Experience feedback on ACHS recommendation

Bosco Lam
Associate Consultant Microbiologist
Princess Margaret Hospital
Hong Kong

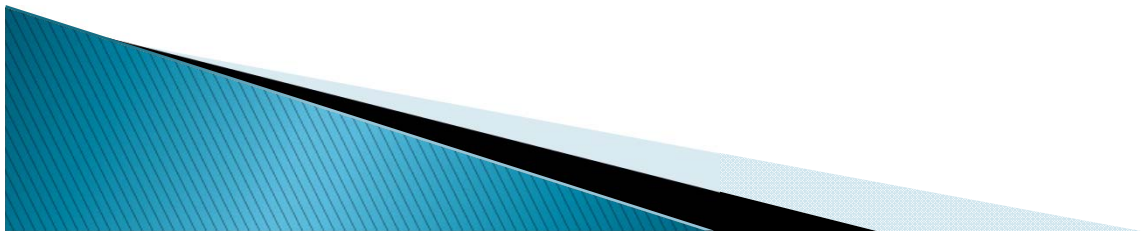
The Australian Council of Healthcare Standards (ACHS)

Recommendations Highlights (common recommendations in 2 or more hospitals)

- Regular biological testing of endoscopes:
  - Implement a regular audit program for microbiological testing of flexible endoscopes in conjunction with Pathology for all flexible endoscopes used throughout the organisation.

Microbiological surveillance culture

- Delay in feedback
  - Real-time technology e.g. ATP (cut-off established?)
- Frequent isolation of nonpathogenic organisms by environmental contamination
- Still lacking uniform standards for sampling and culture technique



Microbiological surveillance culture

- Visual inspection
  - Do not detect soiling on the internal surface of an endoscope
  - Do not detect low but potentially significant concentration of soiling

Weakness / deficiencies in endoscope reprocessing:

Process control Vs product control (microbiological sampling) as solution?

a. Inadequate reprocessing of endoscopes and accessories

- Inadequate cleaning (e. g. inadequate manual cleaning and brushing of endoscope channels)
- Contaminated cleaning accessories (e. g. cleaning brushes)
- Use of unsuitable or incompatible detergents and disinfectants
- Inadequate concentrations and contact time of agents
- Contaminated or time-expired solutions
- Contaminated rinsing water
- Fixed organic material (biofilm) in endoscopes, water pipes, containers, or washer-disinfectors
- Use of nonsterile accessories in invasive diagnosis and treatment (e. g. nonsterile biopsy forceps, polypectomy snares)
- Inadequate reprocessing of water bottles (e. g. no sterilization)
- Use of tap water in water bottles

b. Inadequate transport and storage of endoscopes

- Insufficient drying before storage (e. g. *Pseudomonas* spp.)
- Inappropriate storage conditions

c. Contaminated or defective washer-disinfector

- Contaminated pipes, containers, etc.
- Contaminated final rinsing water
- Mechanical/electronic defects of washer-disinfector
- Incorrect use of washer-disinfector (e. g. wrong connections)
- Lack of regular maintenance of washer-disinfector according to manufacturer's recommendations

d. Design limitations and damaged endoscopes

- Small lumina, branched channels, not accessible to cleaning brushes
- Damage to the surfaces (internal and external) of the endoscope, providing potential for contamination

e. Contaminated water in the endoscopy unit

- Contaminated main water pipes/supply
- Contaminated or inadequate water supply systems (filtration etc.)

Endoscopy 2007; 39: 175 – 181

Microbiological surveillance culture

- Looking for updated guidelines
- Implementation
  - Laboratory support
  - Endoscopy staff
  - Infection control team
- Trials at different units → problem-shooting → testing protocol and frequency established

Infection Control in Endoscopy, 3rd edition, 2010

Gastroenterological Society of Australia (GESA)

Australian Gastrointestinal Endoscopy Association (AGEA)

Gastroenterological Nurses College of Australia (GENCA)

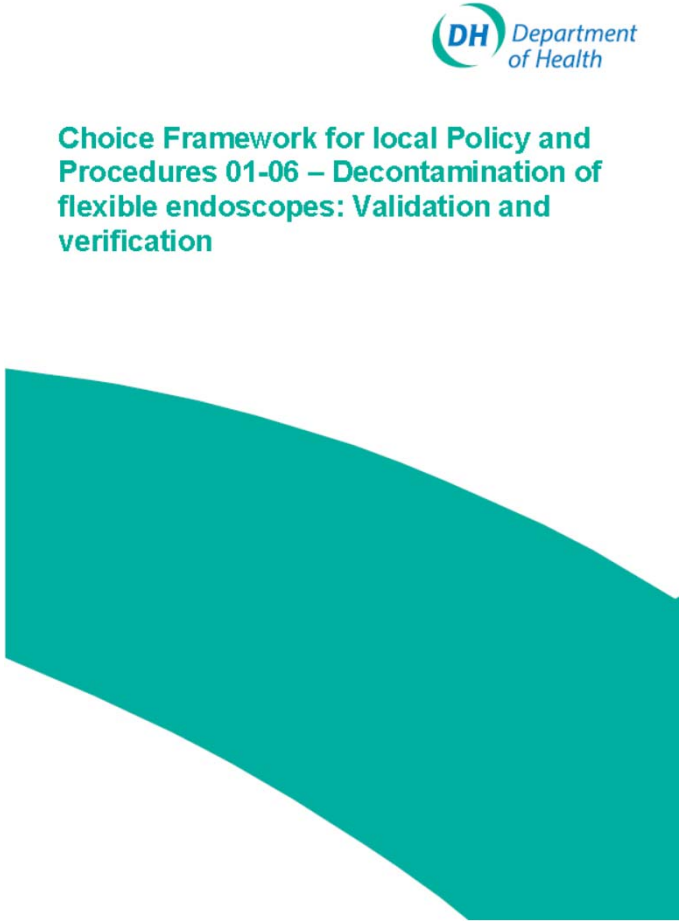
Choice Framework for local Policy and Procedure (CCFP) 01-06 – Decontamination of flexible endoscopes, 2013

supersedes Health Technical Memorandum (HTM) 2030 on endoscope decontamination

5 volumes:

- Policy and management
- Design and installation
- Operational management
- Validation and verification
- Testing methods

Department of Health, UK



ESGE – ESGENA guideline for quality assurance in reprocessing: Microbiological surveillance testing in endoscopy, 2007

European Society of Gastrointestinal Endoscopy (ESGE)

European Society of Gasteroenterology and Endoscopy Nurses and Associates (ESGENA)

ESGE–ESGENA guideline for quality assurance in reprocessing: Microbiological surveillance testing in endoscopy

Authors: U. Beilenhoff[1], C. S. Neumann[2], J. F. Rey[3], H. Biering[4], R. Blum[5], V. Schmidt[6] and the ESGE Guidelines Committee[7]

Institutions: Institutions are listed at the end of the guideline.

Bibliography
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Published ahead of print
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ISSN 0013-726X

Contents

1. Introduction

Microbiological surveillance is an important means for evaluating the outcome quality of reprocessing procedures and is an instrument of regular quality control in gastrointestinal endoscopy, whether endoscopic procedures are performed in hospitals, in private clinics or doctors' offices. It is an instrument for detecting and redressing weaknesses and mistakes in the reprocessing procedure and for preventing the transmission of infectious agents through endoscopy.

This guideline, from the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA), addresses the necessity for microbiological surveillance in endoscopy and provides practical information about testing the quality of the microbiological outcomes of manual and automated reprocessing procedures used in endoscopy.

It is a consensus guideline, prepared in co-operation with endoscopists, microbiologists, hygienists, endoscopy nurses, and representatives from industry.

Aims of this ESGE–ESGENA guideline

These are:

a) To support individual endoscopy departments in developing local standards and protocols for regular microbiological surveillance
b) To support national societies and official bodies in developing national recommendations and quality assurance programs for hygiene and infection control in gastrointestinal endoscopy

Multisociety guideline on reprocessing flexible gastrointestinal endoscopes, 2011

American Society for Gastrointestinal Endoscopy (ASGE)

Society for Healthcare Epidemiology of America (SHEA)

GUIDELINE

Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011

The beneficial role of GI endoscopy for the prevention, diagnosis, and treatment of many digestive diseases and cancer is well established. Like many sophisticated medical devices, the endoscope is a complex, reusable instrument that requires reprocessing before being used on subsequent patients. The most commonly used methods for reprocessing endoscopes result in high-level disinfection. To date, all published occurrences of pathogen transmission related to GI endoscopy have been associated with failure to follow established cleaning and disinfection/sterilization guidelines or use of defective equipment. Despite the strong published data regarding the safety of endoscope reprocessing, concern over the potential for pathogen transmission during endoscopy has raised questions about the best methods for disinfection or sterilization of these devices between patient uses.

To this end, in 2003, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Healthcare Epidemiology of America collaborated with multiple physician and nursing organizations, infection prevention and control organizations, federal and state agencies, and industry leaders to develop evidence-based guidelines for reprocessing GI endoscopes.[1,2] Since that time, high-level disinfectants, automated reprocessing machines, endoscopes and endoscopic accessories have all evolved.[3-6] However, the efficacy of decontamination and high-level disinfection is unchanged and the principles guiding both remain valid.[7]

Additional outbreaks of infection related to suboptimal infection prevention practices during endoscopy or lapses in endoscope reprocessing have been well publicized. A cluster of hepatitis C cases was attributed to grossly inappropriate intravenous medication and sedation practices.[8] In numerous other instances, risk of infection transmission has been linked to less willful, but incorrect, reprocessing as a result of unfamiliarity with endoscope channels, accessories, and the specific steps required for reprocessing of attachments.[9] Recent on-site ambulatory surgery center surveys confirm widespread gaps in infection prevention practices.[10] Given the ongoing occurrences of endoscopy-associated infections attributed to lapses in infection prevention, an update of the multisociety guideline is warranted.

This document provides an update of the previous guideline, with additional discussion of new or evolving reprocessing issues and updated literature citations, where appropriate. Specific additions or changes include review of expanded details related to critical reprocessing steps (including cleaning and drying), reprocessing issues for various endoscope attachments such as flushing catheters, discussion of risks related to selected periprocedural practices including medication administration, and mention of newly recognized issues for which there are incomplete data with which to guide practice. They include endoscope shelf life or "hang time" (the interval of storage after which endoscopes should be reprocessed before use), the role of microbiological surveillance testing of endoscopes after reprocessing and questions regarding endoscope durability and longevity from the standpoint of infection prevention.

0016-5107/$36.00
doi:10.1016/j.gie.2011.03.1183

SPAULDING CLASSIFICATION OF MEDICAL DEVICES AND LEVEL OF DISINFECTION

The classification system first proposed by Dr. E.H. Spaulding divides medical devices into categories based on the risk of infection involved with their use.[11] This classification system is widely accepted and is used by the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), epidemiologists, microbiologists and professional medical organizations to help determine the degree of disinfection or sterilization required for various medical devices. Three categories of medical devices and their associated level of disinfection are recognized:

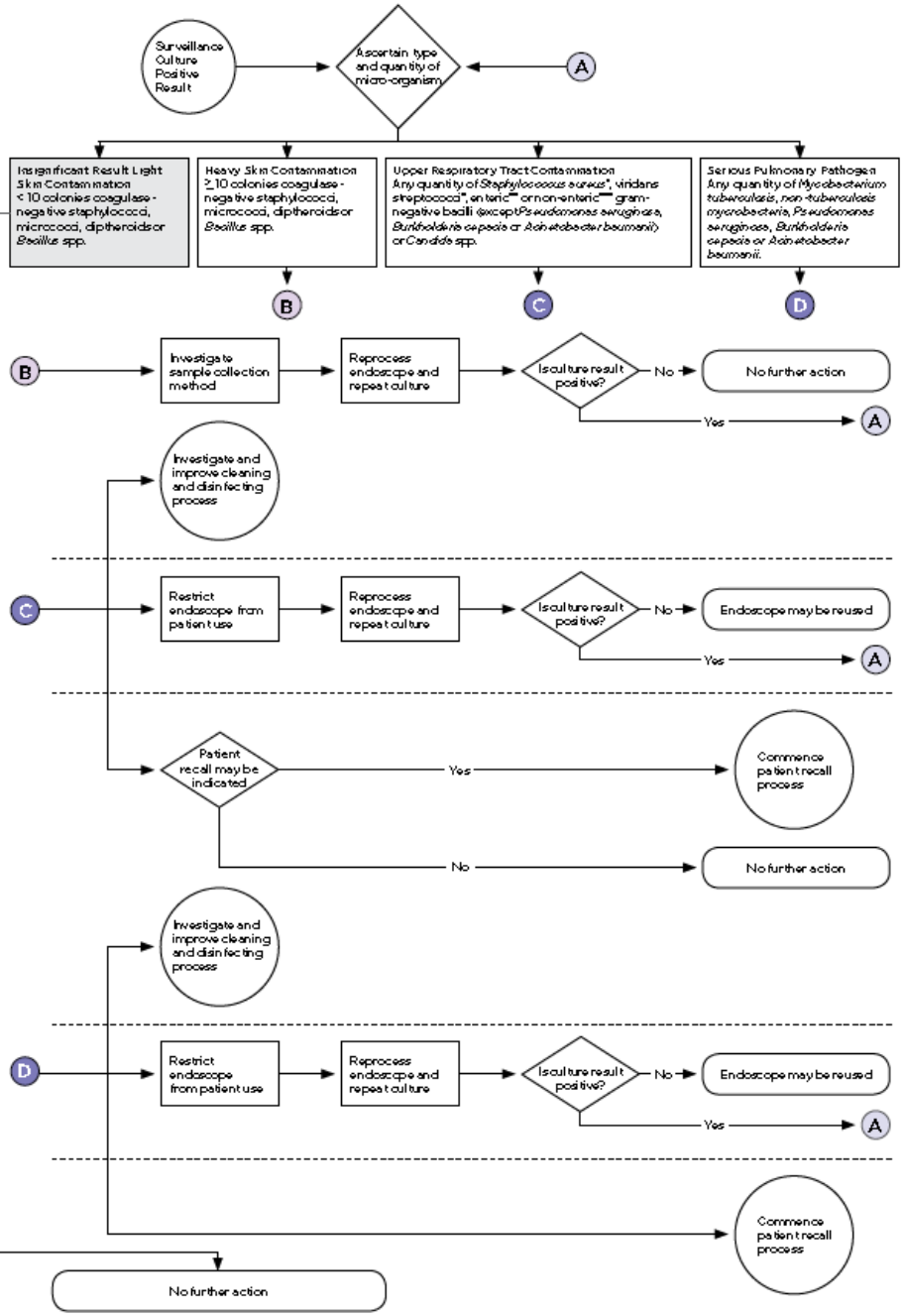
- Critical: A device that enters normally sterile tissue or the vascular system. Such devices should be sterilized, defined as the destruction of all microbial life. Examples of endoscopic instruments that require sterilization are biopsy forceps and sphincterotomes.
- Semicritical: A device that comes in contact with intact mucous membranes and does not ordinarily penetrate sterile tissue. These devices (eg, endoscopes) should receive at least high-level disinfection, defined as the destruction of all vegetative microorganisms, mycobacteria, small or nonlipid viruses, medium or lipid viruses, fungal spores and some, but not all, bacterial spores.

Crosswalk

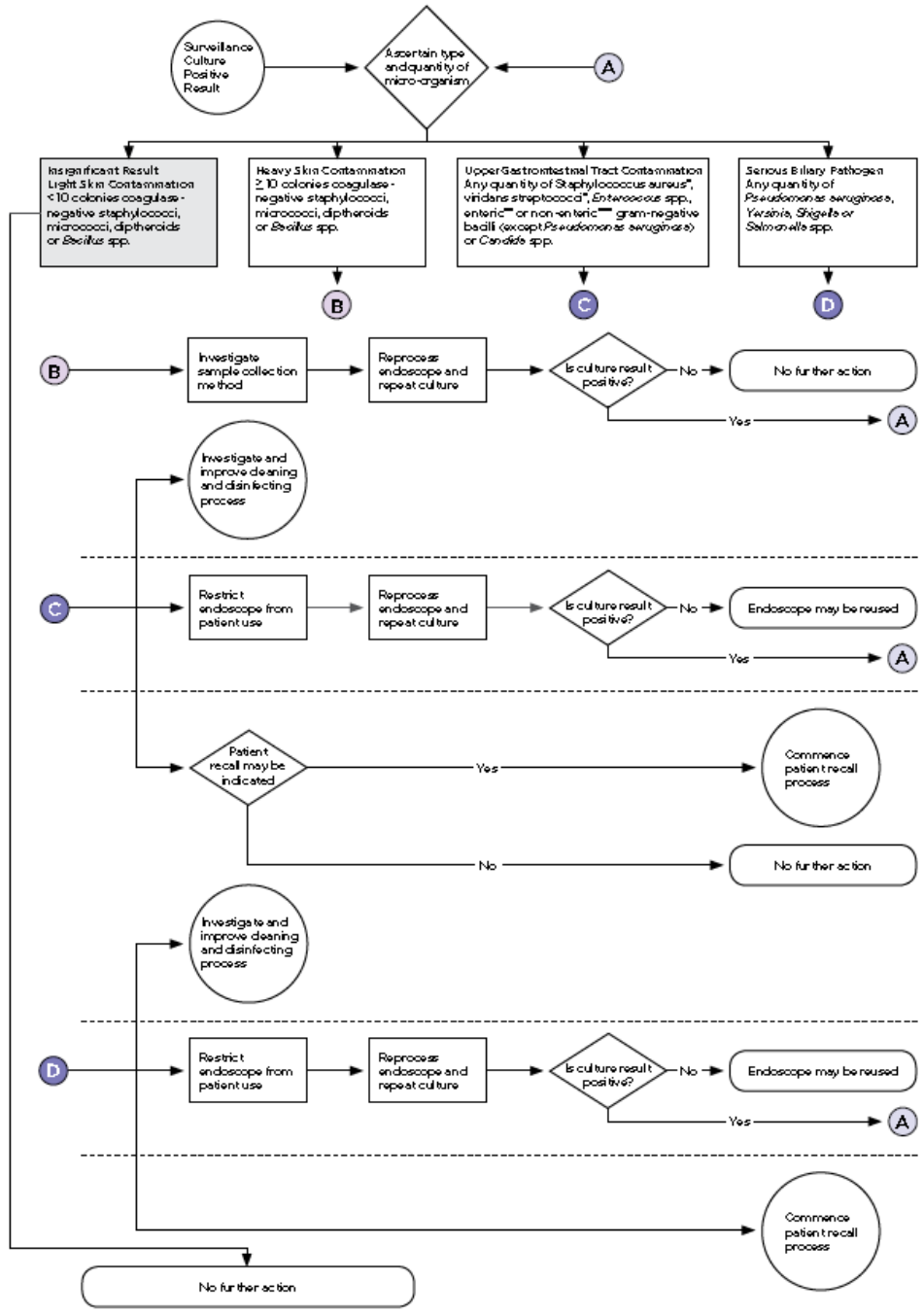
	Endoscopes		AER (rinse water)	
	Indicator organisms	Testing frequency	Indicator organisms	Testing frequency
Australia	GI: oral, enteric (incl. Salmonella), NF Bronchoscope: + rapid-growing AFB	Duodenoscope, bronchoscope, linear endoscopic US: every 4 weeks. Others: every 3 months	NF, rapid-growing AFB	Every 4 weeks

	Result interpretation & actions:
	• >10 CFU Staph epidermidis:
	  • likely contamination during collection
	• Any growth of Pseudomonas / NF in duodenoscope / bronchoscope / associated AER
	  • Remove AER & endoscope from service
	  • Clinical FU of patients undergone the procedures
	• >10 CFU enteric bacteria repeatedly from one instrument only
	  • Mechanical defect in that instrument
	• >10 CFU enteric bacteria from a variety of instruments
	  • Defects in manual cleaning; AER problem
	  • Review cleaning and disinfection techniques
	• Any growth of rapid-growing AFB from bronchoscope
	  • Contaminated AER
	  • Remove that AER from service
	• Any growth of Salmonella / Shigella
	  • concern			

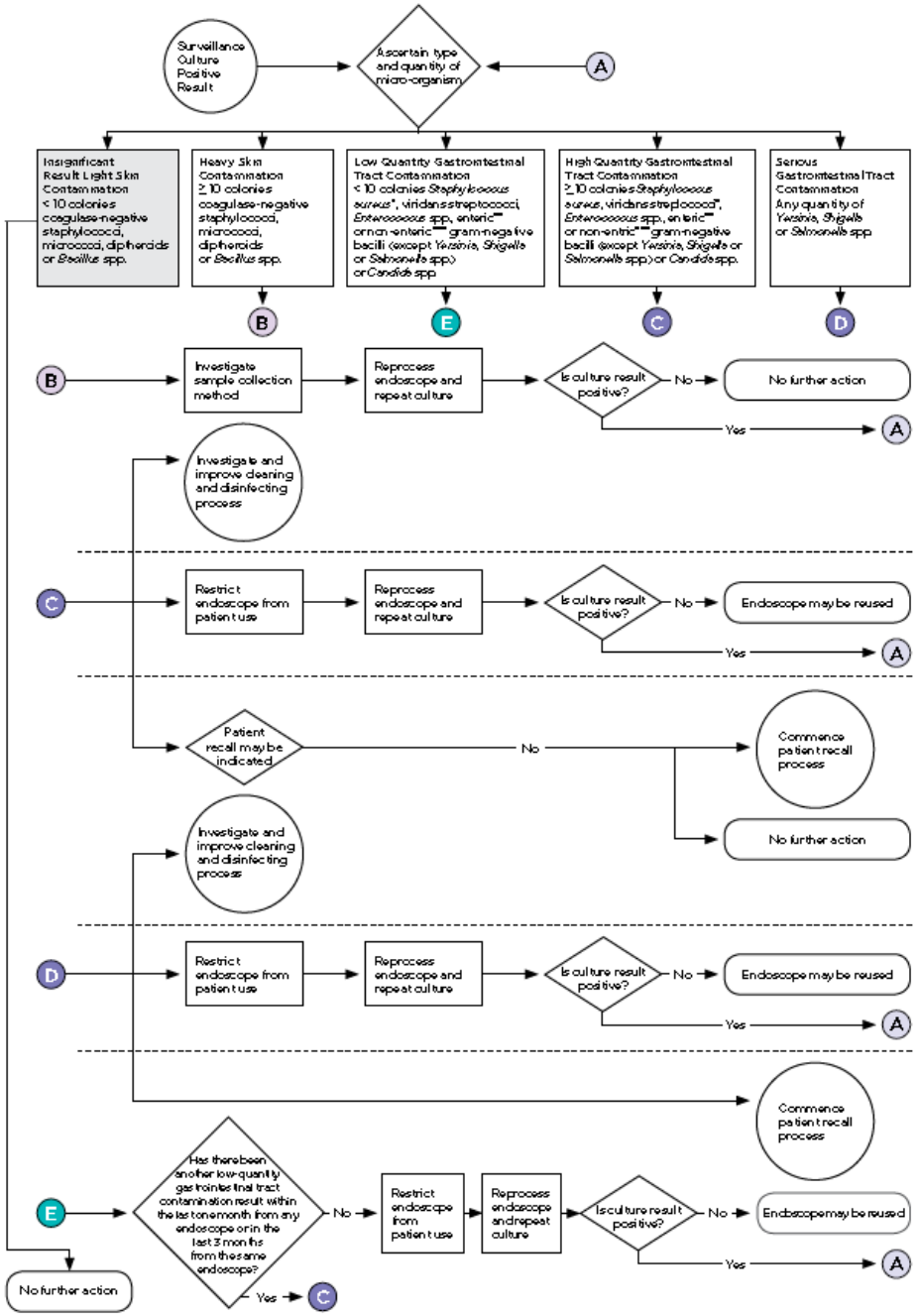
Response to positive bronchoscope cultures



Response to positive duodenoscope cultures



Response to positive gastroscope or colonoscope cultures



Crosswalk

	Endoscopes		AER (final rinse water)	
	Indicator organisms	Testing frequency	Indicator organisms	Testing frequency
UK	TVC + Pseudomonas aeruginosa	optional	TVC + P. aeruginosa Environmental AFB	Every week Every 3 months

	Result interpretation & actions:
	TVC:
	• 10-100 CFU/100ml
	  • Speciate for any P. aeruginosa
	  • Risk assessment
	  • Superchlorinate / repeat self-disinfection
	• >100 CFU/100ml
	  • Speciate for any P. aeruginosa
	  • Risk assessment: consider removing AER from service
	
	Environmental AFB: should be absent in 200ml			

Crosswalk

	Endoscopes		AER (final rinse water)	
	Indicator organisms	Testing frequency	Indicator organisms	Testing frequency
Europe	Enteric, P. aeruginosa, NF, staphylococci, atypical mycobacteria	At least every 3 months; by rotation, each endoscope should be sampled at least once each year. • All channels (flush with 20ml sterile saline) • Outer surfaces (swabs) • Connected water bottle	P. aeruginosa, atypical mycobacteria, Legionella	At least every 3 months (at the same day as testing endoscopes)
	Result interpretation & actions:			

	• Channels:
	  • TVC: <20 CFU / channel
	  • No indicator organisms
	• Outer surfaces:
	  • No indicator organisms
	• Water bottle:
	  • TVC: <10 CFU / 100ml
	  • No indicator organisms
			• TVC: <10 CFU / 100 ml
			• No indicator organisms	

Crosswalk

	Endoscopes		AER (rinse water)	
	Indicator organisms	Testing frequency	Indicator organisms	Testing frequency
USA (2011)	No routine microbiological testing			

Princess Margaret Hospital

- Oct 2014
- started testing with final rinse water

Endoscopy Units

- Endoscopy nurse: collect water sample by aseptic technique
  1. Connect filter tube to AER.
  2. Disinfect the filter tube.
  3. Remove gas filter case from the cleaning cover.
  4. With sterile gloves, take the end of the disinfected filter tube out of the filter case mount.
  5. Close the cleaning cover.
  6. Hold the end of the filter tube with sterile glove.
  7. Place large container under the end of the filter tube.
  8. Start the rinsing program.
  9. Discard first portion of 100 – 500 ml in the large container.
  10. Then collect 100ml water sample in a sterile collection container with membrane with pore size of 0.45μm.
  11. Stop the program.
  12. Send the collection container to Microbiology Laboratory.

Clearly label the type of endoscope and put the water in a transport outer box

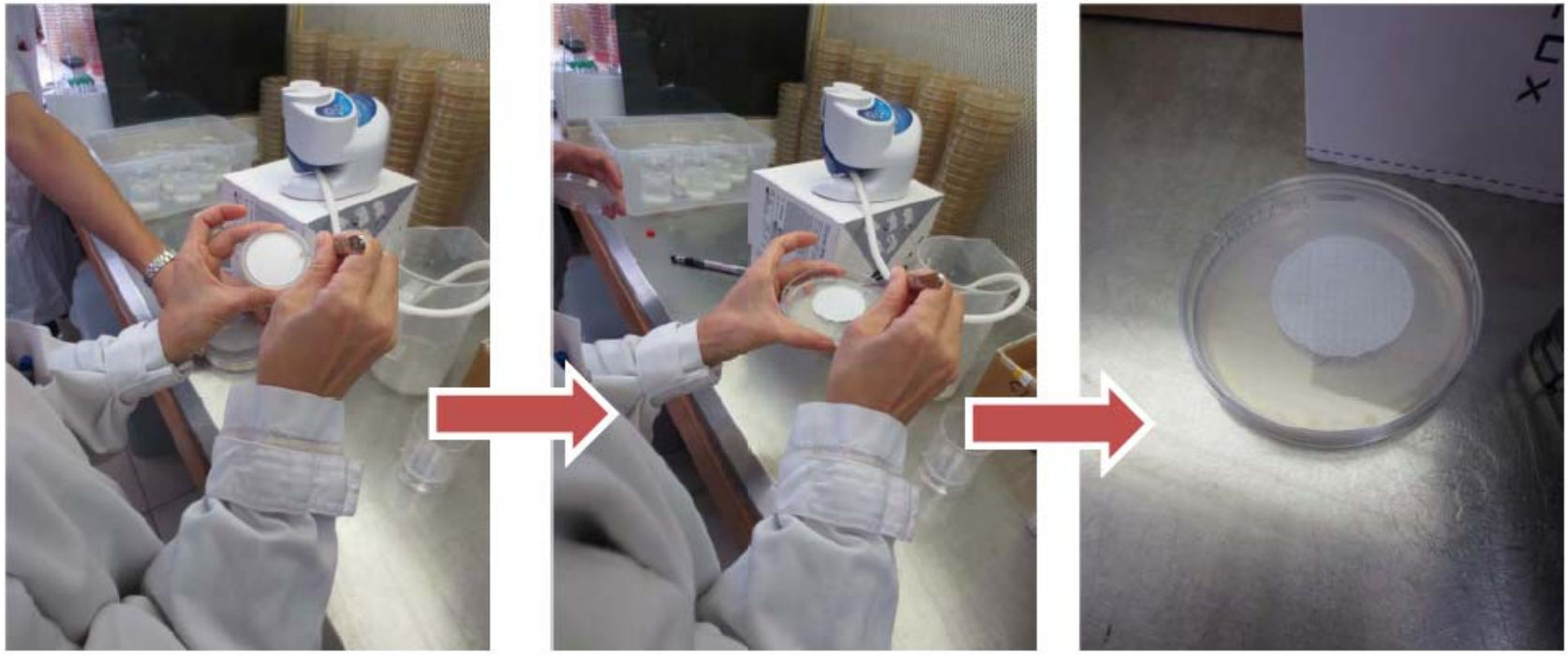
Microbiology Laboratory

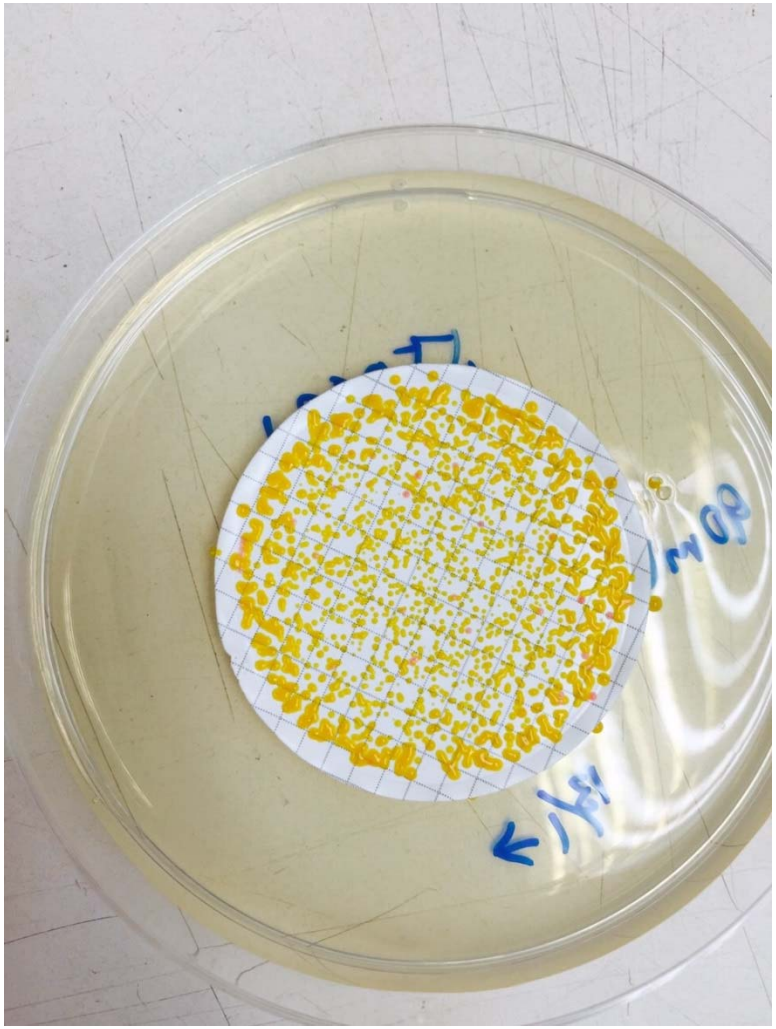
- Lab technologist:
  - With the use of suction pump, filtrate 100ml sample through a membrane filter
  - Remove the disc and plate on Tryptone Glucose Extract Agar (TGEA): *widely adopted for heterotrophic plate count for dairy and water samples*
  - Plate the culture plates in closed plastic bags and incubate at 28°C for 5 days
  - Examine the plates after 48h incubation and at 5 days

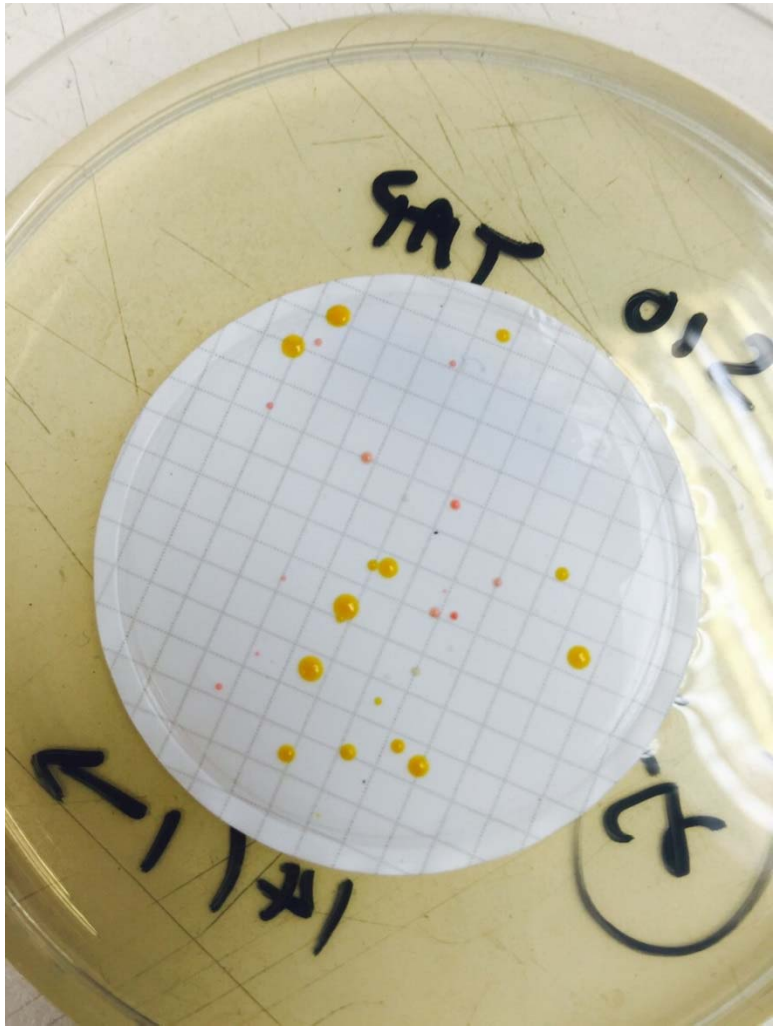
Laboratory – laminar flow workstation & pump

Collect the collection bottle to pump

After water filtration completed, remove the filter paper to the agar plate







Actions for Microbiology Test Result on the Post-disinfection Rinse Water of AER (Automated Endoscope Reprocessing System)

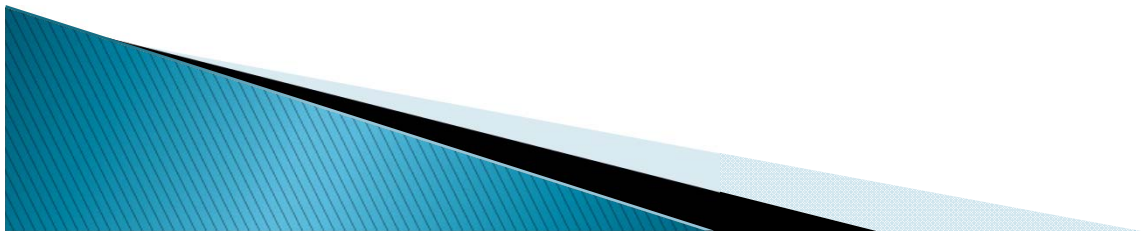
Testing Result	Action Level
<10 CFU/100 ml	1. No action
≥10 to 100 CFU/100 ml	1. Inform ICN 2. Validating disinfectant and disinfection procedures 3. Carry out correct measures 4. Perform self-disinfection 5. Repeat: Collect new samples
≥100 CFU/100 ml	1. Inform ICN 2. Validating disinfectant and disinfection procedures 3. Carry out correct measures 4. Change all filters 5. Perform self-disinfection 6. Repeat: Collect new samples
Repeat testing result:	
<10 CFU/100 ml	Resume normal
≥10 CFU/100 ml	1. Inform ICN 2. Take AER out of service and contact the manufacturer / supplier to detect defect or possible cause. 3. Then replace new water filters (if not yet replaced), perform self-disinfection 4. Repeat again: Collect new samples

References:

1. Advisory Board Cleaning and Disinfection Flexible Endoscopes (SFERD): Professional Standard Handbook Flexible Endoscopes – Cleaning and Disinfection, version 2.1, 2011.
2. Medivators Reprocessing Systems: Protocol to validate the antimicrobial effectiveness of a Medivators AER utilizing a Sampling Connector; Product Bulletin Number 50096-108 Rev. C, April 22, 2004

Infection Control Team

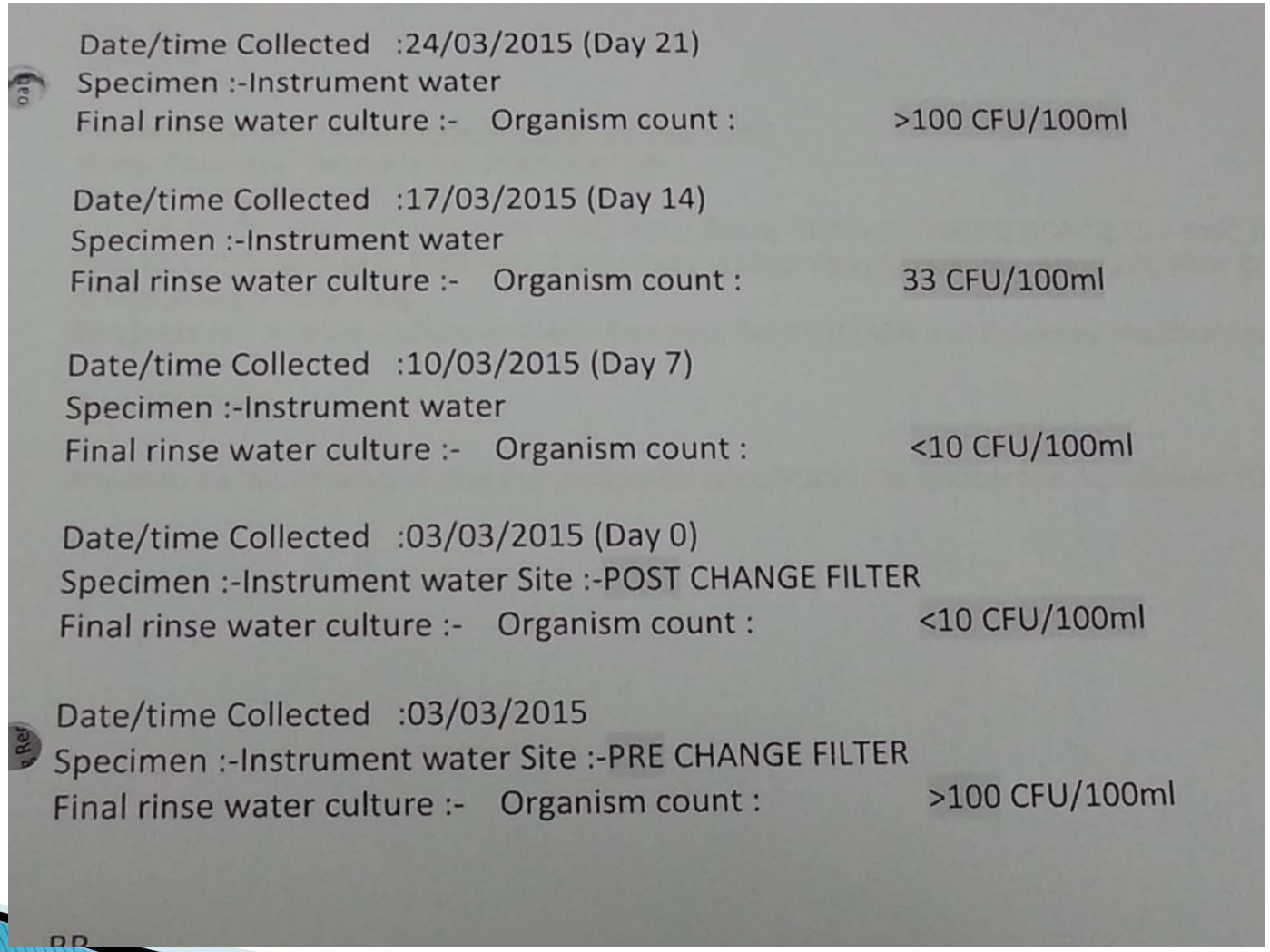
- ICN informs endoscopy unit on alarming results and ask for FU / remedial actions



Actions for not passing the tests

- Repeat / increase frequency of self-disinfection 
- Thoroughly disinfect the filter tube ✖
- Re-position the water drainage ✖
- Change water tap site ✖
- Change water filter ✖
- Change new AER ✖

Effect of changing water filter



Date/time Collected :24/03/2015 (Day 21)
Specimen :-Instrument water
Final rinse water culture :- Organism count : >100 CFU/100ml

Date/time Collected :17/03/2015 (Day 14)
Specimen :-Instrument water
Final rinse water culture :- Organism count : 33 CFU/100ml

Date/time Collected :10/03/2015 (Day 7)
Specimen :-Instrument water
Final rinse water culture :- Organism count : <10 CFU/100ml

Date/time Collected :03/03/2015 (Day 0)
Specimen :-Instrument water Site :-POST CHANGE FILTER
Final rinse water culture :- Organism count : <10 CFU/100ml

Date/time Collected :03/03/2015
Specimen :-Instrument water Site :-PRE CHANGE FILTER
Final rinse water culture :- Organism count : >100 CFU/100ml

Routine established

- Change water filter every month (as recommended by AER manufacturer)
- Increase self-disinfection cycle from every month to biweekly
- AER final rinse water sampling for surveillance culture every 3 months

- → satisfactory results mostly since then

Original Investigation | October 8, 2014

New Delhi Metallo-β-Lactamase-Producing Carbapenem-Resistant *Escherichia coli* Associated With Exposure to Duodenoscopes

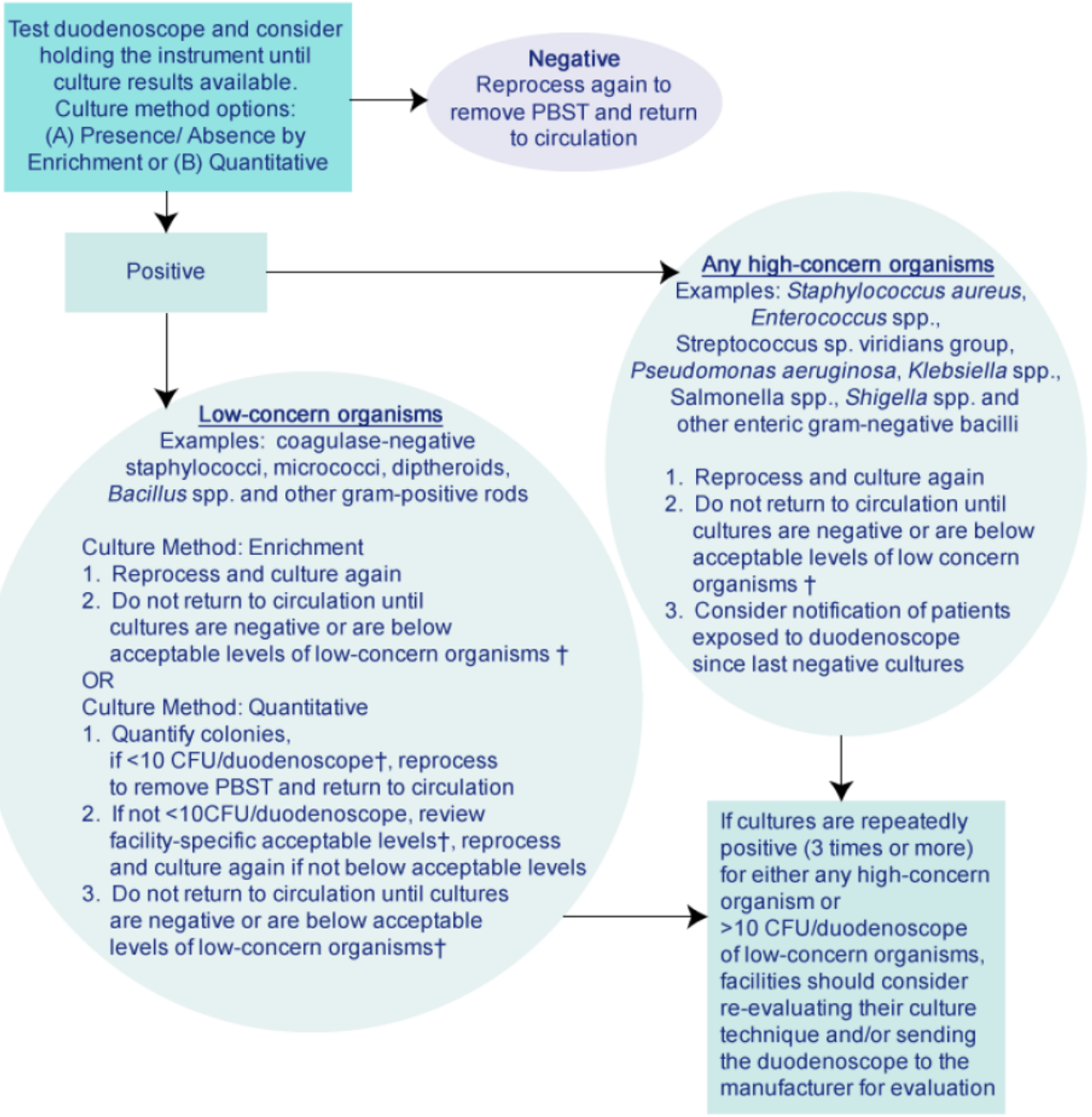
Lauren Epstein, MD, MSc[1,2]; Jennifer C. Hunter, DrPH[1,2]; M. Allison Arwady, MD[2,3]; Victoria Tsai, MPH[3]; Linda Stein, MPH[4]; Marguerite Gribogiannis, MPA[4]; Mabel Frias, MPH[5]; Alice Y. Guh, MD[1]; Alison S. Laufer, PhD[1]; Stephanie Black, MD[6]; Massimo Pacilli, MS[6]; Heather Moulton-Meissner, PhD[1]; J. Kamile Rasheed, PhD[1]; Johannetsy J. Avillan, BS[1]; Brandon Kitchel, MS[1]; Brandi M. Limbago, PhD[1]; Duncan MacCannell, PhD[1]; David Lonsway, PhD[1]; Judith Noble-Wang, PhD[1]; Judith Conway, RN[3]; Craig Conover, MD[3]; Michael Vernon, DrPH[5]; Alexander J. Kallen, MD[1]

JAMA. 2014;312(14):1447-1455.

Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing

- Optimal frequency not established
  - Monthly
  - Every 60 procedures
  - Weekly
  - After each reprocessing
- Sites for sampling
  - Channel
  - Distal end
- Options of sampling methods: e.g. flush-brush-flush; with unestablished sensitivity
- Acceptable results: <10 CFU of Low-concern organisms; no high-concern organisms (NR, S. aureus, enterococci)

Testing duodenoscope after 60 ERCP procedures or once a month



Transmission of CRE bacteria through Endoscopic Retrograde Cholangiopancreatography (ERCP)

Interim Guidance

NOTE: This document was distributed on 3/17/2015. It is subject to change and may be updated as new evidence or information arises. Please watch communications from ASGE and visit www.ASGE.org regularly.

Potential Clinical Scenarios and Possible Options for Management

Scenario A: *At this time*, in the absence of known MDRO/CRE exposure or heightened risk

At this time, given the uncertainties raised by recent reports, even in the absence of known MDRO/CRE exposure or heightened risks for CRE, consider either:

a. One time, post reprocessing surveillance culture of the entire inventory of elevator-equipped endoscopes in the unit.
   - If cultures are employed, endoscopes should be sequestered for a minimum of 48 hours until cultures confirm absence of contamination. Those found to be positive for contamination by pathogenic bacteria should undergo repeat manual cleaning, high-level disinfection, and sequestration, or ETO gas sterilization according to manufacturer's guidelines.

b. Alternatively, proceed with one time ETO sterilization of the entire inventory of elevator-equipped endoscopes, with careful attention to manufacturer's guidelines.

Scenario B: For routine daily practice without known heightened CRE risk

Currently, in the absence of suspected exposure or known risks, no additional reprocessing practices beyond diligent standard washing and HLD of duodenoscopes are advised by the FDA.

Some centers however are employing double cycles of washing and reprocessing for all endoscopes with elevators. Other centers are employing culture and sequestration of these instruments until confirmed clear, or ETO sterilization after each procedure. These options should be reviewed with your hospital infection control staff and administration to determine which approach is most practical and efficacious at your institution.

Patients undergoing procedures using duodenoscopes should be informed during the consenting process that there is a risk of patient-to-patient bacterial transmission associated with the procedure, including uncommon transmission of a multidrug-resistant organism.

Scenario C: Known MDRO or CRE-positive patients

The FDA and ASGE have advised, when ERCP is performed in a patient with a known multi-drug resistant organism such as CRE, that the duodenoscope should be taken out of service until it has been verified to be free of pathogens before reuse. This would entail high-level disinfection followed by either endoscope culture and sequestration until confirmed culture-negative at 48 hours or ETO sterilization. This approach could also be implemented for other flexible endoscopes that have an elevator mechanism.

Scenario D: Infection (or carrier state) with MDRO or CRE identified in a patient with a history of ERCP in recent months

When a patient is newly identified with either a clinical infection or silent carriage of a MDRO/CRE organism, their history should be reviewed to identify potential exposure via endoscopy using an instrument with an elevator (ERCP or EUS) in the prior several months. This interval is poorly defined, but transmission at exposure many months earlier has been described. If exposure via these instruments is a possibility, the following steps should be undertaken:

- Identify the individual endoscope used in the case and culture it according to one of the standardized culture protocols (see CDC interim culture method: http://www.cdc.gov/hai/settings/lab/lab-duodenoscope-culture-method.html). Sequester the scope out of service for at least 48 hours until a culture for high-concern organisms is negative.
- If the endoscope tests positive for MDRO/CRE, then contact the hospital microbiology and infection control departments to assist with characterization of the cultured organisms to ascertain their equivalence.
- With your infection control department, identify all patients in whom the endoscope was used, both during an interval prior to the index patient's exposure and subsequent to their exposure up until the time it was taken out of use for culturing. Notification of these patients should be considered, in line with the CDC's guidance, for potential screening via anal swab PCR or culture and for tracking to identify potential illness.
- Treat the positive CRE contaminated scope with either ETO sterilization according to manufacture guidelines or repeat washing and HLD with sequestration until a repeat culture confirms absence of high-concern organisms after at least 48 hours.

Supplemental Measures for Facilities and Staff that Reprocess Duodenoscopes to Consider:
Among the variety of infection mitigation strategies discussed at the Advisory Committee meeting, several specific supplemental measures have been implemented in individual health care facilities. Combined with strict adherence to the duodenoscope manufacturer's reprocessing instructions, the following supplemental measures may further help reduce the risk of infection transmission associated with the use of duodenoscopes.

- Microbiological Culturing
- Ethylene Oxide Sterilization
- Use of a Liquid Chemical Sterilant Processing System
- Repeat High-Level Disinfection

The FDA recommends health care facilities performing ERCP evaluate whether they have the expertise, training and resources to implement one or more of these options:

- ***Microbiological culturing of duodenoscopes***

  Microbiological culturing involves sampling duodenoscope channels and the distal end of the scope and culturing those samples to identify any bacterial contamination that may be present on the scope after reprocessing. Some facilities have successfully implemented routine or periodic surveillance culturing to assess the adequacy of duodenoscope reprocessing and to identify duodenoscopes with persistent contamination despite reprocessing.

  In March 2015, the CDC released an Interim Duodenoscope Surveillance Protocol that includes duodenoscope sampling and culturing protocols, which may be used as a guide for health care facilities to assess the adequacy of their duodenoscope reprocessing. This interim protocol includes several options for duodenoscope culturing based on the resources and requirements of each healthcare facility. One option is to culture duodenoscopes after every reprocessing cycle and to quarantine the duodenoscope until culture results are known. Another option is to culture at intervals defined by the health care facility, i.e. weekly, monthly or after a fixed number of procedures.

  The CDC's interim duodenoscope surveillance protocol is a good tool; however, the false positive rate, the false negative rate and the limits of detection for microbial surveillance have not yet been established for this method. Nevertheless, persistent duodenoscope contamination as defined in the interim surveillance protocol should lead to action by the health care facility, such as taking the scope out of circulation until negative culture results can be demonstrated following repeat reprocessing.

  Health care facilities evaluating the potential implementation of duodenoscope microbiological culturing following duodenoscope reprocessing should consider the following:

  - Any duodenoscope found to be contaminated should not be returned to use until the contamination has been eliminated from the device. The CDC has provided an interim protocol to assist in interpretation of culture results.
  - Microbiological culturing is resource-intensive and includes added costs of microbiological testing and staff time needed to collect and process samples.
  - Some health care facilities have "outsourced" duodenoscope culturing to environmental or contract laboratories due to lack of on-site experience with culturing, uncertainty in interpretation of results and workflow considerations.
  - Surveillance culture results take time to produce. When duodenoscopes are cultured after every reprocessing cycle, the duodenoscope is typically quarantined and not available for use until culture results are known.
  - Health care facilities should assess their supply and clinical demand for duodenoscopes when considering microbiological culturing implementation.

The way forward…?

- AER final rinse testing:
  - to give a hint to change the current maintenance practice of individual endoscopy unit?
  - Optimal frequency not known to detect real problems timely
  - Speciation? NTM?
- surveillance culture on endoscopes
- High risk endoscopes:
  - ERCP: surveillance on patients with bacteremia (esp. P. aeruginosa) within 14 days?
  - Bronchoscopy: surveillance on BAL with NTM?

Acknowledgement

- Ms Deanna Lee, WM, CEU, PMH
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- Mr K F Pun, WM, IDC, PMH
- Ms S S Lam, NO, ICT, PMH
- Mr W T Hui, SMT, Microbiology Laboratory, PMH

Thank you!