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Commentary

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

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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

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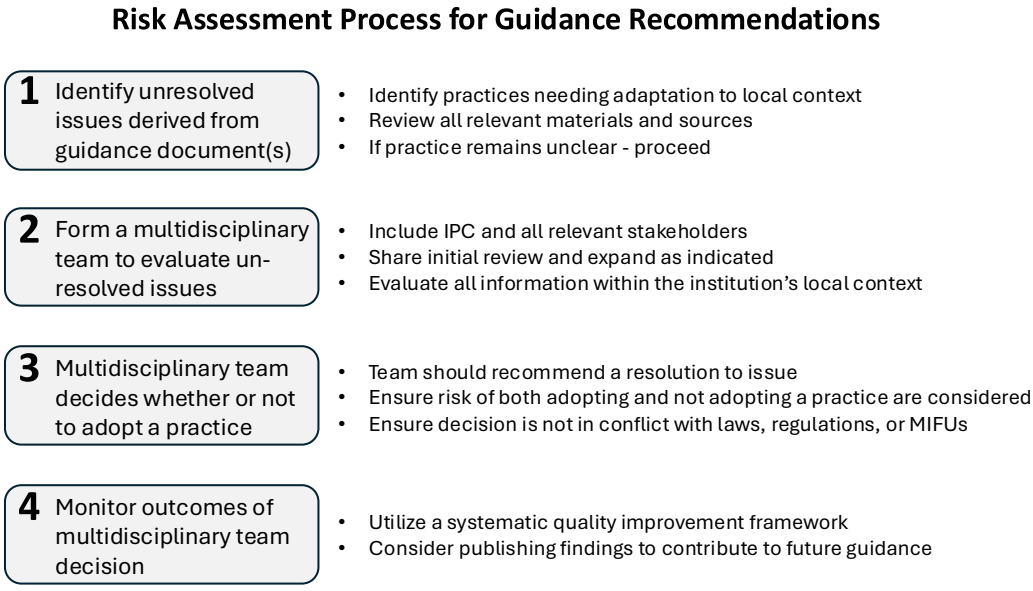


Figure 1. Risk assessment process.

management) to address each question. For example, for questions related to the *Multisociety Guidance*, sterile processing leadership should be included. The review described in Step 1 should be shared with and expanded by the multidisciplinary team to ensure all relevant input is considered. Importantly, all information must be evaluated within an institution's local context, including the likelihood and severity of adverse outcomes, the likelihood and magnitude of benefit, availability of expertise and technology, burden of practice, and resources available. Using a proactive, structured, and standardized approach to risk assessment, such as a failure modes and effects analysis,[11] has proven benefits in the healthcare setting and can work to improve the experience of multidisciplinary decision-making.

(3) Have the multidisciplinary team decide whether to adopt a practice

After thorough review and discussion, the multidisciplinary team should recommend a resolution to the issue, typically whether a practice should be adopted. The decision should include considerations for mitigating risks of adopting or not adopting the practice. The team should ensure that their decision is not in conflict with any laws, regulations, or MIFUs.[12]

(4) Monitor outcomes of the multidisciplinary team's decision

Whether an intervention is or is not implemented, institutions should monitor outcomes, preferably using a systematic quality improvement framework.[13] In this way they can evaluate whether the intervention resulted in improvement or if its harms outweigh its advantages. When monitoring outcomes such as healthcare-associated infections (HAIs), it should be noted that most are identified through passive surveillance and rates are subject to secular variance, and in some cases no validated surveillance definition may exist. When changing a practice, it is difficult to demonstrate the practice affected HAI rates, especially when HAIs were prevented. To demonstrate an effect on transmission, as was the standard in the *Multisociety Guidance*, formally designed studies are needed. In practice, HAIs related to reprocessing failures are typically detected as outbreaks where source identification and mitigation enhance our understanding of transmission. Institutions that choose to publish their experiences can contribute to the body of evidence. By reporting findings in the peer-reviewed published literature, institutions can help move "no recommendations" to firm recommendations in future guidance documents.

Examples from the *Multisociety Guidance*

Example #1 – Team decides to adopt practice

Preparation at the Location of Processing – Question #12, Recommendations 1 and 2:

12. What additional methods, if any, are recommended to assess the cleanliness of reusable medical devices prior to sterilization and high-level disinfection (HLD)?

Recommendation:

(1) Beyond external visual inspection (see 42), no recommendation can be made for additional methods for cleaning verification to prevent transmission events.

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

Step 1 – Members of the IPC Program are aware that cleaning verification testing is currently in use. Based on evidence that testing-based levels of cleaning effectiveness may not correlate with sterilization and infection risk, they propose to Sterile Processing Department (SPD) colleagues that the practice be stopped. SPD relays the proposal to endoscope users who express concern and wish to retain the practice.

Step 2 – A multidisciplinary team is convened and includes representatives from IPC, endoscopy reprocessing leaders, endoscope users, perioperative leadership, supply chain leadership, quality leadership, regulatory leadership, and other key local leaders. The team's review reveals the following:

- Cleaning verification testing is used for high-risk lumened endoscopes

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- Local evaluation has found these tests 'fail' (e.g., show unacceptable levels of contamination per the MIFU) 0.7% of the time. Multiple failure modes have been identified.
  - Additional channel debris has been discovered in failed scopes submitted to be recleaned. Once cleared from the channel, the scopes have passed verification testing
  - Scopes that repeatedly failed cleaning validation were returned to the endoscope manufacturer; necessary repairs were identified by the manufacturer
- There is support for cleaning verification among other professional organizations.[5,8]
- Department leadership asserts that cleaning verification is providing an important service to their patients and do not have concerns about budgetary or training limitations.

Step 3 – The multidisciplinary team decides that continued use of these cleaning verification tests is appropriate.

Step 4 – The team commits to monitoring patient outcomes and investigating potential HAIs identified through passive surveillance among patients undergoing procedures with these endoscopes. SPD and IPC are assigned responsibility for continued monitoring of frequency and apparent cause of cleaning failures. They publish their experience in a peer-reviewed journal.

Example #2 – Team decides to standardize process locally

Handling reusable medical devices after high-level disinfection, Question #32, Recommendations 1 and 2:

32. Is there a maximum time that properly processed non-lumened and lumened devices can be stored, after which facilities should repeat HLD to reduce the risk of transmission of infection?

Recommendation:

(1) No recommendation can be made for a maximum time after which facilities should repeat HLD for devices, including lumened devices, if a maximum time is not specified by the MIFU and the devices have been properly cleaned, processed, and stored without evidence of breaches or events leading to potential contamination (e.g., flood, non-contained construction).
(2) If a maximum time is not specified by the device MIFU, a facility may use a risk assessment to determine whether to use a time- or event-based method for defining how long to store non-lumened and lumened devices.

Step 1 – IPC and SPD leaders at a healthcare system are aware of a variety of endoscope storage practices in the system's hospitals and wish to have a standardized risk-based approach.

Step 2 – IPC and endoscopy reprocessing leaders form a multidisciplinary workgroup to review the evidence and draft the recommendations. The team reviews the most recent evidence-based and consensus guidelines including the *Multisociety Guidance* and reviews the most recent literature on the subject. The team also gathers information on the current state of reprocessing in all facilities within the system, including types of endoscopes used and their MIFUs, types of storage cabinets used and their MIFUs, and current reprocessing protocols including drying steps.

Step 3 – The team concludes that scope drying is a major component of safe scope storage and that a properly dried and stored scope can remain safe for an extended period of time. They note the practice of performing a 10-minute air purge of endoscopes following HLD recommended in the Association for the Advancement of Medical Instrumentation (AAMI) Standard ST91:2021,[8] the AORN Guideline for Processing Flexible Endoscopes,[5] and the Multisociety guideline on reprocessing flexible GI endoscopes and accessories.[6] Additionally, they note an MIFU for a forced air cabinet in use at multiple sites recommends reprocessing if a device is stored greater than 31 days. They develop a process for timing of reprocessing based on how an endoscope is managed and stored following HLD. Considerations include no reprocessing for endoscopes stored in a forced air drying cabinet having continuous air flushing; 7-day reprocessing interval if unused and stored in a conventional cabinet based on existing practice; and reprocessing before each use when an endoscope was not stored in a forced air drying or conventional cabinet and did not undergo a 10-minute air purge.

Step 4 – The team commits to monitoring patient outcomes and investigating potential HAIs identified through passive surveillance among patients undergoing procedures with these endoscopes. The workgroup recognizes that these new guidelines will affect the daily workflow at several hospitals. They share the recommendations and rationale, including evidence of outbreaks associated with improperly dried scopes, with system-level leadership of perioperative services and operations to gain buy-in before rolling out the recommendations to individual hospitals. Processes are tracked by perioperative services and IPC through regular in-person audits.

Example #3 – Team decides to not adopt practice

Approaches to Implementation – Question #42, Recommendation 6:

42. What visual inspection methods are recommended to ensure debris has been removed?

Recommendation: No standardized and readily implementable methods exist for routine, internal (endoscope channels) visual inspection of reusable medical devices; however:

6. No recommendation can be made for the use of borescopic examination to assess the integrity of lumened devices before processing.

Step 1 – An institution with multiple sites where endoscopy is performed is building a new satellite ambulatory facility that will include a large endoscopy suite. A consultant for the design and planning project recommended they install a borescope to inspect lumens of duodenoscopes between manual cleaning and high-level disinfection. The institution's other sites currently do not use a borescope. The project team asks stakeholders to comment on the value of the investment.

Step 2 – A multidisciplinary team is convened that includes IPC, SPD, endoscopy processing, endoscope users, clinical engineering, design project leadership, purchasing leadership, and other key local leaders. Materials reviewed and summarized during team meetings include literature on borescope use, MIFUs, laws and regulations, patient expectations, provider expectations, anticipated personnel training and needs, anticipated maintenance needs, and input from colleagues at partner institutions.

Step 3 – The team recommends against using a borescope in the new facility based on the following factors:

- Their assessment of the available evidence for borescope use to reduce HAIs relative to their practice setting is inconclusive. However, borescopes have been shown to identify

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residual moisture in endoscopes, which may increase the risk of contamination and thus infection transmission.
- Methods for implementing borescope inspection and interpreting the results are unclear. The team has concerns about the ability to train individuals to use the borescope and whether there would be benefit in this context.
- Adding a borescope to one site will create an imbalance with other sites in terms of establishing variation in standards across sites and perception of reprocessing practice and patient safety. If any site has a borescope, all sites need a borescope.
- The team determines that investing resources and efforts in implementing and monitoring a 10-minute forced air drying time is expected to reduce risk more than implementing borescopic inspection.
- The cost of the device and time to perform and respond to borescope assessments is anticipated to be prohibitive given the organization's budget.

Step 4 – The institution proceeds with the project with a focus on monitoring the quality of other aspects of processing, including strict adherence to a 10-minute dry time consistent with the MIFU, and does not include a borescope in the new facility. Stakeholders commit to monitoring patient outcomes and investigating potential HAIs identified through passive surveillance among patients undergoing procedures with these endoscopes. IPC is tasked with following the literature to determine whether borescope use proves essential for proper reprocessing practice.

Example #4 – Team decides to adopt practice

Approaches to Implementation – Question #42, Recommendation 6:

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Recommendation: No standardized and readily implementable methods exist for routine, internal (endoscope channels) visual inspection of reusable medical devices; however:

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Step 1 – An institution with multiple sites where endoscopy is performed is building a new satellite ambulatory facility that will include a large endoscopy suite. A consultant for the design and planning project recommended they install a borescope to inspect lumens of duodenoscopes between manual cleaning and high-level disinfection. The project team asks stakeholders to comment on the value of the investment.

Step 2 – A multidisciplinary team is convened that includes IPC, SPD/endoscopy processing, endoscope users, clinical engineering, design project leadership, patient representatives, purchasing leadership, and other key local leaders. Materials reviewed and summarized during team meetings include literature on borescope use, MIFUs, local laws and regulations, patient expectations, provider expectations, anticipated personnel training and needs, anticipated maintenance needs, and input from colleagues at partner institutions.

Step 3 – The team recommends in favor of using a borescope in the new facility based on the following factors:

- The evidence for borescope use suggests the device can identify endoscope damage. They rationalize that a damaged endoscope is at higher risk of contamination, which in turn could increase the likelihood of infection transmission.
- Partner institutions who use borescopes have shared protocols for their use, maintenance, and interpretation of results that could be adopted by the new facility readily.
- Required cuts to other project areas in order to accommodate the borescope and associated staff (for example, having fewer staff dedicated to reprocessing and less break room space) are deemed acceptable. The institution has a strong IPC research group who advocates for the opportunity to generate evidence necessary to test the hypothesis that borescope use reduces infection rates.

Step 4 – The team commits to monitoring patient outcomes and investigating potential HAIs identified through passive surveillance among patients undergoing procedures with these endoscopes. The institution proceeds with the project including a borescope in the new facility. Human factors consultants are hired to help design the space and processes to optimize training and consistent use of the borescope. The multidisciplinary team develops an algorithm that specifies actions based on the findings of the borescopic examination (e.g., repeat cleaning, return to manufacturer for assessment, etc.). The IPC research group designs a study to evaluate the efficacy of borescope use and assess for impact on prevention of transmission of infection.

Conclusion

While conclusive evidence that supports an actionable recommendation is preferred, "no recommendation" conclusions recognize the limitations of currently available evidence. "No recommendation" was utilized in a subset of recommendations in the *Multisociety Guidance* in these situations, and the responsibility for assessment and implementation was deferred to healthcare facilities to undertake context-sensitive and evidence-informed approaches to issues where evidence currently falls short or is expected to evolve. Such a statement can be seen as an invitation or an opportunity for institutions to conduct multidisciplinary, evidence-informed, tailored risk assessments that help them better understand their unique conditions and for infection prevention and other experts in these topics to help inform and guide facilities as they make practice decisions. Additional research is needed, and new findings can help move "no recommendations" to become recommendations in evidence-based guidelines when the body of evidence is of high quality, is clear, and points in a consistent direction.

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