



Annex A—Minimizing the Risk of Bacterial Transmission from Patient to Patient When Using Duodenoscopes

Annexed to: Best Practices for Cleaning, Disinfection and Sterilization of Medical
Equipment/Devices in All Health Care Settings, 3rd edition

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NOTES: This document is intended to provide best practices only. Health care settings are encouraged to work towards these best practices in an effort to improve quality of care.

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Additional Abbreviation for this Annex

CPE carbapenemase-producing Enterobacteriaceae

Preamble

Purpose of This Document

This document is an extension to the Public Health Ontario [*Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in All Health Care Settings*](#) (main body).

Recent outbreaks have demonstrated that adherence to current guidelines for endoscope reprocessing may not be sufficient to prevent bacterial transmission following the use of endoscopic retrograde cholangiopancreatography (ERCP) endoscopes (i.e., duodenoscopes).¹⁻⁹ Design features inherent to all currently available duodenoscopes make effective cleaning and disinfection challenging.^{1,8,10-12} Until a definitive solution is identified, health care facilities where duodenoscopy is performed need to be aware of the risk of bacterial transmission associated with duodenoscopes and should ensure guidelines for reprocessing endoscopes are strictly followed. Some facilities have also implemented, or are considering the implementation of, additional steps in an attempt to further reduce the risk to patients.

This document outlines current concerns with respect to duodenoscope-associated outbreaks and the effectiveness of duodenoscope reprocessing. It also reviews some of the advantages and disadvantages of potential strategies to reduce the risk of bacterial transmission secondary to duodenoscopy.

The recommendations are based on current professional guidelines for medical device and/or endoscope reprocessing,^{10,13,14} reports of duodenoscope-related outbreak investigations,^{15,16} and expert opinion.¹⁷⁻²³ This document does not replace manufacturers' instructions for duodenoscope reprocessing, the recommendations provided in the [main body](#) of this document (I.2.M, pages 44-48), or other applicable professional guidelines for medical device and/or endoscope reprocessing.

Background

Gastrointestinal endoscopes are challenging to reprocess due to their narrow and angulated internal lumens and irregular, hard to reach surfaces, combined with the high levels of bacterial contamination that occurs following routine use.



Figure 1: Close-up view of an ERCP endoscope tip (Source: US Food and Drug Administration)

Duodenoscopes are side-viewing endoscopes that differ from other gastrointestinal endoscopes in having an elevator mechanism and elevator recess at the distal end of the endoscope that allow accessories to be moved into and out of the endoscope field (Figure 1). Duodenoscopes also have an elevator channel that connects the distal elevator mechanism to the operator controls at the proximal end of the endoscope. In newer models, the elevator channel is sealed, and the channel cannot be accessed for cleaning and cannot be cleaned should it become contaminated.²⁴ The elevator mechanism, recess and channel (if unsealed) are difficult to

access for cleaning and the elevator mechanism contains complex mechanical parts including hinges that are difficult to clean.^{11,24}

Effective reprocessing of endoscopes requires pre-cleaning at the point of use, manual cleaning prior to disinfection, high-level disinfection (HLD) (or sterilization), thorough drying, and safe storage.^{10,25,26} All the steps are essential to ensure adequate removal of bacteria (and other pathogens) from the endoscope and to prevent recontamination. Failure to correctly perform any of the above steps according to the manufacturers' instructions and current professional guidelines can result in bacterial transmission. Transmission can also result from the use of damaged or defective endoscopes, or endoscopes with design flaws that prevent any of these steps from being carried out effectively.^{1,8,12,27,28}

Over the last five years, outbreaks of multidrug-resistant bacteria, and in particular of carbapenemase-producing Enterobacteriaceae (CPE), have been associated with the use of duodenoscopes.³⁻⁷ These outbreaks occurred despite apparent adherence to best practices for endoscope reprocessing.^{11,24} In some cases, duodenoscopes remained culture positive or continued to transmit infection despite multiple reprocessing cycles.^{7,8,20} No evidence of viral transmission has been associated with any of these duodenoscopy-associated outbreaks.¹⁰

Assessments performed by the US Food and Drug Administration and others, have concluded that the root cause of these outbreaks is the design of current duodenoscopes, which prevents complete cleaning of the elevator mechanism, elevator recess and/or elevator channel.^{11,24} Even minor breaches in the protocols for cleaning and drying may also contribute to these outbreaks by leading to biofilm formation and persistent bacterial contamination.

Currently, there is not a clear understanding of the frequency of bacterial transmission related to the use of duodenoscopes or the degree of risk faced by patients. It is likely that the incidence of transmission is considerably higher than the incidence of reported outbreaks, given that the transmission of non-multidrug-resistant, non-CPE bacteria would not be detected or reported in most cases.

A definitive solution to the problem of bacterial transmission secondary to persistent contamination of duodenoscopes following reprocessing must be found and will require design changes to current duodenoscopes. Industry and regulatory bodies should prioritize this issue. In the interim, facilities that perform duodenoscopy must ensure that reprocessing guidelines and updated manufacturers' instructions are meticulously followed, and must identify post-duodenoscopy transmission events or outbreaks. Facilities may also consider adopting additional processes and procedures intended to further reduce this risk that are not included in the recommendations in current endoscopy reprocessing guidelines. These additional measures are based on theoretical considerations and expert opinion. Implementation of additional procedures should be done only after careful consideration of their benefits and risks, and with the recognition that none have yet been demonstrated to reduce the risk of bacterial transmission and/or outbreaks associated with the use of duodenoscopes.

Section One: Potential Strategies to Reduce the Risk of Bacterial Transmission from Duodenoscopes

1. Best Practices for Duodenoscope Reprocessing

Reports of recent outbreaks, while not identifying major deviations from best practices, do identify minor issues related to duodenoscope cleaning and duodenoscope drying that may have led to biofilm formation, subsequent disinfection failure, and bacterial transmission.^{3-5,7} Once biofilm forms within an endoscope, it may persist despite subsequent reprocessing. Thus, consistent adherence to reprocessing recommendations, particularly with regards to pre-cleaning, cleaning, drying and storage of endoscopes, is essential as inconsistency in practices may result in biofilm formation and persistent contamination of the duodenoscope.⁸ Thus, although adherence to current guidance may not be sufficient to eliminate the risk of bacterial transmission secondary to duodenoscopy, the risk of transmission will be higher at centres that do not rigorously adhere to currently recognized best practices.

It is essential that all facilities review their duodenoscope reprocessing policies and protocols to ensure that:

- They are consistent with current best practice guidance and updated manufacturers' instructions.
- They provide appropriate education and training to all individuals involved in endoscope reprocessing.
- They implement a quality assurance program to ensure that best practices are applied consistently and maintained over time.

Health care facilities where duodenoscopy is performed should comply with the best practices described in the following guidance documents:

1. PIDAC's [*Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/ Devices in All Health Care Settings*](#), Section I, chapter 2, sub-section M (pages 44 to 49).
2. Public Health Agency of Canada. [*Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy*](#).

The core components of these best practices relevant for duodenoscope reprocessing include, but are not limited to, the following elements:

- Adhere strictly to best practices for duodenoscope reprocessing as described in current manufacturers' instructions, applicable professional guidelines, and the relevant sections of the [main body](#) of this document (I.2.M, pages 44-48).
- Check regularly for updates to standards, best practice guidelines and manufacturers' instructions;²⁹ adapt their organizational policies and procedures promptly as appropriate; and re-train reprocessing staff whenever procedures are updated.
- All aspects of duodenoscope reprocessing shall be supervised and shall be performed by knowledgeable, trained personnel.^{29,30}

- Health care facilities where duodenoscopy is performed must ensure that all essential steps required for duodenoscope reprocessing are performed consistently including:¹
 - pre-cleaning
 - manual (mechanical) cleaning
 - high-level disinfection or sterilization
 - drying
 - storage and transport
- Storage of duodenoscopes in an appropriately designed storage cabinet for heat sensitive endoscopes (SCHE) is an essential practice to ensure complete drying, prevent biofilm formation, and minimize recontamination or growth of residual bacteria. SCHE are well-ventilated cabinets that allow duodenoscopes to be stored vertically. In one study, storage of endoscopes in a SCHE resulted in a significant reduction in endoscope contamination post-reprocessing.³¹⁻³⁴
- Duodenoscopes shall routinely be inspected for defects, damage or loss of functionality with each use—if problems with the device are identified, the device shall be removed from use following reprocessing and sent to the manufacturer for repair.³⁰
- A plan for regular, preventive maintenance of duodenoscopes should be in place at a frequency established by the facility and manufacturer; this may be particularly important for duodenoscopes that have sealed elevator channels to ensure that the O-rings are functioning as an effective seal and that there has been no contamination of the elevator channel.
- If the health care facility has not recently conducted observational audits of endoscope reprocessing, and particularly duodenoscope reprocessing, it must conduct an audit immediately and then repeat audits regularly (annually at the minimum)¹⁰ or when practices change. Endoscope reprocessing practices must be audited by infection prevention and control in collaboration with the endoscope reprocessing leads to ensure that practice is consistent with facility policies and procedures.
- Health care facilities where duodenoscopy is performed shall have a mechanism in place to link duodenoscopes to the patients for whom they were used in order to facilitate trace-back investigations in the event of an outbreak or reprocessing failure.³⁰
- At any time a duodenoscope is implicated in a transmission event, it should be sent to the manufacturer for assessment and repair, and reprocessed and cultured on return (see Section One, Chapter 4: Microbiological Testing and/or Surveillance of Duodenoscopes on page 10 for indications and instructions for culturing endoscopes).

Recommendations

- 1. Health care facilities that perform duodenoscopy must comply with currently accepted best practices for endoscope reprocessing as outlined in the [main body](#) of this document (I.2.M, pages 44-48) as well as other accepted best practice guidance documents and manufacturers' instructions. (N/A)**
- 2. Endoscopy reprocessing practices must be audited by infection prevention and control in collaboration with the endoscope reprocessing leads to ensure that practice is consistent with facility policies and procedures. (B-III)**
- 3. A duodenoscope that is implicated in a transmission event should be sent to the manufacturer for assessment and repair, and reprocessed and cultured on return. (B-III)**

2. Manual Cleaning of the Elevator Mechanism and Channel

Investigation of outbreaks and transmission events related to duodenoscopes has identified design features that are likely the primary cause of contamination and bacterial transmission.^{3,7,11,35} In particular, the elevator mechanism and recess (and elevator channel in models where this channel is unsealed) are difficult to adequately clean. Persistent bacteria and/or organic debris in these areas can lead to the formation of biofilm that can impede both high-level disinfection and sterilization.³⁵ Additionally, even in newer models with sealed elevator channels, contamination of the channel may still occur and pose an additional challenge, as the channel cannot be accessed for cleaning.^{24,36}

Cleaning is an essential step without which disinfection or sterilization will not be effective.³⁷⁻⁴⁰ Efforts to enhance cleaning of the elevator mechanism, recess and channel are therefore a central focus of manufacturers' and others' recommendation to reduce bacterial transmission in duodenoscopes related to recent outbreaks.^{11,22,25} These recommendations—arising from the US Food and Drug Administration, US Centers for Disease Control and Prevention, and manufacturers—suggest additional cleaning processes including raising and lowering the elevator mechanism throughout the cleaning process to facilitate cleaning on both sides of the mechanism, and careful inspection of the mechanism and recess for organic debris.⁴¹

It remains uncertain the degree to which enhanced methods of cleaning the elevator mechanism, recess and channel can reduce the risk of bacterial transmission. At least one outbreak has been identified at a centre that appeared to be compliant with enhanced manufacturers' recommendations for cleaning.^{42,43} Nevertheless, these new manufacturers' recommendations should be followed. Given the uncertainty about the effectiveness of cleaning, a process for assessing the efficacy of cleaning (beyond what can be achieved through observational audits alone) may be useful.

2.1 Strategies to Enhance Monitoring of Effective Cleaning

It may be useful to consider the use of an audit tool designed to assess the adequacy of the cleaning process. A variety of tests designed to detect adenosine triphosphate (ATP),^{1,11,20,44-56} protein,^{11,44,46,48-53,57} carbohydrate^{44,46,48,57} and hemoglobin^{44,46,48,49,53,57} are currently available.

Adenosine triphosphate (ATP) is present in both bacterial and human cells. ATP bioluminescence testing can be performed following manual cleaning (and prior to disinfection) to check for residual biological residue on duodenoscopes.^{51,52,55} Similarly, a variety of assays exist that can test for the presence of residual protein,^{48,50} blood^{48,49} or carbohydrate⁴⁸ residue on duodenoscopes after cleaning and prior to high-level disinfection. While the ATP bioluminescence test provides a quantitative result in relative light units, the other tests are most often qualitative and indicate either that biological material was detected or not detected. If using these tests, it would be important to test the areas of the duodenoscope of particular concern (e.g., elevator recess and mechanism, elevator channel if accessible).

Any of these tools could be considered for use either on a routine (i.e., for every duodenoscope reprocessed) or periodic (e.g., all scopes weekly or monthly) basis. Testing on a routine basis would ensure that any scope with residual biological material detected would undergo immediate repeat cleaning and this might help prevent the formation of biofilm. Both periodic and routine testing would allow implementation of cleaning procedure review, observational cleaning audits and/or additional training for cleaning staff if the frequency of “failed cleans” was above a predefined threshold.

Disadvantages of using ATP or biomarkers to monitor cleaning include the cost of the monitoring, an increase in turnaround time required due to cleaning.

2.2 Strategies to Enhance Effective Cleaning

A variety of approaches have been proposed that may increase the effectiveness of cleaning. Strategies specific to the elevator recess and mechanism include the use of a magnifying glass or borescope to carefully inspect for gross soil, and to ensure that such soil is removed, prior to disinfection. Additionally, several manufacturers have recommended the use of specific brushes for cleaning hard-to-reach areas.⁵⁸ These brushes should be disposable;¹⁰ if reusable brushes are used, they must be cleaned and high-level disinfected between uses and discarded if damaged.⁵⁹ Raising and lowering the elevator mechanism throughout both the manual cleaning stages and the various rinsing stages may help ensure that debris is removed from all areas of the elevator recess.^{41,58}

Some experts have recommended that high-level disinfection be performed twice to reduce total bacterial burden that may persist, particularly on duodenoscopes where biofilm has developed. For different reasons, it may be useful to perform a “double clean” step prior to disinfection. A double clean may reduce the risk of error and increase the thoroughness of the cleaning step, minimizing the risk for biofilm formation. Use of a different individual for the second clean may also help to prevent errors related to differences in practice between technicians. However, this may not be an option in smaller centres with limited staff and in no case should untrained staff perform cleaning. A disadvantage of double cleaning is an increase in time for cleaning, and the need for extra staffing.

It is also essential to ensure that written cleaning protocols are up to date and that staff performing cleaning are appropriately trained and supervised.

Recommendations:

- 4. Prior to high-level disinfection or sterilization, duodenoscopes must be thoroughly cleaned manually regardless of whether an automated endoscope reprocessor is used. (B-II)¹³**
- 5. Facilities may consider using ATP bioluminescence or testing for other biological markers (e.g., blood, protein, carbohydrate) using a Health Canada approved assay as a quality check of pre-cleaning and manual cleaning processes. (C-III)**
- 6. The elevator mechanism and recess should be carefully inspected during manual cleaning to ensure that all gross contamination is removed; the use of a magnifying lens or borescope to increase detection of gross contamination may be considered. (C-III)²⁰**
- 7. The elevator mechanism shall be raised and lowered throughout the manual cleaning process to allow brushing on both sides of the device. (CSA Z314.8)^{30,41}**
- 8. The elevator mechanism should be raised and lowered while flushing the elevator channel with enzymatic detergent and during subsequent rinsing of the elevator channels with water. (C-III)**
- 9. Facilities may consider a double cleaning process, during which the duodenoscope is manually cleaned twice, ideally by a second trained cleaner. (C-III)**

3. Disinfection of Duodenoscopes

For routine use, duodenoscopes require a minimum of high-level disinfection. Accessories used with duodenoscopes that perform biopsies or otherwise penetrate sterile spaces require sterilization. High temperatures damage duodenoscopes and when sterilization is indicated, low-temperature sterilization processes are required.

In some duodenoscope-related outbreaks, switching from high-level disinfection to low-temperature ethylene oxide sterilization was used as an outbreak control strategy. Because ethylene oxide sterilization was combined with other outbreak control interventions, it is difficult to ascertain whether the change to ethylene oxide contributed to control of the outbreak.^{3,60,61} In one study, contamination with CPE was detected despite the use of ethylene oxide sterilization.⁶² Previous data suggests that when manual cleaning is inadequate and/or when biofilm formation has occurred on the duodenoscope, low-temperature sterilization methods are not effective (and may even be less effective than high-level disinfection).³⁸ Additionally, there are specific concerns with the use of ethylene oxide sterilization as it results in damage to endoscopes, is associated with occupational health risks, and is no longer available at most Ontario health care facilities.¹

In an attempt to reduce the risk of transmission by increasing the margin of safety associated with duodenoscope reprocessing, and given a lack of evidence that low-temperature sterilization is superior to high-level disinfection, double reprocessing has been suggested as a strategy to reduce bacterial contamination of duodenoscopes.¹

There are two double reprocessing strategies that have been described.¹ One involves cleaning and high-level disinfection, followed by an additional low-temperature sterilization step (e.g., ethylene oxide sterilization or liquid chemical sterilization). The other involves cleaning and high-level disinfection, followed by a second high-level disinfection step. The rationale for considering double disinfection is that, for duodenoscopes that remain contaminated after the first reprocessing step, the second step will further reduce the bacterial load, minimizing the risk of infection.¹

While double reprocessing makes theoretical sense, neither double reprocessing strategy has been demonstrated to reduce duodenoscope-related bacterial transmission events or outbreaks. It also bears emphasis that outbreak reports describe situations where duodenoscopes remained contaminated and/or continued to transmit bacteria despite their being reprocessed multiple times,^{4,7} suggesting that once a contaminated biofilm exists, repeated disinfection is not effective.

Disadvantages of a double reprocessing approach include increased cost and turnaround time required for reprocessing and potentially some reduction in the life expectancy of the duodenoscope.

Recommendations:

- 10. Health care facilities at which duodenoscopy is performed may consider double reprocessing as a potential strategy to reduce the risk of bacterial transmission related to duodenoscopes. (C-III)**
- 11. Health care facilities that adopt a double reprocessing strategy can repeat their high-level disinfection step, or add a low-temperature sterilization step to the initial high-level disinfection step, after considering the risks and benefits of the sterilization method chosen, and ensuring that the methods are compatible with the specific duodenoscope used. (C-III)**

4. Microbiological Testing and/or Surveillance of Duodenoscopes

4.1 Surveillance Cultures from Duodenoscopes

Current Canadian, US and European guidelines recommend that culturing of endoscopes is appropriate when epidemiological analysis links exposure to endoscopes with transmission of bacterial pathogens.^{10,15,20,27,63-66} As CPE and other multidrug-resistant bacterial outbreaks associated with duodenoscope use are increasingly being reported, all facilities performing duodenoscopy should have protocols in place to allow culturing of endoscopes, particularly duodenoscopes.^{63,67}

Developing a protocol for duodenoscope sampling and laboratory protocols for testing requires collaboration with the microbiology laboratory that will be performing the testing. It is beyond the scope of this document to provide protocols for sampling endoscopes and processing endoscope cultures. General guidance is available in Public Health Agency of Canada's [*Infection Prevention and Control Guidelines for Flexible Gastrointestinal Endoscope and Flexible Bronchoscopy*](#), and also from the US Centers for Disease Control and Prevention and others.^{10,15,19-21,59,63}

Recommendations:

- 12. All health care facilities that perform duodenoscopy should develop protocols for how duodenoscopes should be sampled and how cultures should be performed (C-III).**
- 13. Sampling and culturing protocols should be developed in collaboration with the microbiology laboratory and microbiologist as well as other stakeholders, including the reprocessing department and infection prevention and control. (A-III)**

4.2 Indications for Culturing Duodenoscopes

4.2.1 ROUTINE SURVEILLANCE OF CULTURES FROM DUODENOSCOPES

There is limited evidence to support the use of routine microbiological surveillance of duodenoscopes or other gastrointestinal endoscopes as a strategy to prevent outbreaks or person-to-person transmission of pathogens related to endoscopy. Canadian and US endoscopy reprocessing guidelines have recommended against the use of routine surveillance cultures, while Australian and European guidelines support the routine use of cultures.^{10,15,20,27,63-66} The sensitivity of culturing endoscopes is not known and likely varies depending on the sampling and testing protocol employed.^{1,19,20}

Data from recent outbreaks of multidrug-resistant Enterobacteriaceae associated with the use of duodenoscopes confirm that outbreaks can occur and persist despite negative cultures from the epidemiologically implicated duodenoscope. Negative cultures are therefore not sufficient to rule out transmission.^{4,61} Additionally, outbreaks have occurred at centres that do routinely culture duodenoscopes.⁸ Conversely, some reports have suggested that the identification of positive cultures from routine surveillance specimens has resulted in more rapid control of duodenoscope-related

outbreaks.^{63,67} Guidance on how to perform microbiologic sampling of duodenoscopes is available from the CDC, although they do not recommend routine culturing of duodenoscopes.²⁰

If routine culture is to be implemented, there are a number of issues that must be considered in addition to the development of sampling and culturing protocols. Issues to consider prior to initiating surveillance include:

- What will be the frequency of testing and will one, some or all duodenoscopes be cultured?
- Will duodenoscopes be quarantined pending the results of culture?
- What is the definition of a positive result?
- What actions should result following a positive result?
 - If a result is positive, how will the positive endoscope be reprocessed and re-tested?
 - If the result is positive from one duodenoscope, should other duodenoscopes be tested?
 - Is contact tracing required (and how will this be done) for patients who underwent duodenoscopy with the positive duodenoscope either post-testing (but before the result was available) or pre-testing (and since the last prior negative result)?

These issues are complex and interdependent. Centres that wish to implement routine microbiological surveillance should address these issues prior to initiating testing and after full discussion with all stakeholders, including microbiology, reprocessing, gastroenterology, infection prevention and control, occupational health and safety, risk management, and others as appropriate for the specific setting.

4.2.2 CULTURING DUODENOSCOPES WHEN INVESTIGATING OUTBREAKS OR SUSPECTED TRANSMISSION EVENTS

It is recommended that duodenoscopes be cultured in the event of a suspected bacterial outbreak or transmission event epidemiologically linked to the use of duodenoscopes.^{10,59} When testing is performed as part of an outbreak investigation, interpretation of the culture result should be made by the outbreak management team and will depend on the specific situation and pathogen involved. However, when the positive culture is interpreted as significant, it is essential that infection prevention and control be notified, and that the implicated duodenoscope be removed from use, inspected for defects by the manufacturer, and reprocessed again. The duodenoscope should not be used until it has been documented as culture-negative.

4.2.3 CULTURING DUODENOSCOPES EXPOSED TO A CPE COLONIZED OR INFECTED PATIENT

The majority of the reported outbreaks related to duodenoscopes involve the transmission of CPE or other multidrug-resistant gram-negative bacteria. It has been documented that duodenoscopes become contaminated with CPE when used on CPE-colonized patients,⁴ and that duodenoscopes may remain positive for CPE and/or transmit CPE to additional patients despite reprocessing.^{4,68}

While CPE are not more resistant to standard reprocessing procedures than similar, less resistant bacteria, transmission events and outbreaks due to CPE are more easily identified. Additionally, CPE have significant patient, infection prevention and control, and public health implications as CPE are resistant to all commonly used antibiotics and infection with CPE is associated with case fatality rates of

close to 50%.^{69,70} Widespread transmission of CPE via duodenoscopes, therefore, has the potential both to amplify the prevalence of CPE in Ontario, and to result in significant disease in exposed individuals.

Given these concerns, any duodenoscope used on a patient known to be colonized or infected with CPE should be removed from use, reprocessed, and then cultured for CPE. If CPE is identified from samples taken from the duodenoscope, the duodenoscope should be inspected for defects by the health care facility and the manufacturer, and reprocessed. The duodenoscope should not be used until it has been documented as culture negative.

Recommendations:

- 14. Culturing of duodenoscopes must be performed when suspected outbreaks or transmission events or outbreaks are associated with the use of duodenoscopes. (A-II)**
- 15. Culturing of duodenoscopes should be performed if it is identified that the duodenoscope was used on a patient suspected or known to be CPE-positive at the time of duodenoscopy. (A-II)**
- 16. Routine microbiological culturing of duodenoscopes is not recommended. Health care facilities that implement routine microbiological surveillance of duodenoscopes should do so only after developing sampling and culturing protocols, establishing definitions for a positive and a negative test, and determining the response required if positive results are obtained. (D-III)**
- 17. Before initiating duodenoscope cultures, health care facilities should develop a plan for response to the culture results in consultation with the clinical laboratory, clinical staff, infection prevention and control, reprocessing, and risk management. (C-III)²⁰**
- 18. When testing is performed as part of an outbreak investigation involving any bacterial pathogen, and the result is positive for the organism associated with the outbreak, the following steps are recommended: (A-III)**
 - a. Infection prevention and control must be notified immediately.**
 - b. The duodenoscope must be:**
 - i. Removed from clinical use.**
 - ii. Assessed by the manufacturer for defects and damage.**
 - iii. Reprocessed and cultured again.**
 - iv. Withheld from use until negative culture results are documented.**
 - c. All steps of the reprocessing process, from pre-cleaning by the initial user to appropriate storage and transport, should be reviewed.**
- 19. When testing is performed following the performance of duodenoscopy on a patient known to be CPE-colonized (but where transmission is not suspected), and the result is positive, the duodenoscope should be:**
 - a. Removed from clinical use. (B-II)**
 - b. Inspected for defects or damage. (A-II)**
 - c. Reprocessed and recultured. (B-III)**
 - d. Withheld from use until negative culture results are documented. (B-III)**
- 20. Duodenoscopes with persistent positive culture results should be sent to the manufacturer for servicing. (A-II)**

5. Clinical Surveillance of Patients Before and After Duodenoscopy and Informed Consent

5.1 Risk and Informed Consent

If duodenoscopy is clinically indicated, patients must not be denied access on the basis of CPE colonization. However, as for all patients, duodenoscopy should never be performed on a patient unless there is a clear clinical indication.

There is a significant risk of bacteremia and/or sepsis following duodenoscopy which is secondary to endogenous bacterial pathogens.¹² There is also now a recognized, though small, risk of infection following duodenoscopy.¹² Patients should be informed of the risk of infection prior to duodenoscopy.

5.2 CPE Surveillance Before Duodenoscopy

All patients should be assessed for risk factors or a history of CPE positivity prior to duodenoscopy.

- For patients known to be positive, appropriate precautions (i.e., Contact Precautions) should be used during all medical visits and during the procedure, and the duodenoscope should be quarantined, reprocessed and cultured post-procedure (see 4.2.3 Culturing duodenoscopes exposed to a CPE colonized or infected patient on page 11).
- For patients with risk factors but no prior history of CPE carriage, a rectal swab or stool specimen should be sent for CPE testing, ideally prior to the procedure. If the procedure is urgent, testing prior to the procedure is not feasible, or the risk factors are identified after duodenoscopy has been performed, testing should still be done at the time of or subsequent to the procedure.
 - If the patient's screening results are positive for CPE, the duodenoscope should be cultured and removed from clinical use (See 4.2.3 Culturing duodenoscopes exposed to a CPE colonized or infected patient on page 11).
 - If duodenoscopy has already been performed on additional patients, all patients who underwent duodenoscopy with the same duodenoscope after the index patient's procedure, and before the duodenoscope was removed from use and assessed, will need to be contacted and tested (See 5.3.2 Contact Tracing on page 14).

Recommendations:

- 21. All patients undergoing duodenoscopy should be screened for CPE risk factors. (B-III)**
- 22. Patients scheduled for duodenoscopy who have CPE risk factors should have surveillance cultures (i.e., rectal swabs) for CPE colonization performed. (B-III)**
- 23. If a patient's surveillance culture results are positive for CPE, the duodenoscope used for the CPE-positive patient should be removed from use, reprocessed, and cultured for CPE after use on the positive patient and prior to re-use, and it should not be returned to use until a negative culture result is documented. All patients exposed to the duodenoscope after its use on the CPE positive patient, and prior to assessment of the duodenoscope, require contact tracing. (C-III)**

5.3 Clinical Surveillance of Patients After Duodenoscopy

5.3.1 CLINICAL SURVEILLANCE OF PATIENTS AFTER DUODENOSCOPY

Given the known risk of bacterial transmission related to duodenoscopy, all post-duodenoscopy infections should be reported to infection prevention and control. Clusters of post-duodenoscopy infection, especially those due to the same organism, should be investigated and the potential role of transmission via a duodenoscope assessed.

If a patient develops CPE colonization or infection, a history of duodenoscopy should be obtained. If duodenoscopy has been performed, the duodenoscope should be considered a potential vehicle for transmission. The appropriate time frame for this remains uncertain, but a patient with new identification of CPE within six months of a duodenoscopy would be a potential concern. For patients without additional risk factors for CPE, even a duodenoscopy one to two years previously may be of concern given the prolonged carriage documented in patients colonized with CPE. Infection prevention and control must be notified about new CPE cases, and if the duodenoscopy was performed at another health care facility, the infection prevention and control service at the facility where duodenoscopy was performed should be notified.

Recommendations:

- 24. If clusters of post-duodenoscopy infection or colonization due to the same organism are identified, health care facilities should investigate, and consider the duodenoscope a potential vehicle of transmission. (A-II)**
- 25. If a single case of new CPE occurs in a patient who has previously undergone duodenoscopy, health care facilities should investigate, and consider the duodenoscope a potential vehicle of transmission. (A-II)**
- 26. All health care facilities (regardless of whether duodenoscopy is performed locally) should seek a history of duodenoscopy in any patient newly identified as CPE-positive and should notify infection prevention and control at the facility where the duodenoscopy was performed. (A-II)**

5.3.2 CONTACT TRACING

Contact tracing of patients who have undergone duodenoscopy may be required in the following situations:

- A duodenoscope-associated outbreak or transmission event is identified.
- Duodenoscopy is performed with a duodenoscope that was contaminated with CPE based on subsequent culture results.
- Duodenoscopy was performed on a patient subsequently identified as CPE-positive based on surveillance specimens collected prior to or at the time of the duodenoscopy but the duodenoscope was used on subsequent patients before being removed from use and cultured. Screening of these patients is recommended even if the subsequent culture result is negative, as the duodenoscope will have been reprocessed multiple times, and a negative result does not ensure that the duodenoscope was negative for the procedures performed after the duodenoscope was used on the CPE positive patient and prior to removal from use.

When contact tracing is indicated, all identified patient contacts should be identified and informed about their potential exposure. They should be counselled about the risk and clinical significance of CPE colonization and infection and offered testing for CPE colonization.

Screening for CPE colonization requires three sets of rectal swabs or stool specimens taken on different days, with at least one specimen obtained more than 21 days after the last exposure.⁷¹

Recommendations:

- 27. Contact tracing must be performed for all patients exposed to duodenoscopes epidemiologically linked to an outbreak or single CPE transmission event. (A-III)**
- 28. Contact tracing must be performed for all patients who underwent duodenoscopy during the period after a specific duodenoscope tested positive for CPE and before the duodenoscope was removed from use for evaluation. (B-II)**
- 29. Contact tracing should be performed for patients who underwent duodenoscopy during the period after a specific duodenoscope was used on a patient known to be infected or colonized with CPE and before the duodenoscope was removed from use for evaluation (C-III). Contacts should be counselled with respect to CPE and offered testing for CPE colonization. (B-III)**
- 30. Contacts should have three sets of specimens of rectal swabs or stool specimens tested on different days for CPE, with at least one set obtained 21 days after their exposure. (B-III)**

Section Two: Summary of Recommendations for Minimizing the Risk of Bacterial Transmission from Patient to Patient when Using Duodenoscopes

The following summary tables are intended to assist with self-assessment internal to the health care setting for quality improvement purposes. See complete text for rationale.

Table 1: Best Practices for Duodenoscope Reprocessing

Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
1. Health care facilities that perform duodenoscopy must comply with currently accepted best practices for endoscope reprocessing as outlined in the main body of this document (1.2.M, pages 44-48) as well as other accepted best practice guidance documents and manufacturers' instructions. (N/A)					
2. Endoscopy reprocessing practices must be audited by infection prevention and control in collaboration with the endoscope reprocessing leads to ensure that practice is consistent with facility policies and procedures. (B-III)					
3. A duodenoscope that is implicated in a transmission event should be sent to the manufacturer for assessment and repair, and reprocessed and cultured on return. (B-III)					

Table 2: Manual Cleaning of the Elevator Mechanism and Channel

Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
4. Prior to high-level disinfection or sterilization, duodenoscopes must be thoroughly cleaned manually regardless of whether an automated endoscope reprocessor is used. (B-II) ¹³					
5. Facilities may consider using ATP bioluminescence or testing for other biological markers (e.g., blood, protein, carbohydrate) using a Health Canada approved assay as a quality check of pre-cleaning and manual cleaning processes. (C-III)					

Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
6. The elevator mechanism and recess should be carefully inspected during manual cleaning to ensure that all gross contamination is removed; the use of a magnifying lens or borescope to increase detection of gross contamination may be considered. (C-III) ²⁰					
7. The elevator mechanism shall be raised and lowered throughout the manual cleaning process to allow brushing on both sides of the device. (CSA Z314.8) ^{30,41}					
8. The elevator mechanism should be raised and lowered while flushing the elevator channel with enzymatic detergent and during subsequent rinsing of the elevator channels with water. (C-III)					
9. Facilities may consider a double cleaning process, during which the duodenoscope is manually cleaned twice, ideally by a second trained cleaner. (C-III)					

Table 3: Disinfection of Duodenoscopes

Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
10. Health care facilities at which duodenoscopy is performed may consider double reprocessing as a potential strategy to reduce the risk of bacterial transmission related to duodenoscopes. (C-III)					
11. Health care facilities that adopt a double reprocessing strategy can repeat their high-level disinfection step, or add a low-temperature sterilization step to the initial high-level disinfection step, after considering the risks and benefits of the sterilization method chosen, and ensuring that the methods are compatible with the specific duodenoscope used. (C-III)					

Table 4: Surveillance Cultures from Duodenoscopes

Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
12. All health care facilities that perform duodenoscopy should develop protocols for how duodenoscopes should be sampled and how cultures should be performed. (C-III)					
13. Sampling and culturing protocols should be developed in collaboration with the microbiology laboratory and microbiologist as well as other stakeholders, including the reprocessing department and infection prevention and control. (A-III)					

Table 5: Indications for Culturing Duodenoscopes

Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
14. Culturing of duodenoscopes must be performed when suspected outbreaks or transmission events or outbreaks are associated with the use of duodenoscopes. (A-II)					
15. Culturing of duodenoscopes should be performed if it is identified that the duodenoscope was used on a patient suspected or known to be CPE-positive at the time of duodenoscopy. (A-II)					
16. Routine microbiological culturing of duodenoscopes is not recommended. Health care facilities that implement routine microbiological surveillance of duodenoscopes should do so only after developing sampling and culturing protocols, establishing definitions for a positive and a negative test, and determining the response required if positive results are obtained (D-III).					
17. Before initiating duodenoscope cultures, health care facilities should develop a plan for response to the culture results in consultation with the clinical laboratory, clinical staff, infection prevention and control, reprocessing, and risk management (C-III). ²⁰					

Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
<p>18. When testing is performed as part of an outbreak investigation involving any bacterial pathogen, and the result is positive for the organism associated with the outbreak, the following steps are recommended: (A-III)</p> <ul style="list-style-type: none"> a. Infection prevention and control must be notified immediately. b. The duodenoscope must be: <ul style="list-style-type: none"> i. Removed from clinical use. ii. Assessed by the manufacturer for defects and damage. iii. Reprocessed and cultured again. iv. <i>Withheld from use</i> until negative culture results are documented. c. All steps of the reprocessing process, from pre-cleaning by the initial user to appropriate storage and transport, should be reviewed. 					
<p>19. When testing is performed following the performance of duodenoscopy on a patient known to be CPE-colonized (but where transmission is not suspected), and the result is positive, the duodenoscope should be:</p> <ul style="list-style-type: none"> a. Removed from clinical use. (B-II) b. Inspected for defects or damage. (A-II) c. Reprocessed and recultured. (B-III) d. Withheld from use until negative culture results are documented. (B-III) 					
<p>20. Duodenoscopes with persistent positive culture results should be sent to the manufacturer for servicing. (A-II)</p>					

Table 6: CPE Surveillance Before Duodenoscopy

Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
21. All patients undergoing duodenoscopy should be screened for CPE risk factors. (B-III)					
22. Patients scheduled for duodenoscopy who have CPE risk factors should have surveillance cultures (i.e., rectal swabs) for CPE colonization performed. (B-III)					
23. If a patient’s surveillance culture results are positive for CPE, the duodenoscope used for the CPE-positive patient should be removed from use, reprocessed, and cultured for CPE after use on the positive patient and prior to re-use, and it should not be returned to use until a negative culture result is documented. All patients exposed to the duodenoscope after its use on the CPE positive patient, and prior to assessment of the duodenoscope, require contact tracing. (C-III)					

Table 7: Clinical Surveillance of Patients After Duodenoscopy

Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
24. If clusters of post-duodenoscopy infection or colonization due to the same organism are identified, health care facilities should investigate, and consider the duodenoscope a potential vehicle of transmission. (A-II)					
25. If a single case of new CPE occurs in a patient who has previously undergone duodenoscopy, health care facilities should investigate, and consider the duodenoscope a potential vehicle of transmission. (A-II)					
26. All health care facilities (regardless of whether duodenoscopy is performed locally) should seek a history of duodenoscopy in any patient newly identified as CPE-positive and should notify infection prevention and control at the facility where the duodenoscopy was performed. (A-II)					

Table 8: Contact Tracing

Recommendation	Compliant	Partial Compliance	Non-compliant	Action Plan	Accountability
27. Contact tracing must be performed for all patients exposed to duodenoscopes epidemiologically linked to an outbreak or single CPE transmission event. (A-III)					
28. Contact tracing must be performed for all patients who underwent duodenoscopy during the period after a specific duodenoscope tested positive for CPE and before the duodenoscope was removed from use for evaluation. (B-II)					
29. Contact tracing should be performed for patients who underwent duodenoscopy during the period after a specific duodenoscope was used on a patient known to be infected or colonized with CPE and before the duodenoscope was removed from use for evaluation. (C-III) Contacts should be counselled with respect to CPE and offered testing for CPE colonization. (B-III)					
30. Contacts should have three sets of specimens of rectal swabs or stool specimens tested on different days for CPE, with at least one set obtained 21 days after their exposure. (B-III) ⁷¹					

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