (1) Use of single-use biopsy port caps and single-use valves; (2) Sterilization of reusable valves and caps, preferably using steam sterilization when materials are compatible; (3) High level disinfection of valves and caps, either keeping the valve/caps together with the endoscope as a set or tracking the individual valve/cap to the patient and the procedure." The GI societies understood we had successfully explained the impracticality of the third recommended option only to have it arbitrated again in a subsequent meeting. Some workgroup members even suggested this information was trackable in electronic health records. When the GI society representatives explained that was not the case, we understood this impractical recommendation would be removed, but it remains.
  - The standard supports marketing of cleaning verification assays for duodenoscopes with claims that they (1) measure bacteria on reprocessed endoscopes, or (2) verify that a reprocessed endoscope is safe, or (3) assure proper high-level disinfection or sterilization, and such claims are considered illegal by the FDA as no such assays have received 510(k) clearance.[9]
  - The GI societies proposed for the normative section of the standard that endoscope culture and repair history should accompany loaned endoscopes. This was moved and then included in the formative section.

ENDOSCOPY UNIT CONSIDERATIONS WHEN ADOPTING A GUIDELINE

Endoscopy units are responsible for establishing protocols that ensure the highest level of quality and safety while maintaining compliance. Unit staff should consider the following to eliminate any ambiguity or conflicting policies and procedures:

- Know the guidelines and standards your facility has adopted for its infection control and prevention program relative to endoscope reprocessing. To comply with CMS standards, endoscopy units must cite references from nationally recognized specialty societies in developing their policies and procedures on endoscope reprocessing.
- Review your infection control policies and reconcile any differences between reprocessing recommendations so that contradictory policies are not developed or followed.
- Ensure your unit is following the adopted guidelines and standards with perfect accuracy and precision.
- Be able to articulate why the unit has selected the guidelines it has selected to follow.
- Keep a copy of this joint statement in your accreditation survey preparation files along with the references to the guidelines and standards your unit has adopted relative to endoscope reprocessing.

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The following individuals contributed to the writing of this statement: Bret T. Petersen, MD, Michael L. Kochman, MD, David A. Greenwald, MD, James Collins, BS, RN, CNOR, Lukejohn W. Day, MD

This joint statement was approved by the governing bodies of the AASLD, ACG, AGA, ASGE, ASCRS, SAGES, and SGNA in January 2022.

DISCLOSURE

The following authors disclosed financial relationships: B. T. Petersen: Consultant for Olympus America; investigator for Boston Scientific and AMBU. M. L. Kochman: Consultant for Olympus, Dark Canyon Labs, Boston Scientific, Virgo Systems, Medtronic, ACI, and Novella; equity position at Endolumik; stock in Dark Canyon Labs

and Virgo Systems. J. Collins: Consultant for Boston Scientific and STERIS. L. W. Day: Consultant for 3T BioSciences, Pfizer, and Boehringer Ingelheim. All other authors disclosed no financial relationships.

ABOUT THE AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

The AASLD is the leading organization of scientists and healthcare professionals committed to preventing and curing liver disease. We foster research that leads to improved treatment options for millions of liver disease patients. We advance the science and practice of hepatology through educational conferences, training programs, professional publications, and partnerships with government agencies and our GI sister societies.

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ABOUT THE AMERICAN COLLEGE OF GASTROENTEROLOGY

The ACG was founded in 1932 and is an organization with a membership of over 17,000 individuals from 86 countries. The College's vision is to be the preeminent professional organization that champions the prevention, diagnosis, and treatment of digestive disorders, serving as a beacon to guide the delivery of the highest quality and compassionate and evidence-based patient care. The mission of the College is to enhance the ability of our members to provide world-class care to patients with digestive disorders and advance the profession through excellence and innovation based on the pillars of patient care, education, scientific investigation, advocacy, and practice management.

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ABOUT THE AMERICAN GASTROENTEROLOGICAL ASSOCIATION

The AGA is the trusted voice of the GI community. Founded in 1897, the AGA has grown to more than 16,000 members from around the globe who are involved in all aspects of the science, practice, and advancement of gastroenterology. The AGA Institute administers the practice, research, and educational programs of the organization.

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ABOUT THE AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY

Since its founding in 1941, the ASGE has been dedicated to advancing patient care and digestive health by promoting excellence and innovation in GI endoscopy. The ASGE, with more than 15,000 members worldwide, promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education.

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ABOUT THE AMERICAN SOCIETY OF COLON AND RECTAL SURGEONS

The 4,000+ member ASCRS is the premier society for colon and rectal surgeons and other surgeons dedicated to advancing and promoting the science and practice of the treatment of patients with diseases and disorders affecting the colon, rectum, and anus. Its board-certified colon and rectal surgeons complete a residency in general surgery, plus an additional year in colon and rectal surgery, and pass an intensive examination conducted by the American Board of Colon and Rectal Surgery.

Website | Twitter

ABOUT THE SOCIETY OF AMERICAN GASTROINTESTINAL AND ENDOSCOPIC SURGEONS

The mission of the SAGES is to improve quality patient care through education, research, innovation, and leadership, principally in GI and endoscopic surgery. The SAGES is a leading surgical society, representing and educating a global community of over 6,000 surgeons that can bring minimal access surgery, endoscopy, and emerging techniques to patients worldwide. The organization sets the clinical and educational guidelines on standards of practice in various procedures, critical to enhancing patient safety and health.

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ABOUT THE SOCIETY OF GASTROENTEROLOGY NURSES AND ASSOCIATES, INC

The SGNA, Inc, is a professional organization of nurses and associates dedicated to the safe and effective practice of gastroenterology and endoscopy nursing. The SGNA carries out its mission by advancing the science and practice of gastroenterology and endoscopy nursing through education, research, and collaboration and by promoting the professional development of its members in an atmosphere of mutual support. For more than 35 years, SGNA has served as the voice of more than 5,000 members and their patients.

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