Complete Summary

GUIDELINE TITLE

Reprocessing failure.

BIBLIOGRAPHIC SOURCE(S)

Standards of Practice Committee, Banerjee S, Nelson DB, Dominitz JA, Ikenberry SO, Anderson MA, Cash BD, Gan SI, Harrison ME 3rd, Shen B, Baron TH, Van Guilder T, Lee KK. Reprocessing failure. Gastrointest Endosc 2007 Nov;66(5):869-71. [5 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Infections caused by a failure to appropriately reprocess endoscopic instruments

GUIDELINE CATEGORY

Counseling
Evaluation
Management

CLINICAL SPECIALTY

Family Practice
Gastroenterology

Infectious Diseases
Internal Medicine

INTENDED USERS

Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide recommendations for situations where breaches in high-level disinfection protocols have occurred and the risk of transmission of bacterial and viral infections is increased

TARGET POPULATION

Patients undergoing endoscopy

INTERVENTIONS AND PRACTICES CONSIDERED

1. Reporting of reprocessing failure to the institution's designated infection control personnel, local and state public health agencies, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, and the manufacturers of the involved equipment
2. Notifying patient in a timely manner
3. Early serologic testing including baseline testing for hepatitis B, hepatitis C, and human immunodeficiency virus (HIV) infection
4. Patient counseling
5. Repeat testing

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In preparing this guideline, a search of the medical literature was performed by PubMed, supplemented by accessing the "related articles" feature of PubMed. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time the guidelines are drafted.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation*

Grade of Recommendation	Clarity of Benefit	Methodologic Strength/ Supporting Evidence	Implications
1A	Clear	Randomized trials without important limitations	Strong recommendation; can be applied to most clinical settings
1B	Clear	Randomized trials with important limitations (inconsistent results,	Strong recommendation; likely to apply to most practice settings

Grade of Recommendation	Clarity of Benefit	Methodologic Strength/ Supporting Evidence	Implications
		nonfatal methodologic flaws)	
1C+	Clear	Overwhelming evidence from observational studies	Strong recommendation; can apply to most practice settings in most situations
1C	Clear	Observational studies	Intermediate-strength recommendation; may change when stronger evidence is available
2A	Unclear	Randomized trials without important limitations	Intermediate-strength recommendation; best action may differ depending on circumstances or patients' or societal values
2B	Unclear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Weak recommendation; alternative approaches may be better under some circumstances
2C	Unclear	Observational studies	Very weak recommendation; alternative approaches likely to be better under some circumstances
3	Unclear	Expert opinion only	Weak recommendation; likely to change as data become available

*Adapted from Guyatt G, Sinclair J, Cook D, Jaeschke R, Schunemann H, Pauker S. Moving from evidence to action: grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, eds. Users' guides to the medical literature. Chicago: AMA Press; 2002. p. 599-608.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendations were graded on the strength of the supporting evidence (Grades 1A-3). Definitions of the recommendation grades are presented at the end of the "Major Recommendations" field.

Recommendations (Level of Evidence Grade 3 for All)

1. When a breach of the high-level disinfection protocol is discovered, it should be reported to the institution's designated infection control personnel, local/state public health agencies, the Food and Drug Administration, the Centers for Disease Control and Prevention, and the manufacturers of the involved equipment.
2. Patients at risk should be notified directly of the breach in a timely manner and of the estimated risk of infection. Successful notification or attempts at notification should be documented.
3. Early serologic testing is imperative to distinguish prior infection(s) from those potentially acquired as a result of the breach in the high-level disinfection protocol. In cases where testing is delayed, it may be difficult to exclude the endoscopic procedure as a potential source of the infection.
4. A toll-free helpline should be established to provide information to all patients at risk.
5. Patients should be advised against donating blood and tissue products and engaging in sexual contact without barrier protection until all serologic testing is complete.
6. Personal counseling should be offered to all patients. The risk of infection should be discussed and placed in context to minimize patient anxiety. In addition, the possibility that the patient might previously have a chronic viral infection should be discussed, along with the role of testing in distinguishing preexisting from newly acquired infections.

7. Patients should be asked whether they developed new symptoms suggestive of transmission of enteric bacteria or viruses after the endoscopic procedure. Prior vaccination history for hepatitis A and B should be documented. If patients have undergone prior hepatitis B vaccination, postvaccination titers should be documented if they were measured. An attempt should be made to identify risk factors for hepatitis B, hepatitis C, and human immunodeficiency virus (HIV). If patients have previously undergone testing for these infections, the results should be documented.
8. Baseline serologic testing for hepatitis B, hepatitis C, and HIV should be performed. Patients should be informed about their baseline serology results in a timely manner.
9. Repeat testing, which may include serology and ribonucleic acid (RNA) tests, should be performed in all cases. The timing and the choice of tests will be influenced by the period of time that has elapsed between patient exposure and initial testing, by the presence or absence of patient symptoms, and by the advice of the institution's infectious diseases specialist. Institutions may consider obtaining follow-up testing at 6 weeks, 3 months, and 6 months post procedure. In some situations, additional follow-up testing may be advisable at 1 year post exposure.

Definitions:

Grades of Recommendation*

Grade of Recommendation	Clarity of Benefit	Methodologic Strength/ Supporting Evidence	Implications
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			when stronger evidence is available
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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Prompt notification of a significant breach in reprocessing allows patients to take precautions to minimize the risk of transmitting infection to others and allows for early serologic testing. This may help distinguish chronic infections from those potentially acquired at the time of endoscopy and to permit earlier initiation of treatment for newly acquired infections.

POTENTIAL HARMS

- Notifying patients of reprocessing failure can cause unnecessary patient distress in a situation where the risk of infection may be very small.
- Adverse publicity associated with the reporting of a reprocessing outbreak might lead patients to avoid potentially life-saving endoscopic procedures because of an unwarranted fear of infection. This in turn could have deleterious health consequences for the community at large because many significant life- and health-threatening conditions may remain undiagnosed and untreated.

QUALIFYING STATEMENTS

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- Further controlled clinical studies may be needed to clarify aspects of this guideline. This guideline may be revised as necessary to account for changes in technology, new data, or other aspects of clinical practice.
- This guideline is intended to be an educational device to provide information that may assist endoscopists in providing care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Clinical decisions in any particular case involve complex analysis of the patient's condition and available courses of action. Therefore, clinical considerations may lead an endoscopist to take a course of action that varies from these guidelines.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Nov

GUIDELINE DEVELOPER(S)

American Society for Gastrointestinal Endoscopy - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society for Gastrointestinal Endoscopy

GUIDELINE COMMITTEE

Standards of Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Society for Gastrointestinal Endoscopy Web site.

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on March 4, 2008.

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