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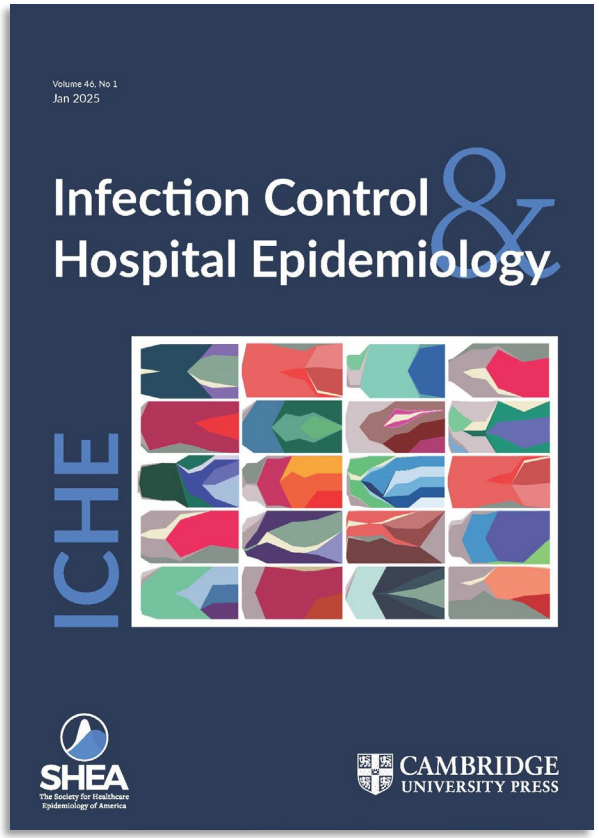

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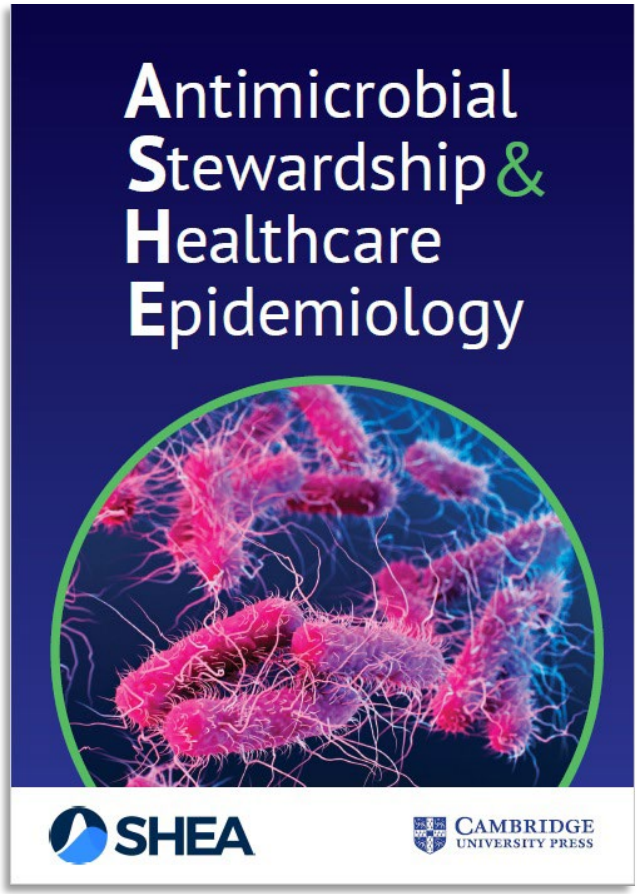

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SCAN TO LEARN MORE

NEW!

SHEA Members Open Forum

Get ready for real discussion! This is a peer-driven, discussion-based program designed for SHEA members to connect, share experiences, and talk through real-world challenges.

April 29th at 4:00 – 5:00 pm ET

Topic: Infection Control Conversations: Preparedness & Response / TBD

Moderator: Harjot K. Singh, MD, ScM

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You Can Help!

Improving Antibiotic Stewardship and Infection Prevention in Nursing Homes

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SHEA Webinar

Town Hall 2026

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April Town Hall Panelists:

Dr. Bernard Camins
Mount Sinai

Dr. Katie Passaretti
Advocate Health

Dr. Chris Nyquist
Children's Colorado

Dr. Tom Talbot
Vanderbilt University

Invited Panelist:

Emily Sickbert-Bennet Vavalle, PHD, CIC
UNC Health

ADVOCATE HEALTH

Sterile Processing and High-Level Disinfection

SHEA April 2026 Town Hall

Katie Passaretti, MD

Chief Infection Prevention Officer, Advocate Health

04/15/2026

Joint Commission IP Hierarchy

1. **Federal/State/Local Laws and Regulations**
2. Manufacturer's Instructions for Use (MIFU)
3. Evidence Based Guidelines and Standards
4. Consensus Documents and Professional Standards (AAMI)
5. Organizational Policies and Procedures

Standards, Consensus and Guidance Documents

SHEA Expert Guidance Document

- Synthesis of scientific evidence, theoretical rationale, current practices, practical considerations, writing group opinion, and consideration of potential harm

AAMI/ANSI

- Standard (ST) – consensus document that provides requirements, specifications or guidelines; Reviewed every 5 years
- Technical Information Report (TIR)– interim standard, cannot include must/shall statements; Reviewed every 3 years

FINAL_APIC-AAMI-TOP-TEN.pdf
2024-Handbook-Final-Updated-112624.pdf

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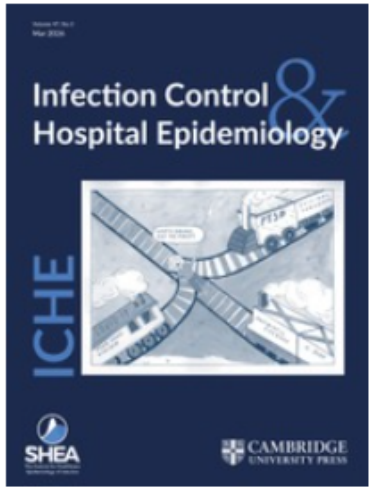
Updated Multisociety Guidance



Multisociety guidance for sterilization and high-level disinfection

Published online by Cambridge University Press: **28 April 2025**

Erica S. Shenoy, David J. Weber, Kathleen McMullen, Zachary Rubin, Priya Sampathkumar, Joshua K. Schaffzin, Emily Sickbert-Bennett, Laraine Washer, Deborah S. Yokoe and Audrey H. Calderwood ...Show all authors Show author details

Shenoy ES, Weber DJ, McMullen K, et al. Multisociety guidance for sterilization and high-level disinfection. *Infection Control & Hospital Epidemiology*. 2025;46(6):561-583. doi:10.1017/ice.2025.41

Endorsed by SHEA, APIC, ASGE, IDSA and SGNA

Balancing Practical Guidance with Feasibility

Topic	New or revised?	Location (recommendation)
Use of the methods outlined in "Handbook for SHEA Sponsored Guidelines and Expert Documents"	New	Methods
How to use and interpret manufacturers' instructions for use (MIFUs)	New	Section 2: Background on the prevention of contamination of reusable medical devices, Manufacturers' instructions for use
How to perform point-of-use treatment for reusable medical devices	New	Prior to sterilization or HLD
When and how to assess effectiveness of sterilization and high-level disinfection (HLD) of reusable medical devices	Revised	Sterilization (14) Special considerations for HLD (29, 30)
Factors to consider when evaluating a sterilization method for a new device or when switching from one sterilization process to another	New	Sterilization (13)
Considerations for sterilization and HLD of critical or semi-critical investigational reusable medical devices	New	Investigational devices (37)
Considerations for sterilization and HLD of 3D-printed devices or implants	New	Investigational devices (38)
When semi-critical devices or their components or may not need to be high-level disinfected	New	High-level disinfection (19, 20)
How to process ultrasound probes used on intact skin	New	High-level disinfection (21)
Considerations for sterilization and HLD of reusable medical devices used with lubricating or defoaming agents	New	Special considerations for HLD (26)
Storage considerations after reusable medical devices have undergone sterilization or HLD	New	Handling reusable medical devices after HLD (31, 32)
When to use sterile, single use components, accessories, or devices	New	Augments and alternatives to HLD (34-36)
Implementation considerations related to sterilization and HLD processing of reusable medical devices	New	Approaches to implementation (42-45)
Rutala et al. 2008, Table 1. Methods of sterilization and disinfection.[3] Readers may refer to Rutala et al. 2023 for a summary of methods for sterilization and HLD that are legally marketed per the US Food and Drug Administration (FDA) and their advantages and disadvantages.[4]	Not included	

Foundational Principles:

- Reinforces Spaulding Classification
  - Critical items – sterilization required
  - Semi-critical items – minimum of HLD
- Emphasizes (and re-emphasizes!) adherence to MIFU
- Explicit attention to feasibility and harm
- Clear acknowledgement of areas with insufficient evidence

Resolving MIFU Challenges

Identify MIFU Issue	• Conflicting Instructions/Unclear language • Unavailable products • Missing MIFU
Contact Manufacturer	• Engage device and/or “accessory” (sterilizer/HLD device or product) manufacturer technical services • Document all communications
Assess Validation	• Process acceptable if **either manufacturer validates** • Do not use if no validation exists
Clarify/ Escalate	• Clarify ambiguity or alternatives with manufacturer • Escalate to FDA DICE if unresolved
Risk-Based Review if Unresolved	• If unresolved, evaluate patient safety, regulatory and legal risk • Ensure leadership awareness

Ultrasound Related Guidance

- 2025 Multisociety Guidance Document ***and*** AAMI TIR99
- Sheaths do NOT eliminate the need for HLD (unless specified by MIFU)
- Sterilization or HLD is ***not required*** for probes applied to intact skin for the intended use of guiding percutaneous procedures (central line placement, etc – the needle is the invasive device, not the probe)




Water Quality Conundrums

Both AAMI and Multisociety guidance emphasize the importance of water quality

Multisociety guidance document

- Limited evidence - Does not give specific guidance on operationalization or prescribe water testing

AAMI ST108 (replaced TIR34) – prescriptive requirements by consensus group

- Critical water for final rinse after HLD
- Routine water testing with defined frequency and locations
- Specific microbial and endotoxin limits
- Can be challenging to implement
  - Companion document on implementation (TIR119) coming soon!

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Other 2025 Multisociety Guidance Document Call-Outs

Drying of lumened devices

Pressure regulated instrument air or HEPA-filtered air to dry lumens

Always dry even if planned for immediate use

Lubricating and defoaming agents

Preferentially choose water-soluble agents over non-water-soluble

- Apply the minimum amount of non-water-soluble defoaming agents needed
- If MIFU doesn't specify, ideal to deliver simethicone directly into the working channel rather than irrigation water bottle

Clean the device after use and before processing to remove lubricating or defoaming agents

Sterilization vs HLD for any semi-critical devices?

Move towards sterilization for semi-critical reusable devices associated with ***high risk of transmission;*** lists considerations in making that decision

No recommendation

Methods of cleaning verification beyond external visual inspection

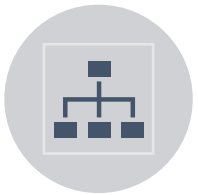
Use of microbial cultures to assess effectiveness of HLD

Maximum time properly processed devices can be stored after which facilities should repeat HLD

Use of “double” HLD

When to replace a new device

Frequency of training HLD/Sterilization staff



Centralized or decentralized structure

ADVOCATE HEALTH

High Level Disinfection and Sterilization

Emily Sickbert-Bennett PhD, MS, CIC, FSHEA

Executive Director, Infection Prevention, UNC Health

Professor of Medicine-Infectious Diseases, UNC School of Medicine

Professor of Epidemiology, UNC Gillings School of Global Public Health

UNC HEALTH® Department of Infection Prevention
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No Disclosures

Infection Control & Hospital Epidemiology (2025), 1–23
doi:10.1017/ice.2025.41

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SHEA Expert Guidance

Multisociety guidance for sterilization and high-level disinfection

What Has Not Changed

- Burden of outcomes associated with contamination of semi-critical reusable medical devices (i.e., endoscopes)

- Spaulding Classification Scheme
  - Critical
  - Semi-critical
  - Non-critical (topic of forthcoming Multisociety guideline!)

- Methods* for sterilization and HLD of reusable medical devices

- Physical, chemical and biological indicators for monitoring sterilization

*New technologies for endocavitary and non-lumened probes:

- UV-C
- Chlorine dioxide

✓ Effectiveness
✓ MIFU
✓ Quality Assurance
✓ Training/Competency

Where the Real Work Begins! *Implementation*

1. Quality assurance – borescope, ATP, microbial cultures
2. Resolution of Manufacturer's Instructions for Use (MIFU) Conflicts
3. Lapses in High Level Disinfection/Sterilization

Quality Assurance Methods

- *No recommendation* can be made for the use of borescopic examination to assess the integrity of lumened devices before processing. The use of borescopes *routinely* in clinical practices has not been well-studied, and borescope examinations likely impose substantial costs and training constraints.

- *No recommendation* can be made for the use of surrogate tests to detect residual organic material (eg, ATP, protein, heme) to assess adequacy of cleaning. Currently, these tests are not correlated with reduction of risk for microbial contamination or transmission.

- *No recommendation* can be made for *routinely* using microbial cultures to assess the effectiveness of the HLD process.

Outbreaks associated with contaminated endoscopes have been linked to identification of luminal damage and retained debris and identification of debris in processed endoscopes has been significantly correlated with microbiological contamination.

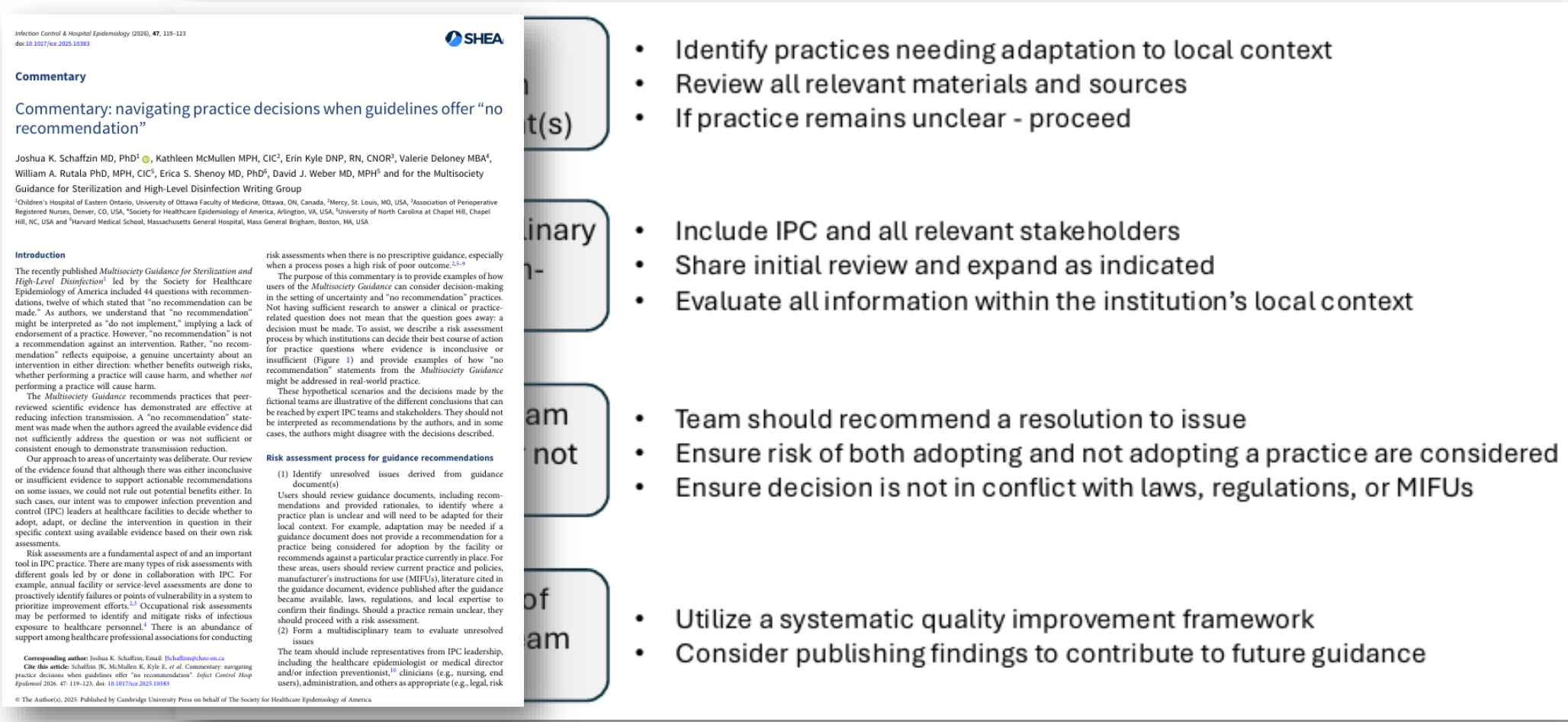
Lack of debris has not been similarly correlated with negative microbiologic contamination.

KEY REMAINING QUESTIONS:

Which findings identified during a borescopic evaluation of an endoscope are associated with a higher risk of post-procedure infection?

Can a validated method to monitor effective endoscope cleaning be established with thresholds that establish post-procedure infection risk?

When there is no recommendation, decisions still have to be made!



Infection Control & Hospital Epidemiology (2026), **47**, 119–123
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Commentary

Commentary: navigating practice decisions when guidelines offer "no recommendation"

Joshua K. Schaffzin MD, PhD[1], Kathleen McMullen MPH, CIC[2], Erin Kyle DNP, RN, CNOR[3], Valerie Deloney MBA[4], William A. Rutala PhD, MPH, CIC[5], Erica S. Shenoy MD, PhD[6], David J. Weber MD, MPH[5] and for the Multisociety Guidance for Sterilization and High-Level Disinfection Writing Group

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Introduction

The recently published *Multisociety Guidance for Sterilization and High-Level Disinfection*[1] led by the Society for Healthcare Epidemiology of America included 44 questions with recommendations, twelve of which stated that "no recommendation can be made." As authors, we understand that "no recommendation" might be interpreted as "do not implement," implying a lack of endorsement of a practice. However, "no recommendation" is not a recommendation against an intervention. Rather, "no recommendation" reflects equipoise, a genuine uncertainty about an intervention in either direction: whether benefits outweigh risks, whether performing a practice will cause harm, and whether *not* performing a practice will cause harm.

The *Multisociety Guidance* recommends practices that peer-reviewed scientific evidence has demonstrated are effective at reducing infection transmission. A "no recommendation" statement was made when the authors agreed the available evidence did not sufficiently address the question or was not sufficient or consistent enough to demonstrate transmission reduction.

Our approach to areas of uncertainty was deliberate. Our review of the evidence found that although there was either inconclusive or insufficient evidence to support actionable recommendations on some issues, we could not rule out potential benefits either. In such cases, our intent was to empower infection prevention and control (IPC) leaders at healthcare facilities to decide whether to adopt, adapt, or decline the intervention in question in their specific context using available evidence based on their own risk assessments.

Risk assessments are a fundamental aspect of and an important tool in IPC practice. There are many types of risk assessments with different goals led by or done in collaboration with IPC. For example, annual facility or service-level assessments are done to proactively identify failures or points of vulnerability in a system to prioritize improvement efforts.[2,3] Occupational risk assessments may be performed to identify and mitigate risks of infectious exposure to healthcare personnel.[4] There is an abundance of support among healthcare professional associations for conducting risk assessments when there is no prescriptive guidance, especially when a process poses a high risk of poor outcome.[2,5–9]

The purpose of this commentary is to provide examples of how users of the *Multisociety Guidance* can consider decision-making in the setting of uncertainty and "no recommendation" practices. Not having sufficient research to answer a clinical or practice-related question does not mean that the question goes away: a decision must be made. To assist, we describe a risk assessment process by which institutions can decide their best course of action for practice questions where evidence is inconclusive or insufficient (Figure 1) and provide examples of how "no recommendation" statements from the *Multisociety Guidance* might be addressed in real-world practice.

These hypothetical scenarios and the decisions made by the fictional teams are illustrative of the different conclusions that can be reached by expert IPC teams and stakeholders. They should not be interpreted as recommendations by the authors, and in some cases, the authors might disagree with the decisions described.

Risk assessment process for guidance recommendations

(1) Identify unresolved issues derived from guidance document(s)

Users should review guidance documents, including recommendations and provided rationales, to identify where a practice plan is unclear and will need to be adapted for their local context. For example, adaptation may be needed if a guidance document does not provide a recommendation for a practice being considered for adoption by the facility or recommends against a particular practice currently in place. For these areas, users should review current practice and policies, manufacturer's instructions for use (MIFUs), literature cited in the guidance document, evidence published after the guidance became available, laws, regulations, and local expertise to confirm their findings. Should a practice remain unclear, they should proceed with a risk assessment.

(2) Form a multidisciplinary team to evaluate unresolved issues

The team should include representatives from IPC leadership, including the healthcare epidemiologist or medical director and/or infection preventionist,[10] clinicians (e.g., nursing, end users), administration, and others as appropriate (e.g., legal, risk

Corresponding author: Joshua K. Schaffzin; Email: JSchaffzin@cheo.on.ca
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t(s)

- Identify practices needing adaptation to local context
- Review all relevant materials and sources
- If practice remains unclear - proceed

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- Include IPC and all relevant stakeholders
- Share initial review and expand as indicated
- Evaluate all information within the institution's local context

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- Team should recommend a resolution to issue
- Ensure risk of both adopting and not adopting a practice are considered
- Ensure decision is not in conflict with laws, regulations, or MIFUs

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- Utilize a systematic quality improvement framework
- Consider publishing findings to contribute to future guidance

- Schaffzin JK, McMullen K, Kyle E, Deloney V, Rutala WA, Shenoy ES, Weber DJ; Multisociety Guidance for Sterilization and High-Level Disinfection Writing Group. Commentary: navigating practice decisions when guidelines offer "no recommendation". Infect Control Hosp Epidemiol. 2025 Dec 22:1-5. doi: 10.1017/ice.2025.10383. Epub ahead of print. PMID: 41427649.

How to interpret or use the Manufacturer's Instruction for Use (MIFU)

- **Document written with expectation that healthcare facilities follow the MIFU**
  - *Before purchasing devices, facilities should evaluate whether they have the equipment, materials, physical space, resources, and space to meet the MIFU*
- **But… the reality is most facilities are likely to experience challenges**
  - *Conflict between device MIFU and the accessory used for processing → device drives the process however conflict needs to be addressed*
  - *Manufacturer does not validate process, but accessory manufacturer specifically validates the process for the device (or the opposite) → acceptable*
  - *MIFU references consumable products that are not available*
  - *MIFU with ambiguous language*
  - *MIFU uses terms without definition/enough detail to implement*
  - *MIFU unclear, too complex*
  - *MIFU not available*

Key Resources: technical services of the manufacturer of the medical device or accessory, FDA Division of Industry and Consumer Education (DICE) or the Manufacturer and User Facility Device Experience (MAUDE) database

If a facility cannot implement the MIFU due to irresolvable challenges and has no further options for recourse, the facility will need to consider the ***safety, legal, and regulatory risks of noncompliance*** *with an MIFU*

Lapses

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY FEBRUARY 2007, VOL. 28, NO. 2

ORIGINAL ARTICLE

How to Assess Risk of Disease Transmission to Patients When There Is a Failure to Follow Recommended Disinfection and Sterilization Guidelines

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

BACKGROUND. Disinfection and sterilization are critical components of infection control. Unfortunately, breaches of disinfection and sterilization guidelines are not uncommon.

OBJECTIVE. To describe a method for evaluating a potential breach of guidelines for high-level disinfection and sterilization of medical devices.

METHODS. The appropriate scientific literature was reviewed to determine the frequency of failures of compliance. A risk assessment model was constructed.

RESULTS. A 14-step protocol was constructed to aid infection control professionals in the evaluation of potential disinfection and sterilization failures. In addition, a model is presented for aiding in determining how patients should be notified of the potential adverse event. Sample statements and letters are provided for communicating with the public and individual patients.

CONCLUSION. Use of a protocol can guide an institution in managing potential disinfection and sterilization failures.

Infect Control Hosp Epidemiol 2007; 28:146-155

In the United States in 1996, there were approximately 46,500,000 surgical procedures and a much larger number of

infection failure on record involved the distribution of an inactive lot of glutaraldehyde disinfectant solution that had

Rutala WA, Weber DJ. How to assess risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. *Infect Control Hosp Epidemiol*. 2007;28(2):146-155. doi:10.1086/511700