GESA
Gastroenterological Society of Australia

GENCA est.1978

Clinical Update

Infection Prevention and Control in Endoscopy 2025 Update

New Zealand Society of Gastroenterology Inc

Sterilizing Research Advisory Council of Australia

This work is wholly funded by GESA.

ISBN: 978-1-7640409-0-7

First published September 2021; updated May 2025.

Disclaimer

The recommendations in this document represent the best available evidence at the time of compilation and are intended to be used as a guide only. The compilers of these recommendations shall not be liable for any loss, direct, indirect or consequential, on whatsoever account for any omission or negligent mis-statement contained herein, or by reason of, arising from or in relation to any such user, by any other person, company or body relying or acting upon or purporting to rely or act upon any matter contained therein or arising thereout.

Suggested citation

Devereaux BM, Jones D, Wardle E, on behalf of the Infection Prevention and Control in Endoscopy Committee. *Infection Prevention and Control in Endoscopy 2025 Update*. Melbourne: Gastroenterological Society of Australia, 2025.

Contact

Gastroenterological Society of Australia
3/517 Flinders Lane
Melbourne VIC 3000
Australia
Phone: 1300 766 176
Website: www.gesa.org.au
Email: gesa@gesa.org.au

Infection Prevention and Control in Endoscopy

2025 Update

Infection Control in Endoscopy Committee:

Chair
Benedict Devereaux

Editorial Group
Benedict Devereaux
Dianne Jones
Elizabeth Wardle

Committee
Eugene Athan
Farzad Bashirzadeh
Sue Greig
Kathryn Haberfield
Mehul Lamba
Vichitra Sukumaran
Karen Vickery

Contents

LIST OF TABLES

LIST OF FIGURES

LIST OF BOXES

Foreword

Infection Prevention and Control in Endoscopy 2025 Update

In this update to *Infection Prevention and Control in Endoscopy 2021*, the Gastroenterological Society of Australia (GESA) and Gastroenterological Nurses College of Australia (GENCA) continue their key leadership roles in providing the most current advice on all aspects of infection prevention and control in endoscopy.

Indeed, this work is the product of a much broader collaboration with learned colleges and societies: the Australasian Society for Infectious Diseases, the Thoracic Society of Australia and New Zealand, the Australasian College for Infection Prevention and Control and the Federation of Sterilizing Research Advisory Councils of Australia.

This edition provides a subject-specific update to the comprehensive 2021 document. The advice in this update supersedes the 2021 recommendations only where new information has come to hand. New or updated content is highlighted in purple throughout this document.

Infection Prevention and Control in Endoscopy 2021

GESA and GENCA have been committed to the highest standards of infection prevention and control in endoscopy for decades. This document has been published under different titles since the early 1980s. The content has evolved but the intent of each edition remains the same: to ensure the highest standards of practice in endoscopic reprocessing and human and environmental resource management to optimise the safe provision of endoscopic procedures to our patients.

The first GESA publication on the risk of infection during gastrointestinal endoscopic procedures, authored by Dr Alistair Cowen, was published in 1987. Subsequent publications under the title of *Infection and Endoscopy* were published in 1991, 1993 and 1995. In 2010, the document was renamed *Infection Control in Endoscopy*, with a further update published in 2011. This resource has now been renamed again as *Infection Prevention and Control in Endoscopy 2021*, to highlight our primary goal of preventing infection transmission related to endoscopic procedures. The authors of this work acknowledge the commitment and expertise of previous contributors and honour them with this edition.

Introduction

Infection Prevention and Control in Endoscopy 2025 Update

Infection prevention and control still form the core of safe and efficient endoscopic procedures. Through the commitment of the Gastroenterological Society of Australia (GESA) and Gastroenterological Nurses College of Australia (GENCA) and our collaborating organisations, Australia remains at the forefront of all aspects of infection prevention and control in endoscopy. Since the publication of *Infection Prevention and Control in Endoscopy 2021*, the Infection Prevention and Control in Endoscopy (IPCE) Committee has continued to monitor the scientific literature and commercial advances in this area. Driven by a dedication to further reduce or eliminate the risk of endoscopic transmission of infectious agents, this update to that document covers recent advances in the field. The discussion of single-use endoscopes has been expanded, along with additions regarding a new system for endoscope reprocessing and a novel single-endoscope drying and storage system that is increasingly being incorporated into practice.

All the recommendations in this update are provided in the context of the new Australian Standard AS 5369:2023 *Reprocessing of reusable medical devices and other devices in health and non-health related facilities*, which supersedes Australian/New Zealand Standards AS/NZS 4187:24 and AS/NZS 4815:2006. It is assumed that all personnel involved in infection prevention and control in endoscopy are across the details of the new Standard.

Committee members remain engaged with international expert colleagues, contributing to the development of uniform standards for endoscope reprocessing and the protocols, techniques and technology required to achieve them. As a result of this vigilance and collaboration, the IPCE Committee is committed to the appropriate evolution of our recommendations. I remain extremely grateful to all Committee members for their expertise and ongoing commitment to this essential, world-leading work. I acknowledge and thank committee members who have resigned since release of the 2021 document: Kate Quoyle, Robyn Brown, Maryann Todman, Mary Jo Waters and Andrew Taylor. I also acknowledge Karen Vickery, who resigns on release of this update, for her many years of expert input, representing an outstanding contribution to infection prevention and control in endoscopy.

An evidence-based infrastructure supports the expert opinion guiding the updates in this document. This update to the comprehensive *Infection Prevention and Control in Endoscopy 2021* resource ensures that every health care practitioner in every endoscopy unit in Australia is equipped and supported to provide the highest level of care to every patient requiring an endoscopic procedure.

Infection Prevention and Control in Endoscopy 2021

GESA and GENCA have a long history of collaborating on publications relating to infection control in endoscopy. *Infection Prevention and Control in Endoscopy 2021* presents the state of the art of infection control in endoscopy, to bring practitioners involved in all aspects of endoscopy up to date with current techniques, protocols, devices and equipment. It also addresses hot topics and controversies in the field.

Infection control is at the core of safe and efficient endoscopic procedures. This has been emphasised in recent years by endoscopy-associated outbreaks of carbapenemase-producing Enterobacterales (CPE) and concerns regarding the use of simethicone during endoscopic procedures. GESA and GENCA's IPCE Committee has published papers specifically addressing both of these issues. At the time of publication of this document, the world continues to confront the COVID-19 pandemic. The IPCE Committee has been active in ensuring the safest possible environment for patients requiring endoscopic care, and the staff providing it, through the publication of nationally consistent recommendations and protocols.

A comprehensive and contemporary understanding of infection control in endoscopy is essential for all involved in endoscopic procedures, whether in smaller ambulatory centres or large tertiary referral centres.

It is also critical irrespective of the complexity of the procedure being performed. Infection prevention and control in endoscopy require attention to issues far broader than just the reprocessing of endoscopes. This publication attends to all aspects of infection control, for which a multidisciplinary, multisociety committee was required. As Chair of the IPCE Committee, I am grateful to all the committee members for their commitment to this essential and comprehensive resource. Their contributions have been far beyond their daily workload. I wish to specifically thank Di Jones and Beth Wardle for their extra contribution in contributing to the editing of the document. All the committee members have drawn on the published evidence but, importantly, have also contributed their own experience and expertise to develop the recommendations presented here. The responsibility of formulating these recommendations, which include topics devoid of definitive published evidence, has been knowingly borne by the committee members.

I am also grateful to the learned colleges and societies they represent for their review and endorsement.

Australia has long been recognised as a major international contributor to infection prevention and control in endoscopy, advocating the highest standards and incorporating the latest evidence and experience to maximise the safety of endoscopic procedures. The recommendations in this publication are comprehensive. It should continue to be the primary reference resource for endoscopy units throughout the country and all those who work in them. It is also essential to remain abreast of relevant national and international standards documents. It is our intention to always be on the front foot in supporting those who are on the frontline, caring for patients requiring endoscopic procedures.

Benedict Devereaux
Chair, IPCE Committee

Summary of changes since *Infection Prevention and Control in Endoscopy 2021*

The following changes or additions have been made in this update:

1. References to Australian/New Zealand Standard (AS/NZS) 4187:2014 *Reprocessing of reusable medical devices in health service organisations* updated to AS 5369:2023 *Reprocessing of reusable medical devices and other devices in health and non-health related facilities*
2. Change of nomenclature from carbapenemase-producing Enterobacterales (CPE) to carbapenemase-producing organisms (CPO) (see section 2.1.1)
3. Expanded discussion on the use of simethicone, including results of recently published studies (see section 3.4.1)
4. New section on timing of elective endoscopic procedures in patients with recent SARS-CoV-2 infection (see section 5.3)
5. Updates to water quality management (see section 7.1 and section 10.9)
6. Expanded discussion of single-use endoscopes and novel options for endoscope reprocessing, drying and storage (see section 8.2)
7. Comment on the availability and monitoring of sporicidal cycles on some automated flexible endoscope reprocessors (AFERs) (see section 9.4)
8. Position on the use of polymerase chain reaction testing relative to conventional microbiological culture techniques for the detection of microorganisms (see chapter 10)
9. Clarification of the frequency of microbiological testing required for loan or repaired endoscopes (see section 10.4)
10. Updates to laboratory procedures (see section 10.7)
11. Specific advice on the inclusion of endoscopy surveillance culture results as a standard agenda item for Infection Control Committee or Medical Advisory Committee meetings and guidance on incident triage meeting actions (see section 10.8)
12. Updated flowcharts and new tables for response to positive microbiological cultures (see section 10.8)

Significant changes are highlighted throughout the document in purple.

SECTION A: CONTEXT

Chapter 1: Risks of infection after endoscopy procedures

Transient bacteraemia has been detected frequently after various types of endoscopic procedures, but clinical infections are rare. The exceptions to this are peristomal infections complicating percutaneous endoscopic gastrostomy (PEG) and post-endoscopic retrograde cholangiopancreatography (ERCP) cholangitis.

Antibiotic prophylaxis has been widely used, but clinical data supporting its effectiveness outside of PEG and ERCP procedures are lacking. Recent guidelines have consequently recommended fewer indications for prophylactic antibiotics, especially in respect of bacterial endocarditis prophylaxis. In this chapter, patient risk factors for infection, risks associated with specific endoscopic procedures and current recommendations for prophylaxis are discussed. Bronchoscopy is discussed separately in section 1.4. Recommendations for antibiotic prophylaxis are discussed in further detail in chapter 6.

1.1 Risk factors

There are various patient- and procedure-related risk factors for endoscopy-associated bacteraemia and infection.

1.1.1 Compromised immune status

There is some evidence that impaired immune status increases the risk of endoscopy-associated infection, although other studies have not shown an increased risk. For example, one case series report of profoundly immunocompromised individuals undergoing upper gastrointestinal endoscopy after bone marrow transplantation described a high rate of clinically significant bacteraemia,[1] but this was not confirmed in two subsequent studies.[2,3] Concern was also raised after two early case reports described serious bacteraemia complicating colonoscopy and biopsy in patients with cirrhosis, but no clinically significant infections have been reported in more recent case series of colonoscopy in such patients, with or without ascites.[4] There are no data suggesting an increased risk of endoscopy-associated infection in individuals with other forms of immunosuppression, such as solid organ transplant recipients or people with human immunodeficiency virus (HIV) infection. Endoscopists may consider prophylactic antibiotics for patients with compromised immune status, especially when there are other risk factors for infection. Specialist infectious diseases advice should be sought if a patient with significant immunosuppression requires an endoscopic procedure.

1.1.2 Intrinsic sources of infection

In situations where an endoscopic procedure involves instrumentation of an infected site, bacteraemia may be induced. ERCP in the setting of cholangitis and colonoscopy in patients with diverticulitis are the most common examples. Antibiotic therapy to cover potential infecting organisms is indicated.

1.1.3 Increased risk of bacterial lodgement during bacteraemia

Any abnormality of the endovascular surface is susceptible to bacterial lodgement during bacteraemia. This applies especially to prosthetic or severely damaged heart valves and, less often, to other endovascular implants, such as recently inserted stents, filters, pacemakers, defibrillators and long-term venous access devices. Foreign materials within the body, but not in the intravascular space, such as prosthetic joints, are also at risk of bacterial lodgement, although the risk appears to be low. The evidence relating infections of these sites to endoscopy is presented in section 1.2.

1.1.4 Procedure-induced tissue damage

The degree of bacteraemia after an endoscopic procedure appears to correlate with the degree of tissue damage and disruption during the procedure (Table 1). For example, rates of bacteraemia are much higher with variceal sclerotherapy and oesophageal dilatation than with diagnostic upper or lower gastrointestinal endoscopy and are likely to lead to higher risks of clinical infection, especially in those with other risk factors. Therefore, endoscopists should consider the likely magnitude of tissue damage when deciding whether to administer antibiotic prophylaxis in an individual patient.

1.2 Significance of bacteraemia

Although the occurrence of bacteraemia after gastrointestinal endoscopic procedures has been extensively studied, the actual risk of clinical infection has not been adequately assessed in large prospective studies. In addition, even when an infection occurs at some time after an endoscopic procedure, it is difficult to prove a direct link with that procedure. Therefore, the degree of risk of clinical infections after gastrointestinal endoscopic procedures remains uncertain and, consequently, conclusions of expert panels over many years have varied widely.

The arguments against bacteraemia being significant include the observations that:

- bacteraemia occurs more frequently after a regular daily activity such as tooth brushing than after most forms of endoscopy;[10]
- clinical infections appear to be rare, based on the small proportion of case reports relative to the large numbers of endoscopic procedures performed; and
- most positive cultures after gastrointestinal procedures are transient and of low load.

1.2.1 Infective endocarditis

Case reports implicating endoscopic procedures as a cause of bacteraemia leading to infective endocarditis were summarised as early as 2009 in the British Society of Gastroenterology (BSG) guidelines on antibiotic prophylaxis in gastrointestinal endoscopy.[5] These cases comprised six individuals with no known valve disease, six with prosthetic valves and 11 with mitral or aortic valve disease of various aetiologies, including mitral valve prolapse. Endocarditis occurred within weeks after both upper endoscopy (12 patients) and lower endoscopy (11 patients), although there was marked variation in the time interval. Infecting organisms were mainly viridans streptococci in those having upper gastrointestinal endoscopy and *Enterococcus* species after lower gastrointestinal endoscopy.

Despite these reports, some authorities are sceptical that there is a true causal link. The 2015 American Society for Gastrointestinal Endoscopy (ASGE) guidelines state that: “There are no data demonstrating a causal association between endoscopic procedures and infective endocarditis”.[12]

Table 1. Approximate incidence of bacteraemia in immunocompetent individuals undergoing endoscopic procedures*

Procedure	Bacteraemia incidence (%)
Rectal digital examination	4
Rigid sigmoidoscopy	5–9
Barium enema	11
Tooth brushing	25
Dental extraction	30–60
Colonoscopy	2–4.4
Diagnostic gastroscopy ± biopsy	4–4.1
Flexible sigmoidoscopy	0.5
ERCP (no duct occlusion)	6–6.4
ERCP (duct occluded)	11–18
Variceal band ligation	6–8.8
Sclerotherapy	10–50
Oesophageal dilatation/prosthesis	34–54
Oesophageal tissue ablative therapy (e.g. laser/argon plasma coagulation)	35
EUS + FNA	2–6
Bronchoscopy ± BAL	0–6
EBUS-TBNA	7

BAL = bronchoalveolar lavage; EBUS-TBNA = endobronchial ultrasound-guided transbronchial needle aspiration; ERCP = endoscopic retrograde cholangiopancreatography; EUS = endoscopic ultrasound; FNA = fine needle aspiration.
* Table adapted from multiple sources.[5-12]

Evidence in support of this view is:

- In none of 17 case series of post-endoscopy bacteraemia reviewed by the authors of the National Institute for Health and Clinical Excellence (NICE) guideline was bacteraemia followed by endocarditis or clinically significant infection evident.[13]
- In the only published case–control analysis of this subject, there were slightly higher rates of recent upper (2.9% vs 1.5%) or lower (5.1% vs 2.9%) gastrointestinal endoscopy in 273 individuals who developed endocarditis, compared with matched controls without endocarditis, but the difference was not statistically significant. There was, however, a statistically significant association between recent barium enema and a diagnosis of infective endocarditis.[14]

1.2.2 Infected joint prostheses

As prosthetic joint infection can be associated with significant morbidity, many clinicians recommend prophylactic antibiotics because of a theoretical risk of bacterial seeding after gastrointestinal endoscopy, especially within 6 months of implantation. The actual risk appears to be low, as there are only two case reports of septic arthritis of prosthetic joints associated with endoscopic procedures.[12,15-17]

1.2.3 Infections of vascular grafts and other non-valvular cardiovascular devices

There are no case reports directly implicating endoscopy as a cause of infection of non-valvular vascular grafts and devices, including stents, pacemakers, filters and defibrillators. The American Heart Association (AHA) stated that there was no evidence that gastrointestinal endoscopic procedures cause infection of such devices at any time after implantation.[18]

1.3 Association of gastrointestinal endoscopy with clinical infections

1.3.1 Infections associated with percutaneous endoscopic gastrostomy

Peristomal infection is the most common adverse event related to PEG placement, as the inevitably contaminated gastrostomy appliance is drawn through the mouth, stomach and abdomen. A recent large retrospective series in a single tertiary centre reported peristomal infection in 171 of 781 patients (21.9%). Diabetes, hospital stay longer than 7 days and hypoalbuminaemia were the main risk factors.[19]

1.3.2 Infections associated with endoscopic retrograde cholangiopancreatography

When compared with all other endoscopic procedures, ERCP has the highest rate of serious infective complications. Cholangitis and associated sepsis are the most frequently reported infective adverse events. Less often, liver abscess, acute cholecystitis, infected pancreatic pseudocyst and infection after duodenal perforation are reported. The main risk factor for biliary infection after ERCP is failure to relieve obstruction of the biliary system, particularly following opacification of a duct obstructed by stricture or stone material with contrast agent. This is a particular challenge with hilar cholangiocarcinomas and in the setting of primary sclerosing cholangitis. In one study, incomplete biliary drainage was present in 91% of patients with sepsis.[20]

Several cases and outbreaks of cholangitis and septicaemia after ERCP, due to *Pseudomonas* species and enteric organisms, were reported in the 1980s and early 1990s. A prospective study of 2067 consecutive ERCPs performed during 2002–2003 found a sepsis rate of 1.5%, with a 26% mortality rate among these patients. Ten of 30 patients with identified bacterial causes had infections with *Pseudomonas*, *Klebsiella* and *Enterobacter*, which were felt to be exogenously introduced, presumably due to deficiencies in the endoscope cleaning process.[21] These are ubiquitous commensal organisms, with *Pseudomonas* species colonising almost any damp surface. The major causes of infection in single clinical cases of infection or mini-epidemics have included:

- inadequate disinfection of the endoscope, with particular faults being related to inadequate cleaning and disinfection of the forceps raising channel (an intrinsic risk in duodenoscopes);[22,23]
- failure to rinse the endoscope channels with alcohol at the end of the post-session cleaning and disinfection process and to subsequently dry the channels with forced air;[22,24]

- contamination of the water feed system and water;[24,25] and
- contamination of disinfecting machines by *Pseudomonas* species (see section 8.5.1). It is essential that cleaning and monitoring protocols for endoscopes and cleaning machines are carefully followed.

Of great concern, outbreaks of CPE have been reported at multiple centres internationally. The first report of patient-to-patient transmission of CPE by duodenoscopes was in 2010.[26] CPE transmission has been ascribed to duodenoscope defects, non-adherence to reprocessing protocols, delayed drying and difficulties in cleaning the complex distal tip. It is important to note that all endoscopic instruments may be a source of CPE transmission. In response to these CPE outbreaks, GESA and GENCA published the *Australian infection control in endoscopy consensus statements on carbapenemase-producing Enterobacteriaceae* to minimise the risk of CPE transmission.[27]

With the availability of a single-operator, single-use cholangioscope, both cholangioscopy and pancreatoscopy are increasingly being performed. Infection-related complications mainly relate to cholangioscopy. In a prospective study of 57 patients, the risks of bacteraemia and clinical cholangitis after ERCP with cholangioscopy were reported as 8.8% and 7%, respectively. The risk of bacteraemia was higher when biopsy samples were taken.[28]

The main risk associated with pancreatoscopy is pancreatitis. However, antibiotic prophylaxis could be considered in the presence of a pancreatic duct stricture, pancreatic duct stones or a fluid collection communicating with the main pancreatic duct.

McCafferty and colleagues have summarised duodenoscope-, colonoscope- and gastroscope-associated infections in the United States, France, China, Germany, the Netherlands and the United Kingdom.[29]

1.3.3 Infections associated with endoscopic ultrasound-guided fine needle aspiration

The risk of infective complications after endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) is reported as 0.03% for solid lesions and 0.22% for cystic lesions. This is based on a meta-analysis evaluating 10,032 EUS-FNA examinations of solid lesions and 909 examinations of cystic lesions.[30]

1.4 Association of bronchoscopy with clinical infections

Bronchoscopy has an overall complication rate of 1%–3%, and the risk of infection being transmitted by the bronchoscope is low (Table 1). Bronchoscopy does not confer a risk of infective endocarditis or infections of joint prostheses, vascular grafts or cardiac devices. However, pseudo-outbreaks (see section 3.3) continue to be reported, and lapses in cleaning, decontamination, storage and maintenance of bronchoscopes, AFERs and water filters have been cited as reasons for both true and pseudo-infections.[31-35]

The most common organisms in bronchoscopy-related pseudo-infections include *Pseudomonas aeruginosa*, *Serratia marcescens*, mycobacteria and environmental fungi. However, *Pseudomonas* and *Serratia* species and *Mycobacterium tuberculosis* are also among the most common organisms reported in true infections. Specific recommendations on antibiotic prophylaxis are given in Table 5 in section 6.4.

In 2013, eight patients were infected with CPE after bronchoscopy.[36] Two bronchoscopes tested positive for these organisms and were found to have defects in the internal surfaces of the working channels. Similar results and conclusions were reported in another study in 2019.[37] In 2014, the US Food and Drug Administration (FDA) was notified that 14 patients who had undergone bronchoscopy had tested positive for CPE.[38] The bronchoscopes that tested positive for CPE had been repaired by a third-party manufacturer. The cause of these infections is unclear.

An investigation into possible transmission of *Enterobacter cloacae* (an opportunistic pathogen spread by dirty hands or contaminated medical devices) via an endobronchial ultrasound scope could not find an explanation. The instrument had been repaired by the original equipment manufacturer and there were no lapses in cleaning protocols, as assessed by an independent assessor, but intermittent growth of *E. cloacae* continued to occur. Biofilm formation causing intermittent positive culture results was put forward as a possibility but could not be proven.[39]

Chapter 2: Organisms

Current reprocessing standards, as detailed in this publication (see chapter 8), effectively inactivate viable microorganisms (excluding prions), such as bacteria, multidrug-resistant organisms, viruses and other infectious agents. Breaches in reprocessing may result in instrument contamination and possible organism transmission to patients undergoing endoscopic procedures, resulting in colonisation or clinically significant infections. Many of these pathogens can also contaminate the environment, providing another pathway for transmission.

2.1 Bacteria

2.1.1 Carbapenemase-producing organisms

Carbapenemase-producing organisms (CPO) include carbapenemase-producing Enterobacterales (CPE), as well as carbapenemase-producing *Acinetobacter* spp and *Pseudomonas* spp.

The carbapenem group of antibiotics (imipenem, meropenem, doripenem and ertapenem) provides broad antibiotic cover, and these agents are used for treatment of severe infections. CPO develop resistance to carbapenems through several mechanisms, including the acquisition of genes encoding carbapenemase enzymes, modification of efflux pumps or porin loss. Examples of these carbapenemases are KPC, NDM, OXA, IMP and VIM. The genes encoding for carbapenemases are found on mobile genetic elements (plasmids), together with genes that code for resistance to other classes of antibiotics (aminoglycosides, fluoroquinolones and cephalosporins), often making CPO multidrug resistant.

Within the Enterobacterales family, carbapenemases are most often found in *Klebsiella pneumoniae*, *Enterobacter* spp and *Escherichia coli*, although they have also been reported in other genera of gram-negative bacteria, such as *Pseudomonas*, *Acinetobacter*, *Serratia* and *Citrobacter* spp.

The clinical significance of infection with CPO is considerable. Due to their resistance to multiple antimicrobial agents, there are limited therapeutic options to treat infections. It is already evident that human infections with CPO may be associated with high morbidity and mortality.

Patient-to-patient transmission of CPO by endoscopic instruments can result in serious illness, and prevention must be a priority of every endoscopic unit. Reported endoscopic transmission of CPE has been predominantly related to instruments with complex tips (e.g. duodenoscopes and linear echoendoscopes), but all endoscopic instruments can transmit CPO.

Strict adherence to current reprocessing protocols, with particular attention to cleaning the complex tips of duodenoscopes and echoendoscopes and appropriate instrument drying and storage, is essential to minimise the risk of CPO transmission. Although previously recommended in the consensus statement on CPE, microbiological testing and quarantine of endoscopes following reprocessing after use on CPE-positive patients are no longer required.

All cases of suspected CPO transmission related to endoscopic procedures should be investigated by an outbreak management team.

2.1.2 Extended-spectrum beta-lactamase Enterobacterales

Extended-spectrum beta-lactamase (ESBL) Enterobacterales are gram-negative bacteria that produce a beta-lactamase enzyme that has the ability to break down commonly used antibiotics, such as penicillins and cephalosporins (e.g. ceftazidime, ceftriaxone and cefotaxime) and render them ineffective for treatment. The most common ESBL-producing bacteria are some strains of *E. coli* and *K. pneumoniae*.

2.1.3 *Pseudomonas* species

P. aeruginosa is a common hospital environmental organism, and endoscope and accessory contamination represents exogenous rather than endogenous contamination. Other environmental *Pseudomonas* species may also contaminate

equipment and the environment. These organisms have a propensity for formation of biofilms (see section 3.2.1). In the past 30 years, *P. aeruginosa* has been a key organism implicated in infections in endoscopy units.

2.1.4 Vancomycin-resistant enterococci

All enterococci are commensals of the bowel. Transmission of vancomycin-resistant enterococci (VRE) during endoscopy is possible in any situation where there is a breakdown in the cleaning or disinfection process or environmental contamination.

2.1.5 Mycobacteria

2.1.5.1 Mycobacterium tuberculosis

There are no proven cases of *M. tuberculosis* associated with gastrointestinal endoscopy; however, there have been numerous infections associated with bronchoscopy.

The US Centers for Disease Control and Prevention (CDC) recommend that bronchoscopy should not be performed on patients with active tuberculosis unless absolutely necessary.[40,41] Avoiding bronchoscopy in these patients is important to reduce contamination of bronchoscopes and the subsequent risk of transmission to other bronchoscopy patients, as well as to avoid contamination of staff or items in the bronchoscopy suite when patients cough during or after the procedure.

A disturbing development in mycobacterial disease is the increase in multidrug-resistant tuberculosis. This further reinforces the importance of avoiding bronchoscopy in patients with suspected or proven tuberculosis whenever possible.

2.1.5.2 Environmental mycobacteria

Non-tuberculous mycobacteria are mycobacteria other than *M. tuberculosis* and *Mycobacterium leprae*. They are also referred to as atypical mycobacteria, mycobacteria other than tuberculosis (MOTT), or environmental mycobacteria.

Non-tuberculous mycobacteria are environmental organisms that can be found in soil, dust and water, including natural water sources (e.g. lakes, rivers and streams) and municipal water sources (e.g. water that people drink or use for showering). They can form difficult-to-eliminate biofilms.[42]

These isolates have been associated with:

- bronchoscopy (specifically related to faulty suction valves and cracked biopsy channels);
- contaminated topical anaesthetic solutions; and
- contaminated AFER machines.

2.1.6 *Clostridioides difficile*

The defining concern with *Clostridioides difficile* (previously known as *Clostridium difficile*) is that it is a spore-forming organism. There are several reports of possible endoscopic transmission; however, reprocessing with high-level disinfectants provides inactivation of *C. difficile* spores. The environmental contamination that occurs during endoscopic procedures is of particular concern with *C. difficile*, necessitating the use of a sporicidal agent for room surface cleaning (see section 7.5.2).

2.1.7 *Helicobacter pylori*

Although there is historical evidence from research studies that *Helicobacter pylori* could be transmitted via gastric tubes and endoscopy and biopsy procedures, *H. pylori* transmission from patient to patient should not occur where there is compliance with current reprocessing standards.

2.1.8 *Salmonella* and related enteric species

Salmonellae and related enteric species (*Citrobacter* spp, *Enterobacter* spp, *E. coli*, *Klebsiella* spp, *Proteus* spp, *Serratia* spp, *Shigella* spp and *Yersinia pestis*) have been transmitted during endoscopy procedures and resulted in clinically significant infections.

2.2 Blood-borne viruses

The risk of transmission of blood-borne viruses related to endoscopy procedures highlights the need to ensure that prompt and meticulous endoscope cleaning removes all traces of blood and proteinaceous material.

Generally, and not specific to endoscopic procedures, the risk of transmission of blood-borne viruses from an infected patient to a health care worker varies (Table 2).[43]

Table 2. Risk of transmission of blood-borne viruses to health care workers

Blood-borne virus	Risk of transmission (%)
Hepatitis B virus	1–62*
Hepatitis C virus	0–7
Human immunodeficiency virus	0.3

* The infectivity of people with hepatitis B depends on their hepatitis B e-antigen status, with wide variability reported in the literature.

2.2.1 HIV

Infective HIV particles are present in the blood and other body fluids of people with HIV infection. Needle-stick injury involving HIV-positive blood can result in transmission of HIV to health care workers. To date, there has been no unequivocal demonstration of transmission of HIV during gastrointestinal endoscopy.

2.2.2 Hepatitis B virus

Hepatitis B is a highly infectious virus, with high concentrations of viral particles found in the blood of symptomatic people with hepatitis B infection and asymptomatic hepatitis B virus carriers. Despite the high infectivity of hepatitis B, there is only a single well-documented case of transmission of hepatitis B by endoscopy.[44] Clinical studies reviewing patients who have had endoscopic procedures performed on the same list as a patient with known hepatitis B infection have not documented evidence of infection.

2.2.3 Hepatitis C virus

Human body fluids, including blood, saliva, ascites and urine, may contain significant concentrations of hepatitis C virus in infected individuals. Epidemiological studies have linked hepatitis C virus transmission with gastrointestinal endoscopy.[45] Transmission was related to the reuse of syringes and single-use medication vials during sedation for endoscopy procedures. The current evidence indicates that adherence to cleaning and disinfection protocols minimises the risk of transmission during endoscopic procedures.

2.3 Other infectious agents

A wide variety of other bacteria, viruses, fungi and protozoa may be transmitted by endoscopy.

2.3.1 Yeasts

Candida infection of immunocompromised patients has been linked to upper gastrointestinal endoscopy, and an epidemic of pseudo-infection with the yeast *Rhodotorula rubra* has been reported in bronchoscopy patients.

2.3.2 Parasites and worms

Parasites (protozoa) and worms (helminths) detected in samples taken at endoscopy include *Cryptosporidium* spp, *Strongyloides stercoralis*, *Giardia* spp, *Schistosoma* eggs and hookworm.

The oocysts of *Cryptosporidium* are highly resistant to various chemical disinfectants, including peracetic acid and sodium hypochlorite.[46] However, the infectivity of *Cryptosporidium parvum* decreases rapidly on dry surfaces. Therefore, it is reasonable to conclude that current cleaning, high-level disinfection (HLD) and drying processes are adequate to prevent nosocomial transmission of *C. parvum* via endoscopes.[47] The sensitivity of many other uncommon infectious agents to chemical disinfectants is largely unknown.

2.3.3 *Tropheryma whipplei*

The potential for the transmission of *Tropheryma whipplei* (which causes Whipple's disease) by endoscopy and duodenal biopsy has been suggested.[48] However, as *T. whipplei* is phytogenetically related to mycobacteria, HLD should effectively inactivate this organism.

2.3.4 Human prion diseases

The most common transmissible spongiform encephalopathy (TSE) is the sporadic form of Creutzfeldt–Jakob disease (sCJD), with an annual incidence worldwide of one to two cases per million

people. In addition to sCJD, other TSEs can be genetically linked in family groups. The genetic forms of TSE account for about 10% of total cases. TSE can also be transmitted or acquired by contaminated reusable medical devices (RMDs) or transplant tissue; these cases are referred to as iatrogenic CJD and account for about 1% of cases. TSEs, including CJD, are associated with neurological changes caused by abnormal prion protein and appear to be restricted to high-risk tissue of the central nervous system. The risk of transmission in endoscopy is low, including in nasal endoscopy procedures, as long as the olfactory epithelium is not breached.

Variant Creutzfeldt–Jakob disease (vCJD) is a TSE that was first reported as a novel human prion disease in 1996. It was acquired from infection with the bovine spongiform encephalopathy agent, most likely by ingestion. In vCJD, abnormal protein has been found in the central nervous system and has also been detected in lymphoid tissues, including tonsils, spleen and gastrointestinal lymphoid tissue.

Although three vCJD cases may have been transmitted by blood transfusion, there are no known cases of transmission by surgical instruments or endoscopes. This may, however, be possible, because sCJD has been transmitted by neurosurgical instruments used on the brain, and abnormal prion protein binds avidly to steel surfaces and can be difficult to remove from surgical instruments.

For further information relating to endoscopy in patients with TSEs, including CJD and vCJD, refer to the Australian Government Department of Health infection control guidelines.[49]

Chapter 3: Mechanisms of infection

3.1 Endogenous infection

Endogenous infection associated with endoscopy occurs as a result of breakdown of a normal barrier (e.g. via biopsy of mucosa, entering the bronchial tree), thereby allowing the patient's own microbial flora access to a normally sterile site. This mechanism of infection is responsible for most clinically important infections associated with modern endoscopy but is not related to cleaning, disinfecting or storing of endoscopes.

3.2 Exogenous infection

Exogenous infection associated with endoscopy arises from one of three sources.

- Infective agents are transmitted from one patient to the next via the endoscope or its accessory equipment. Transmission can occur with all endoscopic instruments; however, recent transmission events have been most often reported to involve bronchoscopes (e.g. tuberculosis, *P. aeruginosa*) and duodenoscopes (e.g. CPE). Transmission is probably largely unnoticed.
- Hospital environmental organisms may contaminate the endoscope or accessory equipment and be introduced into a patient during subsequent endoscopic procedures. Contamination may come from the general hospital environment, the water supply or endoscope reprocessing machines.
- There is an increased risk of infection when aerosol-generating procedures are performed and during manual cleaning of the endoscope.

The overall risk of endoscopy-associated exogenous colonisation or infection is unknown.

Specific risk factors for transmission include:

- failure to effectively clean the endoscope, including use of a single endoscope for both gastroscopy and colonoscopy in the same patient;
- damage to the endoscope;
- poor endoscope design, which leads to an inability to effectively clean and disinfect the endoscope;
- failure to adequately clean and reprocess accessories;
- contaminated or faulty AFERs or their filters, especially if contaminated by non-tuberculous mycobacteria, *Pseudomonas* species or related bacteria; and
- reuse of single-use items, including biopsy forceps used during gastroscopy being reused during subsequent colonoscopy in the same patient.

Anaesthetic practices may also contribute to exogenous infection. In the US, the most common cause of serious viral infection associated with endoscopy is poor intravenous sedation practice. Reuse of syringes and incorrect technique of multidosing from medication vials have been identified as the cause of hepatitis C virus transmission.[50,51]

3.2.1 Biofilm and endoscopic instruments

Some bacteria are only capable of existing in a planktonic state (free suspension). Most bacteria, including *Pseudomonas* spp, *Legionella* spp and atypical mycobacteria, exist either in a planktonic state or as biofilms. Biofilm is formed when these bacteria adhere to a surface and secrete large amounts of extracellular polymeric substances to form a protective matrix or film around themselves. These biofilms protect the bacteria against physical (e.g. brushing, fluid flow) and chemical (e.g. disinfectant) forces, making the microorganisms more difficult to remove or destroy.

Analysis of endoscope biofilms has shown that they are principally composed of environmental organisms into which pathogenic organisms are incorporated. This emphasises the importance of maintaining a good water supply, clean environmental conditions and sufficient drying of the endoscope after rinsing, to prevent these environmental organisms from forming biofilm.[52]

Biofilms are known to exist in municipal and hospital water pipes, especially old or altered configurations with pipes that have no flow but remain connected ("dead-run/dead-leg" pipes). This can lead to chronically contaminated water being delivered to the endoscopy suite, with the release of planktonic organisms from biofilm. Filter banks are generally used to prevent contaminated water from reaching AFERs, but the filters themselves may rapidly clog or develop biofilms and require repeated applications of oxidising agents or hot water to remain effective. Iron fragments in old plumbing can also damage these filters. When considering the purchase of reprocessing equipment or environmental changes to the reprocessing area, and for ongoing care and maintenance of equipment and services, a multidisciplinary taskforce, including engineers, water filtration experts, clinical microbiologists and endoscopy and reprocessing staff, is required to optimise outcomes.

Biofilms can become established in endoscopes and accessories (e.g. water bottles) despite recommended cleaning and HLD protocols, especially at defective sites in the endoscope channels.[53] In vitro studies found that significantly more *E. coli* and *Enterococcus faecium* attached to damaged endoscope channels than to undamaged channels. Biofilms can also become established in AFERs, and their elimination can occasionally necessitate extensive and costly maintenance or replacement.

Biofilms that develop in endoscopes and AFERs may not be detectable by surveillance culturing, as bacteria within the superficial layers may have been destroyed by cleaning and disinfection, while those embedded within the deeper layers remain viable.[54] Thus, to identify bacteria growing from biofilm, sampling for microbiological surveillance cultures should be performed after an endoscope has been stored for at least 12 hours following HLD. However, routine surveillance culturing may still not detect "viable but not culturable bacteria".

3.3 Pseudo-infection or pseudo-epidemic

Pseudo-infection or pseudo-epidemic refers to a scenario where the same organism is recovered in the laboratory from one or more patient samples with a common source of contamination (e.g. a bronchoscope). The source of the contaminating organism is not a patient; the organism is introduced into the sample at some point during sample acquisition or processing. Although the organism is isolated, it may not cause disease. Pseudo-infection has been reported with bronchoalveolar lavage samples and ERCP samples.[55] Microbiology laboratory staff should look out for any repeated isolation of the same microorganism from bronchoalveolar lavage or bile fluid culture, and notify infection control and endoscopy staff if found.

3.4 Simethicone use during endoscopy procedures

Concern has been raised about the use of simethicone, a defoaming agent, during endoscopic procedures. A detailed mucosal assessment is essential in performing high-standard endoscopic procedures but is impaired by bubbles within the gastrointestinal lumen.

Published reports have documented residual liquid or crystalline simethicone in endoscope channels after HLD. There are no data confirming that simethicone can be cleared from channels by brushing. Multiple case series have reported benefits of simethicone use during gastroscopy and colonoscopy in improving mucosal assessment, polyp detection rate and adenoma detection rate and in reducing procedure time. There are no published reports of adverse events related specifically to the use of simethicone, delivered either orally or via any endoscope channel. In addition, no published study has provided data showing that simethicone directly increased traditional or build-up biofilm formation.[56]

The use of simethicone is under ongoing review by gastrointestinal endoscopy representative organisations internationally. Further research is required to determine if simethicone use is associated with biofilm formation and/or an increased risk of transmission of clinically significant infectious microorganisms. A key question is the relevance of the route of administration. The three major endoscope manufacturers advise against the use of simethicone. There are no definitive data guiding the optimal route of administration (either via endoscope channels or orally before gastroscopy or with the colonoscopy preparation). All endoscopists and endoscopy unit managers are advised to monitor published studies

Box 1. Recommendations on simethicone use*

- The continued use of simethicone is considered reasonable as it improves mucosal inspection during gastroscopy and colonoscopy and likely facilitates adenoma detection at colonoscopy. *Evidence Level: IA, Recommendation Grade: A*
- The smallest effective quantity of simethicone should be added to lavage fluid. A suggested, yet untested, concentration would be 2–3 mL of 120 mg/mL (i.e. 0.24%–0.36% [g/L]) simethicone added to 1 L of sterile water. *Evidence Level: IV, Recommendation Grade: D*
- Simethicone may be administered orally or through any endoscope irrigating channel. *Evidence Level: IV, Recommendation Grade: D*
- Strict adherence to instrument reprocessing protocols is essential. The importance of immediate bedside pre-clean endoscope decontamination that includes post-procedure flushing and prompt commencement of manual or machine cleaning is highlighted. *Evidence Level: IIb, Recommendation Grade: B*

* Source: *Simethicone use during gastrointestinal endoscopy: position statement of the Gastroenterological Society of Australia.*[57]

and expert opinion statements over time and adjust their practice accordingly.

Given the evidence for improved quality of endoscopic imaging and polyp detection, and without definitive evidence of clinical adverse events over decades of use, continued use of simethicone, administered orally or through any endoscope channel, is considered appropriate. The IPCE Committee formulated and published a position statement giving recommendations on the use of simethicone during endoscopic procedures in 2019 (Box 1).[57] Strict adherence to instrument reprocessing protocols is essential.

3.4.1 Updates on simethicone use *(new in 2025)*

The recommendations regarding the use of simethicone during endoscopic procedures have not changed since *Infection Prevention and Control in Endoscopy 2021*. Over the past 4 years, several studies have supported the use of simethicone when administered as an oral pre-medication for gastroscopy or with colonoscopy preparation. Importantly, no study explored the use of simethicone administered through the endoscope at the time of the procedure.

For gastroscopy, five randomised controlled trials (RCTs) and one prospective cohort study concluded that simethicone improved mucosal visibility.[58-63] Three studies explored combinations of antifoaming and mucolytic agents.[58,62,63] Cao and colleagues concluded that preprocedural oral administration of a combination of simethicone and Pronase achieved superior mucosal visualisation compared with saline, simethicone or Pronase alone in patients undergoing upper endoscopy.[59] One RCT reported superiority of combination simethicone and N-acetyl cysteine.[62] However, another RCT reported that simethicone alone provided similar mucosal visibility and may be an alternative to combination premedication.[58] The use of any other single agent was not superior to the use of simethicone alone.

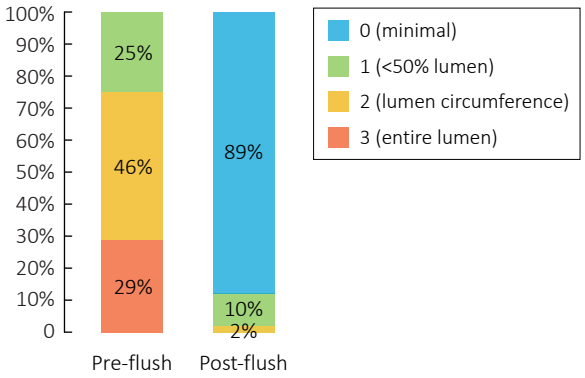
For colonoscopy, two RCTs and four systematic reviews and/or meta-analyses reported a benefit from the addition of simethicone to colonoscopy preparation.[64-69] Jung and colleagues concluded that simethicone was particularly effective when administered on the day of the procedure.[64] One meta-analysis reported that the addition of simethicone increased the adenoma detection rate,[68] whereas another meta-analysis did not, despite finding an increased polyp detection rate.[67]

No published study has reported an association between the use of simethicone and endoscopic transmission of infection. Although the studies noted here assessed the use of simethicone ingested orally before the procedure, and this route of administration was favoured in an expert review,[70] there are no data implicating the use of simethicone administered intraprocedurally via any endoscope channel in the transmission of infection.

A recent study evaluated the in vitro impact of simethicone on disinfection efficacy. The results showed that, under test conditions, simethicone did not reduce the efficacy of *ortho*-phthalaldehyde disinfectant (against *Staphylococcus aureus*, *K. pneumoniae* and *P. aeruginosa*) and that a higher concentration (66 mg/mL) of simethicone showed bactericidal activity.[71]

A water-soluble alternative to simethicone has also recently been identified. The product is an over-the-counter supplement based on ginger root extract and containing no sugars, thickeners or binding agents.[72] In a prospective, open-labelled pilot study, use of this new agent was assessed during colonoscopies performed by 13 endoscopists in 114 patients. A significant decline in luminal bubbles was reported with its use (Figure 1). This was not a randomised study, and further research is required to determine if use of this agent would affect drying effectiveness, biofilm formation or microbiological contamination.[72] Studies will also be needed to assess its use in upper gastrointestinal endoscopy. However, the manufacturer is developing a distribution network for its use in endoscopy procedures, and it is envisaged to be available in Australia in 2026.

Figure 1. Bubble scores before and after flushing with water-soluble alternative to simethicone*



* Reproduced from Mallard TS, et al. *Am J Infect Control* 2023; Licence: CC BY NC ND.[72]

SECTION B: PREVENTION

Chapter 4: Education, training and assessment of staff in endoscope reprocessing

Only personnel who have completed appropriate training can undertake reprocessing of endoscopes, as it requires specialised knowledge and skills.[56,73-85] Education and training programs in Australia include the GENCA Fundamentals of Endoscope Reprocessing Workshop, GENCA Endoscope Reprocessing Online Learning Package and various endoscope and AFER manufacturer education programs. Personnel assigned to reprocess endoscopes should also receive device-specific (i.e. from endoscope, AFER and controlled-environment storage cabinet [CESC] manufacturers) and chemistry-specific (i.e. detergent and biocide) reprocessing instructions to ensure proper cleaning and HLD or sterilisation.

Reprocessing competency is specific to the endoscopes, reprocessing and storage equipment in each unit. As required by AS 5369:2023, a documented education and training program should be in place in each endoscopy unit.[86]

Skills-based assessment of personnel who reprocess endoscopes should be performed and documented:

- at commencement of the role at a specific unit — this also applies to “casual/relieving” staff and medical staff who may be required to reprocess endoscopes, particularly after hours;
- annually (e.g. as part of performance development review);
- anytime a breach is identified;
- when a major technique is introduced or when a new type/model or loan endoscope or reprocessing/storage equipment is introduced; and
- in the context of local quality control.

The skills-based assessment should include, at a minimum, all the information contained in the education training programs outlined above and practice-specific processes. GENCA, as a professional organisation, offers independent assessment of learning from its online endoscope reprocessing training package. Skills-based assessments need to be developed for and be specific to each endoscopy unit, based on casemix and the endoscopes and reprocessing/storage equipment used. Each unit should regularly revise the assessment to ensure relevance and currency.

Systematic reviews of endoscopy-related infections have shown that most reported outbreaks originate from non-compliance with existing national and international guidelines.[10,87,88] Regular audits should be performed to assess compliance with guidelines and recommendations and to identify any non-compliance.

Chapter 5: Standard and transmission-based precautions

5.1 Standard precautions

Standard precautions are the minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where health care is delivered. Standard precautions are based on the safe-work principles that treat all blood and body fluids, including non-intact skin and mucous membranes, as potentially infectious. They are designed to protect staff against most infectious microorganisms carried by patients.

It is essential to establish and maintain standard precautions as part of infection prevention and control in an endoscopy unit. These safe-work practices form the basis for all infection prevention and control practice and are designed to protect both patients and health care workers.[81]

Standard precautions consist of:

- hand hygiene, consistent with the World Health Organization's "Five Moments for Hand Hygiene";[89]
- use of appropriate personal protective equipment (PPE);
- safe use and disposal of sharps;
- routine environmental cleaning;
- reprocessing of reusable medical equipment and instruments;
- respiratory hygiene and cough etiquette;
- aseptic technique;
- waste management; and
- appropriate handling of linen.

Standard precautions should be used in the handling of blood (including dried blood); all other body fluids, secretions and excretions (excluding sweat), regardless of whether they contain visible blood; non-intact skin; and mucous membranes.

Endoscopy services should consider the following areas when developing policies and procedures:

- hand hygiene, skin and nail care;
- appropriate use of PPE by all staff;
- patient placement and patient movement within the organisation and endoscopy service;
- sharps handling and disposal;
- reprocessing of RMDs and other reusable instruments and equipment;
- possible use of single-use endoscopes;
- personal hygiene and cough etiquette;
- aseptic technique;
- environmental cleaning;
- waste handling and disposal;
- handling and storage of used and clean linen;
- consumer and patient education relating to infection prevention and control, antimicrobial stewardship and multiresistant organisms;
- management of occupational exposures;
- workforce vaccination for specific infectious diseases;
- safe management of hazardous substances; and
- multidosing of injectate (e.g. as used for endoscopic mucosal resection).

These areas will be discussed further throughout this publication.

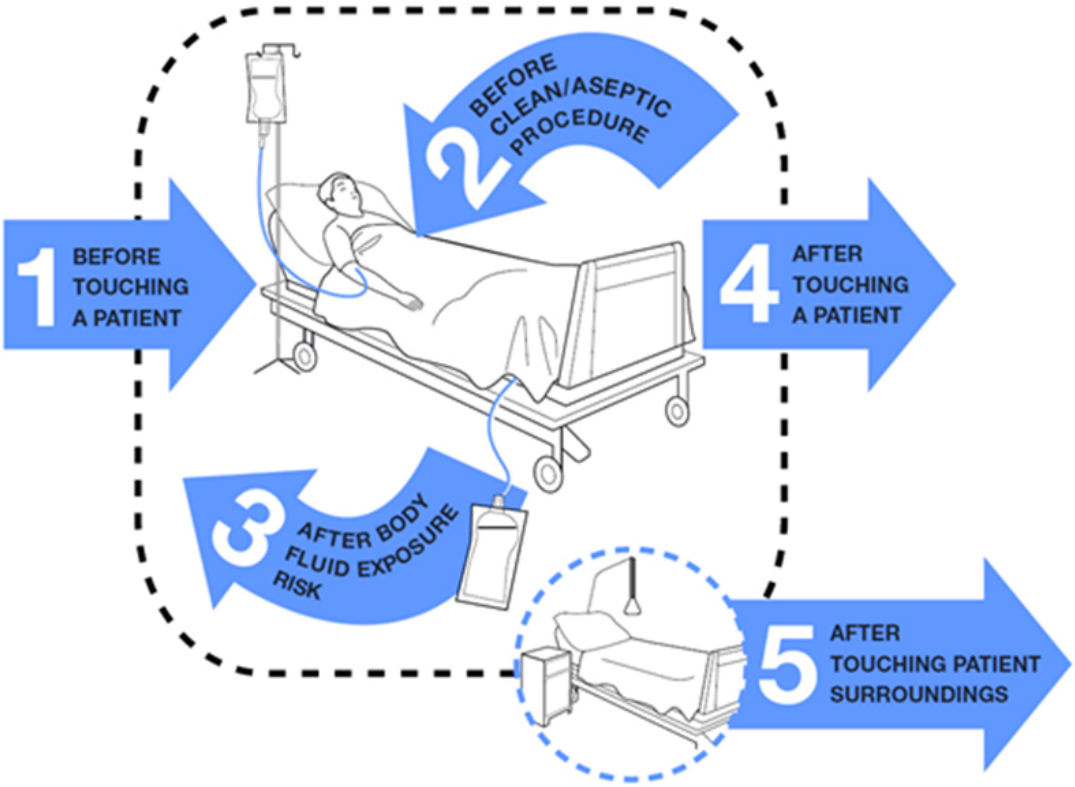
5.1.1 Hand hygiene

Based on substantial evidence, the Five Moments for Hand Hygiene approach (Figure 2) is designed to minimise the risk of transmission of microorganisms between the healthcare worker, the patient and the environment.

Hand hygiene must also be performed before putting on gloves and after removing gloves.

Figure 2. Five Moments for Hand Hygiene*

It is recommended that routine hand hygiene is performed:



* World Health Organization; Licence: CC BY-NC-SA 3.0 IGO.[89]

For the endoscopy unit, hand hygiene using alcohol-based hand rub or washing hands with soap and water must be performed:

- regardless of whether or not gloves are worn;[81]
- before putting on gloves and after removing gloves;
- before and after each patient contact;
- before and after each procedure;
- before and after handling or reprocessing RMDs, including endoscopes; and
- after environmental cleaning activities.

5.1.2 Personal protective equipment

Appropriate PPE is determined by the level of precautions applied to a particular patient or clinical scenario (Box 2). PPE should be used appropriately. When choosing which PPE is required, the risk of exposure to blood or body fluids must be evaluated. The types of PPE chosen based on that risk should be worn in a manner that provides maximum protection to the health care worker and patient and in a manner consistent with manufacturer instructions.[78]

The possibility of splashing by blood, body fluids and hazardous substances is not necessarily predictable, and everyone likely to encounter splashing should wear PPE. It is also important to use work practices that minimise the likelihood of splashing and production of aerosols. PPE must provide a protective barrier to the wearer and be fluid-resistant.

PPE is **not**:

- cotton gowns;
- street clothing, scrubs or uniforms; or
- prescription reading glasses or magnifying lenses.

PPE may include:

- gloves;
- eye protection;

Box 2. Personal protective equipment (PPE) consistent with standard and transmission-based precautions in the endoscopy unit*

PPE consistent with standard precautions:†

- non-sterile single-use disposable gloves
- protective facewear (wraparound glasses or preferably single-use disposable/regularly cleaned reusable face shield)
- single-use disposable or reusable impervious long-sleeved gown, or reusable non-impervious gown with disposable plastic apron and arm sleeves, with hand wash in between procedures **or** single-use apron with arms bare below the elbow, with hand and forearm wash in between procedures‡

PPE consistent with standard plus contact and droplet precautions:

- fluid-resistant surgical mask
- non-sterile single-use disposable gloves
- protective facewear (wraparound glasses or preferably single-use disposable/regularly cleaned reusable face shield)
- impervious long-sleeved disposable gown (± single-use apron)

PPE consistent with standard plus contact and airborne precautions:

- fluid-resistant PFR (P2 or N95) respirator mask or PAPR if PFR mask is not available§
- non-sterile single-use disposable gloves
- protective facewear (wraparound glasses or preferably single-use disposable/regularly cleaned reusable face shield)
- impervious long-sleeved disposable gown
- masks; and
- protective clothing.

PPE must be:

- changed between patients, tasks or procedures or when visibly contaminated;
- worn by health care workers when performing endoscopic procedures or reprocessing used endoscopes, associated accessories, instruments and equipment;
- used in any clinical situation where exposure to blood or body fluids is anticipated;
- used when handling and disposing of clinical waste;
- used when aseptic technique is required; and
- worn when undertaking environmental cleaning.

PAPR = powered air purifying respirator; PFR = particulate filter respirator.
* Consideration may be given to also wearing surgical scrubs during endoscopic procedures.
† Note that a surgical mask is not required for standard precautions.
‡ Assuming facility exists for hand and forearm wash in between procedures.
§ Before starting the procedure, PPE should be fit-checked for everyone who will be in the room during the procedure to confirm it is correctly fitted.

The selection and use of eye protection should be in accordance with AS 1336-2014.[90] To assess what eye protection is required, consideration should be made of any risks associated with the task. For instance:

- when handling hazardous substances, where splashing of the concentrated solution may occur, chemical safety goggles should be used if indicated by the manufacturer;
- when handling small quantities of dilute solutions, chemical safety spectacles with side shields may suffice; and
- when reprocessing endoscopes, face shields should be used to protect the wearer from exposure to biological and chemical hazards.

When performing endoscopic procedures, standard and transmission-based precautions mandate the use of PPE as noted in Box 2. Biological contamination of the proceduralist during endoscopic procedures has been reported and demonstrates the need for full face protection.[91]

As the reprocessing area is a contaminated area, staff should wear appropriate PPE, non-essential personnel should be excluded, and food or drinks should not be stored or consumed in this area.

5.1.3 Patient placement and movement within the organisation and endoscopy service

It is important to consider the maintenance of transmission-based precautions for all patient movements and transfers within the health service organisation, including to and from the endoscopy unit. Key factors in the success of this are communicating the precautions required at each handover of care or responsibility and documenting in the clinical record what is required to maintain a safe environment for patients and the workforce.

5.1.4 Multidosing of injectate

Outbreaks of blood-borne virus infections in endoscopy have largely been linked to breaches of protocol involving the use of multiple-dose vials or solution containers related to anaesthetic practices. When using injectate for tissue elevation obtained by multidosing from a single source, it is vital that the critical procedures for preventing transmission are followed. Aseptic technique is mandated. A single bag of injectate (e.g. gel) may be prepared with a colour dye and/or adrenaline and used as the source for multiple individual syringes of injectate. It is essential that the injectate bag is labelled with additives and the contents signed off by two staff members. The bag should be appropriately disposed of at the end of the day. The syringes should be labelled and are for single patient use. Devices approved for multiple access (needleless system) must be used to maintain sterility of injectate. Optimally, multidosing from a single source should be avoided, and a single-use pre-prepared syringe of proprietary injectate should be used.

5.2 Transmission-based precautions

In addition to standard precautions, transmission-based precautions are applied to patients suspected or confirmed to be colonised or infected with agents transmitted by contact, droplet or airborne routes (Box 3).

5.2.1 Contact precautions

Contact precautions are implemented in the presence of known or suspected infectious agents that are spread by direct or indirect contact with the patient or the patient's environment. Poor hand hygiene is most often cited as a cause of contact transmission.

Direct contact transmission:

- involves body-surface to body-surface contact and physical transfer of microorganisms between a susceptible person (host) and an infected or colonised person; and
- more often occurs between a health care worker and a patient than between patients.

Indirect contact transmission:

- involves contact of a susceptible person (host) with a contaminated intermediate object, such as needles, dressings, gloves or contaminated (unwashed) hands.

Disease is more likely to develop after direct or indirect contact transmission when the pathogen is highly virulent or has a low infectious dose or the patient or health care worker is immunocompromised.

In the endoscopy setting, transmission by contact, droplet or airborne routes may particularly apply to infectious agents such as multiresistant organisms, VRE, *Shigella* species, *C. difficile*, norovirus, influenza, severe acute respiratory syndrome coronavirus (SARS-CoV-2) and *M. tuberculosis* (Table 3). Common multiresistant organisms in Australia and New Zealand include multiresistant *S. aureus*, ESBL-producing gram-negative bacilli, CPO and VRE. Ideally, patients who are highly infectious should have endoscopy delayed until their infectivity is reduced. However, if endoscopy is deemed urgent, additional appropriate transmission-based precautions should be used by staff who have direct contact with these patients.

5.2.2 Droplet precautions

Droplet precautions are implemented for patients who are known or suspected to be infected with a microorganism transmitted by droplets (large particles >5 µm in size) that are generated by a patient when coughing, sneezing, talking or during procedures involving the respiratory tract (e.g. suctioning or bronchoscopy). These droplets are propelled a short distance (<1 m) through the air and may settle on environmental surfaces or deposit directly on the nasal or oral mucosa of the new host. Examples of infections caused by droplet transmission include mumps,

Box 3. Standard and transmission-based precautions: definitions and examples

Standard precautions

These apply to all patients and include the use of PPE as appropriate or when indicated, based on the risk of contact with, or splash and splatter by, blood and body fluids. This means PPE does not need to be used for all patients, but only when a risk is identified. The PPE chosen should be consistent with the risk (e.g. gloves ± a gown for direct contact; gown, face and eye protection with face shield or goggles and mask for splash).

Transmission-based precautions*

Contact precautions

If contact precautions are applied to a specific patient or procedure when a risk is identified, PPE is required (not chosen) to be used by all HCWs providing care to that patient, every time. Contact precautions are applied when it has been determined, based on risk, that standard precautions may not control the transmission of the infectious agent that is known or suspected to be involved. This means that standard precautions apply, **plus** the addition of wearing gloves and a disposable impervious gown or apron.

Droplet precautions

If droplet precautions are applied to a specific patient or procedure, PPE is required (not chosen) to be used by all HCWs providing care to that patient, every time. Droplet precautions are applied when it has been determined, based on risk, that standard precautions may not control the transmission of the infectious agent that is known or suspected to be involved or during the procedure being performed. This means that standard precautions apply, **plus** the addition of wearing a surgical mask and protective eye wear.

Airborne precautions

If airborne precautions are applied to a specific patient or procedure, PPE is required (not chosen) to be used by all HCWs providing care to that patient, every time. Airborne precautions are applied when it has been determined, based on risk, that standard precautions may not control the transmission of the infectious agent that is known or suspected to be involved or during the procedure being performed. This means that standard precautions apply, **plus** the addition of wearing a particulate filter respirator, such as a P2 or N95 respirator (mask), and protective eye wear.

HCW = health care worker; PPE = personal protective equipment.
* Transmission-based precautions is a collective term incorporating contact, droplet and airborne precautions.

rubella, pertussis, influenza, norovirus (if the patient is vomiting) and SARS-CoV-2. Surgical masks must be worn when within 1 m of the patient.

5.2.3 Airborne precautions

Airborne precautions are implemented in the presence of known or suspected infectious agents that are transmitted from person to person by airborne droplet nuclei (small particle residue <5 µm). The droplets contain microorganisms that remain suspended in the air and can be dispersed widely by air currents within a room or over long distances.

When airborne precautions are needed for relevant infectious agents (e.g. measles, varicella zoster, SARS-CoV-2, tuberculosis – **possible, suspected or proven**), a room with negative-pressure ventilation with at least 12 air changes per hour, if available, should be used for the procedure and recovery.[93] All staff in the room should wear a close-fitting particulate filter respirator (PFR), such as a P2 or N95 respirator mask, during the procedure and for about 20 minutes (based on air changes per hour) after the patient has left the room. Staff should have received instruction and training in the use of these respirator masks and have undergone fit testing.

Table 3. Examples of organisms for which a combination of precautions is required*

Organism	Type of organism	Mode of transmission	Required precautions	Duration of precautions
Clostridioides difficile	Bacterial	Contact	S + C	Duration of illness/colonisation
Carbapenemase-producing organisms	Bacterial	Contact	S + C	Duration of illness/colonisation
Vancomycin-resistant enterococci	Bacterial	Contact	S + C	Duration of illness/colonisation
Varicella zoster	Viral (enveloped)	Airborne droplets; direct contact with fluid in blisters or nasopharyngeal secretions	S + C + A	Until all lesions are dry and crusted over
Herpes zoster	Viral (enveloped)	Direct contact with fluid in blisters	S + C	Duration of illness (if there are wound lesions, until wounds cease draining, are dry and crusted)
Influenza	Viral (enveloped)	Droplet; contact (both direct and indirect)	S + C + D	Until more than 72 hours after the patient receives anti-influenza medication; or until 5 days have elapsed since onset of respiratory symptoms (may be longer for young children or immunosuppressed or ICU patients)
Norovirus	Viral (non-enveloped)	Contact; droplet (in certain circumstances)	S + C (+ D if determined to be necessary by risk assessment)	For a minimum of 48 hours after the resolution of symptoms or to control institutional outbreaks
Respiratory syncytial virus	Viral (enveloped)	Contact; droplet	S + C + D	Duration of illness
Severe acute respiratory syndrome coronavirus	Viral (enveloped)	Contact; droplet; airborne	S + C + D + A	Duration of illness + 10 days after resolution of fever, provided respiratory symptoms are absent or abating
Mycobacterium tuberculosis	Bacterial	Airborne	S + A	Usually until after 1 week of treatment and three sputum smears test negative; consult with respiratory physician

A = airborne precautions; C = contact precautions; D = droplet precautions; ICU = intensive care unit; S = standard precautions.
* Adapted from the National Health and Medical Research Council *Australian guidelines for the prevention and control of infection in healthcare*.[92]

It is important to note that patients with possible tuberculosis should not routinely undergo bronchoscopy, although this may be required for diagnosis in patients with negative sputum smear results. Therapeutic bronchoscopic interventions, such as ablative procedures (both heat and cold therapies), balloon dilatation and airway stenting, are now being used in the management of tuberculosis-related stenosis. These bronchoscopic procedures are less invasive therapeutic strategies than conventional surgery in the treatment of endobronchial tuberculosis and its complications.[94]

5.2.4 Managing patients in an endoscopy unit with transmission-based precautions

The general requirements for managing patients in an endoscopy unit where transmission-based precautions are required are as follows:

- Standard signage should be used to inform endoscopy staff how to minimise risk of transmission, keeping in mind that, for some infectious agents, a combination of precautions may be required (Table 3).
- The appropriate PPE for different transmission precautions should be used, such as wearing of gloves, fluid-resistant aprons or gowns (Box 2).
- Appropriate hand hygiene technique is important; for example, if *C. difficile* infection is suspected or confirmed, hand hygiene is performed using soap and water (alcohol rubs must not be used).
- Protocols for placement of patients on procedure lists should be followed.
- During recovery, patients should also be provided with a surgical mask if they cannot be recovered in a negative-pressure room.
- Environmental cleaning of the room should be performed after a patient with a high-risk microorganism has undergone endoscopy.

It is essential to note that the appropriate level of precautions required during endoscopic procedures can change. As highlighted during the COVID-19 pandemic, the level of precautions may need to be upgraded in response to specific transmission risks to patients and endoscopy unit staff. GESA published detailed guidance advising on the appropriate level of precautions, and therefore PPE, to be used at different stages of the pandemic.[95]

5.3 Elective endoscopic procedures in patients with recent SARS-CoV-2 infection *(new in 2025)*

SARS-CoV-2 infection remains prevalent in Australia and New Zealand.[96,97] However, with widespread adoption of vaccination, the availability of oral antiviral treatment and evolution of SARS-CoV-2 variants, the overall morbidity and mortality associated with SARS-CoV-2 infection have significantly reduced. Most patients diagnosed with new SARS-CoV-2 infection now have minimal to no symptoms. The World Health Organization declared an end to the COVID-19 global health emergency in May 2023,[98] and mandatory isolation periods for patients diagnosed with SARS-CoV-2 infection were lifted in both Australia and New Zealand.

Since the pandemic began in 2020, various SARS-CoV-2 variants have emerged. The Omicron variant was first identified in November 2021 and went on to become the dominant SARS-CoV-2 variant in most countries. The Omicron variants are more transmissible than previous variants.[99] However, the risk of severe disease or death from Omicron infection is much lower than from previous variants.[100,101]

Following a new SARS-CoV-2 infection, the respiratory tract viral load rises rapidly over a few days, before falling sharply at about 1 week. Compared with previous variants, the greatest likelihood of infectious viral shedding from an Omicron variant occurs slightly later, with more infectious days. People with SARS-CoV-2 infection can be contagious for 1–2 days before diagnosis and up to 8–10 days after infection.[102-104] The decision regarding the safety and timing of an elective endoscopic procedure on a patient with recent SARS-CoV-2 infection needs to be based on two factors: procedure-related risk to the patient and risk of transmission to health care workers.

5.3.1 Periprocedural risks in patients with recent SARS-CoV-2 infection

Clinical studies early in the pandemic suggested increased morbidity and mortality in patients undergoing major surgery after a recent SARS-CoV-2 infection.[105-107] However, these studies were performed before widespread adoption of vaccination and when infections were often caused by non-Omicron variants. Therefore, extrapolation of these older studies to contemporary clinical practice requires caution.

DROMIS-22 was a large French multicentre prospective observational study conducted between 15 March and 30 May 2022 (when Omicron was predominant), which assessed postsurgical respiratory morbidity in patients with and without recent SARS-CoV-2 infection.[108] Of the 4928 patients included, 4388 (92.4% of those with available data) were vaccinated. There was no increased risk of respiratory morbidity or 30-day mortality in patients who had SARS-CoV-2 infection within either 3 weeks or 8 weeks before surgery, compared with patients without recent infection. The OpenSAFELY study assessed surgical outcomes in the English National Health Service from March 2018 to March 2022, encompassing pre-COVID-19, early COVID-19 and post-vaccination COVID-19 eras.[109] In patients undergoing surgery within 2 weeks of SARS-CoV-2 infection, the study showed significantly lower mortality in the post-vaccination era, compared with during the early COVID-19 pandemic, when widespread vaccination was not available. Notably, endoscopy procedures were excluded from both these studies.

The American Society of Anesthesiologists updated its guidance in June 2023, recommending that low-risk patients undergoing low-risk surgery may be eligible for scheduling within 2–7 weeks after SARS-CoV-2 infection.[110] Similarly, the Australian and New Zealand College of Anaesthetists suggested in its 2023 guidelines that, for most patients, it is safe to proceed with surgery 2–3 weeks after SARS-CoV-2 infection, provided no ongoing symptoms are present.[111]

We did not find any high-quality evidence specifically assessing morbidity and mortality associated with endoscopic procedures in patients with recent SARS-CoV-2 infection because endoscopic procedures were excluded from major cohort studies. Overall, in the vaccination era, and with evolution of low-virulence Omicron strains, perioperative morbidity and mortality are much lower than were estimated early in the COVID-19 pandemic. The peak transmissibility of Omicron variants appears to be in the first few days after infection; however, a small proportion of patients will remain contagious up to 10 days after infection.

5.3.2 Timing of elective endoscopy in patients with recent SARS-CoV-2 infection

Recommendations for timing of endoscopic procedures (Box 4) vary depending on the severity of the disease (Table 4).[112] Elective endoscopic procedures should be delayed until the patient is no longer infectious and has demonstrated complete recovery from SARS-CoV-2 infection.

Box 4. Timing of endoscopic procedures in patients with recent SARS-CoV-2 infection

For patients with mild illness:

- A patient whose symptoms have completely resolved can proceed to an elective endoscopic procedure 10 days after SARS-CoV-2 infection.
- A patient who remains symptomatic at Day 10 after SARS-CoV-2 infection should have the elective endoscopy procedure deferred until 5 days after resolution of symptoms.

For patients with moderate or more severe illness:

- A patient whose symptoms have completely resolved can proceed to an elective endoscopic procedure 4 weeks after SARS-CoV-2 infection
- A patient with ongoing symptoms 4 weeks after SARS-CoV-2 infection requires medical review before being scheduled for an elective endoscopic procedure

SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Table 4. Severity of COVID-19 in adults*

Severity of disease	Definition
Mild illness	An individual with no clinical features suggestive of moderate or more severe disease: • no OR mild symptoms and signs (fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhoea, loss of taste and smell) • no new shortness of breath or difficulty breathing on exertion • no evidence of lower respiratory tract disease during clinical assessment or on imaging (if performed)

Moderate illness	A stable patient with evidence of lower respiratory tract disease:
	• during clinical assessment, such as:
	  • oxygen saturation 92%–94% on room air at rest
	  • desaturation or breathlessness with mild exertion
	• or on imaging

Severe illness	A patient with signs of moderate disease who is deteriorating, OR A patient meeting any of the following criteria: • respiratory rate ≥30 breaths/min • oxygen saturation <92% on room air at rest or requiring oxygen • lung infiltrates >50%

Critical illness	A patient meeting any of the following criteria:
	• respiratory failure, defined as any of:
	  • severe respiratory failure (PaO2/FiO2 <200)
	  • respiratory distress or acute respiratory distress syndrome
	  • deteriorating despite non-invasive forms of respiratory support (i.e. non-invasive ventilation, or high-flow nasal oxygen)
	  • requiring mechanical ventilation
	• hypotension or shock
	• impairment of consciousness
	• other organ failure

FiO2 = fraction of inspired oxygen; PaO2 = partial pressure of oxygen in the arterial blood.

* Reproduced from: National Clinical Evidence Taskforce. Definition of disease severity. In: *Australian guidelines for the clinical care of people with COVID-19*, version 72, 2023.[112]

These recommendations must be individualised and do not obviate the need for appropriate clinical judgement. Any public health orders in the relevant jurisdiction will supersede the advice provided here. These recommendations provide guidance on planning of elective endoscopic procedures only. Any patient requiring an urgent endoscopic procedure should proceed based on clinical judgement, with attention given to local infection prevention and control policies.

Chapter 6: Recommendations for antibiotic prophylaxis to reduce risk of infection related to endoscopy

6.1 Infective endocarditis prophylaxis

All the major published guidelines now recommend that patients undergoing gastrointestinal endoscopic procedures should not be given antibiotics solely to prevent infective endocarditis, even in people with high-risk cardiac lesions. The AHA, NICE, ASGE and BSG had previously recommended prophylactic antibiotics for patients with high-risk cardiac lesions undergoing procedures with a high to moderate likelihood of causing bacteraemia. It is important to note that the changes are not the result of new data but are a reinterpretation of the existing evidence, with greater emphasis on recommendations that are based on direct evidence.

The new recommendations against the use of prophylactic antibiotics are based on the following rationale:[4,113-115]

- Reports of cases of infective endocarditis associated with gastrointestinal procedures are anecdotal.
- No data have shown a conclusive link between gastrointestinal procedures and the development of infective endocarditis. The single published case–control study did not show a statistically significant link between prior gastrointestinal endoscopy and infective endocarditis.[14]
- Bacteraemia is more commonly detected after daily activities such as tooth brushing than after endoscopy.
- There are no data showing that antibiotic prophylaxis prevents infective endocarditis after gastrointestinal endoscopic procedures.
- There are reports of infective endocarditis occurring despite antibiotic prophylaxis.
- Only an extremely small number of cases of infective endocarditis may be prevented, even if antibiotic prophylaxis were 100% effective.
- There is a risk of anaphylaxis due to antibiotics and a risk of *C. difficile* infection.
- Even if antibiotics prevent some cases of infective endocarditis, this intervention may not be cost-effective.

The arguments in favour of using antibiotics for infective endocarditis prophylaxis in high-risk individuals are:

- Endocarditis usually follows bacteraemia, which is well documented to occur after gastrointestinal endoscopic procedures.
- There are case reports of infective endocarditis after gastrointestinal endoscopic procedures.
- Although rare, infective endocarditis can be a catastrophic event when it does occur.
- Individuals with underlying cardiac risk factors for infective endocarditis can usually be identified.
- The relevant bacteria are usually sensitive to antibiotics.
- Antibiotics have been shown to reduce bacteraemia rates after endoscopy; a randomised study showed bacteraemia in 0/132 patients given antibiotics compared with 13/132 controls.
- There is some evidence that antibiotic administration during dental or surgical procedures reduces the risk of endocarditis.[116] In a rabbit model, antibiotic prophylaxis reduced the risk of infection in damaged valves after high bacterial challenge. A retrospective case–control study of patients at risk suggested that antibiotic prophylaxis reduced the rate of infective endocarditis in dental practice.
- The risk of serious side effects of antibiotics is small (e.g. the incidence of penicillin-related anaphylaxis is about 1/5000).
- It is recommended that clinicians refer to the Australian Therapeutic Guidelines for advice on antibiotic use in patients with particular medical conditions.[117,118]

6.2 Antibiotic prophylaxis for endoscopic retrograde cholangiopancreatography

The aim of administering prophylactic antibiotics before ERCP is to prevent infection becoming established in the bile duct at the time of the procedure, thus preventing systemic infection. The antibiotic must be present in therapeutic levels in the bile duct during the ERCP. The 2018 Tokyo Guidelines provide recommendations for antibiotic treatment of cholangitis, and these can be extrapolated to antimicrobial prophylaxis for ERCP.[119] Optimal treatment may vary between institutions, and choice of an appropriate antibiotic should be guided by the Australian Therapeutic Guidelines, local patterns of antibiotic resistance and patient factors that increase the risk of multidrug-resistant organisms: previous biliary interventions, the presence of a biliary stent and a recent history of courses of broad-spectrum antibiotics.

6.3 Antibiotic prophylaxis for endoscopic ultrasound-guided fine needle aspiration

Antibiotic prophylaxis is not recommended for EUS-FNA of solid lesions but is suggested for cystic lesions.[12] Current practice remains to minimise the risk of infecting a cyst by performing one needle pass, achieving complete drainage and administering antibiotics during and/or after the procedure. Interestingly, a recent multicentre prospective, randomised study suggested that antibiotic prophylaxis is not required for EUS-FNA of pancreatic cystic lesions.[120] However, further data are needed regarding the risks and benefits of prophylactic antibiotics in this setting.

6.4 Antibiotics used in prophylaxis

Recommendations for antibiotic prophylaxis in various clinical scenarios are given in Table 5.

6.4.1 Ampicillin and amoxycillin

Ampicillin and amoxycillin are effective against gram-positive bacteria, including streptococci and enterococci, which cause most cases of infective endocarditis. These agents are the first choice when antibiotics are used for infective endocarditis prophylaxis.

6.4.2 Aminoglycosides

Aminoglycosides, such as gentamicin, increase the bactericidal activity of ampicillin or amoxycillin against streptococci and enterococci. Aminoglycosides are active against most gram-negative organisms, including most *Pseudomonas* species. Although the risk of nephrotoxicity or ototoxicity is negligible with only one or two doses, care must be taken when using aminoglycosides for patients with a history of pre-existing renal impairment. Nephrotoxicity is dose-dependent and usually reversible. Increasingly, however, there is concern about aminoglycoside-induced ototoxicity. Unlike nephrotoxicity, ototoxicity is permanent and irreversible and may occur when gentamicin blood levels are within the therapeutic range.[121]

6.4.3 Quinolones

Ciprofloxacin has good activity against aerobic gram-negative bacteria and is therefore widely used for preventing cholangitis in patients undergoing ERCP. Oral ciprofloxacin is recommended when it can be taken because it is as effective as, but cheaper than, the intravenous preparation. It is much less active against gram-positive species, including enterococci, and is therefore not suitable for prevention of endocarditis.

6.4.4 Glycopeptides

Glycopeptides, such as vancomycin or teicoplanin, have a broad spectrum of activity against gram-positive bacteria. Their major role is to cover streptococcal and enterococcal infection in patients with recent exposure to penicillin, ampicillin or amoxycillin and in individuals who are allergic to penicillins. Teicoplanin has the advantage over vancomycin of being simpler and faster to administer, as well as maintaining more sustained blood levels after a single dose. VRE are also being encountered with increasing frequency in some hospitals.

6.4.5 Other beta-lactam agents

Cephalosporins have no activity against enterococci, but third-generation cephalosporins, such as ceftriaxone, do have a broad spectrum of activity against gram-negative organisms. Ureidopenicillins, such as piperacillin, are also broad-spectrum agents but have limited activity against most strains of staphylococci. Like cephalosporins, they may provoke *C. difficile* infection.

Table 5. Recommendations for antibiotic prophylaxis

Scenario for prophylaxis	Rationale	Recommendation	Antibiotic options*
Patient with high-risk cardiac lesion undergoing endoscopic procedure with high risk of bacteraemia (see section 1.1.4)	Infective endocarditis prophylaxis	Not routinely recommended	
		Reasonable to consider antibiotics for individual patients after weighing risks and benefits	Ampicillin or vancomycin or teicoplanin if allergic to penicillin
Clinical infection in or adjacent to region of endoscopy (e.g. patient with diverticulitis undergoing colonoscopy, or with cholangitis undergoing ERCP)	Prevention of procedure-related bacteraemia	Recommended	Appropriate antibiotics to cover common organisms (see text and Australian Therapeutic Guidelines)
	Treatment of infection	Recommended	Ampicillin or vancomycin or teicoplanin if allergic to penicillin
	Prophylaxis of infective endocarditis where high-risk cardiac factors coexist	Recommended	
Patient receiving peritoneal dialysis undergoing colonoscopy	Prevention of potential translocation of colonic bacteria resulting in peritonitis[122]	Recommended	Ampicillin 1 g IV and gentamicin 3 mg/kg IV 30 min before colonoscopy
PEG tube placement	Prevention of peristomal infection	Recommended	Cephazolin 2 g IV 30 min before procedure or amoxycillin–clavulanic acid 1.2 g IV before procedure High risk of MRSA: add vancomycin 15 mg/kg IV
ERCP with removal of stones or straightforward stent placement	Prevention of cholangitis	Not recommended	
ERCP with predicted unresolved obstruction†	Prevention of cholangitis	Recommended	First-line: ceftriaxone 2 g or piperacillin–tazobactam 4.5 g (single dose) Second-line: oral ciprofloxacin or gentamicin 2 mg/kg IV
ERCP with biliary tract obstruction involving the hilum or sclerosing cholangitis†	Prevention of cholangitis	Recommended	First-line: ceftriaxone 2 g or piperacillin–tazobactam 4.5 g (single dose) Second-line: oral ciprofloxacin or gentamicin 2 mg/kg IV
ERCP in setting of pancreatic necrosis, pseudocysts or cysts with connection to pancreatic duct†	Prevention of cholangitis	Recommended	First-line: ceftriaxone 2 g or piperacillin–tazobactam 4.5 g (single dose) Second-line: oral ciprofloxacin or gentamicin 2 mg/kg IV

Table 5. Recommendations for antibiotic prophylaxis (continued)

Scenario for prophylaxis	Rationale	Recommendation	Antibiotic options*
EUS-FNA of solid lesion	Prevention of local infection	Not recommended	
EUS-FNA of cystic lesion	Prevention of cyst infection	Recommended	First-line: metronidazole 500 mg (child: 12.5 mg/kg up to 500 mg) IV within 120 min before procedure *and* cephazolin 2 g (child: 30 mg/kg up to 2 g) IV within 60 min before procedure (intraoperative redosing may be required) *or* gentamicin 2 mg/kg (adult and child) IV over 3–5 min within 120 min before procedure
EBUS-TBNA of cystic lesion or necrotic nodes	Prevention of cyst infection	Recommended	Amoxycillin–clavulanic acid 875 mg/125 mg orally twice daily
Bronchoscopy with endobronchial valve insertion	Prevention of chest infection	Recommended	Amoxycillin–clavulanic acid 875 mg/125 mg orally twice daily
Severe immunosuppression (neutrophil count $<0.5 \times 10^9$/L) and high-risk procedure (see section 1.1.1)	Prevention of bacterial sepsis	Recommended	Ceftriaxone 2 g or piperacillin–tazobactam 4.5 g (single dose)
Patient with cirrhosis and upper gastrointestinal bleeding	Prevention of infections such as bacterial peritonitis	Recommended	Ceftriaxone 1 g IV or gentamicin 2 mg/kg IV given immediately before procedure (discuss with hepatologist and/or infectious disease physician)
Patients with vascular grafts and other non-valvular cardiovascular devices	Prevention of graft infection	Not recommended	
Joint prosthesis	Prevention of infection of joint prosthesis	Not recommended	
		Some clinicians recommend antibiotic prophylaxis within 6 months of placement prosthesis of; it is reasonable to consider antibiotics in individual patients after weighing risks and benefits	

EBUS-TBNA = endobronchial ultrasound-guided transbronchial needle aspiration; ERCP = endoscopic retrograde cholangiopancreatography; EUS = endoscopic ultrasound; FNA = fine needle aspiration; IV = intravenously; MRSA = methicillin-resistant *Staphylococcus aureus*; PEG = percutaneous endoscopic gastrostomy.

* Alternative antibiotics may be appropriate. Refer to Australian Therapeutic Guidelines.[117,118]

† Antibiotic selection should be influenced by whether the indication for the ERCP is a condition acquired in the community or in a health care setting and should take into account the local epidemiology of multidrug-resistant organisms.

Chapter 7: Prevention of endoscope contamination by environmental pathogens

7.1 Water

Water quality (see also section 10.9, and section 7.2 on biofilm) is a whole-of-hospital issue and not simply an endoscopy unit problem.[123-129] A water risk management plan should be in place to guide decision making when water quality does not meet requirements, as well as to specify when and what routine hospital-wide water testing is required.

The endoscopy unit must ensure that water delivered to the unit is of acceptable quality. Endoscopy unit water management efforts can become an expensive and ineffective waste of time if wider problems are not resolved. Many individual systems have been used; these include removal of biofilm using oxidising agents, and line and filter sterilisation using physical agents such as hot water, chemicals such as chlorine-releasing agents and high-level disinfectants, reverse membrane osmosis and ultraviolet irradiation systems.[130] The chosen method must be compatible with the filters and AFER(s) in use. Choosing and maintaining a local system must be a multidisciplinary approach, with involvement of hospital engineers, AFER manufacturer representatives, water treatment specialists, filter manufacturers, clinical microbiologists, infection prevention and control officers, and endoscopy reprocessing personnel.[131-133]

No system is foolproof, and water quality delivered to the AFER should be evaluated and appropriate water treatment systems installed and maintained to provide water of the requisite quality for endoscope reprocessing. If cultures taken from the machine outlet test positive, culturing of the water supply to the AFER may be required.

7.1.1 Quality of water supply to AFERs and for manual cleaning

To ensure the water used to clean and rinse endoscopes is of sufficient quality, as per AS 5369:2023,[86] the specifications given in Table 6 should be met. The AFER manufacturer should advise the user of any water treatment required to ensure that the quality of the water meets these requirements and/or those of the AFER manufacturer.

Potable water is used for manual cleaning and rinsing before disinfection; it is not required to be bacteria-free.

7.1.2 Quality of water used for post-disinfection rinsing

The final rinse water for all AFERs should be bacteria-free, in addition to meeting the requirements listed in Table 7, as per the recommendations in AS 5369:2023.[86] Monthly microbiological testing of AFER post-disinfection rinse water has long been recommended in IPCE publications. Sampling of rinse water after disinfection, as described, will evaluate the entire fluid pathway from supply to the AFER (which includes the internal filtration) to the final rinse of the endoscope (see section 10.8.4 for interpretation of results).

Table 6. Water quality for pre-cleaning, cleaning and rinsing (before disinfection)

Substance or parameter	Specification	Frequency of testing*
Water hardness	<150 mg/L	Monthly
Chloride	<120 mg/L	Monthly

* This testing is likely to be routinely performed by the health service organisation maintenance staff.

Table 7. Water quality for automated flexible endoscope reprocessor final rinse water

Substance	Specification	Frequency
Chemical purity	As per manufacturer's instructions	Manufacturer's instructions only
Total viable count	≤10 CFU/100 mL	Monthly
Pseudomonas aeruginosa and atypical *Mycobacterium* species	Nil detected/100 mL	Monthly
Endotoxin	≤30 EU/mL	Annually

7.2 Biofilm

Prevention of biofilm is the key to infection control. Biofilm and the presence of organic debris significantly reduce the activity of disinfectants and may compromise their effectiveness. Cleaning endoscopes immediately after use to remove organic debris and prevent the maturation of any biofilm is recommended.[134]

There has been a focus on duodenoscope contamination over recent years, as a result of outbreaks of endoscope-related transmission of multiresistant organisms like CPE. It is accepted that the complex tips of duodenoscopes and linear echoendoscopes are a source of transmission of CPE because of inherent difficulties in achieving adequate removal of biological material.[26,135-144] Other endoscopes without complex tips have also been linked to patient-to-patient transmission of CPE.[142,145-148] In one study, six of 10 screened patients were colonised with carbapenemase-producing *K. pneumoniae*, and two developed clinical infections after undergoing gastroscopies using a colonised instrument.[145] Viable microorganisms were recovered from 64% of endoscopic instruments after HLD in a series published in 2015.[149] In another study, bacteria were detected in nine of 15 patient-ready endoscopic instruments (60%): two gastroscopes, three colonoscopes and four bronchoscopes.[150] An interim report from the US FDA in April 2019 on the clinical studies undertaken by the three main endoscope manufacturers stated that 5.4% of patient-ready duodenoscopes remained culture-positive for high-concern organisms.[151] Therefore, mechanisms of bacterial retention and subsequent mobilisation must have been present. Routine microbiological testing has not identified evidence of this problem in Australia.

A major factor contributing to the contamination of flexible endoscope channels is the formation of both traditional biofilm and build-up biofilm. Traditional biofilm forms during continuous hydration. Build-up biofilm forms over repeated cycles of exposure to fluids and dry storage and encompasses aspects of traditional biofilm formation in addition to partial fixation and non-sterile storage. Build-up biofilm is more compact and adherent than traditional biofilm and develops gradually over successive cycles of reprocessing. Build-up biofilm may contain viable but non-culturable bacteria, which can "rebound" under wet storage conditions.[56]

Published studies have reported conflicting results on the adequacy of endoscope reprocessing, with some reporting zero or low levels of detectable bacteria after disinfection or sterilisation, and others reporting 35%–60% of endoscopes growing organisms of concern.[152] Existing protocols predominantly target planktonic organisms. However, there is increased emphasis on targeting biofilm that develops in endoscope channels and may harbour bacteria. Biofilm represents a major challenge to endoscope reprocessing, as it is difficult to detect, monitor and remove. In addition to meticulous channel flushing and cleaning, it is increasingly appreciated that adequate instrument and, in particular, channel drying is essential to prevent its formation. Viable microorganisms in endoscope channel biofilm can survive reprocessing.[153] A build-up biofilm model that mimics the cumulative effect of reprocessing protocols on flexible endoscopes has been developed.[154] Effectiveness of HLD may decrease if build-up biofilm develops within instrument channels, as it is associated with the survival of a wide range of microorganisms.

In a more recent study using an *E. coli* and *P. aeruginosa* biofilm model, it was reported that if biofilm accumulates within endoscope channels during repeated reprocessing, neither the detergent nor high-level disinfectant will provide the expected level of bacterial removal.[155] This was supported by a recent study in which biofilm was detected by confocal laser scanning and scanning electron microscopy in all 39 endoscope channels examined after HLD.[52] As yet, there is no practical technique available to assess for the presence of biofilm in endoscope channels. Borescopes are narrow-calibre, non-lumened endoscopes used for the inspection of endoscope channels. They are expensive, of unproven accuracy in the detection of biofilm and not widely available, although their use is under ongoing investigation. In a series published in 2018, the channels of 59 endoscopes were inspected using a borescope.[156] No biofilm was identified, but channel scratches were seen in 86% of inspections, with shredding in 59% and debris in 23%. No intrachannel moisture was seen in the 74 inspections of instruments that had been forced-air dried and stored vertically overnight, compared with moisture being present in five of 18 inspections (28%) after storage alone.

Adenosine triphosphate (ATP) testing is effective in identifying residual organic material and improving quality of manual cleaning of endoscopes, including those with an elevator mechanism.[157] However, ATP assays are insufficiently sensitive or specific for the assessment of instrument HLD adequacy.[158]

7.3 Ventilation

Ventilation of the endoscopy suite is an important consideration for procedure, reprocessing and recovery areas. The endoscopy suite requires appropriate ventilation to minimise staff inhalation of infectious particles. For reprocessing areas, a minimum of 12 air exchanges per hour is required. The time taken to remove droplet particles by number of air changes per hour is shown in Table 8.[159]

Specific recommendations for ventilation have been made for procedure rooms where bronchoscopy is performed.[160,161] The US CDC recommend that bronchoscopy be performed in a high-efficiency particulate air (HEPA)-filtered negative-pressure room.

Table 8. Time required for removal of particles, by air changes per hour

Air changes per hour	Time to remove 99% of particles (min)	Time to remove 99.9% of particles (min)
2	138	207
4	69	104
6	46	69
12	23	35
15	18	28
20	14	21
50	6	8

For the management of infectious hazards and heat production from equipment, ventilation requirements, including airflow, air changes per hour, temperature and humidity, may vary in each of the following areas (refer to the Australasian Health Facility Guidelines[162]):

- endoscopy procedure suite — gastrointestinal
- endoscopy procedure suite — respiratory
- reprocessing — decontamination area
- reprocessing — HLD/sterilising area
- storage areas.

Other useful references are local jurisdictional engineering policies and guidelines for health services, ACORN (Australian College of Perioperative Nurses) Standards, AS 1668.2:2012 *The use of ventilation and air-conditioning in buildings*, the Australian Commission on Safety and Quality in Health Care's guidance on optimising ventilation for infection prevention and control in healthcare settings, and contemporary guidelines relating to COVID-19 or other pandemics.[159,163]

7.4 Design of work environment and contamination protocols

7.4.1 Work areas

Work areas should be carefully planned and organised to ensure staff safety and to protect reprocessed endoscopes from recontamination or damage. In procedural work areas, attention to aseptic technique is used to prevent contamination of accessories

(e.g. in ERCP procedures, items such as catheters, sphincterotomes and balloons are usually contained within sterile drapes placed within a bowl or on another surface). Workflow should move from dirty to clean. Distinct and separate physical segregation of the dirty cleaning areas from the post-reprocessing clean areas is integral in the development of a reprocessing facility to meet the requirements of AS 5369:2023, section 5.6.[86]

In the cleaning area, at least one sink designated for the cleaning of endoscopes is required. Dual-bowl sinks promote efficiency in reprocessing endoscopes. The sink should be well maintained and constructed of a non-porous material (e.g. stainless steel, porcelain or a plastic-bonded material). It must be of sufficient dimensions to adequately contain any coiled endoscope without causing damage to the instrument. Height-adjustable, ergonomically designed sink workstations allow staff to immerse and fully retrieve an endoscope safely from the sink without potential for injury (e.g. by stretching). The sink should be supplied with hot and cold running water. Water may be supplied at a constant temperature via a thermostatic mixing valve.

A volumetric dosing pump for the chemical cleaning agent and an automated flushing system should be located at the sink if endoscopes are being manually cleaned. A leak tester for the specific brand of endoscope should be located adjacent to the sink.

An area within the reprocessing room that is suitable for holding endoscopes after cleaning and while awaiting HLD or sterilisation is required. A separate area is needed for HLD or sterilisation of endoscopes. In the HLD/sterilisation area, planning and maintenance are needed to ensure that the water supply, drainage, electrical points, air supply, computer equipment and connections for the AFER and space to safely access the equipment all meet the equipment supplier's specifications, regulatory requirements and safe practices. Space for cabinet storage of the endoscopes after HLD or sterilisation will also be needed.

For HLD reprocessing of an endoscope, AFERs were mandated in 2016.[27] Pass-through AFERs offer the optimal solution for compliance with the principle of separation of clean and dirty. The use of an automated cleaning process in a validated AFER is also preferred, as an automated process removes the human factor inherent in a manual cleaning process that may negatively affect consistency and compliance. Studies have shown and supported reduced rates of transmission of infection using AFERs compared with manual cleaning or reprocessing.[164]

Manual cleaning of an endoscope is required where the AFER manufacturer's validated cleaning instructions mandate manual cleaning of the device and as the step before reprocessing of an endoscope in an AFER if the system is not approved for a fully automated process. Manual cleaning may also be undertaken before automated cleaning.

Provision of a magnification light in the work area will aid inspection of endoscopes for visual cleanliness and identification of damaged areas (e.g. distal tip lens). Use of a borescope should be considered for inspection of lumens. The utility and practicality of borescope examination of endoscope channels remains under investigation.[156,165-167]

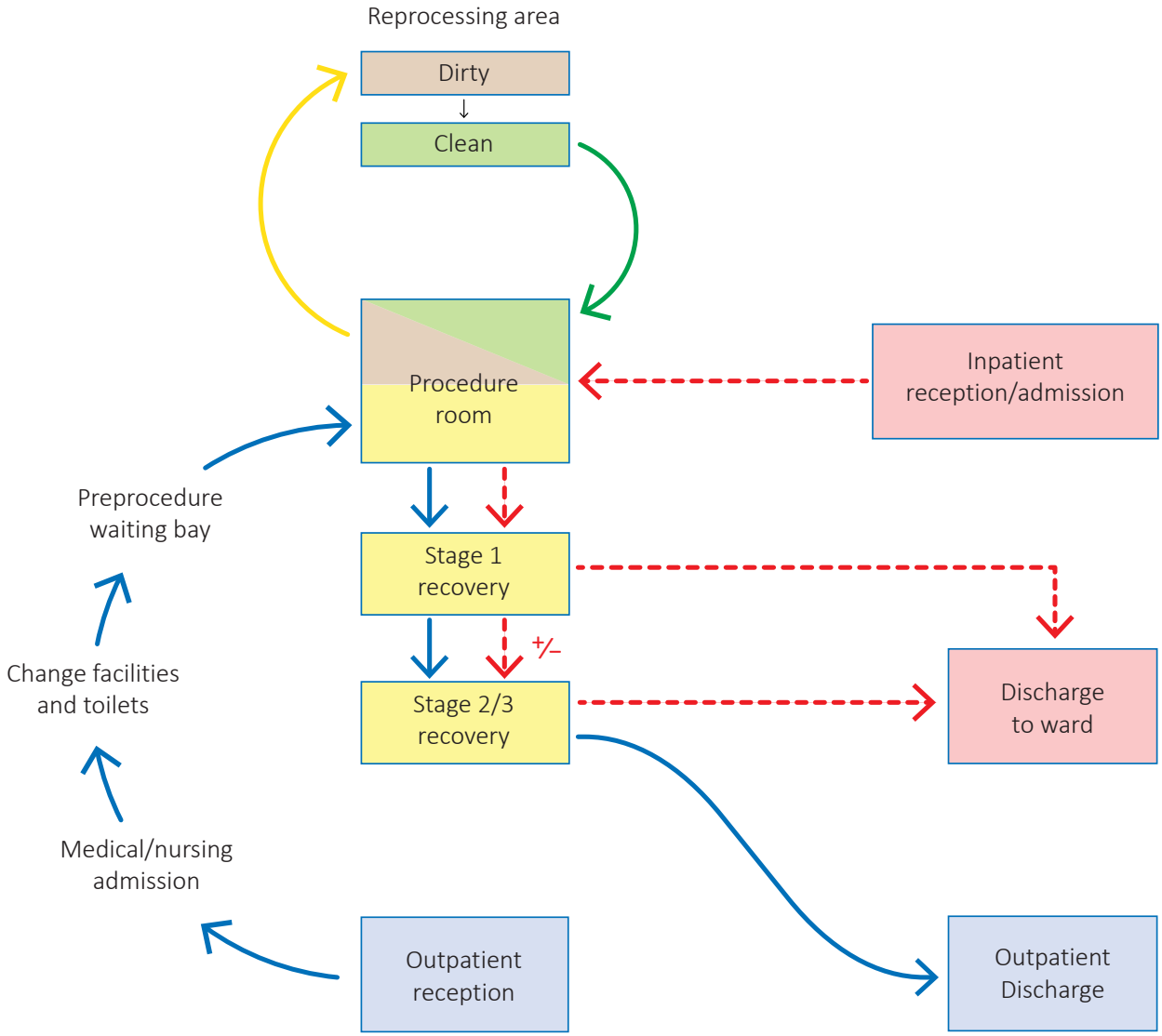
7.4.2 Endoscopy unit design (patient flow)

Endoscopy unit design is influenced by the space available and the structural characteristics of that space. It is essential that endoscopy units are purpose-designed and -constructed. It is optimal that an appropriately sized clear floor area is allocated for the construction of the endoscopy unit, rather than "fitting" it into an existing suboptimal area. The location of an endoscopy unit in a large hospital should be considered in relation to its proximity to the emergency department, operating theatres, intensive care unit, wards and drop-off/pick-up zones.

The specifics of a particular unit's design are outside the scope of this document, but key general principles are as follows:

- There should be unidirectional patient flow from arrival in the unit to discharge, with no or minimal interaction between pre- and post-procedure patients.
- Inpatients should also follow a unidirectional flow, with minimal interaction between inpatients and outpatients.
- Endoscopic instruments and accessories should proceed in a unidirectional flow from clean areas

Figure 3. Patient and endoscopic instrument pathways in an endoscopy unit



to dirty areas, without contact between clean and dirty equipment.

- Pass-through AFER systems facilitate unidirectional flow of dirty to clean in the reprocessing area.
- There should be provision of storage for equipment and consumables within the endoscopy unit to avoid contamination during procedures and reprocessing.

The patient and endoscopic instrument pathways should only intersect in the procedure room (Figure 3).

These unidirectional pathways form the basis for infection control in endoscopy. The successful application of these principles is reliant on the physical characteristics of the endoscopy unit space.

In addition to attending to infection control principles, such patient flow pathways optimise the patient experience, minimising their exposure to confronting or unpleasant interactions (e.g. a well outpatient being exposed to a critically unwell inpatient). At all stages of patient flow, patient confidentiality and modesty should be a priority. Endoscopy unit efficiency and patient safety are enhanced by the Stage 1 recovery area being in close proximity to the procedure rooms. Remote recovery areas limit the ability of proceduralists, anaesthetists and procedural nursing staff to monitor patients after their procedures.

The endoscopic instrument pathway is also central to maintenance of infection control principles. As noted in the consensus statement on CPE, "Endoscopic procedures should only be performed in centres where adequate facilities for safe cleaning and reprocessing are available for appropriately trained staff to reprocess endoscopes".[27] After reprocessing, appropriate instrument storage using a controlled-environment storage technique (CEST) is mandated (see section 8.8). The efficacy of the successful completion of these key steps is negated if unidirectional instrument flow is not adhered to, with the potential for contamination of clean instruments by dirty ones.

Endoscopists and unit managers should refer to the Australasian Health Facility Guidelines for Day Surgery/ Procedure Unit for further guidance on endoscopy unit design.[162]

In addition to these general principles, endoscopy unit design should accommodate several specific risk scenarios:

- A specific inpatient admission and discharge room is optimal to facilitate separation of inpatients and outpatients and provide a space for "isolation" of inpatients with infectious diseases.
- An "isolation" room is also of benefit to isolate infectious patients (e.g. those with tuberculosis) or to ensure separation of immunocompromised patients from the general patient population.
- A negative-pressure room is recommended for the performance of bronchoscopy.[93] It is also optimal for the performance of gastrointestinal endoscopic procedures on patients with airborne infectious diseases. New builds or major redevelopments will be required to comply with current guidelines and standards.

Specific scheduling considerations are relevant to infection control in the endoscopy unit due to the inherent transmission risks associated with endoscopic procedures:

- Procedures on markedly immunosuppressed patients (e.g. cytopenic patients on chemotherapy) should be performed first on the list (immunosuppressed patients should be separated from other patients in pre-procedure and recovery areas).
- Procedures on patients with known communicable infections (e.g. infectious diarrhoea, *C. difficile*, VRE, CPO) should be performed last on the list to facilitate terminal cleaning/disinfection.
- Procedures on patients with possible tuberculosis should be performed last on the list, and preferably at the end of the day, as this will limit the amount of time that the procedure room is not able to be used (patients with tuberculosis should be separated from other patients in pre-procedure and recovery areas).

7.5 Environmental cleaning

As detailed in section 7.4, consideration of infection prevention and control is essential in the design of endoscopy procedure and reprocessing areas. Unidirectional flow of personnel and equipment for reprocessing, that includes separation of dirty and clean workflows in procedure and clean-up areas, is important. Separation of patient care areas from contaminated spaces and equipment is crucial to prevent cross-infection. Procedure rooms will be used for a variety of patients whose infection status may be unknown. Standard precautions must be used for all patients regardless of their diagnosis or presumed infectious status (see section 5.1). The workforce in an endoscopy unit will often have multiple roles and responsibilities. It is important that all staff involved in cleaning of the equipment or environment are supported by appropriate regular training and assessment.

7.5.1 Routine cleaning

Cleaning is important for infection control — particularly in work areas — because deposits of dust, soil and microbes on surfaces can transmit infection. Contaminated areas, such as procedural rooms or isolation rooms, must be cleaned after each session, spot-cleaned after each case or thoroughly cleaned, as necessary. The basic principles that should be followed are shown in Box 5. It is essential to refer to national and jurisdictional guidelines for environmental cleaning.

Surfaces should be easy to clean and maintained in good repair to minimise any risk of cracks, chips or surface damage that will increase the risk of

Box 5. Basic principles of routine environmental cleaning*

- Written cleaning protocols, including methods and frequency of cleaning, should be prepared. Protocols should include policies for the supply, preparation, dispensing and use of all cleaning and disinfectant products.
- Standard precautions, including wearing of appropriate personal protective equipment, should be implemented when cleaning surfaces and facilities (see chapter 5).
- Cleaning methods should avoid generation of aerosols.
- All cleaning items should be changed after each use and cleaned and dried before being used again. They should also be changed immediately after use in cleaning of blood or body fluid spills. Single-use cleaning items, such as lint-free cleaning cloths, are preferred, where possible.
- Sprays should not be used because they can generate aerosols, become contaminated and are difficult to clean. Sprays are not effective, as they do not touch all areas evenly on the surface to be cleaned.
- Detergents should not be mixed with other chemicals.
- All cleaning solutions should be prepared fresh before use or dispensed from a regulated dispensing unit that calibrates the correct dose and dilution for application.

* Adapted from Victorian *Infection control guidelines: cleaning and waste disposal procedures*.[168]

contamination being retained and not removed during cleaning processes. Surfaces and floors need to be impervious to water and body fluids.

Cleaning agents used should be designed for the purpose for which they are to be used and compatible with the materials to be cleaned. Storage, handling and any required mixing or dilution should be consistent with manufacturer instructions.

Cleaning products and equipment should be appropriate for the task to be completed and used in accordance with manufacturer instructions. Cleaning products may be single-use or reusable. If reusable cleaning equipment is used, it should be reprocessed between uses according to manufacturer instructions and stored dry when not being used. Appropriate PPE should be used at all times by those undertaking cleaning activities.

Routine cleaning with detergent and water, followed by rinsing and drying, is the most useful method for removing contamination and microorganisms from surfaces. Detergents help to loosen the contaminant, and rinsing with clean water removes the loosened contamination and any detergent residues from the surface. Drying the surface makes it harder for microorganisms to survive or grow.[92]

Physical (mechanical or manual) cleaning is the most important step in cleaning. Sole reliance on use of a disinfectant without physical cleaning is not recommended. A combination of a detergent and a Therapeutic Goods Administration (TGA)-listed hospital-grade disinfectant with specific claims, or a chlorine-based product, such as sodium hypochlorite (two-in-one clean), may be used for surface cleaning in specific infection control situations.

To clean effectively, any environmental cleaning product must:

- be compatible with the surface to be cleaned (as per the manufacturer's instructions);
- be stored so as to minimise any contamination; and
- be used at the right concentration.

To effectively disinfect or kill microorganisms, any environmental disinfectant product must:

- have enough time in contact with the surface to kill the microorganisms (as per the manufacturer's instructions);
- be used at the right concentration;
- be applied to a clean, dry surface; and
- be effective against the particular microorganisms.

The requirements for environmental cleaning of the procedure area should be consistent with the cleaning

of any procedure room or operating theatre where the endoscopic procedure is performed.

Cleaning between cases should include any frequently touched surfaces and equipment in the immediate procedure zone (e.g. endoscopy stack, diathermy unit, electrocardiograph leads, SpO_2 lead, computer keyboard and mouse used during the procedure) or areas where there is visible contamination. In addition to cleaning between cases, end-of-day cleaning should be completed in all areas of the endoscopy unit and reprocessing areas. There should also be a documented schedule for cleaning of specialised equipment, AFERs, CESCs and the general environment. Sterile stock or unused endoscope equipment should not be exposed to contamination by moisture, direct contact, aerosols, splash or damage.

Most microorganisms do not survive for long on clean surfaces when exposed to air and light, and routine cleaning with detergent and water should be used to reduce microorganism numbers. Disinfectants might be used after routine cleaning (two-step cleaning) for multiresistant organisms or other potentially infectious material (e.g. blood) or during an outbreak of a specific infectious disease (e.g. norovirus).[92]

7.5.2 Cleaning for specific infection risks

The risk of transmission of particular infections should be assessed and the standard precautions applied, and, where necessary, the cleaning schedule or product should be adjusted according to the infectious agent.

Infection transmission following an endoscopic procedure on a patient with a multiresistant organism may result in severe adverse outcomes. Contact precautions should be followed. This will require all patient surrounds and frequently touched surfaces or objects (e.g. bedrails, trolleys, doorknobs, light switches, tap handles, privacy screens and curtains) to be changed or cleaned with a suitable detergent and disinfected with a TGA-listed hospital-grade disinfectant.

This process must involve either:

- a two-step clean, which involves physical cleaning using a detergent solution, followed by use of a chemical disinfectant; or
- a two-in-one clean, in which a combined detergent and disinfectant wipe or solution is used and mechanical or manual cleaning action is involved.

Sole reliance on use of a disinfectant without mechanical or manual cleaning is not recommended. Cleaning and disinfection of surfaces after endoscopy on a patient with *C. difficile* infection requires use of sodium hypochlorite or an approved alternative, after cleaning with detergent.[92]

As emerging cleaning or disinfection methods are developed, it is important to evaluate the evidence before any changes are made to environmental cleaning or disinfection practices.

7.5.3 Cleaning of biological spills

Spills of blood or other potentially infectious fluids or substances should be promptly cleaned by:

- wearing gloves and other PPE appropriate to the task;
- confining and containing the spill;
- cleaning visible matter with disposable absorbent material and discarding the used cleaning materials in the appropriate waste container; and
- cleaning the spill area with a cloth or paper towels using a detergent solution.[92]

Chapter 8: Reprocessing

8.1 Effectiveness of recommended reprocessing protocols

The reprocessing of reusable endoscopes remains at the core of infection prevention and control in endoscopy. A study published in 1990 showed that recommended protocols removed all microbiological contamination from endoscopes used to examine patients with HIV and hepatitis B virus infection.[169] It also confirmed that endoscopes artificially contaminated with serum containing high titres of these viruses had all microbiological activity removed by appropriate reprocessing.[169] These results have since been confirmed by other studies, including one that quantified the dramatic reduction in bacterial contamination by cleaning of colonoscopes,[170] another that found only six positive surveillance cultures out of 2374 collected over a 5-year period in a Melbourne endoscopy unit,[171] and a study which found that:

- when followed meticulously, recommended reprocessing protocols removed microbiological contamination;
- bacterial contamination was an accurate index of viral contamination; and
- even minor deviations from cleaning protocols resulted in persistent microbiological contamination after disinfection.[172]

Not all investigators have been able to confirm such satisfactory results after recommended reprocessing, and rates of infection after endoscopy may be significantly higher than traditionally thought.[173] Unfortunately, even when reprocessing appears to be done in accordance with recommendations, unexpected breakdowns in infection control can occur and lead to patient infections. These breakdowns can occur for various reasons, such as unseen endoscope damage, disinfectant-resistant microorganisms or incorrect detergent concentration. This supports the need for additional testing of endoscope reprocessing by surveillance culture (see chapter 10). It also emphasises that current reprocessing techniques are less than ideal and have a lower margin of safety than is desirable, reinforcing the need for all steps in the reprocessing protocol to be carried out meticulously. This reality is a driving force behind the development of single-use endoscopes (see section 8.2).

The most important step in the process of endoscope decontamination is scrupulous manual or mechanised cleaning before disinfection. Viruses and bacteria can persist for long periods on surfaces, especially in the presence of biological material. Manual cleaning refers to the physical task, performed by hand, of removing biological material from the endoscope with appropriate brushes, cloths, detergents and water. It should not be confused with mechanised cleaning, whereby a cleaning process is performed by a machine. Endoscope reprocessing machines that perform mechanised cleaning are now in common use and provide an equivalent level of efficacy for removal of biological material and microorganisms as optimal manual cleaning. Such machines should ultimately replace manual cleaning to provide standardisation of the cleaning process and remove the human factors that can adversely affect the quality of manual cleaning.

For manual cleaning to be effective, it must:

- be performed by a person with an accurate and complete knowledge of the structure of the endoscope and who is trained in cleaning techniques;
- be undertaken immediately after the endoscope is used (starting with bedside pre-cleaning), so that biological material does not dry and harden;
- follow a protocol that, using appropriate detergents and cleaning equipment, allows all surfaces of the endoscope, internal and external, to be cleaned; and
- be followed by thorough rinsing to ensure that all debris and detergents are removed before disinfection.

A standard for testing of cleaning efficacy in endoscope manual reprocessing protocols has not yet been

developed. Methods such as ATP bioluminescence or protein challenge are used as a way to provide a marker of cleanliness and may be incorporated into quality monitoring processes when manual cleaning is undertaken.[86,174,175] The determination of cleaning efficacy of washer–disinfectors has been studied, and the standard is prescribed in International Organization for Standardization (ISO) standard 15883-1.[176]

8.2 Novel options for endoscope reprocessing *(new in 2025)*

Disruptive technologies are increasingly affecting the options for instrument reprocessing. Single-use endoscopes are routinely used internationally as alternatives to reusable instruments or for specific indications in some units. Although they obviate the need for reprocessing and vastly reduce the risk of endoscopic transmission of infection, these benefits need to be weighed against the financial and environmental costs of single-use devices. The result of this cost–benefit analysis will vary across units and jurisdictions.

More recently, an endoscope manufacturer has developed a novel approach to endoscope reprocessing.[177] This system provides endoscope inspection, microbiological culturing, HLD and ethylene oxide sterilisation. Endoscopes are then dispatched to endoscopy units throughout the country in sealed, sterile bags, with the microbiological reports, ready for immediate patient use. When stored in their sterile bags, the endoscopes have a shelf life of 18 months. This system has several potential advantages for patients and endoscopy units, including helping to improve access to endoscopy procedures in regional and remote areas. The supply of sterile endoscopes is initially focusing on maintaining an operational endoscope fleet during the time endoscopes are out of service for maintenance or repairs. The microbiological testing guidelines for loan endoscopes provided through conventional systems remain unchanged, and endoscopes on loan are to be tested within 72 hours of receipt of the instrument. Endoscopes that have undergone a sterilisation cycle, are contained within a sterile barrier system and have a microbiological culture result provided are excluded from this requirement. The loan instrument should then be retested according to the routine schedule for the type of endoscope if it remains on loan.

The full impact of this process and technology will become clear over time, and it is essential that every step is subject to detailed analysis.

The final stage of reprocessing is storage. The use of a CEST is mandated for the storage of endoscopes after HLD. Initially only available within cabinets, appropriate alternatives for drying and storage of endoscopes have been developed. In one such system, the drying component uses laminar airflow, followed by turbulent flow of heated air, to dry endoscope channels. The instrument is then stored in a single-instrument bag. A plasma containing a few parts per million of ozone molecules is instantly generated inside the device and insufflated into the bag. This system offers a shelf life of 31 days. Another available system provides for storage in a vacuum-sealed bag, offering a shelf life of 30 days. All endoscopes must be stored (and transported) in temperature- and humidity-controlled environments consistent with manufacturer instructions for use (IFU) and AS 5369:2023.[86]

8.3 Variation in reprocessing regimens based on infective status

The reprocessing of RMDs should be a robust, validated process that will render all items safe for use for the next patient. Variation in this process should not be dependent on perceived infective status of a patient.

Several surveys have shown that the practice of varying the cleaning and disinfection regimen according to the known infective status of the patient is widespread.[178] A 1992 study found that in up to half the endoscopy units surveyed in Massachusetts, staff changed their reprocessing techniques after procedures on patients with known HIV, tuberculosis or viral hepatitis infection.[179] Common practices include using ethylene oxide sterilisation or prolonging chemical immersion times for endoscopes used in patients with these infections. Such an approach is illogical, potentially dangerous and, indeed, ineffectual.[180] Many patients who have these infectious diseases either do not know or choose to conceal such knowledge at the time of an endoscopic procedure.

It is therefore imperative to have a cleaning and disinfection schedule that deals effectively with both unrecognised and recognised cases — a principle that underlies all recommendations in this publication.[181]

The only exceptional situation is that of suspected pulmonary tuberculosis, which does not require any change in the cleaning and disinfection regimen, but which should deter the bronchoscopist from undertaking a procedure in the first place due to the risk of airborne transmission to staff and other patients. PPE used when wet leak testing and/or manually cleaning any RMD associated with bronchoscopy should include the use of a PFR mask.

8.4 Endoscope structure

Different endoscope types and models have features in common and important differences that need to be appreciated for them to be properly cleaned. The manufacturer supplies an instruction manual with each endoscope. It is essential that every person responsible for endoscope reprocessing reads these instruction manuals and is familiar with the specific characteristics of each model of endoscope they are required to clean. This is of particular importance when reprocessing loan endoscopes, which may be a different model to those usually in use in the unit.

The internal structure of an endoscope's channels is illustrated in Figure 4.

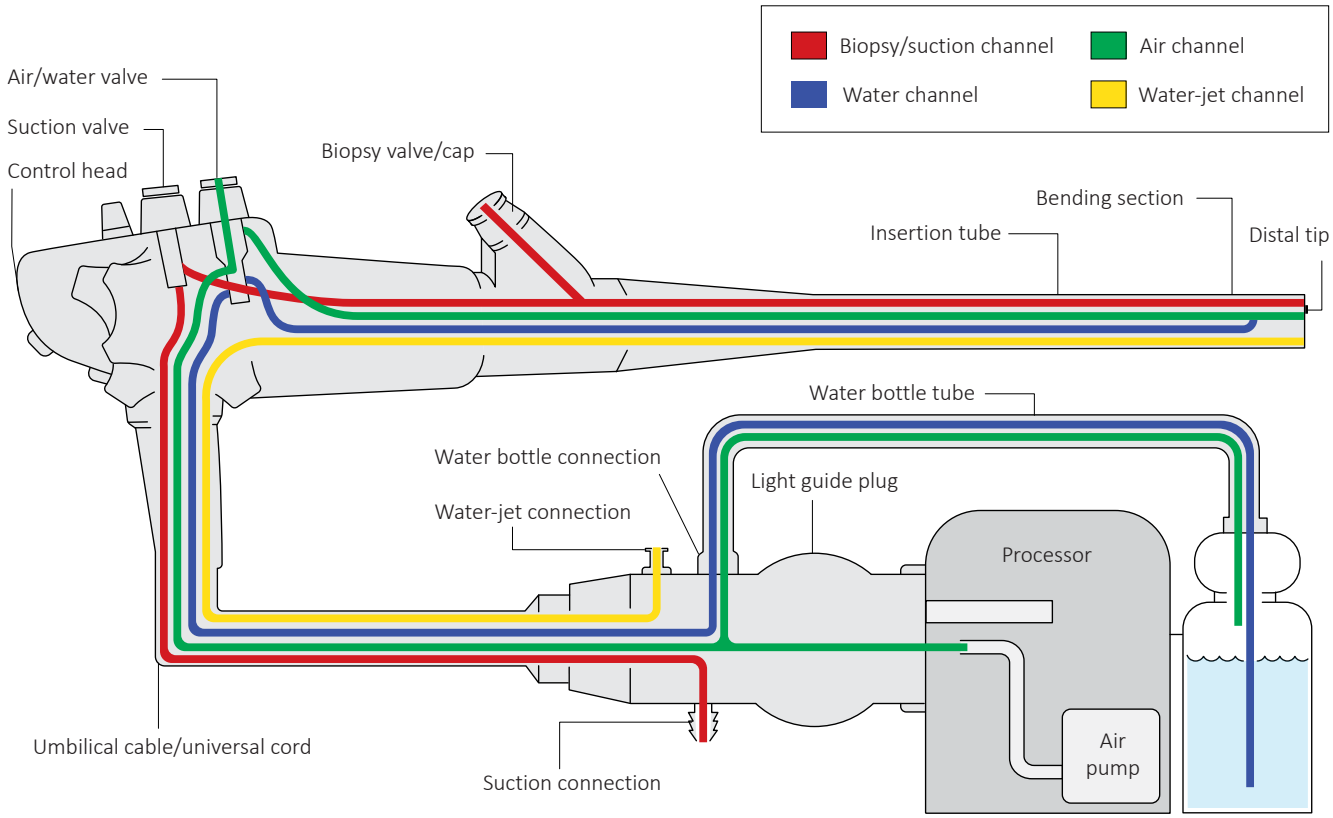
8.4.1 Common external features

All flexible endoscopes have a light guide plug, an umbilical cable (cord), a control head and an insertion tube.

8.4.1.1 Light guide plug

The light guide plug connects into the light source. The air–water and suction channels have ports in the light guide plug. The terminals in the light guide plug of some endoscopes are not waterproof and must be covered by the soaking cap supplied with the

Figure 4. Schematic of an endoscope



instrument before cleaning. Periodical checks should be made to ascertain continued water tightness of these caps.

8.4.1.2 Umbilical cable/universal cord

The umbilical cable connects the light guide plug to the control head of the endoscope. The external surface may be contaminated by splashes or hand contact during endoscopic procedures.

8.4.1.3 Control head

The control head contains the angulation control wheels that allow the operator to flex the tip of the instrument, and suction and air–water valves for control of air and water flow from the distal tip.

8.4.1.4 Insertion tube

The insertion tube enters the patient's body and is grossly contaminated during the procedure. The distal tip of the insertion tube houses the microchip, the openings for the suction, air–water and water jet-washing channels and the lens covering the flexible fibre-optic light guides. The section of the insertion tube adjacent to the distal tip is known as the bending section. The outer covering is made from soft flexible material and is particularly vulnerable to damage, especially if handled carelessly.

8.4.2 Common internal features

The suction and air–water channels and the fibre-optic light guide extend from the light guide plug to the distal tip. In non-video models, an additional fibre-optic bundle, the image guide, extends from the control head to the distal tip. The cables, which allow the tip to be flexed, run through the insertion tube. Any damage to either the umbilical cable or the insertion tube can potentially damage any of the internal structures. Care must be taken during cleaning procedures to ensure that the umbilical cable and insertion tube do not become kinked or acutely bent. Kinks in the biopsy channels trap debris and lead to failure of the cleaning process and/or biofilm growth and build-up. Suspected damage should be referred to the supplier for assessment and repair. A negative leakage test does **not** exclude damage to internal endoscope structures.

Flushing (jet-washing) channels are found in many endoscopes. These are grossly contaminated during procedures and must be independently flushed during cleaning, whether or not they have been used.

8.4.3 Special internal features

Duodenoscopes and linear echoendoscopes have an additional channel, the forceps elevator (raiser), which is extremely fine (capacity, 1–2 mL). In many models, these are now sealed. Models that are not sealed require scrupulous attention during the cleaning process. Cleaning adaptors for this channel are provided with each duodenoscope or therapeutic endoscope and must be used.

Some endoscopes are configured with a carbon dioxide channel connected to the air channel, rather than being connected via the water bottle. Cleaning protocols should include individual flushing of this channel.

Balloon channels are found in some enteroscopes and echoendoscopes. Cleaning protocols should include individual flushing of this channel.

Some colonoscopes have stiffening control, which enables adjustable stiffening of the insertion tube. This must be set to zero before reprocessing starts, as damage to the cables can result from coiling.

8.5 Cleaning equipment

8.5.1 Automated flexible endoscope reprocessors

Machines designed to disinfect and rinse endoscopes are widely used in the Western world. ISO 15883, particularly Parts 1 and 4, published by the European Committee for Standardization and the ISO, provides an international standard that specifies requirements for machine manufacturers, as well as guidance on routine and periodic tests for users to perform.[182] This ISO standard is referenced in AS 5369:2023,[86] so is applicable to the Australian and New Zealand context.

Modern AFERs, when correctly designed, installed, maintained and used, provide reliable and effective HLD and chemical sterilisation, reducing unpopular, time-consuming, arduous and repetitive manual tasks and occupational exposure to irritant chemicals. In this document, the term AFER, rather than AER

(automated endoscope reprocessor), is used, to highlight that the recommendations relate to the reprocessing of flexible endoscopic instruments and not rigid devices.

Some AFERs remove the need for manual cleaning as an essential prerequisite to HLD. Mechanising the cleaning step of reprocessing offers clear advantages in terms of reproducibility and standardisation. However, although some machines have a cleaning cycle, unless the TGA approval to market the device has been based on the instrument not undergoing prior manual cleaning, this step must be completed. Given the many reports of infection and pseudo-infection caused by failure of staff to follow endoscope cleaning protocols, and surveys continuing to show variability in manual cleaning practices, the use of fully automated endoscope reprocessors is recommended.[183-185]

Note that the complex design of the distal tip of endoscopes with forceps elevator mechanisms makes it imperative that these machines have specific processes or attachments to ensure that this section of the instrument is effectively reprocessed.

AFERs have been responsible for pseudo-infection epidemics and many serious clinical infections, including patient deaths.[186] A particular risk is choosing the wrong cycle (e.g. choosing a cycle of disinfection only versus detergent flush plus disinfection when manual cleaning of the endoscope has not been performed).

All users need to be aware of the risk of machine colonisation, suitable methods of machine decontamination and the need for bacteriological surveillance. AFERs rarely show microbial contamination in the first 6 months of use, but contamination becomes increasingly likely as the machine ages. Common predisposing causes include the development of biofilms, valve wear, surface irregularities, line fissuring and filter failures.

A maintenance schedule that ensures tanks, pipes, strainers and filters of both the machine and water treatment system are kept free of biofilms and other deposits should be instituted. Heat disinfection is the preferred maintenance method.

Just as for endoscopes, microbial monitoring of AFERs is essential. Machines shown to be contaminated should not be used until cleaned and proven to be microbiologically safe (see chapter 10). Machines repaired in the unit, which include a breach of the water line, should undergo testing before use. These can be used immediately while awaiting microbiological test results. On return of a machine after offsite maintenance or on receipt of a loan AFER, the equipment validation protocols of Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) should be performed (see section 9.2).

8.5.2 Ultrasonic cleaners

Ultrasonic cleaners are an adjunct for the cleaning of medical devices, not for disinfection or sterilisation. They are used to remove soil from joints, crevices, lumens and other areas that are difficult to clean by other methods.[187] As the ultrasonic cleaner generates aerosols, it must be covered with a lid during operation.

Factors that influence the effectiveness of ultrasonic cleaning are:

- energy — created by the mechanical action of the generators and transducers to produce the cleaner's cavitation action;
- target soil — the type of soil being cleaned;
- degassing — freeing trapped air;
- chemical activity — the type and amount of cleaning solution;
- water quality — hardness and pH;
- water temperature — hot or cold cleaning solution;
- time — length of exposure to cavitation;
- human factors — training, loading procedures, proper use of equipment; and
- other factors, such as pre-cleaning and safety.[188]

Ultrasonic cleaners should be monitored regularly to ensure they are working correctly.[188,189] AS 2773:2019 describes various methods for this monitoring, including commercially available products.[190] Ultrasonic cleaners require a printout for each cycle, daily testing and annual PQ.[86]

8.6 High-level disinfectants and sterilising agents

Peracetic acid is predominantly used as the biocide for endoscope reprocessing in Australia. Other chemical agents in use include hydrogen peroxide and aldehyde preparations. Vaporised hydrogen peroxide is used for low-temperature sterilisation of compatible endoscopes.

Sterilants and disinfectants for use in endoscope reprocessing are regulated by the TGA. These products must be included in the Australian Register of Therapeutic Goods as a Class IIb medical device before they can be supplied. Only those chemicals approved for use and registered on the Australian Register of Therapeutic Goods may be used to reprocess endoscopes.

Evidence of testing protocols to support the use of a chemical as a high-level disinfectant or sterilant in a specific AFER is required for TGA approval. AFERs are licensed for use with particular chemicals used within specific parameters.

8.7 Steps of reprocessing

The steps required for endoscopic instrument reprocessing are summarised in Box 6 and illustrated in Figure 5.

8.7.1 Immediate bedside decontamination

This is an essential step of the reprocessing regimen to ensure the removal of gross contamination from the endoscope. It must be performed **immediately** after completion of the endoscopic procedure. Bronchoscopes do not have air–water channels but should otherwise be processed according to the steps below.

Step 1. **Immediately** after each procedure, with the endoscope still attached to the light source, grasp the control head. Using a disposable cloth or sponge soaked in detergent solution, wipe the control head and insertion tube to the distal tip. Discard the cloth or sponge. Note: remove balloons from echoendoscopes and enteroscopes and any removable component from the distal tip of any endoscope.

Box 6. Steps required for endoscopic instrument reprocessing

1. Immediate bedside pre-cleaning and decontamination
2. Leak testing*
3. Manual cleaning*
4. Rinsing after cleaning*
5. Visual inspection
6. High-level disinfection*†
7. Rinse after high-level disinfection (± alcohol flush)*
8. Drying
9. Storage

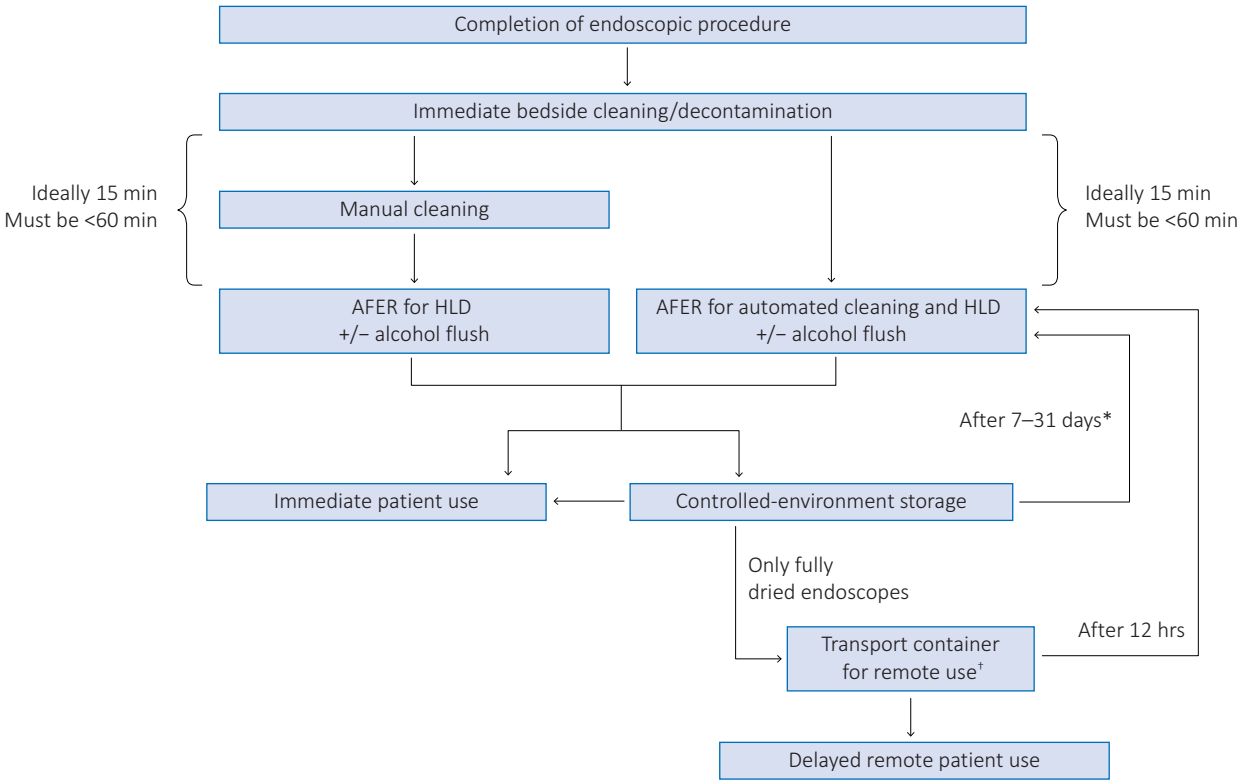
* Steps 2, 3, 4, 6 and 7 can be performed by some automated flexible endoscope reprocessors (AFERs).
† AFERs are mandated for high-level disinfection/sterilisation in Australia.

Step 2. Place distal tip in detergent solution. Aspirate through suction channel by alternately suctioning cleaning fluid and air, raising and lowering the instrument tip into and out of the cleaning solution. Continue aspiration until clear. Note that patient secretions from bronchoscopy are clear and may be difficult to identify when aspirating. The volume of fluid to be aspirated through the channel during bedside cleaning is 250 mL or as determined by the AFER manufacturer, if greater, as this is a prerequisite step to the automated cleaning process.

Step 3. Fully depress and release the air–water button several times to flush the water channel. Occlude the air button to force air through the air channel.

Step 4. Depending on the brand of endoscope, either (a) insert the special air–water channel feed button and depress the button to flush both air and water channels with water, then release for air flow to expel the water from both channels; **or** (b) move the lever on the water feed connector to close off the water supply, then depress the water feed button until water is expelled. Disconnect the water bottle connector from the endoscope, taking care not to contaminate its end.

Figure 5. Endoscope reprocessing flowchart *(updated in 2025)*



AFER = automated flexible endoscope reprocessor; HLD = high-level disinfection.
* Permissible storage times of disinfected endoscopes before reprocessing is required may vary according to the manufacturer's instructions for use for each controlled-environment storage technique approved by the Therapeutic Goods Administration. Extended storage of wrapped or bagged sterilised endoscopes is as per the manufacturer's instructions for use.
† See section 8.10.

Step 5. Flush the water-jet channel, either by depressing the foot pedal or using a syringe flush.

Step 6. Flush the forceps elevator (if present) with a syringe of clean water (2 mL).

Step 7. Remove the endoscope from the light source. If applicable, ensure protective caps are applied before immersing in solutions.

Attention should be given to the risk of a retained deployable device (e.g. a clip or stent) in an endoscope channel after use. This relies on a high level of clinical suspicion and can be difficult to confirm. Each endoscopy unit should formulate a standard operating procedure to respond to this risk. It is essential that medical and nursing staff communicate with the reprocessing staff about the risk of a retained device. Remedial actions could include passing a brush through all endoscope channels (not just the working channel). If available, a borescope could be used to inspect the endoscope working channel. These techniques do not give a 100% guarantee of detection or clearance of a retained foreign body. If there is residual concern of a retained device, the instrument should be returned to the manufacturer for servicing.

After pre-cleaning, transfer the endoscope to the reprocessing area in a manner that will not contaminate the environment and ensure it is clearly identified as contaminated equipment. Care should be taken to ensure that the exterior of the transport case is not contaminated when loading.

Manual cleaning of the endoscope or commencement of the AFER cleaning cycle should occur without delay, **ideally within 15 minutes, but it must be within 1 hour**. Manufacturers' protocols for delayed processing should be followed if required.

8.7.2 Leak testing

Leak testing detects damage to the external surfaces and internal channels of the endoscope that can lead to inadequate disinfection and further damage of the endoscope. Leak testing should be performed after each use prior to manual cleaning, or it may be performed by the AFER at the start of the reprocessing cycle. Remove all valves and buttons before leak testing.

The risk of aerosol generation during wet leak testing is potentially significant. For manual cleaning after a procedure performed on a patient with suspected or confirmed COVID-19, dry leak testing should be performed in the procedure room while staff are still in full airborne-precaution PPE. Wet leak testing is not recommended. The risk associated with the recommendation to not perform a wet leak test is that a leak may go undetected. Confirmation of the leak test process within the machine cycle is required.

8.7.3 Manual or automated cleaning

Automated cleaning is recommended as the optimal process. Cleaning technologies continue to evolve, and an FDA-approved machine that is not part of an AFER but is solely designed to replace the manual cleaning process has been developed and is completing regulatory approvals in Australia, the UK and Europe. The AFER or other cleaning technology manufacturer's instructions for use (IFU) must be followed before connecting the endoscope and beginning the cycle.

When not using an AFER with automated cleaning or an alternative cleaning technology, manual cleaning — including brushing and flushing of channels and ports consistent with the manufacturer's IFU — is required before HLD or sterilisation. To avoid omission of steps in this process, one person should complete the entire manual cleaning of the endoscope. If a change in personnel occurs during cleaning, the process should be recommenced.

For any endoscopy procedure where there is a risk of aerosol transmission, single-use items should be used if available to reduce the risk of personnel and environmental contamination during cleaning of reusable equipment.

Step 1. Make up detergent solution as per manufacturer's instructions. Enzymatic or biofilm-removing products should be used.[191] Detergent solution should not be reused.

Note: All brushing and flushing cleaning steps must be completed **underwater** to avoid generation of aerosols.

Step 2. Brush and clean reusable buttons and biopsy caps, paying particular attention to internal surfaces. Once brushed, buttons should undergo ultrasonic cleaning before sterilisation. Disposable biopsy caps should be used unless they are not available for the particular endoscope. Single-use buttons are available.

Step 3. Place endoscope in detergent solution and wash all outer surfaces. Discard cloth or sponge after use.

Step 4. Brush all sections of the suction channels, biopsy channels and other channels as per manufacturer's instructions, using a brush applicable for the channel size. Brushes for endoscopes may be a bristle or bladed design. A bladed design may be superior for biofilm removal.[192] Some twin-channel endoscopes require brushes of differing sizes. If the brush contains obvious debris, it should be cleaned before being withdrawn from the channel. Some brushes are designed to be used with a pull-through method instead of withdrawing the brush. Each channel should be brushed until all visible debris is removed.

Using a soft brush, gently clean the distal tip.

Thoroughly brush the control wheels, around and in valve seats and the biopsy port. Check that all visible debris has been removed.

Step 5. Fit cleaning adaptors. Thoroughly flush all channels with detergent, ensuring solution is obtained from a separate supply to that in which the endoscope is immersed. The volume of fluid to be flushed through the channels is identified in the manufacturer's IFU. Ensure all air is displaced from the channels. Leave the detergent solution in contact for the specified time. Purge with air to remove detergent solution from all channels.

8.7.4 Rinsing after manual cleaning

Step 1. Rinse outer surfaces. Flush all channels with clean (potable) water (i.e. tap water that has been freshly drawn and not used for any other instrument). It is essential that all detergent be removed before disinfection.

Step 2. Purge channels with air to remove rinsing water.

8.7.5 Visual inspection

After manual cleaning, the endoscope and its accessories must be visually inspected. Reprocessing training should include recognition of excessive wear or damage. Some endoscopes may require the use of light magnification to assist with the inspection process.

After fully automated endoscope reprocessing, which includes machine cleaning, inspection for endoscope damage should then be performed before storage.

Borescopes provide the capability to inspect the endoscope biopsy channel for damage, the presence of foreign matter and identification of biological material.[156,165-167]

8.7.6 Automated high-level disinfection/sterilisation

AFERs are mandated for disinfection/sterilisation in Australia.[27] Connect the endoscope to the AFER. Choose the relevant disinfection cycle (HLD or sporicidal).

At completion of the cycle, check that cycle parameters have been met and all channel adaptors are still connected. If required for immediate use, remove the channel adaptors and dry the exterior of the endoscope. Endoscopes to be dried in cabinets will require connectors specific to those cabinets, and these may be those used in the AFER.

8.7.7 Rinse after high-level disinfection

This step is performed as part of the AFER cycle. Some AFERs have an alcohol flush capability as a terminal step in their process.

8.7.8 Drying

At completion of reprocessing, endoscopes are wet. Those to be used immediately will not require further channel drying. All others require forced-air drying of the channels, either manually for 10 minutes with regulated, compressed air, or preferably within a TGA-approved forced-air or channel-purge endoscope drying CESC or other approved CEST.[56] The parameters for drying are specific to each cabinet and will vary by type of endoscope, temperature, humidity and time. European Standard (EN) 16442 requires that the drying process is complete within 3 hours.[193] Although 70% alcohol has traditionally been used to assist with drying, increasing emphasis on forced-air drying of channels has concurrently de-emphasised the utility of alcohol flushes.

8.7.8.1 Importance of instrument channel drying after high-level disinfection

The importance of endoscope channel drying in preventing bacterial proliferation and the potential for endoscopy-related infection transmission has been appreciated for nearly 30 years. In 1991, it was conclusively shown that if reprocessed duodenoscopes were stored with moisture in the channels, significant bacterial proliferation would occur in the instrument channel during storage of 24–72 hours.[24] However, the problem is that the manufacturers' IFU do not define what level of dryness is required or specify how endoscope channels can be assessed to determine whether the required level of dryness has been achieved.[56]

Borescopes can be used to inspect endoscope channels for residual fluid. A 2016 study showed the utility of borescope assessment to determine if there was channel damage, organics residue or moisture in the endoscope channels after reprocessing and overnight storage.[194] A subsequent study found that residual fluid was detected in 49% of endoscope channels with the use of borescope examinations and humidicator paper. One of the three sites included in the study, which used 10 minutes of manual forced-air flushing of channels before storage, had no residual fluid, whereas the other two sites had residual fluid in 85% of endoscopes. These latter two sites relied on the AFER alcohol flush and air purge cycle without additional drying. This study also concluded that

humidicator strips were a reasonable alternative to borescope examinations, as they had a 95.5% positive predictive value and 100% negative predictive value.[195]

A recent study reported that manual forced-air flushing with medical-grade air for 10 minutes was not as effective as automated HEPA-filtered air flushing for 10 minutes. In addition, rare fluid drops were detected after 24 hours of storage despite no droplets being detected immediately after 10 minutes of automated air flushing,[183] highlighting the interplay of temperature and air humidity within the channels. These data supported GESA and GENCA's mandating of CESCs in all endoscopy units in Australia in 2018. More recently, it has been shown that CESCs were able to dry the internal channels of bronchoscopes, duodenoscopes and colonoscopes within 1 hour, compared with non-drying cabinets, in which channel drying could not be achieved after 24 hours of storage.[196] Instrument drying technologies have evolved, as discussed in section 8.2, and may provide alternatives for achieving rapid drying of endoscopes.

8.7.8.2 The role of alcohol flush

There are few published data to support the use of an alcohol flush before drying of endoscopes when CESCs are in use.[56] One study reported that the use of alcohol flush versus no alcohol flush did not improve endoscope contamination rates when reprocessed duodenoscopes were stored in CESCs.[197] Concern has also been raised that alcohol could act as a fixative for any residual protein material in endoscope channels. There may continue to be a role for use of an alcohol flush where rapid drying of an endoscope is required after HLD/sterilisation.

8.8 Endoscope storage

As a result of greater understanding of the development of build-up biofilm arising from repeated cycles of moisture and drying, and the associated risk of microorganism transmission and its prevention by adequate channel drying, the use of a TGA-approved CESC for storage of all endoscopic instruments was mandated in the consensus statement on CPE.[27] CESCs are not simple endoscope storage cupboards but devices that control the storage environment, including temperature and humidity. Key points regarding endoscope storage are given in Box 7. New CESTs are discussed in section 8.2.

Box 7. Key points regarding endoscope storage

- Sufficient controlled-environment storage techniques (CESTs) should be available to store all endoscopic instruments in use.
- After completion of high-level disinfection in an automated flexible endoscope reprocessor, endoscopes should be immediately stored using the CEST unless being immediately used for another procedure.
- It is better for an endoscope to be stored using a CEST for any period of time than to be left with any residual moisture in the instrument channels.
- Controlled-environment storage cabinet (CESC) doors should be opened for the minimal amount of time required to place or remove an endoscope.
- After removal of a fully dried endoscope from a CEST, it should be stored in a covered container that prevents contamination while awaiting use. Only fully dried endoscopes should be used at a remote site (e.g. operating theatre or intensive care unit); that is, the endoscope should have been stored in the CESC for the time specified for that particular cabinet to dry all the channels, or using an alternative CEST as determined by the manufacturer's instructions for use.
- The maximum time within which an instrument may be used after removal from a CEST is 12 hours (even if stored in a sealed container). After 12 hours, the instrument should undergo a full reprocessing cycle.
- Unused endoscopes should undergo a full reprocessing cycle before being stored using a CEST.

Cabinets compliant with EN 16442 that are designed for drying of endoscopes must also be used for their storage.[193] Endoscopes should remain within the cabinet until required for use. Manufacturer's instructions will state the length of time an endoscope can remain ready for patient use without requiring further reprocessing. Technological developments may

provide alternative methods of controlled storage for processed endoscopes (see section 8.2).

It is important to emphasise that this recommendation is for all endoscopic instruments, not only those with complex tips. The basis for this recommendation is that biofilm formation, particularly within endoscopic instrument channels, is a key factor in the potential transmission of microorganisms during endoscopic procedures and that adequate drying is essential to prevent its formation. In a study using an in vitro biofilm model, the authors concluded that routine cleaning procedures do not reliably remove biofilm from endoscope channels if adequate drying is not completed before storage.[198] The use of CESCs has been shown to limit bacterial proliferation.[199,200] A multicentre Chinese study of 79 endoscope channels from 66 hospitals also found that biofilm build-up may relate to inadequate drying, with biofilm being detected in 36/66 biopsy–suction channels (54.6%) and 10/13 air–water channels (76.9%).[201]

Endoscopy units should install only TGA-approved CESCs, several of which are available. The endoscopes are hung vertically in some cabinets and stored in drawer-like containers in others. All deliver a continuous flow of clean air through the channels of the instrument. It is essential to adhere to the manufacturer's IFU and to be aware of the specific CESC's channel drying time. Instrument storage technologies continue to evolve, and processes that provide wrap- or bag-sealed endoscopes may represent appropriate alternatives (see section 8.2).

The consensus statement on CPE acknowledged that the installation of CESCs in all endoscopy units constituted a significant capital expenditure and may pose a challenge because of their space requirements.[27] Therefore, a deadline for compliance in Australia was proposed, to allow sufficient time to attend to these challenges. However, all units were immediately required to demonstrate that they had instituted a plan to meet the compliance date. It is also essential that units ensure their CESCs are compliant with current standards and compliance dates, as these may change over time.

A practical benefit of the use of CESCs is the extended time that instruments can be stored before use, without the need for reprocessing. A systematic review assessed the proportion of contaminated endoscopes, defined as those with the presence of any pathogen >10 CFU/mL, in seven studies that sampled all channels of endoscopes stored for various lengths of time.[202] Drawing from these data, it was considered safe to use an endoscopic instrument that had been stored for 7 days without the need for preprocedural reprocessing. Storage time can be adjusted for cabinets that have TGA approval for storage of longer than 7 days. This will confer financial savings for endoscopy units and health services. Each CESC manufacturer will have conducted studies specific to their cabinet and the "ready for immediate patient use" storage time may need to be adjusted based on these results.

8.9 Major reprocessing equipment failure

8.9.1 Automated flexible endoscope reprocessor

In the event of a major failure of an AFER, the machine should be taken out of use and the manufacturer contacted. In the absence of an ability to complete HLD on "dirty" endoscopes, they should be manually cleaned and rinsed and stored in a dry area. Once AFER reprocessing resumes, the endoscopes should undergo a complete reprocessing cycle. They should then undergo microbiological testing after 12 hours of storage. The endoscopes can then return to patient use.

8.9.2 Controlled-environment storage cabinet

Should a CESC failure occur, all endoscopes should be reprocessed before use. The cabinet manufacturer should be contacted for maintenance, and a determination made as to when the cabinet may be returned to service.

8.10 Transport of endoscopes ready for patient use

Endoscopes can be transported using the tray from the AFER or CESC or in a closed container or wrap that will prevent contamination. Not infrequently, endoscopes must be transported to a procedural area (e.g. intensive care unit or operating theatre) that is remote from the endoscopy suite and, therefore, the CESC. If an endoscope must be transported to another hospital, transport cases specifically designed for this

purpose are commercially available. Only endoscopes that have completed the drying time mandated for the specific cabinet should be transferred to these areas. Endoscopes that are transferred and stored in this manner but not used must be reprocessed before being returned to the CESC. The maximum time within which an endoscope can be used after placement in the transport device is 12 hours.

8.11 Endoscope accessory equipment

As endoscopic accessories have been implicated in the transmission of infection and pseudo-outbreaks, the cleaning and disinfection or sterilisation of reusable endoscopic accessories is just as important as that for the endoscope.[203-205] As with endoscopes, effective cleaning of accessories is a mandatory prerequisite to sterilisation.

The Spaulding classification provides a system to determine the level of reprocessing necessary for an RMD based on the item's intended use:

- Critical RMDs require cleaning followed by sterilisation.
- Semi-critical RMDs require cleaning followed by HLD at a minimum; however, sterilisation of these items is strongly recommended if possible.

The requirements of AS 5369:2023 are applicable to all health service organisations.[86] Each individual health service organisation should develop its own workplace procedures based on the requirements of AS 5369:2023 to ensure its reprocessing activities result in a safe RMD that can be used for diagnostic and treatment purposes and is not hazardous to staff or the environment.[86]

Use of single-use medical devices may provide health service organisations with efficiencies, particularly during emergency endoscopic procedures after hours. For any procedure where there is a risk of aerosol transmission, single-use items should be used if available. Difficult-to-clean RMDs, labour-intensive procedures, access to and the high cost of reprocessing equipment and control of inventory should all be considered when performing a risk assessment of RMDs versus single-use sterile devices as best practice.[86]

Medical devices labelled as, or intended for, single use and that have already been used should not be reprocessed or reused.

8.11.1 Cleaning

All reusable equipment should undergo cleaning, with all visible soiling removed. Any multicomponent equipment should be dismantled as far as possible for cleaning. Further processing is likely to be performed in the central sterilising services department.

If endoscopic units perform their own sterilisation, any complex-structured accessories should be placed in an ultrasonic cleaner and processed according to the manufacturer's recommendations. Items should then be processed through a washer–disinfector before packaging for sterilisation.

Additional specific processes may be required for individual items (e.g. manual cleaning and flushing channels of water bottle connectors). Accessory items that have been manually cleaned should be thoroughly rinsed and dried before HLD or sterilisation.

8.11.2 Disinfection and sterilisation

Critical accessories that enter sterile tissue or the vascular system must be sterile. Non-critical accessory equipment used in gastroenterological procedures requires HLD as a minimum. Non-sterilisable reusable accessories should not be used where a sterilisable alternative exists. HLD should not be used for equipment that can be sterilised.

8.11.3 Considerations for specific accessory items

8.11.3.1 Water bottles and connectors

By virtue of their design, water bottles are difficult to clean and reprocess.[86] These accessory items should be steam-sterilised according to the manufacturer's instructions, with a new bottle used for each session, as they have been implicated in the transmission of infection.[206] The use of single-use bottles and accessory tubing will be required if steam sterilisation is not available.

For a procedure that is conducted under standard plus contact and airborne precautions, single-use bottles

and connectors should be used to avoid removing contaminated equipment from the procedure room.

8.11.3.2 Dilators

Reusable graduated dilators have a small-diameter wire channel that is difficult to clean. It is now recommended that single-use dilators be used.

Weighted reusable dilators (which do not have a lumen and are commonly referred to as bougies) should be reprocessed according to the manufacturer's instructions (HLD or sterilisation).

8.11.3.3 Cleaning equipment

Most items of cleaning equipment, such as brushes, are single use and should be disposed of after use.

Reusable channel connectors used during manual cleaning should undergo daily steam sterilisation.

Flushing pumps that have internal channels require daily disinfection as per the manufacturer's instructions. The channel connectors and intake tubing of these pumps will be disinfected as part of the daily process. Some models have external tubing that is for single-day use.

8.11.3.4 Connectors to controlled-environment storage cabinets

Many CESCs use the same channel connectors that are used in the AFER. As such, these are reprocessed during each cycle of use. For connectors that are not processed with the endoscope in the AFER, cleaning and sterilisation or HLD will be required. These should be processed according to the manufacturer's IFU and usually on a weekly basis.

SECTION C: QUALITY MONITORING

Chapter 9: Quality monitoring of endoscope reprocessing

Quality control is fundamental to the delivery of safe and effective clinical services. This is especially important in endoscopy because equipment cleaning and disinfection present specific challenges, and failure of reprocessing has led to numerous reported infections after endoscopy procedures. These failures have often been attributed to non-adherence to up-to-date guidelines and recommendations and have involved various human errors and equipment faults. Failures in endoscope reprocessing are relatively common.[207-209] These facts support the need for a comprehensive and multifactorial quality control program in every endoscopy unit or wherever endoscopy is performed.[210]

Suppliers of reprocessing equipment, RMDs (endoscopes and accessories) and chemical agents all need to supply IFU that are consistent with Australian reprocessing requirements and the reprocessing technologies available. IFU are not consistent internationally because of regional variations in conditions or requirements.

Endoscopy units and sterilising services undertaking reprocessing of RMDs need to confirm that the IFU are current, consistent and compatible for each of the steps in reprocessing of RMDs. Currency of IFU may need to be checked on an annual basis with the supplier.[211]

Quality monitoring in endoscopy incorporates:

- the environment in which reprocessing is undertaken;
- the reprocessing equipment used;
- the operators using the equipment and reprocessing the endoscopes; and
- the reprocessing processes.

Quality monitoring requires that documentation of each step of endoscope reprocessing is maintained to demonstrate adherence to reprocessing protocols every time an endoscope is reprocessed. Documentation is essential for patient tracing in the event that a look-back investigation is necessary.

9.1 Commissioning new equipment

The purchase of new endoscopes and reprocessing equipment is a substantial financial outlay for any organisation. For the equipment to function as required, it must be installed correctly, according to the manufacturer's instructions, and be prepared and assessed for correct functionality before patient use. This is an entire organisational undertaking.

9.2 Equipment validation

As a component of quality assurance, equipment validation is crucial for producing consistent and high-quality products. Key equipment validation protocols are IQ, OQ and PQ.[212] These are set by the manufacturer and should be completed in conjunction with the supplier or an independent organisation as part of the installation process (see example in Box 8). A report should be made available to the purchaser that shows that these tests have been completed and the equipment has been successfully installed, operates as expected and produces an endoscope ready for safe use on a patient. This report will state if there are any inconsistencies in the functioning of the equipment that may require resolution before use.

9.2.1 Installation Qualification

IQ verifies that an instrument or unit of equipment being qualified (as well as its subsystems and any ancillary systems) has been installed and configured according to the manufacturer's specifications or installation checklist. It is a process of establishing, by objective evidence, that all key aspects of the process

Box 8. Example of qualification processes for validating water treatment for endoscopy

Installation Qualification (IQ)
The needs of the reprocessing equipment in the unit are established. The supplier can ascertain that the treatment process (filtration, reverse osmosis plant, continuous flow loop, etc) has been designed and manufactured to meet the installation specification.

Operational Qualification (OQ)
During installation, the supplier performs testing to demonstrate the capability of the installed water treatment process. This flow is tested at maximum use for all reprocessing machines.

Performance Qualification (PQ)
The supplier and/or end user tests the performance of the water treatment plant with sampling of all reprocessing machines to determine that it meets the criteria outlined in this document for microbial culture (see section 10.6) and other parameters (see section 7.1) and is compliant with AS 5369:2023.[86] This testing should be repeated to determine ongoing compliance.

equipment and ancillary system installation comply with the approved specification. It documents that the system has the necessary prerequisite conditions to function as expected.

9.2.2 Operational Qualification

OQ is performed after meeting each protocol of IQ. OQ's purpose is to obtain and document evidence that equipment performance is consistent with the user requirements and specifications when operating within the manufacturer-specified operating ranges. This includes identifying and inspecting individual components of the equipment that can affect final product quality. All testing is documented. Any non-conformance is documented and resolved, and later conformance is then demonstrated.

9.2.3 Performance Qualification

The final step of qualifying equipment is PQ, which is performed immediately after IQ and OQ. This phase is the process of establishing, by objective evidence, that the equipment, in simulated real-world conditions, consistently produces a product that meets all predetermined requirements. PQ is an annual requirement, with assessments undertaken at defined intervals, or after any major maintenance, repairs or modifications to equipment, or if there is a change of endoscope type or manufacturer. Requalification should also be performed as part of routine quality assurance processes.

9.3 Controlled-environment storage cabinets

Optimally, CESCs should be positioned close to both the endoscope reprocessing area and the procedure rooms. This is not possible in every unit, in which case the priority should be proximity to the reprocessing area, to avoid delays in placing wet, reprocessed endoscopes in the CESC.

The function of drying is complex and will incorporate the quality of air delivered to the cabinet, the mechanisms that are used to deliver that quality (e.g. HEPA filtration, type of compressor) and strict control of air pressure, humidity and temperature so as to avoid dew point. Piped-in air is preferred. The compressor needs to be oil-free and filtered to avoid contamination of the supplied air. Compressors must be able to provide large quantities of air in a short period but run reliably for extended periods. HEPA-filtered air is optimal.

Each manufacturer must provide defined, measurable parameters that can be monitored to ensure continued CESC performance.

CESCs must comply with the standards set out in AS 5369:2023.[86] In particular, they must comply with EN 16442:2015 and must have IQ–OQ–PQ checks, with PQ repeated annually (Box 9).

IQ and OQ are the responsibility of the vendor. PQ is the responsibility of the hospital or endoscopy unit but may be conducted by the vendor.

Box 9. Equipment validation checks for controlled-environment storage cabinets

Installation Qualification (IQ)
Is the location and operating environment of the workspace correct?

Operational Qualification (OQ)
Does the storage cabinet operate correctly?

Performance Qualification (PQ)
Is the combination of the workspace, machine and operators delivering an approved outcome?

PQ requires annual testing of the microbiological and air quality performance of the cabinet. Additional interval testing should be undertaken if organisms of concern are identified in microbiological cultures of endoscopes, and other sources of contamination have been excluded (see section 10.6.4.1). Endoscope drying rates and air quality are also tested. PQ can provide an insight into the interaction of endoscopy staff with the CESC. Endoscopy unit staff must be appropriately trained in the use of cabinets and specifically in avoidance of microbiological contamination. Under EN 16442, units with failed PQ microbiological tests are required to identify pathogens in the cabinets. The pathogen identified may be a guide to the source of the contamination (e.g. skin contact from a member of the endoscopy staff).

9.4 Automated flexible endoscope reprocessors

IQ and OQ are the responsibility of the AFER vendor. PQ is the responsibility of the hospital or endoscopy unit but may be conducted by the vendor or a qualified independent contractor. PQ requires annual testing of the AFER.

Documentation that the AFER has been validated for reprocessing the endoscope and endoscope components should be provided by the manufacturer. Model-specific reprocessing protocols for both the endoscope and AFER should be obtained, and compatibility verified. Often there is discrepancy between the endoscope manufacturer IFU and the AFER IFU. The processes that ensure the provision of a patient-ready endoscope will take precedence in such a situation. For example, in brushless cleaning: where an endoscope manufacturer's IFU includes manual cleaning, this is superseded by the AFER IFU when incorporating automated cleaning. Some AFERs have the capacity for sporicidal cycles, and monitoring the effectiveness of this cycle can be completed with the inclusion of a biological indicator placed within the bowl of the AFER.

9.5 Water

The requirements for water used in endoscope reprocessing are outlined in section 7.1. In particular, the need for final rinse water in AFERs to be tested for endotoxin levels should be noted (AS 5369:2023).[86] Monitoring standards are detailed in section 7.1.2 and monitoring intervals in section 10.4.

9.6 Preventive maintenance

Maintaining the safe, effective and efficient use of all equipment requires regular inspections, preventive maintenance programs, PQ and challenge testing of the endoscopes, reprocessing equipment and associated equipment (e.g. plumbing valves, filters, dosing systems) as per manufacturer's instructions and relevant standards. A multidisciplinary approach, including infection control, engineering, product technicians and others, is best suited to achieve this outcome.

Manufacturers' service contracts are advantageous as they allow for scheduled preventive maintenance inspections, as well as conducting repairs and providing loan equipment for use.

9.7 Endoscopes for repair

Unless a damaged endoscope has a suspected leak, it should be fully cleaned, disinfected and dried before being sent to a manufacturer for repair. If there is a suspected leak, contact the manufacturer for instructions on reprocessing and transport.

Advise the manufacturer of the most recent reprocessing that has been undertaken on the damaged endoscope and send documentation or confirmation of this with the endoscope. In most circumstances, the endoscope does not need to be placed in a biohazard bag; in exceptional

circumstances, such as an endoscope that has not been cleaned or is under infection control advice, place the endoscope in a biohazard bag or sheet and notify the courier of the biohazard status.

Send endoscopes for repair in the appropriate endoscope carrying case and include results of the most recent microbiological cultures.

9.8 Endoscopes received: newly purchased, on loan or on return from repair

The internal channel configuration diagram should be provided or available online for all endoscopes received on loan. A copy of the most recent microbiological test results may be requested from the supplier of loan instruments.

All endoscopes returning from servicing or received on loan are to be cleaned and disinfected before use. Endoscopes can be used after cleaning and disinfection and do not need to be kept quarantined while awaiting microbiological surveillance test results.

A microbiological surveillance culture for bacteria should be performed within 72 hours of receipt of the endoscope. If the result of the culture is positive, the instructions in section 10.7 should be followed.

Results of microbiological cultures from loan endoscopes should be provided to the manufacturer when the loan endoscope is returned.

Chapter 10: Microbiological surveillance cultures

Microbiological surveillance of endoscopes and AFERs has been a component of quality management in most endoscopy units in Australia and New Zealand since 1995. In Australia, the laboratory that performs microbiological testing must be accredited by the National Association of Testing Authorities (NATA) and include human pathology and clinical non-human specimen testing as part of its accredited scope of practice.

Microbiological cultures have not been universally adopted and are not mandated in the US. However, in 2015, the US FDA highlighted the importance of duodenoscope cultures after several endoscopy-related CPE outbreaks.[213] In a recently published study from a single US endoscopy centre, microbiological cultures were an essential component of optimising duodenoscope reprocessing protocols. This resulted in the withdrawal of duodenoscopes with a high rate of culture positivity, which in turn contributed to an overall decline in the HLD defect rate.[214]

With the introduction of CESCs, microbiological testing of endoscopes and storage cabinets has been outlined by the National Standards Authority of Ireland in EN 16442.[193]

Increasingly, laboratories are using polymerase chain reaction (PCR) testing to assess for the presence of microorganisms. The significance of PCR test results relative to standard microbiological culture results is unclear and requires investigation. PCR testing detects the presence of microbial components but does not confirm whether the microorganisms are viable or non-viable.

10.1 Rationale

Poor compliance with recommendations for endoscope reprocessing, faulty or contaminated AFERs or CESCs, or occult endoscope damage all increase the risk of transmission of infectious agents to patients undergoing endoscopic procedures. Endoscope and AFER microbiological cultures have identified breakdowns in infection control protocols that were unlikely to have been detected by other quality control measures.[215-219] In a retrospective series of 846 endoscope culture samples from a teaching hospital in France, 118 (14%) were positive for indicator organisms. The authors concluded that cultures were indispensable in monitoring reprocessing, reinforced good practice and detected instruments requiring maintenance.[220]

Experience in Australia and New Zealand has shown that the published recommendations for interpreting positive findings have allowed users to deal appropriately with insignificant contaminants and that negative culture results at a time of minor infection control breakdown have helped avoid unnecessary patient recall and testing. Published positivity rates of routine endoscope surveillance cultures have varied from high to very low.[171,221-224] The recommendations for surveillance cultures detailed below represent the minimum expected of Australasian endoscopy units.

10.2 Recommendation

This publication recommends the use of surveillance cultures of endoscopes, AFERs and CESCs as a quality control marker of the adequacy and completeness of the entire cleaning, disinfection and storage process and the structural integrity of the endoscope. The recommendations for when and how to perform these cultures are based on the international literature and local anecdotal experience.

10.3 Testing: what to look for

10.3.1 Bacteria

Bacterial cultures should be directed towards detecting pathogens of the anatomical site inspected by the instrument.

10.3.1.1 Gastrointestinal endoscopes

Bacteria relevant to gastrointestinal endoscopes are oral and enteric microorganisms, such as coliforms (including *Salmonella* spp and *Shigella* spp), enterococci, viridans streptococci and non-fermenting gram-negative bacilli (including *Pseudomonas* spp), but not anaerobes. Refer to Figures 6 and 7 in section 10.8

for the procedure to follow when microorganisms have been isolated from an endoscope.

10.3.1.2 Bronchoscopes

Bacteria relevant to bronchoscopes are the same as those for gastrointestinal endoscopes plus rapid-growing mycobacteria. Culturing to identify *M. tuberculosis* is not included in routine surveillance but is performed when there is a suspected outbreak or pseudo-outbreak of *M. tuberculosis* infection in patients who have undergone bronchoscopy. Refer to Figure 8 in section 10.8 for the procedure to follow when microorganisms have been isolated from a bronchoscope.

10.3.1.3 Automated flexible endoscope reprocessors

Bacteria relevant to AFERs are non-fermenting gram-negative bacilli (including *Pseudomonas* spp) and rapid-growing mycobacteria. Refer to Figure 9 in section 10.8 for the procedure to follow when microorganisms have been isolated from an AFER.

Testing for *Legionella* spp, anaerobes or *H. pylori* is **not** recommended.

10.3.1.4 Controlled-environment storage cabinets

Bacteria relevant to CESCs are non-fermenting gram-negative bacilli (including *Pseudomonas* spp) and rapid-growing mycobacteria. In addition, organisms related to human contact contamination (e.g. staphylococci) and fungi may be significant. Refer to Figure 10 in section 10.8 for the procedure to follow when microorganisms have been isolated from a CESC.

10.3.2 Viruses

Routine microbiological surveillance for viruses is not recommended.

10.4 Frequency of testing

Differential risks of infection transmission mean that the following recommendations (summarised in Table 9), which are themselves empirical, vary with both the proposed use of an endoscope and the method of disinfection:

- AFERs should be tested every month.
- Duodenoscopes, bronchoscopes and linear echoendoscopes should be monitored every month.
- All other gastrointestinal endoscopes and radial echoendoscopes should be monitored every 3 months.
- Endoscopes that have been reprocessed through a sterilisation cycle and stored in a wrapped state should be monitored every 3 months.
- Endoscopes received on loan or after repair can be used after reprocessing without the need for quarantining; however:
  - unless a microbiological culture has already been commercially completed and the result provided, endoscopes on loan or after repair are to be cultured within 72 hours of receipt of the instrument. The instrument should then be retested according to the routine schedule for the type of endoscope if it remains in use for that period of time.
- CESCs (EN 16442) should be tested as part of annual PQ.
- Further microbiological screening may be undertaken, in consultation with a clinical microbiologist, if:
  - there is a clinical suspicion of cross-infection related to endoscopy;
  - positive surveillance cultures occur;
  - alterations are made to the plumbing of the endoscopy reprocessing area;
  - new reprocessing protocols are introduced in the unit;
  - new models of equipment (endoscope or AFER) are used; or
  - as a means of quality check for new staff responsible for endoscope reprocessing.

10.5 Microbiological testing protocols

Endoscopes should be sampled after standard processing and storage of at least 12 hours to allow detection of microorganisms arising from a biofilm. Endoscopes that have undergone sterilisation and are stored in a wrapped state should be removed from the packaging and tested at the interval indicated in section 10.4. There should also be an interval of 12 hours from the last use of an AFER before

Table 9. Recommended frequency of endoscope and reprocessor testing and microorganisms of interest *(new in 2025)*

Device or scope	Recommended frequency of testing	Microorganisms of interest
AFER	Monthly	Non-fermenting gram-negative bacilli (including *Pseudomonas* spp) and rapid-growing mycobacteria
Duodenoscopes and linear ultrasound endoscopes	Monthly	Coliforms (including *Salmonella* spp), enterococci, viridans streptococci and non- fermenting gram-negative bacilli (including *Pseudomonas* spp)
Bronchoscopes*	Monthly	As for duodenoscopes, plus rapid-growing mycobacteria
Gastroscopes, colonoscopes, radial ultrasound endoscopes and enteroscopes	3-monthly	As for duodenoscopes
Processed endoscopes stored in wrapped state	3-monthly	As for duodenoscopes or bronchoscopes
Water supply for AFER's final rinse water	Monthly	Non-fermenting gram-negative bacilli (including *Pseudomonas* spp) and rapid-growing mycobacteria
Loan instruments	Within 72 hours of receipt (unless testing already completed and result provided) and then on routine schedule	As for duodenoscopes or bronchoscopes

AFER = automatic flexible endoscope reprocessor.

* Culture to identify *Mycobacterium tuberculosis* is not included in routine surveillance but should be performed on the next scheduled sampling from a bronchoscope that has been used on a patient who has a positive *M. tuberculosis* culture.

microbiological sampling. For CESCs, contact plate testing should be undertaken 7 days from the last cleaning of the cabinet.

10.6 Sampling methods

10.6.1 Endoscopes

1. Prepare a sterile field with a sterile drape of sufficient size to accommodate the endoscope and sampling equipment.
2. Sterile water or normal saline (10 mL) should be withdrawn from a freshly opened container using a sterile cannula or needle and syringe and placed into a sterile specimen container.
3. Sterile water or normal saline is flushed into each of the channels to be brush sampled. The volume of fluid required is different for each endoscope and will vary from 5 mL to 50 mL. Fluid should be flushed until it emerges from the distal tip. Any fluid that emerges from the distal tip is collected into the sterile specimen container. Attention should be paid to keeping the tip of the endoscope from touching the container, to avoid contamination.
4. A sterilised reusable or single-use endoscope brush is passed down the biopsy channel, withdrawn, and the tip agitated in the container containing the sterile water. This procedure should also be performed on any brushable channel of any endoscope (e.g. the balloon channel of an echoendoscope). The brush will need to be handled using sterile gloves; sterile gowns are optional. Reusable endoscope brushes should be cleaned and sterilised by steam under pressure or low-temperature sterilisation before sampling.
5. Using a sterile syringe, aliquots of sterile water are flushed through each of the air and water channels, suction channel, biopsy channel and forceps elevator, and balloon and jet channels where applicable. Flushing should be performed

from the connection points in the light guide plug and flow to the distal tip. The volume of fluid required is different for each endoscope and will vary from 5 mL to 50 mL; channel volume information should be provided by the endoscope manufacturer. Fluid should be flushed until it emerges from the distal tip. Air is then syringed through to empty the remaining fluid from each of the channels. For duodenoscopes with a fixed duodenal cap, 5 mL of sterile water should be flushed into the cap and collected. The total rinse fluid is collected in a sterile specimen container.

6. The samples should be pooled in a single container that is labelled and sent with a request form detailing the following:
   - type of endoscope sampled and serial number;
   - name of person to whom report should be sent; and
   - test requested – endoscope testing (see section 10.3).
7. Samples should be refrigerated, transported to the laboratory as soon as possible and kept cold during transport.
8. In the event of a persistently positive surveillance culture from an endoscope, the individual channels may need to be sampled and the rinse fluid placed into separate collection containers.
9. Antegrade sampling may need to be augmented by retrograde sampling in some instances (e.g. if there is suspicion of clinical transmission and antegrade samples are not positive, irregular positive cultures, AFER contamination, or pseudo-infections associated with bronchoscopy). Retrograde sampling is obtained by using the suction button of the endoscope to suction back the fluid used for flushing to the proximal channel opening.[215]
10. At the completion of sample collection, the endoscope needs to undergo standard reprocessing and storage before use.

10.6.2 Automated flexible endoscope reprocessors

Early detection of machine contamination is best achieved by a concentration process. The exact method of sample collection for an AFER will vary depending on the design of the individual machine. The AFER manufacturer should provide detailed instructions of the sampling method. Sample collection should be undertaken a minimum of 12 hours after the last use of the AFER. Ensure water line disinfection has not occurred during this time.

For machines using a filter process, a sterile, sealed, bacteria-retentive 0.2 µm or 0.45 µm filter should be connected to the outlet of the machine where it normally attaches to the endoscope, and at least 200 mL of fluid cycled through the filter in the rinse cycle mode. When completed, the filter should be placed into a specimen container and forwarded to the laboratory, where the disc can be removed and plated directly.

Some machines have a cycle for collection of water samples. These interrupt the flow of water into the bowl, allowing collection from the water outlet within the machine. Sample volume should be at least 200 mL. Care should be taken not to contaminate the outlet when collecting the sample.

If the machine does not provide either of these sampling processes, at least 200 mL of water remaining from a reprocessing cycle needs to be collected with a syringe and sterile cannula from the basin.

10.6.3 AFER water supply (for investigation of water contamination)

It is likely that a concentration process will also best achieve detection of rinse-water microorganisms.

After wiping the tip of the water faucet with 70% alcohol and allowing it to air dry, 50 mL of water should be run through the faucet and discarded. Then, using aseptic handling techniques, a 400 mL sample of water should be collected in a sterile container and sent to the laboratory, where a filtration process will concentrate the sample.[225]

As microorganisms (especially *Pseudomonas* species) can multiply in fluids, any delay, such as samples being collected in the late afternoon and not processed until the following day, may lead to erroneous results. Therefore, it is essential that the sample is promptly processed after collection. If there is likely to be any unavoidable delay, the sample should be refrigerated.

10.6.4 Controlled-environment storage cabinets

The testing laboratory should provide detailed instructions for the transfer of culture plates to the laboratory.[193]

10.6.4.1 Contact plates

It is recommended that the efficacy of cleaning and disinfection procedures be verified by determining the contamination level using contact agar plates placed in four zones in the CESC:

- two zones that could physically be in contact with the endoscope during storage;
- one zone at another location in the chamber of the storage cabinet; and
- one zone at the bottom of the cabinet.

The zones tested have a surface area of about 25 cm².

Sampling requires the use of tryptone soya contact agar plates with lecithin, polysorbate 80, sodium thiosulphate and L-histidine.

The sampling method is as follows:

- Roll the agar surface of the plate firmly over the surface to be sampled (see video at https://www.youtube.com/watch?v=KdndbLKHxmw).
- The media plate will leave a residue on the sampling site, which should be removed with a 70% alcohol wipe after sampling.

Label the agar plate with equipment/machine details, location of sample, and date and time of sampling.

Contact plates should be returned to the microbiology department immediately after exposure for incubation.

10.6.4.2 Air sampling

Samples to determine the quality of the air circulating in the CESC are collected using four tryptone soya agar plates with lecithin, polysorbate 80, sodium thiosulphate and L-histidine.

The four agar plates, with the lids removed, are placed at the bottom of each cabinet tray at equal distance from one another for 1 hour.

Plates should be returned to the microbiology department immediately after exposure for incubation.

10.7 Laboratory procedures

10.7.1 Endoscopes and rinse fluid from an automated flexible endoscope reprocessor

These samples may be processed in a clinical or environmental laboratory.

1. The collected sample should be centrifuged for 15 minutes at about 3000 rpm, then decanted to 1 mL and resuspended.
2. Transfer 100 µL of the sample and spread over the entire surface of the plate. Seal plates with parafilm to ensure they do not dry out.

Endoscopes			
Blood agar plate	O_2	Minimum 48 hours	35 ± 2°C
Blood agar plate	O_2	Minimum 48 hours	28 ± 2°C
AFER			
Blood agar plate	O_2	7 days	28 ± 2°C

3. Plates will need to be checked at 48 hours to identify rapidly growing bacteria, and attention should be paid to ensure the plates do not dry out. (Note: ISO 15883-4:2018 (E) describes an alternative method of testing for atypical *Mycobacterium* species in AFER rinse water by incubating on Middlebrook agar plates for 28 days at 30 ± 2°C before concluding that no growth has occurred.)
4. Semi-quantification of bacterial growth (e.g. no growth, 1–10 colonies, 10–100 colonies, >100 colonies) should be performed.
5. Any microorganisms isolated should be identified to genus ± species level in the microbiology report to to allow interpretation as detailed below and in Figures 6–10. Susceptibility testing is not routinely required.
6. If there is any growth of microorganisms, the unit that sent the samples should be notified that working day.

Should microfilter discs be used to sample the final rinse water of an AFER, the following protocol should be followed:

- Use a sterile 5 mL syringe to draw any remaining fluid through the filter.
- Loosen the top to release pressure and, using aseptic techniques, insert the metal disc provided into the groove around the filter housing.
- Twist the metal disc to prise the housing apart. Repeat around the circumference until the housing is open.
- Using sterile forceps, remove the filter paper and place on blood agar, with grid side up. Seal plates with parafilm and incubate aerobically at 28 ± 2°C for 7 days.

10.7.2 Controlled-environment storage cabinets

10.7.2.1 Contact plates

The tryptone soya contact plates should be incubated at 30°C for 5 days to determine the presence of bacteria and filamentous fungi.

After 5 days of incubation, the colonies are counted and the results expressed as number of colony-forming units (CFU) per plate (e.g. Site A, front left: 10 CFU). The total number of colonies isolated from each of the four plates is added together for a total count in CFU (e.g. Total: 20 CFU).

The contamination levels identified should be less than 25 CFU/25 cm^2.

A contamination level lower than 25 CFU is not satisfactory if the microorganisms recovered are considered to be pathogenic for the intended use of the device. This situation can require further investigation to identify the type and source of contamination.

10.7.2.2 Air sampling

On receipt in the laboratory, the tryptone soya plates should be incubated at 30°C for 5 days.

After 5 days of incubation, the colonies are counted and the results expressed in number of CFU per plate (e.g. Site 1, front left: 10 CFU). The total number of colonies isolated from each of the four plates is added together for a total count in CFU (e.g. Total: 20 CFU).

The tests are considered satisfactory if the total number of colonies on the four agar plates is less than 50 CFU.

A contamination level lower than 50 CFU is not satisfactory if the microorganisms recovered are considered to be pathogenic for the intended use of the device. This situation can require further investigation to identify the type and source of contamination.

10.8 Response to positive cultures

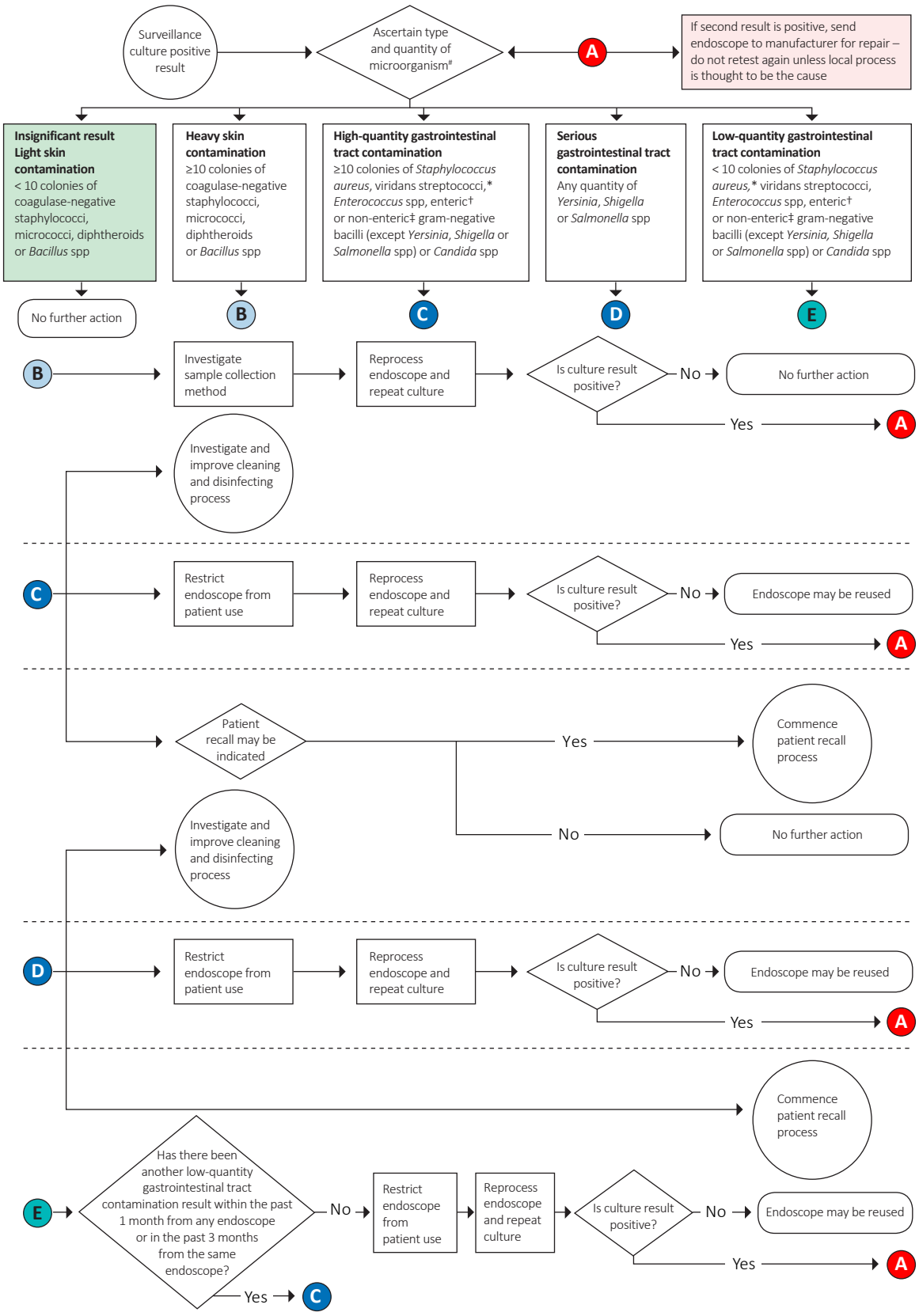
Once microorganisms have been isolated from an endoscope, AFER or CESC and identified, the procedure that should be followed is detailed in section 10.8.1 for gastroscopes and colonoscopes, section 10.8.2 for duodenoscopes, section 10.8.3 for bronchoscopes, section 10.8.4 for AFERs and section 10.8.5 for CESCs. The procedures are now summarised in tables, in addition to being illustrated in updated flowcharts.

All endoscopy surveillance culture results for endoscopes, AFERs, CESCs and water should be a standard agenda item at the organisation's Infection Control Committee or Medical Advisory Committee meeting for oversight of the results and organisational awareness of risks. Any incident triage meeting should involve infection prevention staff, specialty consultants and members of the workforce responsible for reprocessing RMDs. Discussion should focus on the patient journey and outcomes, specimens collected and test results, the endoscope journey (cleaning, reprocessing, storage, maintenance and routine microbiological testing) and the AFER (maintenance, filter changes, weekly biological testing and monthly microbiological test results).

10.8.1 Gastroscopes and colonoscopes

When cultures of a sample taken from a gastroscope or colonoscope show the presence of microorganisms, the procedure for responding is illustrated in Figure 6 and summarised in Table 10.

Figure 6. Response to positive cultures from a gastroscope or colonoscope *(updated in 2025)*



- - - The horizontal dashed lines in each process separate pathways that must **each** be followed.

\# For ≥10 colony-forming units of any other organism not mentioned, follow pathway B.

* *Staphylococcus aureus* or viridans streptococci, when found together with coagulase-negative staphylococci, micrococci, diphtheroids or *Bacillus* spp, should be treated as skin contaminants.

† Enteric gram-negative bacilli include *Escherichia coli*, *Klebsiella* spp, *Enterobacter* spp, *Serratia* spp, *Morganella* spp, *Citrobacter* spp and *Proteus* spp.

‡ Non-enteric gram-negative bacilli include *Pseudomonas* spp (including *Pseudomonas aeruginosa*), *Alcaligenes* spp, *Flavobacterium* spp, *Stenotrophomonas maltophilia* and *Acinetobacter* spp.

Table 10. Recommendations based on testing results for gastroscopes and colonoscopes *(new in 2025)*

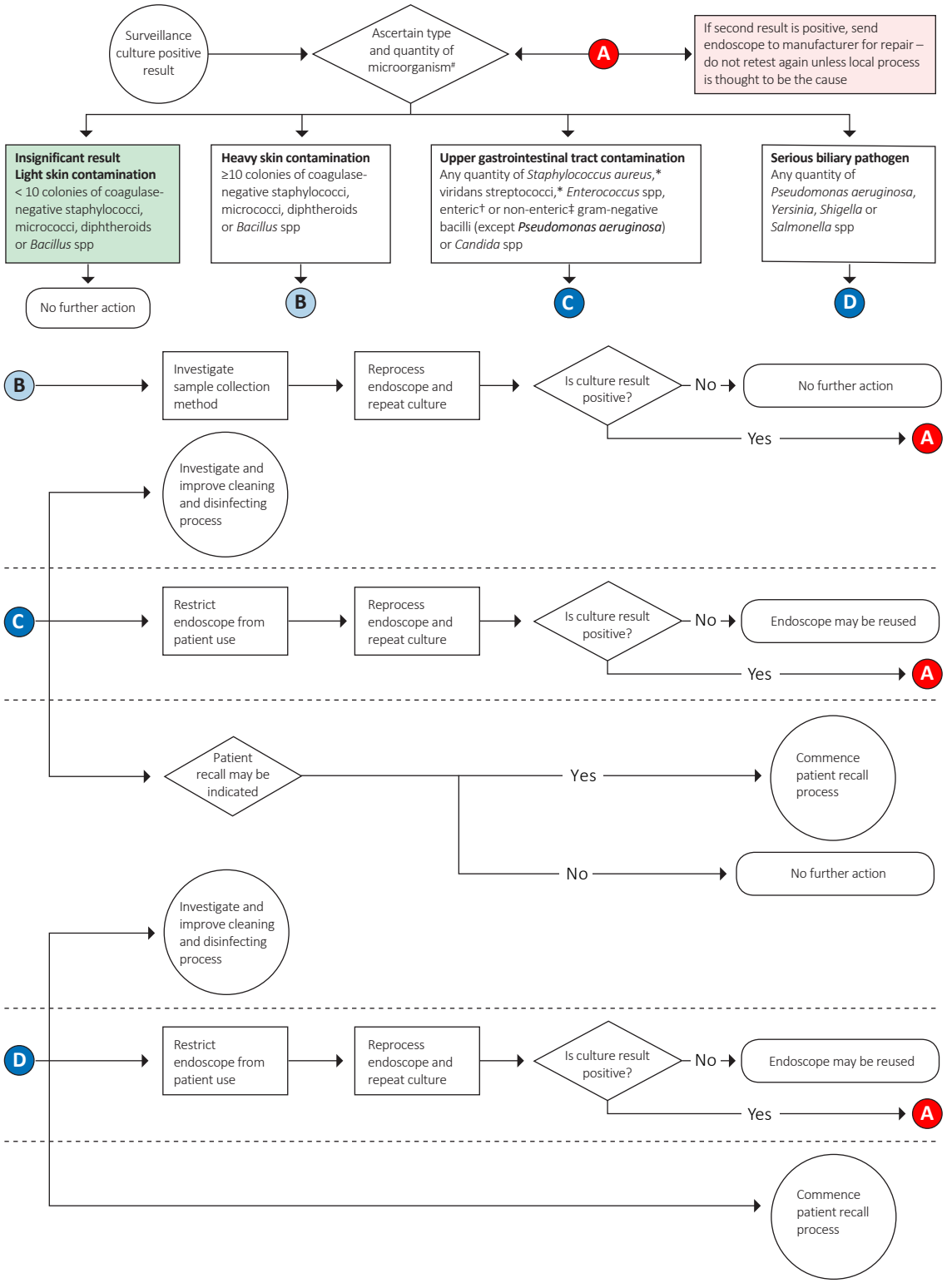
Culture classification	Culture result	Interpretation	Action
Light skin contamination	<10 colonies of skin flora (CNS, *Bacillus* spp, diphtheroids or micrococci)	Insignificant result	• No further action • If a repeated problem, educate staff on sample collection technique
Heavy skin contamination	≥10 colonies of skin flora (CNS, *Bacillus* spp, diphtheroids or micrococci)	Probable contamination during sample collection	• Investigate sample collection procedure • Reprocess endoscope and repeat culture • If repeat culture negative, no further action • If repeat culture positive, send endoscope to manufacturer for service or repair
Low-quantity gastrointestinal tract contamination	<10 colonies of *S. aureus*,* viridans streptococci,* *Enterococcus* spp, enteric or non-enteric gram-negative bacilli† (except *Yersinia*, *Salmonella* or *Shigella* spp) or *Candida* spp	Breaches in cleaning or disinfection process	• Investigate and improve cleaning and disinfecting procedure • Restrict endoscope from patient use • Reprocess endoscope and repeat culture • If repeat culture negative, endoscope may be reused • If repeat culture positive, send endoscope to manufacturer for service or repair
High-quantity gastrointestinal tract contamination	≥10 colonies of *S. aureus*,* viridans streptococci,* *Enterococcus* spp, enteric or non-enteric gram-negative bacilli† (except *Yersinia*, *Salmonella* or *Shigella* spp) or *Candida* spp	Significant breach in cleaning or disinfection process	• Investigate and improve cleaning and disinfecting procedure • Restrict endoscope from patient use • Patient recall may be indicated • Reprocess endoscope and repeat culture • If repeat culture negative, endoscope may be reused • If repeat culture positive, consider structural fault in endoscope and send to manufacturer for service or repair
Serious gastrointestinal tract contamination	Any quantity of *Yersinia*, *Salmonella* or *Shigella* spp	Major breach in cleaning or disinfection process	• Investigate and improve cleaning and disinfecting procedure • Restrict endoscope from patient use • Initiate patient recall • Reprocess endoscope and repeat culture • If repeat culture negative, endoscope may be reused • If repeat culture positive, consider structural fault in endoscope and send to manufacturer for service or repair

CNS = coagulase-negative staphylococci; *S. aureus* = *Staphylococcus aureus*.
* *S. aureus* or viridans streptococci, when found together with CNS, micrococci, diphtheroids or *Bacillus* spp, should be treated as skin contaminants.
† Enteric gram-negative bacilli include *Escherichia coli*, *Klebsiella* spp, *Enterobacter* spp, *Serratia* spp, *Morganella* spp, *Citrobacter* spp and *Proteus* spp. Non-enteric gram-negative bacilli include *Pseudomonas* spp (including *Pseudomonas aeruginosa*), *Alcaligenes* spp, *Flavobacterium* spp, *Stenotrophomonas maltophilia* and *Acinetobacter* spp.

10.8.2 Duodenoscopes

When cultures of a sample taken from a duodenoscope show the presence of microorganisms, the procedure for responding is illustrated in Figure 7 and summarised in Table 11.

Figure 7. Response to positive cultures from a duodenoscope *(updated in 2025)*



- - - The horizontal dashed lines in each process separate pathways that must **each** be followed.
\# For ≥10 colony-forming units of any other organism not mentioned, follow pathway B.
* *Staphylococcus aureus* or viridans streptococci, when found together with coagulase-negative staphylococci, micrococci, diphtheroids or *Bacillus* spp, should be treated as skin contaminants.
† Enteric gram-negative bacilli include *Escherichia coli*, *Klebsiella* spp, *Enterobacter* spp, *Serratia* spp, *Morganella* spp, *Citrobacter* spp and *Proteus* spp.
‡ Non-enteric gram-negative bacilli include *Pseudomonas* spp. (including *P. aeruginosa*), *Alcaligenes* spp, *Flavobacterium* spp, *Stenotrophomonas maltophilia* and *Acinetobacter* spp.

Table 11. Recommendations based on testing results for duodenoscopes *(new in 2025)*

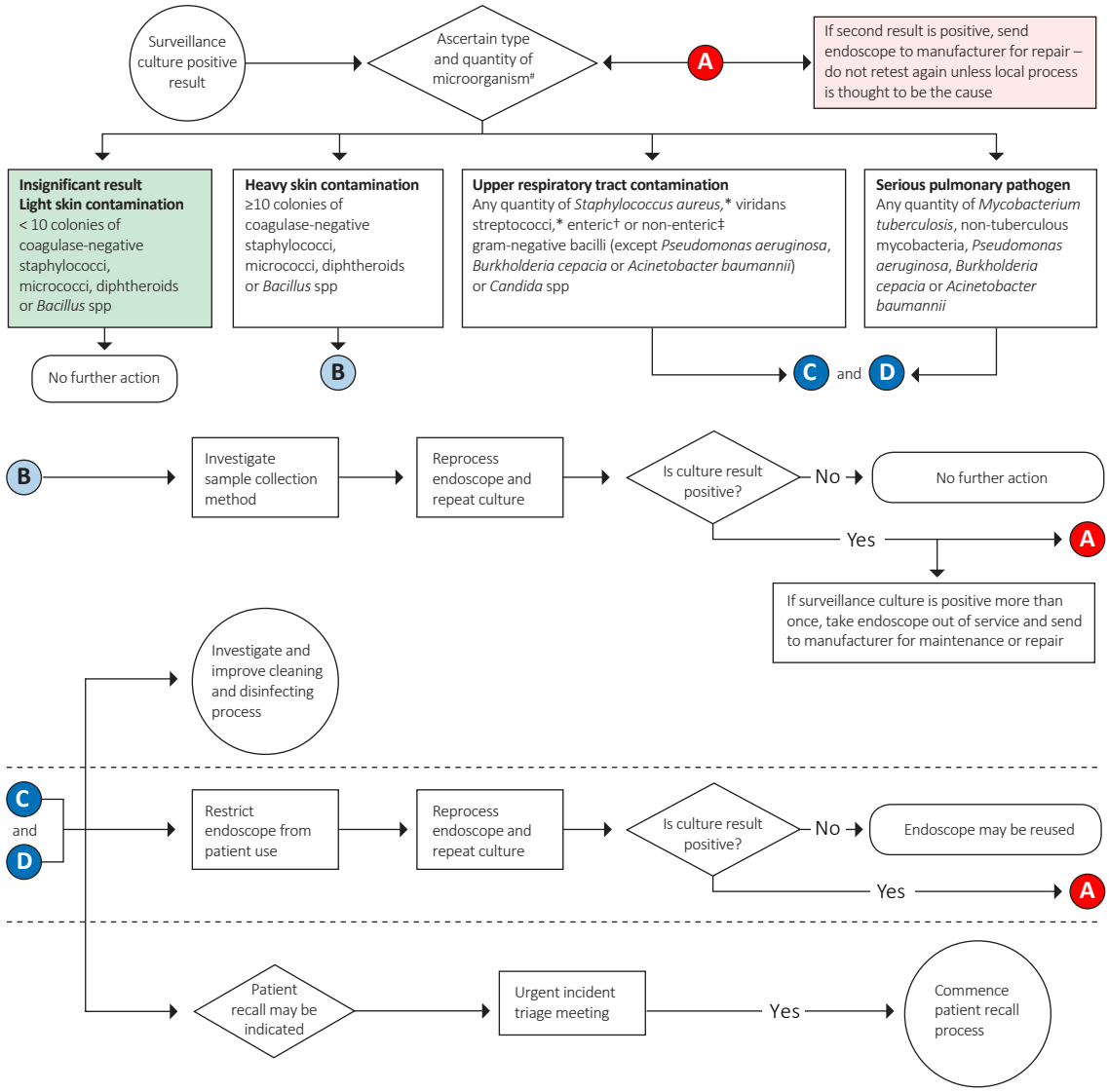
Culture classification	Culture result	Interpretation	Action
Light skin contamination	<10 colonies of skin flora (CNS, *Bacillus* spp, diphtheroids or micrococci)	Insignificant result	• No further action • If a repeated problem, educate staff on sample collection technique
Heavy skin contamination	≥10 colonies of skin flora (CNS, *Bacillus* spp, diphtheroids or micrococci)	Probable contamination during sample collection	• Investigate sample collection procedure • Reprocess endoscope and repeat culture • If repeat culture negative, no further action • If repeat culture positive, send endoscope to manufacturer for service or repair
Upper gastrointestinal tract contamination	Any quantity of *S. aureus*,* viridans streptococci,* *Enterococcus* spp, enteric or non-enteric gram-negative bacilli† (except *P. aeruginosa*) or *Candida* spp	Incomplete cleaning or disinfection	• Investigate and improve cleaning and disinfecting procedure • Restrict endoscope from patient use • Patient recall may be indicated • Reprocess endoscope and repeat culture • If repeat culture negative, endoscope may be reused • If repeat culture positive, send endoscope to manufacturer for service or repair
Serious biliary pathogen	Any quantity of *P. aeruginosa*, *Yersinia*, *Shigella* or *Salmonella* spp	Incomplete cleaning or disinfection	• Investigate and improve cleaning and disinfecting procedure • Restrict endoscope from patient use • Initiate patient recall • Reprocess endoscope and repeat culture • If repeat culture negative, endoscope may be reused • If repeat culture positive, consider structural fault in endoscope and send to manufacturer for service or repair

CNS = coagulase-negative staphylococci; *P. aeruginosa* = *Pseudomonas aeruginosa*; *S. aureus* = *Staphylococcus aureus*.
* *S. aureus* or viridans streptococci, when found together with CNS, micrococci, diphtheroids or *Bacillus* spp, should be treated as skin contaminants.
† Enteric gram-negative bacilli include *Escherichia coli*, *Klebsiella* spp, *Enterobacter* spp, *Serratia* spp, *Morganella* spp, *Citrobacter* spp and *Proteus* spp. Non-enteric gram-negative bacilli include *Pseudomonas* spp (including *P. aeruginosa*), *Alcaligenes* spp, *Flavobacterium* spp, *Stenotrophomonas maltophilia* and *Acinetobacter* spp.

10.8.3 Bronchoscopes

When cultures of a sample taken from a bronchoscope show the presence of microorganisms, the procedure for responding is illustrated in Figure 8 and summarised in Table 12.

Figure 8. Response to positive cultures from a bronchoscope *(updated in 2025)*



- - - The horizontal dashed lines in each process separate pathways that must **each** be followed.
\# For ≥10 colony-forming units of any other organism not mentioned, follow pathway B.
* *Staphylococcus aureus* or viridans streptococci, when found together with coagulase-negative staphylococci, micrococci, diphtheroids or *Bacillus* spp, should be treated as skin contaminants.
† Enteric gram-negative bacilli include *Escherichia coli*, *Klebsiella* spp, *Enterobacter* spp, *Serratia* spp, *Morganella* spp, *Citrobacter* spp and *Proteus* spp.
‡ Non-enteric gram-negative bacilli include *Pseudomonas* spp (including *P. aeruginosa*), *Alcaligenes* spp, *Flavobacterium* spp, *Stenotrophomonas maltophilia* and *Acinetobacter* spp.

Table 12. Recommendations based on testing results for bronchoscopes *(new in 2025)*

Culture classification	Culture result	Interpretation	Action
Light skin contamination	<10 colonies of skin flora (CNS, *Bacillus* spp, diphtheroids or micrococci)	Insignificant result	• No further action • If a repeated problem, educate staff on sample collection technique
Heavy skin contamination	≥10 colonies of skin flora (CNS, *Bacillus* spp, diphtheroids or micrococci)	Probable contamination during sample collection	• Investigate sample collection procedure • Reprocess endoscope and repeat culture • If repeat culture negative, no further action • If repeat culture positive, send endoscope to manufacturer for service or repair
Upper respiratory tract contamination	Any quantity of *S. aureus*,* viridans streptococci,* non-tuberculous mycobacteria, enteric or non-enteric gram-negative bacilli† other than those classed as serious pathogens (see below) or *Candida* spp	Breaches in cleaning or disinfection process	• Investigate and improve cleaning and disinfecting procedure • Restrict endoscope from patient use • Reprocess endoscope and repeat culture • If repeat culture negative, endoscope may be reused • If repeat culture positive, send endoscope to manufacturer for service or repair
Serious pulmonary pathogen	Any growth of *M. tuberculosis*, *P. aeruginosa*, *B. cepacia* or *A. baumannii*	Major breach in cleaning or disinfection process	• Investigate and improve cleaning and disinfecting procedure • Restrict endoscope from patient use • Initiate patient recall • Reprocess endoscope and repeat culture • If repeat culture negative, endoscope may be reused • If repeat culture positive, retest and consult a clinical microbiologist

A. baumannii = *Acinetobacter baumannii*; *B. cepacia* = *Burkholderia cepacia*; CNS = coagulase-negative staphylococci; *M. tuberculosis* = *Mycobacterium tuberculosis*; *P. aeruginosa* = *Pseudomonas aeruginosa*; *S. aureus* = *Staphylococcus aureus*.

* *S. aureus* or viridans streptococci, when found together with CNS, micrococci, diphtheroids or *Bacillus* spp, should be treated as skin contaminants.

† Enteric gram-negative bacilli include *Escherichia coli*, *Klebsiella* spp, *Enterobacter* spp, *Serratia* spp, *Morganella* spp, *Citrobacter* spp and *Proteus* spp. Non-enteric gram-negative bacilli include *Pseudomonas* spp (including *P. aeruginosa*), *Alcaligenes* spp, *Flavobacterium* spp, *Stenotrophomonas maltophilia* and *Acinetobacter* spp.

10.8.4 Automated flexible endoscope reprocessors

When cultures of a sample taken from an AFER show the presence of microorganisms, the procedure for responding is illustrated in Figure 9 and summarised in Table 13.

Figure 9. Response to positive cultures from an automated flexible endoscope reprocessor (AFER) ***(updated in 2025)***

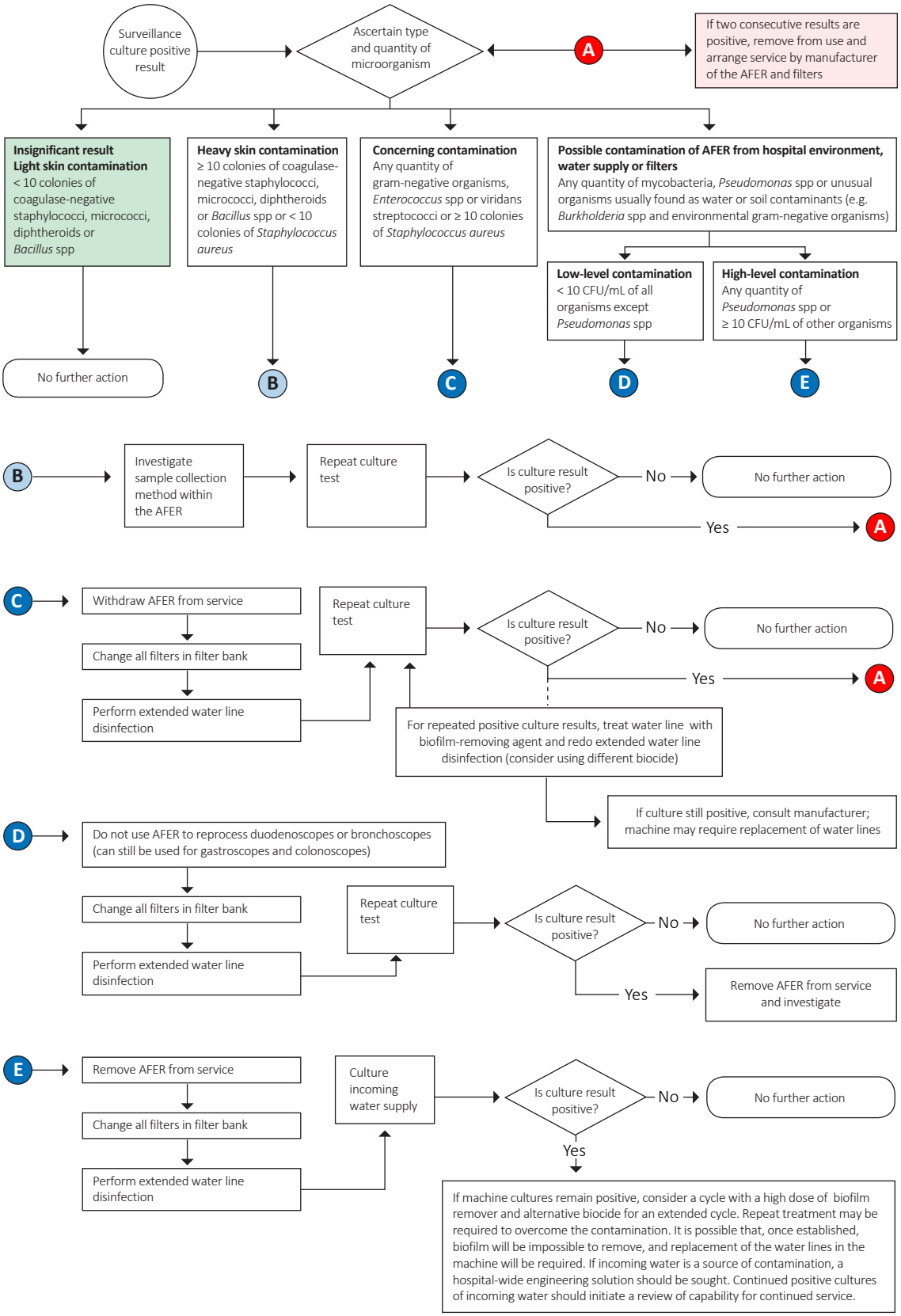


Table 13. Recommendations based on testing results for automated flexible endoscope reprocessors *(new in 2025)*

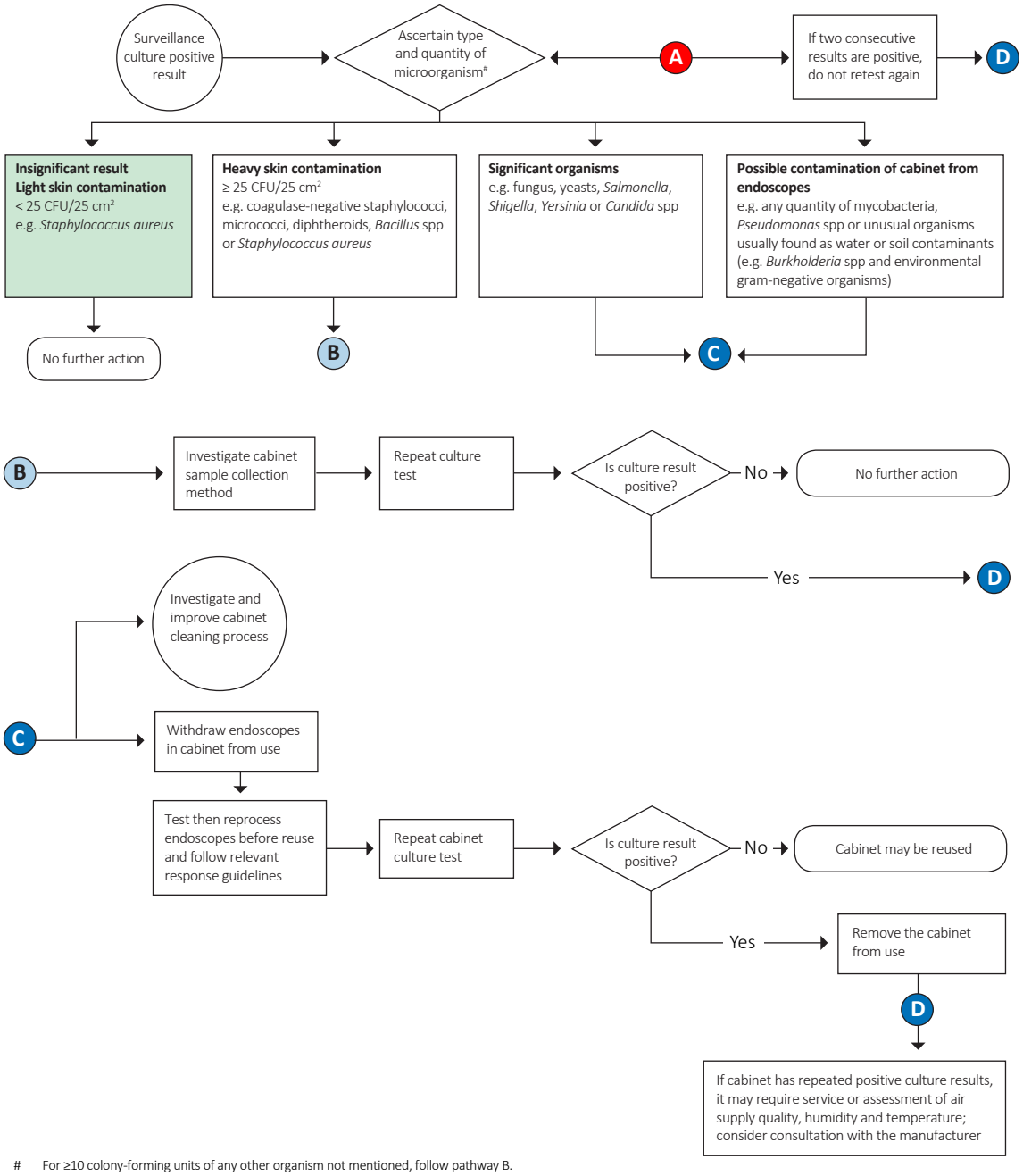
Culture classification	Culture result	Interpretation	Action
Light skin contamination	<10 colonies of skin flora (CNS, *Bacillus* spp, diphtheroids or micrococci)	Insignificant result	• No further action • If a repeated problem, educate staff on sample collection technique
Heavy skin contamination	≥10 colonies of skin flora (CNS, *Bacillus* spp, diphtheroids or micrococci) or <10 colonies of *S. aureus*	Probable contamination during sample collection	• Investigate sample collection procedure • Repeat culture • If repeat culture negative, no further action • If repeat culture positive, contact manufacturer for service or repair
Concerning contamination	Any quantity of gram-negative bacilli, *Enterococcus* spp or viridans streptococci, or ≥10 colonies of *S. aureus*	Ineffective water line disinfection; possible biofilm growth in line	• Withdraw AFER from service • Change all filters in filter bank • Perform extended water line disinfection • Repeat culture • If repeat culture negative, no further action • If repeat culture positive, treat water line with biofilm-removing agent and redo extended water line disinfection; consider using different biocide • If culture remains positive, consult manufacturer as machine may require replacement of water lines
Possible contamination from hospital environment, water supply or filters	Any quantity of mycobacteria, *Pseudomonas* spp or unusual organisms usually found as water or soil contaminants (e.g. *Burkholderia* spp and environmental gram-negative organisms)		
Low-level contamination: <10 CFU/mL of all organisms except *Pseudomonas* spp		Possible contamination from hospital environment, water supply or filters	• Do not use AFER to process bronchoscopes or duodenoscopes (can be used for gastroscopes and colonoscopes) • Change all filters in filter bank • Perform extended water line disinfection • Repeat culture • If repeat culture negative, no further action • If culture remains positive, consult manufacturer, as machine may require replacement of water lines
High-level contamination: Any quantity of *Pseudomonas* spp or ≥10 CFU/mL of other organisms		Ineffective water line disinfection; possible biofilm growth in line	• Withdraw AFER from service • Change all filters in filter bank • Perform extended water line disinfection • Culture incoming water supply • If repeat culture negative, no further action • If culture remains positive, consider an extended cycle with a high dose of biofilm remover and alternative biocide; repeat treatment may be needed • Replacement of water lines may be required • If incoming water is a source of contamination, seek a hospital-wide engineering solution • Continued positive cultures of incoming water should initiate a review of capability for continued service

AFER = automatic flexible endoscope reprocessor; CNS = coagulase-negative staphylococci; *S. aureus* = *Staphylococcus aureus*.

10.8.5 Controlled-environment storage cabinets

When cultures of a sample taken from a CESC show the presence of microorganisms, the procedure for responding is illustrated in Figure 10 and summarised in Table 14.

Figure 10. Response to positive cultures from a controlled-environment storage cabinet *(updated in 2025)*



For ≥10 colony-forming units of any other organism not mentioned, follow pathway B.

Table 14. Recommendations based on testing results for controlled-environment storage cabinets *(new in 2025)*

Culture classification	Culture result	Interpretation	Action
Light skin contamination	<25 CFU/25 cm^2 (e.g. *S. aureus*)	Insignificant result	• No further action
Heavy skin contamination	≥25 CFU/25 cm^2 (e.g. CNS, micrococci, diphtheroids, *Bacillus* spp or *S. aureus*)	Probable contamination during sample collection	• Investigate cabinet sample collection procedure • Repeat culture • If repeat culture negative, no further action • If repeat culture positive, consult manufacturer as service of air supply quality, humidity and temperature may be needed
Significant organisms	Fungus, yeasts, *Salmonella*, *Shigella*, *Yersinia* or *Candida* spp	Major breach in cleaning or disinfection process	• Investigate and improve cabinet cleaning process • Withdraw endoscopes in the cabinet from use • Test then reprocess endoscopes before use and follow relevant response guidelines • Repeat cabinet culture • If repeat culture negative, cabinet may be reused • If repeat culture positive, remove cabinet from use and consult manufacturer, as service of air supply quality, humidity and temperature may be needed
Possible contamination of cabinet from endoscopes	Any quantity of mycobacteria, *Pseudomonas* spp or unusual organisms usually found as water or soil contaminants (e.g. *Burkholderia* spp and environmental gram-negative organisms)	Possible contamination from hospital environment, water supply or filters	

CFU = colony-forming units; CNS = coagulase-negative staphylococci; *S. aureus* = *Staphylococcus aureus*.

10.9 Water quality monitoring

The quality requirements for water used in endoscope reprocessing are outlined in section 7.1. Levels of bacterial endotoxin are used as a water quality marker. Endotoxins are heat-stable, negatively charged lipopolysaccharide–protein complexes embedded in the outer membrane of gram-negative bacteria and some cyanobacteria. They are not affected by most sterilisation processes, such as steam, ethylene gas and gamma or electron beam irradiation. Bacterial cell death, antibiotics and antibodies may cause the release of endotoxins, which cause an inflammatory response. Water treatment processes capable of ensuring low levels of endotoxins should be used. Monitoring intervals and standards are determined in Table 8.1 of AS 5369:2023.[86]

Increased levels of endotoxins are an indication of decreasing water quality. Action should be taken to determine the source of the endotoxins and remediate the system; however, unless the total viable count is also at an unacceptable level, the AFER may continue to be used after a risk assessment.

10.10 Proof of process

10.10.1 Accreditation, approval and training

Endoscopy should only be undertaken at sites that have adequate facilities for cleaning and disinfection.[27,226] A site audit tool may be developed to allow staff to identify whether their practice is compliant with the recommendations in this document.[227] Many state health departments have their own audit tools that can be used.

All reprocessing (cleaning, disinfection and sterilisation) must be undertaken in line with relevant national and international guidelines and recommendations and with consideration of manufacturer instructions. Manufacturer instructions must be consistent with Australian reprocessing requirements. Current and complete IFU documents must be provided to the reprocessing area and endoscopy staff.

Only staff who have completed a structured education or training program and who have had their competency to perform the tasks of cleaning, disinfection and sterilisation assessed, or those who are undergoing supervised training, shall carry out these tasks.[27] These staff should have a clear understanding of both the important principles involved in the cleaning and disinfection of endoscopes and accessories, as described in these recommendations, and the details of each step of the reprocessing protocol.

10.10.2 Documentation required

As part of the quality monitoring system, documentation records prospectively ensure that all staff are following the correct procedure and that the equipment and solutions are functioning correctly at the time of reprocessing each endoscope. These records also allow retrospective investigation into the possible transmission of infection or the source of endoscope contamination.

Records to be kept include, but are not limited to:

- details of the organisation's preventive maintenance program for all reprocessing equipment, endoscopes, accessories and associated equipment (this documentation should be retained in line with requirements for retention of records and should include any decommissioned equipment); and
- an inventory of all endoscopes in use, under repair or decommissioned, including (but not limited to):
  - endoscope manufacturer and model;
  - unique identifier for the endoscope;
  - number of procedures performed;
  - location of the endoscope manufacturer's IFU;
  - equipment used for HLD and/or sterilisation; and
  - status of the endoscope (i.e. in use, out for repair, decommissioned).

Documentation for tracking endoscope reprocessing will likely be obtained from multiple sources and may be stored in a combination of paper and electronic systems. Some commercial tracking systems permit input from various systems.

For every list, the documentation required is the order of patients on the list.

For every endoscope reprocessed, the documentation required is:[118]

- date of procedure;
- patient details — this could be formatted on a facility label (the name is to be linked to the details of the process that prepared the instrument ready for use on that patient);
- instrument details (individual serial number);
- name of the person who completed the manual cleaning phase of reprocessing or who connected the endoscope to the AFER for automated reprocessing, or name of the person who connected the endoscope to the AFER after manual cleaning;
- name of the person who removed the instrument from the AFER and released the endoscope as ready for patient use; and
- these time points should be identifiable if required: procedure end/immediate bedside decontamination, manual cleaning (if performed), placement in AFER and commencement and completion of storage time in CESC.

For other parameters, the documentation required is:

- batch number of disinfectant;
- ultrasonic testing (if located in endoscopy unit); and
- water filtration pressure checks may be required on some AFERs.

Modern AFERs monitor the process parameters for the machine cycle and prevent the continuation of the cycle if the parameters have not been met. These data are recorded within the machine, and the record is also provided on a computer printout docket. If a manual record system is in use, these dockets should be attached to the unit record and a copy can be attached to the patient's health care record. If the unit records are held electronically, the process records from the machine should be downloaded to a facility-specific safe storage.

Documentation also includes use of an incident reporting system to record any reprocessing incidents that involve endoscopes, accessories or associated equipment.

Chapter 11: Response to possible endoscopy-related infection transmission

The approach to an investigation of possible endoscopy-related infection transmission depends on the source of the initial concern:

- A complaint may be received from a patient who became ill or was found to be infected with a blood-borne virus after endoscopy.
- Clinical staff may notice patients with a similar disease after endoscopy.
- Laboratory staff may isolate the same microorganism from a cluster of patients who have recently had an endoscopic procedure.
- A fault in an item of equipment or a product (e.g. batch of disinfectant) may be identified.
- A breakdown in protocol (e.g. a new staff member has not been using the correct channel connectors) may be identified.
- A microbiological surveillance culture of an endoscope or AFER may return a positive result.[228,229]

11.1 Actions and investigations required

The initial actions that should be taken to investigate possible endoscopy-related infection transmission are as follows:

1. Do not ignore or trivialise evidence of a potential problem.
2. Ask for independent help early and be open, honest and cooperative. Initial advice should be sought from an infection control practitioner, epidemiologist, public health specialist or infectious disease specialist. Members of the IPCE Committee (see Appendix 2) are experienced with investigating possible transmission events and willing to be contacted for advice.
3. Inform key stakeholders (medical and nursing directors and risk management staff) if a significant problem is confirmed.

Immediate action and subsequent investigations will depend on the presenting scenario (see Table 15).

If transmission of infection or a major problem with endoscope cleaning or disinfection is suspected, wider investigation and public notification may be indicated. Before undertaking this, an appropriate local, state or federal working group should be established to manage the process. The following people should be considered as members of the working group:

- endoscopy unit manager;
- relevant clinicians;
- infection control practitioner, epidemiologist or public health specialist;
- microbiologist or infectious disease specialist;
- relevant administration staff from the organisation;
- state or federal health representatives (essential and likely to take overall responsibility for the investigation);
- manufacturers of any equipment or product implicated in the problem;
- someone with expertise in communication;
- a lawyer; and
- a representative of the local patient advocacy service.

Table 15. Immediate actions and investigations required, by presenting scenario

Scenario	Immediate action	Investigations

Single patient with alleged pathogen or disease after endoscopy	• Arrange clinical review of the patient to:
	  • ensure patient wellbeing
	  • determine microbial cause
	  • identify other possible causes of disease or sources of infection.
	External clinical input is necessary but should not deter ongoing clinical involvement by staff from the unit under investigation.
		If plausible and there is a temporal link to endoscopy:
		• Look for other cases (this may involve contacting patients who had a procedure at that time for clinical review and laboratory testing for the same disease or microorganism).
		• Perform a case–control analysis if required to determine a link with endoscopy.
		• Review endoscopy unit documentation, protocols and relevant equipment and products.
		• Review surveillance cultures.
		• Analyse QC and tracking records for any common link between affected patients (e.g. same endoscope, AFER, staff member).

Cluster of patients with similar pathogens or diseases after endoscopy	• Arrange clinical review of patients to:
	  • ensure patient wellbeing
	  • determine microbial cause.
	External clinical input is necessary but should not deter ongoing clinical involvement by staff from the unit under investigation.
	• Withdraw endoscope(s) or AFER(s) from use or rectify protocol if implicated by initial investigation of cases.
	• If patients have hepatitis C, consider multidose sedative vial contamination or inappropriate reuse of single-use items for preparation and administration of procedural sedative as a cause.
		• Look for other cases (this may involve contacting patients who had a procedure at that time for clinical review and laboratory testing for the same disease or microorganism).
		• Perform a case–control analysis if required to determine a link with endoscopy.
		• Review endoscopy unit documentation, protocols and relevant equipment and products.
		• Review surveillance cultures and consider genomic testing.
		• Analyse QC and tracking records for any common link between affected patients (e.g. same endoscope, AFER, staff member).

Cluster of positive cultures (e.g. bronchial washings, bile) for same microorganism after endoscopy	• Arrange clinical review of patients with positive cultures to ensure patient wellbeing. • Withdraw endoscope(s) or AFER(s) from use or rectify protocol if implicated by initial investigation of cases.	• Look for other cases (this may involve contacting patients who had a procedure at that time for clinical review and laboratory testing for the same microorganism). • Review endoscopy unit documentation, protocols and relevant equipment and products. • Review surveillance cultures. • Analyse QC and tracking records for any common link between positive cultures (e.g. same endoscope, AFER, staff member). • Perform targeted environmental sampling.

Table 15. Immediate actions and investigations required, by presenting scenario (continued)

Scenario	Immediate action	Investigations
Defect in equipment or product or breakdown in protocol	• Stop using any defective equipment or products. • Impound any items that may not have been properly reprocessed. • Correct the defect or protocol.	• Determine the approximate duration of the problem. • Determine how serious the problem has been in terms of patient risk (review endoscopy unit documentation, compliance with protocols and surveillance cultures for the duration of the problem). Note that many processes have margins for error, and a fault in equipment or protocol may not indicate significant patient risk. • Determine the cause of the problem. • If confirmed to be a significant problem, consider notification and review or testing of patients at risk.
Positive surveillance cultures	• See flowcharts in section 10.8.	• See flowcharts in section 10.8.

AFER = automated flexible endoscope reprocessor; QC = quality control.

11.2 Patient recall and testing

The decision to recall and test patients at risk is difficult. Benefits of patient recall and testing include detecting patients with infection or colonisation, which may make it possible to treat their infection and/or prevent transmission to others; and providing community and patient assurance that the clinicians and organisation are responsive and open.

Disadvantages of patient recall and testing include the following:

- Publicity that follows recall and testing of patients may lead to unwarranted fear and avoidance of endoscopy in the community, leading to missed opportunities for diagnosis and treatment.
- A small number of patients who are notified of a risk, even a very small risk, may experience significant anxiety.
- Patient follow-up is costly in terms of time and other resources.
- The resulting patient benefit is likely to be small, as transmission of significant infection is rare even when an error in reprocessing occurs.[230-232]
- As it is often uncertain how long an identified problem has existed, patients who had their endoscopic procedure before the problem developed may be unnecessarily recalled and tested.
- Patients with previously undiagnosed blood-borne virus infection may falsely attribute this to the endoscopy.

The following are general principles for how to conduct patient recall and testing:

- Nominate a spokesperson for the group.
- Maintain a document register or “trail”.
- Prepare written information regarding the problem, risks involved, rationale for action, how testing will be undertaken and how and when results will be made available.
- Contact affected patients early to inform them of the problem and the estimated risks. Successful notification or attempts at notification should be recorded.
- Apologise for the problem and emphasise the low risk of transmission of infection.
- If patient testing is indicated, the earlier this is done, the better. Early identification of affected patients may expedite treatment, reduce the risk of further transmission and aid epidemiological

investigation. Early serological testing may help distinguish between patients whose blood-borne virus infection was pre-existing and those who acquired the infection from an endoscopic procedure.

- Advise patients at risk of blood-borne infections not to donate blood or tissue products or engage in sexual activity without barrier protection until serological testing is complete.
- Inform relevant staff within the organisation, general practitioners in the area, health authorities and industry representatives (e.g. AFER suppliers).
- If appropriate, make available a free informational video, telephone information line or one-to-one counselling service for patients and staff.
- The cost of patient recall and testing may be borne by the facility responsible for the problem, the local health authority or the manufacturer of faulty equipment.
- If the media are to be notified, ensure that patients are notified first. Prepare a media release in anticipation of media interest.

Patients who had an endoscopy around the time of suspected or proven endoscopy-related transmission of any microorganism, a high-risk defect in equipment or breakdown in protocol, or a cluster of positive surveillance cultures that indicate a major defect in equipment or breakdown in protocol should be tested for blood-borne viruses (hepatitis B, hepatitis C, HIV). The results of patients' previous blood-borne virus testing or vaccination should be located. Baseline and follow-up testing should be performed according to local protocols for blood-borne virus exposure.

Patients who underwent bronchoscopy at the time of an apparent outbreak (or pseudo-outbreak) of any specific bacteria or mycobacteria should be tested for that microorganism.

Patients who underwent bronchoscopy at the time of an apparent high-risk defect in equipment or breakdown in protocol, after a patient with known pulmonary or laryngeal tuberculosis underwent bronchoscopy, should be tested for *M. tuberculosis*.

SECTION D: WORKPLACE HEALTH AND SAFETY

Chapter 12: Legislation

In each jurisdiction (Commonwealth, state or territory), there is occupational health and safety legislation that details broad duties of the workplace parties. Commonly included in each Act are requirements for:

- ensuring the workplace health and safety of employees at work;
- providing systems of work that are safe and without risk to health;
- preventing occupational injuries and diseases; and
- protecting the health and safety of others (e.g. workplace visitors) in relation to work activities.

The Act may also include requirements for:

- providing a safe working environment;
- providing information, instruction and training;
- maintaining plant in a safe condition; and
- rehabilitation and maximum recovery from incapacity of injured employees.

The key principle in each Act is the "duty of care". This imposes obligations on employers to ensure the workplace health and safety of employees at work. This obligation extends to the health and safety of others, such as contractors, patients and visitors. There is also an obligation on employees to ensure their own workplace health and safety and that of others, and to cooperate with employers on workplace health and safety matters.

The workplace health and safety websites of the state, territory and Commonwealth governments are listed in Box 10. In addition, the relevant legislation for each jurisdiction can be accessed via the Australasian Legal Information Institute (www.austlii.edu.au).

Box 10. Government workplace health and safety websites

- WorkSafe Queensland — www.worksafe.qld.gov.au
- SafeWork New South Wales — www.safework.nsw.gov.au
- WorkSafe Australian Capital Territory — www.worksafe.act.gov.au
- WorkSafe Victoria — www.worksafe.vic.gov.au
- WorkSafe Tasmania — www.worksafe.tas.gov.au
- SafeWork South Australia — www.safework.sa.gov.au
- WorkSafe Western Australia — www.commerce.wa.gov.au/worksafe
- Northern Territory WorkSafe — https://worksafe.nt.gov.au
- Comcare Australia — www.comcare.gov.au
- Safe Work Australia — www.safeworkaustralia.gov.au
- WorkSafe New Zealand — www.worksafe.govt.nz

Chapter 13: Risk management

Risk management is the process that underpins health and safety management. It involves systematically identifying hazards, assessing and controlling risks arising from those hazards, and monitoring and reviewing activities to make sure that risks are effectively managed. AS 5369 provides a risk management framework.[86]

Effective consultation, training and information management are essential parts of the risk-management process and can be applied in all workplaces.

13.1 Biological hazards

Biological hazards associated with reprocessing endoscopes and accessories include blood and other body fluids, with the resulting risk of acquiring an infectious disease from exposure to these fluids. As noted in section 2.2 (see Table 2), the risk of blood-borne virus transmission from an infected patient to a health care worker varies.

For discussion of the infectious agents that can contaminate endoscopes, see chapter 2. The risk relates to the handling of a used endoscope and the potential for splashing and the production of aerosols during manual cleaning. Aerosols create three risks during cleaning:

- risk of exposure to infectious microorganisms contained in the aerosol;
- risk of exposure to chemicals contained in the aerosol; and
- risk of environmental contamination due to aerosols from the cleaning process being dispersed and deposited on surfaces.

It is imperative that cleaning techniques are designed to avoid splashing and generation of aerosols. The layout of the endoscopy unit should include clearly defined areas for contaminated, clean and sterile equipment to avoid cross-contamination (see section 7.4).[86]

13.2 Cytotoxic hazards

Cytotoxic drugs are a subset of antineoplastic drugs — therapeutic agents intended for, but not limited, to the treatment of cancer. Handling cytotoxic drugs is an occupational risk to workers.

Exposure may occur during endoscopy when handling patient waste (excreta),[233] as body fluids from patients receiving chemotherapy may contain traces of cytotoxic drugs and their active metabolites. Precautions should be taken for up to 7 days after treatment, as it is known that most cytotoxic drugs will be excreted within this time. All excreta from patients who have received chemotherapy should thus be considered contaminated for up to 7 days.[234]

Workers who handle the biological fluids, excreta, contaminated bedding and soiled equipment of patients who have received cytotoxic drugs should wear gloves and a protective gown. Face protection should be worn when there is a risk of splashing.

Disposable incontinence briefs soiled by patients who have received cytotoxic drugs should be placed in a cytotoxic waste container. They should not be disposed of in the receptacles used for infectious biomedical waste, which is autoclaved and sent to landfill.[235] Cytotoxic agents may remain active despite this processing.[236] However, for patients in the community, it is considered that all body waste can be safely disposed of in most household toilets, using a full flush.[237]

Contamination of endoscopes will occur when they are used on patients currently receiving chemotherapy medication. There is a paucity of literature regarding removal of cytotoxic residue from any equipment. However, the principles of chemical oxidation now used in disposal of cytotoxic waste would indicate that modern endoscope reprocessing technology should remove any traces of the cytotoxic medication and its metabolites.[238]

13.3 Management of occupational exposures

All endoscopy units should have an appropriate sharps disposal policy. Sharps injury poses a threat of infection transmission, and careless practices by medical or nursing staff should not be tolerated.

All endoscopy units should also have a clearly defined policy for sharps injuries and blood and body fluid exposures. In general, this should follow the protocols laid out in the relevant state or territory health department infection control guidelines.

It is essential that prompt action be taken to report an occupational exposure, so that immediate counselling, evaluation and treatment can be instigated. When antiretroviral therapy is recommended, it is most effective when commenced as soon as possible.

13.4 Workforce vaccination

Vaccination is a measure by which some protection from infection due to occupational exposure can be provided to health care workers. It is important that staff are aware of their immune status.

The *Australian immunisation handbook* provides detailed information on immunisation schedules and vaccines.[239] Staff vaccination programs should comply with these procedures, which acknowledge that there may be circumstances that require special consideration before vaccination (e.g. when a health care worker is pregnant).

The *Australian immunisation handbook* recommends that health care workers be vaccinated against infections they may encounter, which can include hepatitis B, hepatitis A, measles, mumps, rubella, influenza and varicella. In the absence of a mandate, all staff should be strongly encouraged to undergo COVID-19 vaccination, and hospital systems should facilitate this. Endoscopy units should be familiar with the recommendations in Commonwealth, state and health district guidelines.

A recommendation of particular importance for endoscopy is that hepatitis B vaccine be administered as soon as possible before or after commencing employment (with post-vaccination testing to identify non-responders), particularly for those with potential exposure to blood or body fluids.

In special circumstances, the following vaccination recommendations may also apply:

- Mantoux tuberculin test-negative health care workers at high risk may be offered BCG vaccination.
- Health care workers likely to encounter hepatitis A (e.g. in communities with substantial Indigenous populations, custodial carers, or carers of intellectually impaired people) should receive hepatitis A vaccination.

Each state or territory may also have its own guidelines for vaccination of health care workers that should be followed.

13.5 Hazardous substances

Hazardous substances are chemicals and other substances that can cause injury, illness or disease. Their health effects may be acute or chronic. Workplace health and safety personnel should be notified if there is a suspicion that exposure to a hazardous substance is causing health effects.

The manufacturer or importer of a substance is responsible for determining whether it is hazardous.

Under the Approved Criteria classification system, a substance is deemed hazardous if:

- any of its ingredients is entered in the Hazardous Chemical Information System (HCIS) at concentrations above the cut-off concentration;[240] or
- it meets the criteria in the 2004 National Occupational Health and Safety Commission (NOHSC) Approved Criteria for Classifying Hazardous Substances.[241]

Under the new Globally Harmonised System of Classification and Labelling of Chemicals (GHS), a substance is deemed hazardous if it meets any of the criteria in the GHS.[242]

If a substance does not meet any of these criteria but is considered to be causing adverse health effects

in the workplace, the avenues for investigation and reporting are:

- supervisor;
- workplace health and safety representative;
- workplace health and safety officer;
- state/territory workplace health and safety department; and
- Safe Work Australia.

Workplace health and safety regulations exist in each state and territory to protect against exposure to hazardous substances in the workplace. These regulations place responsibilities on people, including suppliers, manufacturers and employers, for hazardous substances. As hazardous substances regulations differ between each state or territory, the following provides only an overview of the legislation. Reference should be made to the regulations in the relevant state or territory to obtain specific local requirements.

Suppliers of hazardous substances must:

- produce a current Safety Data Sheet (SDS) for each hazardous substance they supply;
- provide the SDS to the purchaser at least the first time that the substance is supplied and whenever the SDS is amended or revised; and
- label the substance in accordance with the regulations.

The employer is required to:

- obtain a current SDS (published within the past 5 years) for all hazardous substances used in the workplace;
- keep a register that includes a list of all hazardous substances used in the workplace and the current SDS for each one;
- ensure each SDS is located near the chemical storage and use areas;
- ensure that all containers of hazardous substances are appropriately labelled;
- if a hazardous substance is decanted from its original container into a second container, also ensure the second container is appropriately labelled with the product name and relevant risk phrases and safety phrases as they appear on the original container's label (e.g. "R36 Irritating to eyes", "R38 Irritating to skin");
- conduct and keep records of a risk assessment;
- conduct and keep records of environmental monitoring and health surveillance if indicated by the risk assessment; and
- provide and keep records of induction and ongoing training.

13.5.1 Management of spills

The use of hazardous substances mandates that equipment and procedures are in place to manage an accidental release of these substances. The SDS includes instructions on managing spills of the substance, including any need for breathing apparatus. The aims of spill management are to minimise harm to personnel and limit environmental impact. Depending on volume, some spills require involvement of the fire and rescue services for containment and cleaning.

Storage of chemicals in a hazardous substance storage cabinet is required for most of the chemicals used in endoscope reprocessing. These storage cabinets usually incorporate a leakproof containment sump within the cabinet. Spill kits should be kept adjacent to any location in the endoscopy unit where chemicals are either stored or used and must be readily accessible. It is advantageous to check the spill kit contents on a regular basis to ensure all components are "in date" and functioning appropriately.

The contents of a spill kit should include:

- SDS for the relevant chemical;
- signage to be placed near the spill, warning others of the danger;
- PPE appropriate for the particular chemical (this may include a carbon filter respirator, waterproof gown, chemical resistant gloves and boots);
- containment booms to be placed around the perimeter of the spill to stop further spread of the fluid;
- absorbent material specific to the chemical (e.g. mats, pads or granules);
- neutralising agents if required for the chemical; and
- garbage bags for collection of all used bunds and absorbent mats.

After containment and clearance of the spill, the area will require full cleaning. Details of the spill, including the persons affected and involved, should be recorded and lodged with an occupational safety officer. Spill kit contents must be replaced after use.

13.5.2 Safety Data Sheet

An SDS provides information about the hazardous substance that will assist with risk assessment, such as:

- a statement indicating whether the substance has been classified as hazardous to health;
- the contents of the substance;
- what the substance should be used for and how to use it safely;
- the substance's health effects;
- first aid instructions;
- advice about safe storage and handling; and
- instruction on management of spills.

The required information about any hazardous substances used in the workplace includes:

- the ways in which the substance enters the body (e.g. skin absorption, inhalation or ingestion);
- what the acute and chronic health effects are;
- the exposure standard for the substance; and
- the recommended control measures.

13.5.3 Risk assessment of a hazardous substance

The risks involved with using a hazardous substance need to be assessed and managed, following the process outlined in this chapter.

To assess the risks involved in the use of a hazardous substance, further information beyond that provided in the SDS is necessary, including identifying:

- where and how the substance is used;
- who is likely to be at risk from exposure to the substance;
- the tasks that may cause exposure;
- whether monitoring or health surveillance is required;
- whether anyone is showing health effects from exposure; and
- what controls are already in place, whether these controls are effective in managing the risk and whether they should be reviewed.

For more information on this process, see *Managing risks of hazardous chemicals in the workplace: code of practice*.[243]

A risk assessment should be conducted and documented every 5 years, or earlier if:

- a work practice involving a hazardous substance is significantly changed;
- new information about the substance is available;
- health surveillance or monitoring shows control measures need to be reviewed; or
- new or improved control measures are implemented.

If there is a need to perform a risk assessment of any hazardous substances used in the workplace, it is advisable to contact work health and safety personnel for assistance. Examples of the risk assessment process, as applied to the use of peracetic acid, *ortho*-phthalaldehyde or glutaraldehyde, are provided in the GENCA Endoscope Reprocessing Modules.[244]

13.6 Reproductive hazards

Reproductive hazards can be biological hazards or hazardous substances. Hazardous substances that are teratogenic can produce abnormalities in a developing fetus. Work health and safety personnel or a medical practitioner can discuss any concerns about reproductive risks and provide advice on fitness to work with any hazardous substances while pregnant.

13.7 Environmental recycling

Increasingly, health systems are conscious of the environmental impact of their processes. This is particularly relevant with the increased use of single-use equipment. Endoscopy units are encouraged to formulate a waste management protocol, with an emphasis on recycling. Recycling may result in a significant reduction in waste disposal expenses. This can be coordinated with the hospital system or may require the engagement of a third-party provider.

Appendix 1: Abbreviations

AFER	automated flexible endoscope reprocessor
AHA	American Heart Association
ASGE	American Society for Gastrointestinal Endoscopy
AS/NZS	Australian/New Zealand Standard
ATP	adenosine triphosphate
BSG	British Society of Gastroenterology
CDC	Centers for Disease Control and Prevention
CESC	controlled-environment storage cabinet
CEST	controlled-environment storage technique
CFU	colony-forming units
COVID-19	coronavirus disease 2019
CPE	carbapenemase-producing Enterobacterales
CPO	carbapenemase-producing organisms
EN	European Standard
ERCP	endoscopic retrograde cholangiopancreatography
ESBL	extended-spectrum beta-lactamase
EUS	endoscopic ultrasound
FDA	Food and Drug Administration
FNA	fine needle aspiration
GENCA	Gastroenterological Nurses College of Australia
GESA	Gastroenterological Society of Australia
HEPA	high-efficiency particulate air
HLD	high-level disinfection
IPCE	Infection Prevention and Control in Endoscopy
IFU	instructions for use
ISO	International Organization for Standardization
NICE	National Institute for Health and Clinical Excellence
PEG	percutaneous endoscopic gastrostomy
PFR	particulate filter respirator
PPE	personal protective equipment
RMD	reusable medical device
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
sCJD	sporadic Creutzfeldt-–Jakob disease
SDS	Safety Data Sheet
TGA	Therapeutic Goods Administration
TSE	transmissible spongiform encephalopathy
vCJD	variant Creutzfeldt–Jakob disease
VRE	vancomycin-resistant enterococci

Appendix 2: IPCE Committee

Infection Prevention and Control in Endoscopy 2025 Update is a multidisciplinary project, with the IPCE Committee comprising experts from a wide range of specialties and representing many organisations:

Benedict Devereaux, MB BS, MPhil, FASGE, FACG, FGESA, FRACP
GESA and Professor, University of Queensland School of Medicine

Eugene Athan, OAM, MB BS(Hons), FRACP, MPH, MD
Australasian Society for Infectious Diseases and Professor, Deakin University

Farzad Bashirzadeh, MD, FRACP
Thoracic Society of Australia and New Zealand

Sue Greig, RN, MN(Infection Control), CIPC-E
Australasian College for Infection Prevention and Control

Kathryn Haberfield, RN, GradDipCritCareNurs, CertInfectionControlSterilisation, DipMgmt, CertIVSterilisationServices
Federation of Sterilising Research and Advisory Council of Australia (FSRACA) Victoria

Dianne Jones, OAM, RN, DipAppSc, BAppSc, FACN, FGESA
GENCA

Mehul Lamba, MD, MMedSc, FRACP
New Zealand Society of Gastroenterology and Clinical Senior Lecturer, University of Otago

Vichitra Sukumaran, MB BCh BAO, FRACP, FRCPA
Clinical Microbiologist and Director of Infectious Diseases, Logan Hospital

Karen Vickery, BVSc(Hons), MVSc, PhD
Associate Professor, Macquarie University

Elizabeth Wardle, RN, BN
GENCA

Appendix 3: Author disclosures

Ben Devereaux is currently a consultant to Olympus Australia and was a consultant on the Olympus Sapphire/Olympus On-Demand project. He has received speaking fees from Boston Scientific, Olympus, Cook Medical, Pentax (via EUS Taskforce Asia Pacific) and Johnson & Johnson. He has been a consultant to Boston Scientific and was Australian Principal Investigator for the SpyGlass AMEA (Asia, Middle East, Africa) registry and the EXALT single-use duodenoscope multinational study, which were sponsored and funded by Boston Scientific. He was a member of the Gastroenterology Clinical Committee for the Medicare Benefits Schedule Review Taskforce in 2018. He is an extended Board and committee member of EUS Taskforce Asia Pacific, supported by Pentax, Cook Medical and Boston Scientific. He has received overseas travel grants from Pentax Medical, Olympus and Mylan. He is the editor of the *Handbook of clinical pancreatology*, second edition, which received unconditional educational grants from Olympus, Pentax, Fuji Film, CR Kennedy, Boston Scientific, Cook Medical and Mylan.

Sue Greig has been employed by Ramsay Health Care as a National Manager, Infection Prevention and Control since July 2019. She provides casual consultancy work giving expert evidence and was a consultant on the Olympus Sapphire/Olympus On-Demand project. She has been invited to co-author several chapters of an infection prevention and control textbook in development with Elsevier. She has been a professional development speaker for the Federation of Sterilizing Research Advisory Councils of Australia (FSRACA) state and national seminars, conferences and workshops. She was a practitioner member of the Australian Health Practitioner Regulation Agency's Nursing and Midwifery Board of NSW from 2017 to 2023 and is a Life Member of the Australasian College for Infection Prevention and Control.

Kathryn Haberfield holds unpaid positions as President of FSRACA Victoria and FSRACA Victoria Conference Convenor.

Dianne Jones has been a sponsored speaker at national and international seminars, conferences and workshops. She is a member of the Olympus Australia Infection Control Advisory Group and was a consultant on the Olympus Sapphire/Olympus On-Demand project. She is a past company secretary and Board member of GENCA, Past President and Board Member of the Society of International Gastroenterological Nurses and Endoscopy Associates, and a current Director of the Australian & New Zealand Gastroenterology International Training Association. She holds shares in Nanosonics, an Australian company that manufactures ultrasound probe reprocessing equipment.

Karen Vickery was a member of a working party for the World Gastroenterology Organisation's *Endoscope disinfection update: a guide to resource sensitive reprocessing*. She had conference and travel expenses paid by organising committees of national and international conferences between 2017 and 2019 and has received travel support from the Whiteley Corporation. She has consulted for Nanosonics on various projects involving cleaning and sterilisation since October 2023.

Elizabeth Wardle is employed by Uniting Care and is a representative of GENCA on the Standards Australia HE-023 (Processing of Medical and Surgical Instruments) committee. She is a member of the Olympus Australia Infection Control Advisory Group and Boston Scientific advisory groups, was a consultant on the Olympus Sapphire/Olympus On-Demand project and is a Past President and Board member of GENCA.

All other authors declare no conflict of interest.

Appendix 4: Endorsing organisations

Infection Prevention and Control in Endoscopy 2025 Update has been endorsed, or is pending endorsement, by the following organisations:

- Federation of Sterilizing Research Advisory Councils of Australia
- New Zealand Society of Gastroenterology
- Australasian College for Infection Prevention and Control (*pending*)
- Australasian Society for Infectious Diseases (*pending*)
- Thoracic Society of Australia and New Zealand (*pending*)

References

1. Bianco JA, Pepe MS, Higano C, et al. Prevalence of clinically relevant bacteremia after upper gastrointestinal endoscopy in bone marrow transplant recipients. Am J Med 1990; 89: 134-136.
2. Kaw M, Przepiorka D, Sekas G. Infectious complications of endoscopic procedures in bone marrow transplant recipients. Dig Dis Sci 1993; 38: 71-74.
3. Forbes GM, Rule SA, Herrmann RP, et al. A prospective study of screening upper gastrointestinal (GI) endoscopy prior to and after bone marrow transplantation (BMT). Aust N Z J Med 1995; 25: 32-36.
4. Llach J, Elizalde JI, Bordas JM, et al. Prospective assessment of the risk of bacteremia in cirrhotic patients undergoing lower intestinal endoscopy. Gastrointest Endosc 1999; 49: 214-217.
5. Allison MC, Sandoe JA, Tighe R, et al. Antibiotic prophylaxis in gastrointestinal endoscopy. Gut 2009; 58: 869-80.
6. Nelson DB. Infectious disease complications of GI endoscopy: Part I, endogenous infections. Gastrointest Endosc 2003; 57: 546-556.
7. El Batrawy S, Elassal G, Moustafa A, Hafez H. Bacteremia associated with bronchoscopy. Egypt J Chest Dis Tuberc 2014; 63: 701-704.
8. Steinfort DP, Johnson DF, Irving LB. Incidence of bacteraemia following endobronchial ultrasound-guided transbronchial needle aspiration. Eur Respir J 2010; 36: 28-32.
9. Yigla M, Oren I, Bentur L, et al. Incidence of bacteraemia following fibreoptic bronchoscopy. Eur Respir J 1999; 14: 789-791.
10. Kovaleva J, Peters FT, van der Mei HC, Degener JE. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clin Microbiol Rev 2013; 26: 231-254.
11. Leiten EO, Martinsen EM, Bakke PS, et al. Complications and discomfort of bronchoscopy: a systematic review. Eur Clin Respir J 2016; 3: 33324.
12. ASGE Standards of Practice Committee, Khashab MA, Chithadi KV, et al. Antibiotic prophylaxis for GI endoscopy. Gastrointest Endosc 2015; 81: 81-89.
13. Richey R, Wray D, Stokes T. Prophylaxis against infective endocarditis: summary of NICE guidance. BMJ 2008; 336: 770-771.
14. Strom BL, Abrutyn E, Berlin JA, et al. Risk factors for infective endocarditis: oral hygiene and nondental exposures. Circulation 2000; 102: 2842-2848.
15. Coelho-Prabhu N, Oxentenko AS, Osmon DR, et al. Increased risk of prosthetic joint infection associated with esophago-gastro-duodenoscopy with biopsy. Acta Orthop 2013; 84: 82-86.
16. Ainscow DA, Denham RA. The risk of haematogenous infection in total joint replacements. J Bone Joint Surg Br 1984; 66: 580-582.
17. Yeung CM, Lichstein PM, Maguire JH, et al. An unexpected pathogen causing prosthetic joint infection following screening colonoscopy. Arthroplast Today 2019; 5: 427-430.
18. Baddour LM, Bettmann MA, Bolger AF, et al. Nonvalvular cardiovascular device-related infections. Circulation 2003; 108: 2015-2031.
19. Vizhi K, Rao HB, Venu RP. Percutaneous endoscopic gastrostomy site infections–incidence and risk factors. Indian J Gastroenterol 2018; 37: 103-107.
20. Motte S, Deviere J, Dumonceau JM, et al. Risk factors for septicemia following endoscopic biliary stenting. Gastroenterology 1991; 101: 1374-1381.
21. Palabıyıkoglu I, Tekelı E, Aysev D, et al. ERCP related sepsis. Am J Infect Dis 2005; 1: 86-88.
22. Centers for Disease Control (CDC). Nosocomial infection and pseudoinfection from contaminated endoscopes and bronchoscopes--Wisconsin and Missouri. MMWR Morb Mortal Wkly Rep 1991; 40: 675-678.
23. Struelens MJ, Rost F, Deplano A, et al. *Pseudomonas aeruginosa* and Enterobacteriaceae bacteremia after biliary endoscopy: an outbreak investigation using DNA macrorestriction analysis. Am J Med 1993; 95: 489-498.
24. Alfa MJ, Sitter DL. In-hospital evaluation of contamination of duodenoscopes: a quantitative assessment of the effect of drying. J Hosp Infect 1991; 19: 89-98.
25. Bass DH, Oliver S, Bornman PC. *Pseudomonas* septicaemia after endoscopic retrograde cholangiopancreatography--an unresolved problem. S Afr Med J 1990; 77: 509-511.
26. Carbonne A, Thiolet JM, Fournier S, et al. Control of a multi-hospital outbreak of KPC-producing *Klebsiella pneumoniae* type 2 in France, September to October 2009. Euro Surveill 2010; 15: 19734.
27. Devereaux BM, Athan E, Brown RR, et al. Australian infection control in endoscopy consensus statements on carbapenemase-producing Enterobacteriaceae. J Gastroenterol Hepatol 2019; 34: 650-658.
28. Othman MO, Guerrero R, Elhanafi S, et al. A prospective study of the risk of bacteremia in directed cholangioscopic examination of the common bile duct. Gastrointest Endosc 2016; 83: 151-157.
29. McCafferty CE, Aghajani MJ, Abi-Hanna D, et al. An update on gastrointestinal endoscopy-associated infections and their contributing factors. Ann Clin Microbiol Antimicrob 2018; 17: 36.
30. Wang KX, Ben QW, Jin ZD, et al. Assessment of morbidity and mortality associated with EUS-guided FNA: a systematic review. Gastrointest Endosc 2011; 73: 283-290.

31. Botana-Rial M, Leiro-Fernández V, Núñez-Delgado M, et al. A pseudo-outbreak of *Pseudomonas putida* and *Stenotrophomonas maltophilia* in a bronchoscopy unit. Respiration 2016; 92: 274-278.

32. Ofstead CL, Quick MR, Wetzler HP, et al. Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. Chest 2018; 154: 1024-1034.

33. Akinbobola AB, Sherry L, McKay WG, et al. Tolerance of *Pseudomonas aeruginosa* in in-vitro biofilms to high-level peracetic acid disinfection. J Hosp Infect 2017; 97: 162-168.

34. Weber DJ, Rutala WA. Lessons learned from outbreaks and pseudo-outbreaks associated with bronchoscopy. Infect Control Hosp Epidemiol 2012; 33: 230-234.

35. Machida H, Seki M, Yoshioka N, et al. Correlation between outbreaks of multidrug-resistant *Pseudomonas aeruginosa* infection and use of bronchoscopes suggested by epidemiological analysis. Biol Pharm Bull 2014; 37: 26-30.

36. Zweigner J, Gastmeier P, Kola A, et al. A carbapenem-resistant *Klebsiella pneumoniae* outbreak following bronchoscopy. Am J Infect Control 2014; 42: 936-937.

37. Galdys AL, Marsh JW, Delgado E, et al. Bronchoscope-associated clusters of multidrug-resistant *Pseudomonas aeruginosa* and carbapenem-resistant *Klebsiella pneumoniae*. Infect Control Hosp Epidemiol 2019; 40: 40-46.

38. US Food and Drug Administration. MAUDE adverse event report: Olympus Medical Systems Corp Evis Exera bronchovideoscope bronchoscope. Silver Spring, Md: FDA, 2014. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=4380504&pc=EOQ (accessed 7 May 2021).

39. Dickson A, Kondal P, Hilken L, et al. Possible pseudotransmission of *Enterobacter cloacae* associated with an endobronchial ultrasound scope. Am J Infect Control 2018; 46: 1296-1298.

40. US Centers for Disease Control and Prevention. Diagnosis of tuberculosis disease. In: Core curriculum on tuberculosis: what the clinician should know. 7th ed. Atlanta: CDC, 2021: 46-72.

41. Lewinsohn DM, Leonard MK, LoBue PA, et al. Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention clinical practice guidelines: diagnosis of tuberculosis in adults and children. Clin Infect Dis 2017; 64: 111-115.

42. US Centers for Disease Control and Prevention. Healthcare-associated infections: Nontuberculous Mycobacteria (NTM) infections. Atlanta: CDC, 2019. https://www.cdc.gov/hai/organisms/nontuberculous-mycobacteria.html (accessed 3 September 2021).

43. Communicable Diseases Network Australia. Australian national guidelines for the management of healthcare workers living with blood borne viruses. 2019.

44. Birnie GG, Quigley EM, Clements GB, et al. Endoscopic transmission of hepatitis B virus. Gut 1983; 24: 171-174.

45. Andrieu J, Barny S, Colardelle P, et al. [Prevalence and risk factors of hepatitis C virus infection in a hospitalized population in a gastroenterology unit. Role of endoscopic biopsies] [French]. Gastroenterol Clin Biol 1995; 19: 340-345.

46. Briancesco R, Veschetti E, Ottaviani M, Bonadonna L. Peracetic acid and sodium hypochlorite effectiveness in reducing resistant stages of microorganisms. Cent Eur J Public Health 2005; 13: 159-162.

47. Barbee SL, Weber DJ, Sobsey MD, Rutala WA. Inactivation of *Cryptosporidium parvum* oocyst infectivity by disinfection and sterilization processes. Gastrointest Endosc 1999; 49: 605-611.

48. La Scola B, Rolain JM, Maurin M, Raoult D. Can Whipple's disease be transmitted by gastroscopes? Infect Control Hosp Epidemiol 2003; 24: 191-194.

49. CJD Infection Control Guidelines Working Group. Creutzfeldt–Jakob disease infection control guidelines. Canberra: Australian Government Department of Health, 2013. https://www.health.gov.au/resources/publications/creutzfeldt-jakob-disease-infection-control-guidelines?language=en (accessed 28 March 2025).

50. Centers for Disease Control and Prevention (CDC). Transmission of hepatitis B and C viruses in outpatient settings--New York, Oklahoma, and Nebraska, 2000–2002. MMWR Morb Mortal Wkly Rep 2003; 52: 901-906.

51. Center for Disease Control and Prevention (CDC). Acute hepatitis C virus infections attributed to unsafe injection practices at an endoscopy clinic--Nevada, 2007. MMWR Morb Mortal Wkly Rep 2008; 57: 513-517.

52. Johani K, Hu H, Santos L, et al. Determination of bacterial species present in biofilm contaminating the channels of clinical endoscopes. Infect Dis Health 2018; 23: 189-196.

53. Santos LCS, Parvin F, Huizer-Pajkos A, et al. Contribution of usage to endoscope working channel damage and bacterial contamination. J Hosp Infect 2020; 105: 176-182.

54. Bisset L, Cossart YE, Selby W, et al. A prospective study of the efficacy of routine decontamination for gastrointestinal endoscopes and the risk factors for failure. Am J Infect Control 2006; 34: 274-280.

55. Seoane-Vazquez E, Rodriguez-Monguio R, Visaria J, Carlson A. Exogenous endoscopy-related infections, pseudo-infections, and toxic reactions: clinical and economic burden. Curr Med Res Opin 2006; 22: 2007-2021.

56. Alfa MJ, Singh H. Impact of wet storage and other factors on biofilm formation and contamination of patient-ready endoscopes: a narrative review. Gastrointest Endosc 2020; 91: 236-247.

57. Devereaux BM, Taylor ACF, Athan E, et al. Simethicone use during gastrointestinal endoscopy: position statement of the Gastroenterological Society of Australia. J Gastroenterol Hepatol 2019; 34: 2086-2089.

58. Nabi Z, Vamsi M, Goud R, et al. Pre-medication with simethicone and N-acetyl cysteine for improving mucosal visibility during upper gastrointestinal endoscopy: a randomized controlled trial. Indian J Gastroenterol 2024; 43: 986-994.

59. Cao L, Zheng F, Wang D, et al. The effect of using premedication of simethicone/pronase with or without postural change on visualization of the mucosa before endoscopy: a prospective, double blinded, randomized controlled trial. Clin Transl Gastroenterol 2024; 15: e00625.

60. Sun X, Xu Y, Zhang X, et al. Simethicone administration improves gastric cleanness for esophagogastroduodenoscopy: a randomized clinical trial. Trials 2021; 22: 555.

61. Chen X, Dai N, Deng Y, et al. Premedication with reformulated simethicone and sodium bicarbonate improves mucosal visibility during upper gastrointestinal endoscopy: a double-blind, multicenter, randomized controlled trial. BMC Gastroenterol 2021; 21: 124.

62. Mahawongkajit P, Kanlerd A. A prospective randomized controlled trial comparing simethicone, N-acetylcysteine, sodium bicarbonate and peppermint for visualization in upper gastrointestinal endoscopy. Surg Endosc 2021; 35: 303-308.

63. Fuentes-Valenzuela E, Perez-Arenas E, de Benito Sanz M, et al. Prospective cohort study to evaluate premedication with simethicone and n-acetilcysteine for upper diagnostic gastrointestinal endoscopy. Rev Esp Enferm Dig 2023; 115: 10-15.

64. Jung W, Oh GM, Kim JH, et al. When should patients take simethicone orally before colonoscopy for avoiding bubbles: a single-blind, randomized controlled study. Medicine (Baltimore) 2023; 102: e33728.

65. Li DF, Luo MH, Du QQ, et al. Efficacy of low-dose versus high-dose simethicone with polyethylene glycol for bowel preparation: a prospective randomized controlled trial. J Gastroenterol Hepatol 2020; 35: 1488-1494.

66. Cao RR, Wang L, Gao C, et al. Effect of oral simethicone on the quality of colonoscopy: a systematic review and meta-analysis of randomized controlled trials. J Dig Dis 2022; 23: 134-148.

67. Liu X, Yuan M, Li Z, et al. The efficacy of simethicone with polyethylene glycol for bowel preparation: a systematic review and meta-analysis. J Clin Gastroenterol 2021; 55: e46-e55.

68. Pan P, Zhao SB, Li BH, et al. Effect of supplemental simethicone for bowel preparation on adenoma detection during colonoscopy: a meta-analysis of randomized controlled trials. J Gastroenterol Hepatol 2019; 34: 314-320.

69. Moolla M, Dang JT, Shaw A, et al. Simethicone decreases bloating and improves bowel preparation effectiveness: a systematic review and meta-analysis. Surg Endosc 2019; 33: 3899-3909.

70. Speer T, Vickery K, Alfa M, Saenz R. Minimizing the risks of simethicone in endoscope reprocessing. J Clin Gastroenterol 2023; 57: 153-158.

71. Anderson GG, Segars K, Sanchez AM, et al. Effect of simethicone on the bactericidal efficacy of a high-level disinfectant. J Med Microbiol 2024; 73.

72. Mallard TS, Roswell SS, Sylvester EP, et al. A water-soluble alternative to simethicone for gastrointestinal endoscopy: results of a clinical trial. Am J Infect Control 2023; 51: 1192-1195.

73. Malvar C, Nguyen-Vu T, Shergill A, et al. The structure and delivery of a novel training course on endoscope reprocessing and standard precautions in the endoscopy unit. VideoGIE 2020; 5: 176-179.

74. Zierler R, Flatscher G, Miorini T. Sterile Supply Specialist Training Course Level II: Reprocessing endoscopes. Luzern: WFHSS, 2013.

75. Society of Gastroenterology Nurses and Associates Practice Committee. Standards of infection prevention in reprocessing flexible gastrointestinal endoscopes. Chicago: SGNA, 2016. https://www.sgna.org/Portals/0/SGNA%20Standards%20of%20infection%20prevention%20in%20reprocessing_FINAL.pdf (accessed 5 May 2021).

76. Shin HY, Jang DH, Jun JK. A nationwide survey on the effectiveness of training on endoscope reprocessing within the national cancer screening program in Korea. Am J Infect Control 2021; 49: 1031-1035.

77. England DM. Implementing a comprehensive endoscope reprocessing program. Infect Control Today 2016; 24 (8). https://www.infectioncontroltoday.com/view/implementing-comprehensive-endoscope-reprocessing-program (accessed 22 September 2021).

78. Ali ZH, Taha NM. Effect of infection control training program on nurse's performance and microbial results on GIT endoscopes. Adv Life Sci Technol 2014; 27: 6-16.

79. Working Party of the British Society of Gastroenterology Endoscopy Committee. BSG Guidance for decontamination of equipment for gastrointestinal endoscopy. London: BSG, 2020.

80. Cividino M, Moore D, Deeves M. Recommendations for education, training and certification for reprocessing in clinical office settings. Toronto: Ontario Agency for Health Protection and Promotion (Public Health Ontario), 2016. https://www.publichealthontario.ca/-/media/documents/R/2016/recommendations-certification-clinical-office.pdf?la=en (accessed 6 May 2021).

81. ASGE Quality Assurance in Endoscopy Committee, Calderwood AH, Day LW, et al. ASGE guideline for infection control during GI endoscopy. Gastrointest Endosc 2018; 87: 1167-1179.

82. El-Maghawry HA, El-Hawy LL. Effect of training educational program on nurses' performance as reagarding infection control procedures and endoscopies reprocessing techniques in GIT endoscopy unit. Egypt J Occup Med 2019; 43: 57-73.

83. Health Technical Memorandum 01-06: Decontamination of flexible endoscopes. Part A: Policy and management. London: UK Department of Health, 2016. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/530418/HTM0106_PartA.pdf (accessed 6 May 2021).

84. Health Technical Memorandum 01-06: Decontamination of flexible endoscopes. Part C: Operational management. London: UK Department of Health, 2016. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/530422/HTM0106_PartC.pdf (accessed 6 May 2021).

85. Murdani A, Kumar A, Chiu HM, et al. WEO position statement on hygiene in digestive endoscopy: focus on endoscopy units in Asia and the Middle East. Dig Endosc 2017; 29: 3-15.

86. Standards Australia. AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities, 2023.

87. Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. Ann Intern Med 1993; 118: 117-128.

88. Nelson DB, Muscarella LF. Current issues in endoscope reprocessing and infection control during gastrointestinal endoscopy. World J Gastroenterol 2006; 12: 3953-3964.

89. World Health Organization. Five moments for hand hygiene. Geneva: WHO, 2021. https://www.who.int/gpsc/tools/Five_moments/en/ (accessed 8 June 2021).

90. Standards Australia. AS/NZS 1336:2014: Eye and face protection - guidelines, 2014.

91. Johnston ER, Habib-Bein N, Dueker JM, et al. Risk of bacterial exposure to the endoscopist's face during endoscopy. Gastrointest Endosc 2019; 89: 818-824.

92. National Health and Medical Research Council. Australian guidelines for the prevention and control of infection in healthcare. Canberra: NHMRC, 2019. https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019 (accessed 5 May 2021).

93. Total Alliance Health Partners International. International health facility guidelines: Part D – Infection control. Sydney: TAHPI, 2017: 6.

94. Mondoni M, Repossi A, Carlucci P, et al. Bronchoscopic techniques in the management of patients with tuberculosis. Int J Infect Dis 2017; 64: 27-37.

95. Devereaux B, Kaffes A, Strasser S, et al. GESA updated advice on preventative measures during gastrointestinal endoscopic procedures during the COVID-19 pandemic. Melbourne: GESA, 2020. https://www.gesa.org.au/education/covid-19/ (accessed 6 May 2021).

96. Australian Government Department of Health and Aged Care. Monitoring and reporting on COVID-19: COVID-19 case notifications. Canberra: Commonwealth of Australia, 2025. https://www.health.gov.au/topics/covid-19/monitoring-and-reporting#covid19-case-notifications (accessed 25 March 2025).

97. Health New Zealand | Te Whatu Ora. COVID-19: Current cases. Wellington, 2025. https://www.tewhatuora.govt.nz/for-health-professionals/data-and-statistics/covid-19-data/covid-19-current-cases (accessed 25 March 2025).

98. World Health Organization. Coronavirus disease (COVID-19) pandemic. Geneva: WHO, 2023. https://www.who.int/europe/emergencies/situations/covid-19 (accessed 26 March 2025).

99. Chatterjee S, Bhattacharya M, Nag S, et al. A detailed overview of SARS-CoV-2 Omicron: its sub-variants, mutations and pathophysiology, clinical characteristics, immunological landscape, immune escape, and therapies. Viruses 2023; 15: 167.

100. Ward IL, Bermingham C, Ayoubkhani D, et al. Risk of covid-19 related deaths for SARS-CoV-2 omicron (B.1.1.529) compared with delta (B.1.617.2): retrospective cohort study. BMJ 2022; 378: e070695.

101. Nyberg T, Ferguson NM, Nash SG, et al. Comparative analysis of the risks of hospitalisation and death associated with SARS-CoV-2 omicron (B.1.1.529) and delta (B.1.617.2) variants in England: a cohort study. Lancet 2022; 399: 1303-1312.

102. Gregory CO, Hall A. COVID-19: Transmission. In: CDC Yellow Book 2024. Atlanta: Centers for Disease Control and Prevention (CDC), 2025. https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/covid-19#transmission (accessed 26 March 2025).

103. Boucau J, Marino C, Regan J, et al. Duration of shedding of culturable virus in SARS-CoV-2 Omicron (BA.1) infection. N Engl J Med 2022; 387: 275-277.

104. Bouton TC, Atarere J, Turcinovic J, et al. Viral dynamics of Omicron and Delta severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants with implications for timing of release from isolation: a longitudinal cohort study. Clin Infect Dis 2023; 76: e227-e233.

105. COVIDSurg Collaborative. Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study. Lancet 2020; 396: 27-38.

106. COVIDSurg Collaborative, GlobalSurg Collaborative. Timing of surgery following SARS-CoV-2 infection: an international prospective cohort study. Anaesthesia 2021; 76: 748-758.

107. Deng JZ, Chan JS, Potter AL, et al. The risk of postoperative complications after major elective surgery in active or resolved COVID-19 in the United States. Ann Surg 2022; 275: 242-246.

108. Garnier M, Constantin JM, Cinotti R, et al. Association of preoperative COVID-19 and postoperative respiratory morbidity during the Omicron epidemic wave: the DROMIS-22 multicentre prospective observational cohort study. EClinicalMedicine 2023; 58: 101881.

109. McInerney CD, Kotze A, Bacon S, et al. Postoperative mortality and complications in patients with and without pre-operative SARS-CoV-2 infection: a service evaluation of 24 million linked records using OpenSAFELY. Anaesthesia 2023; 78: 692-700.

110. American Society of Anesthesiologists, Anesthesia Patient Safety Foundation. ASA and APSF joint statement on elective surgery procedures and anesthesia for patients after COVID-19 infection. Schaumburg, Ill: American Society of Anesthesiologists, 2023. https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/asa-and-apsf-joint-statement-on-elective-surgery-procedures-and-anesthesia-for-patients-after-covid-19-infection (accessed 26 March 2025).

111. Australian and New Zealand College of Anaesthetists. PG68(A) Guideline on surgical patient safety for SARS-CoV-2 infection and vaccination 2023. Melbourne: ANZCA, 2023. https://www.anzca.edu.au/safety-and-advocacy/standards-of-practice/professional-documents (accessed 26 March 2025).

112. National Clinical Evidence Taskforce. Definition of disease severity. In: Australian guidelines for the clinical care of people with COVID-19, version 72, 2023. https://app.magicapp.org/#/guideline/L4Q5An/section/nV2P3n (accessed 26 March 2025).

113. Eloubeidi MA, Tamhane A, Varadarajulu S, Wilcox CM. Frequency of major complications after EUS-guided FNA of solid pancreatic masses: a prospective evaluation. Gastrointest Endosc 2006; 63: 622-629.

114. Dickman MD, Farrell R, Higgs RH, et al. Colonoscopy associated bacteremia. Surg Gynecol Obstet 1976; 142: 173-176.

115. LeFrock JL, Ellis CA, Turchik JB, Weinstein L. Transient bacteremia associated with sigmoidoscopy. N Engl J Med 1973; 289: 467-469.

116. The role of prophylactic antibiotics for preventing infective endocarditis in people undergoing dental or other minor procedures. Best Pract J 2015; (68): 23-27.

117. Expert Group for Antibiotic Guidelines. Therapeutic Guidelines: Antibiotic. Melbourne: Therapeutic Guidelines Ltd, 2020. https://tgldcdp.tg.org.au/guideLine?guidelinePage=Antibiotic&frompage=etgcomplete (accessed 6 May 2021).

118. Expert Group for Gastrointestinal Guidelines. Therapeutic Guidelines: Gastrointestinal. Melbourne: Therapeutic Guidelines Ltd, 2020. https://tgldcdp.tg.org.au/guideLine?guidelinePage=Gastrointestinal&frompage=etgcomplete (accessed 6 May 2021).

119. Gomi H, Solomkin J, Schlossberg D, et al. Tokyo guidelines 2018: antimicrobial therapy for acute cholangitis and cholecystitis. J Hepatobiliary Pancreat Sci 2018; 25: 3-16.

120. Colan-Hernandez J, Sendino O, Loras C, et al. Antibiotic prophylaxis is not required for endoscopic ultrasonography-guided fine-needle aspiration of pancreatic cystic lesions, based on a randomized trial. Gastroenterology 2020; 158: 1642-1649.e1.

121. O'Sullivan ME, Perez A, Lin R, et al. Towards the prevention of aminoglycoside-related hearing loss. Front Cell Neurosci 2017; 11: 325.

122. Li PK, Szeto CC, Piraino B, et al. ISPD Peritonitis recommendations: 2016 update on prevention and treatment. Perit Dial Int 2016; 36: 481-508.

123. Marek A, Smith A, Peat M, et al. Endoscopy supply water and final rinse testing: five years of experience. J Hosp Infect 2014; 88: 207-212.

124. Willis C. Bacteria-free endoscopy rinse water –– a realistic aim? Epidemiol Infect 2006; 134: 279-284.

125. Muscarella LF. Application of environmental sampling to flexible endoscope reprocessing: the importance of monitoring the rinse water. Infect Control Hosp Epidemiol 2002; 23: 285-289.

126. Joint Working Group of the Hospital Infection Society and the Public Health Laboratory Service. Rinse water for heat labile endoscopy equipment. J Hosp Infect 2002; 51: 7-16.

127. Bartley PB, Ben Zakour NL, Stanton-Cook M, et al. Hospital-wide eradication of a nosocomial *Legionella pneumophila* serogroup 1 outbreak. Clin Infect Dis 2016; 62: 273-279.

128. Bradley C. Water quality in endoscope reprocessing. Birmingham: Hospital Infection Research Laboratory, City Hospital, 2015.

129. MacKay WG, Leanord AT, Williams CL. Water, water everywhere nor any a sterile drop to rinse your endoscope. J Hosp Infect 2002; 51: 256-261.

130. Pang J, Perry P, Ross A, Forbes GM. Bacteria-free rinse water for endoscope disinfection. Gastrointest Endosc 2002; 56: 402-406.

131. Phillips G, McEwan H, Butler J. Quality of water in washer-disinfectors. J Hosp Infect 1995; 31: 152-154.

132. McKnight A, Cadwallader H, Thomas L. Is filtered rinse water for endoscopy sterile? Australian Infection Control Association 12th National Conference. Perth, WA, 1998.

133. Peadon J. Achieving filtered water with endocleaners. Australian Infection Control Association 12th National Conference. Perth, WA, 1998.

134. Darbord JC. Importance of cleaning for reprocessing endoscopes and thermolabile sterile medical devices: French use and regulations. J Hosp Infect 2004; 56 Suppl 2: S40-S43.

135. Sanderson R, Braithwaite L, Ball L, et al. An outbreak of carbapenem-resistant *Klebsiella pneumoniae* infections associated with endoscopic retrograde cholangiopancreatography (ERCP) procedures at a hospital. Am J Infect Control 2010; 38: e141.

136. Alrabaa SF, Nguyen P, Sanderson R, et al. Early identification and control of carbapenemase-producing *Klebsiella pneumoniae*, originating from contaminated endoscopic equipment. Am J Infect Control 2013; 41: 562-564.

137. Epstein L, Hunter JC, Arwady MA, et al. New Delhi metallo-β-lactamase-producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes. JAMA 2014; 312: 1447-1455.

138. Kola A, Piening B, Pape UF, et al. An outbreak of carbapenem-resistant OXA-48 – producing *Klebsiella pneumonia* associated to duodenoscopy. Antimicrob Resist Infect Control 2015; 4: 8.

139. Smith ZL, Oh YS, Saeian K, et al. Transmission of carbapenem-resistant Enterobacteriaceae during ERCP: time to revisit the current reprocessing guidelines. Gastrointest Endosc 2015; 81: 1041-1045.

140. Humphries RM, Yang S, Kim S, et al. Duodenoscope-related outbreak of a carbapenem-resistant *Klebsiella pneumoniae* identified using advanced molecular diagnostics. Clin Infect Dis 2017; 65: 1159-1166.

141. Bourigault C, Le Gallou F, Bodet N, et al. Duodenoscopy: an amplifier of cross-transmission during a carbapenemase-producing Enterobacteriaceae outbreak in a gastroenterology pathway. J Hosp Infect 2018; 99: 422-426.

142. Gastmeier P, Vonberg RP. *Klebsiella* spp. in endoscopy-associated infections: we may only be seeing the tip of the iceberg. Infection 2014; 42: 15-21.

143. Chapman CG, Siddiqui UD, Manzano M, et al. Risk of infection transmission in curvilinear array echoendoscopes: results of a prospective reprocessing and culture registry. Gastrointest Endosc 2017; 85: 390-397.e1.

144. Petersen BT. Duodenoscope reprocessing: risk and options coming into view. Gastrointest Endosc 2015; 82: 484-487.

145. Naas T, Cuzon G, Babics A, et al. Endoscopy-associated transmission of carbapenem-resistant *Klebsiella pneumoniae* producing KPC-2 beta-lactamase. J Antimicrob Chemother 2010; 65: 1305-1306.

146. Orsi GB, García-Fernández A, Giordano A, et al. Risk factors and clinical significance of ertapenem-resistant *Klebsiella pneumoniae* in hospitalised patients. J Hosp Infect 2011; 78: 54-58.

147. Koo VS, O'Neill P, Elves A. Multidrug-resistant NDM-1 *Klebsiella* outbreak and infection control in endoscopic urology. BJU Int 2012; 110: E922-E926.

148. Chang CL, Su LH, Lu CM, et al. Outbreak of ertapenem-resistant *Enterobacter cloacae* urinary tract infections due to a contaminated ureteroscope. J Hosp Infect 2013; 85: 118-124.

149. Ofstead CL, Wetzler HP, Doyle EM, et al. Persistent contamination on colonoscopes and gastroscopes detected by biologic cultures and rapid indicators despite reprocessing performed in accordance with guidelines. Am J Infect Control 2015; 43: 794-801.

150. Ofstead CL, Doyle EM, Eiland JE, et al. Practical toolkit for monitoring endoscope reprocessing effectiveness: identification of viable bacteria on gastroscopes, colonoscopes, and bronchoscopes. Am J Infect Control 2016; 44: 815-819.

151. US Food and Drug Administration. Infections associated with reprocessed duodenoscopes. Silver Spring, Md: FDA, 2019. https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/infections-associated-reprocessed-duodenoscopes (accessed 5 May 2021).

152. Singh H, Duerksen DR, Schultz G, et al. Impact of cleaning monitoring combined with channel purge storage on elimination of *Escherichia coli* and environmental bacteria from duodenoscopes. Gastrointest Endosc 2018; 88: 292-302.

153. Neves MS, da Silva MG, Ventura GM, et al. Effectiveness of current disinfection procedures against biofilm on contaminated GI endoscopes. Gastrointest Endosc 2016; 83: 944-953.

154. Alfa MJ, Howie R. Modeling microbial survival in buildup biofilm for complex medical devices. BMC Infect Dis 2009; 9: 56.

155. da Costa Luciano C, Olson N, Tipple AF, Alfa M. Evaluation of the ability of different detergents and disinfectants to remove and kill organisms in traditional biofilm. Am J Infect Control 2016; 44: e243-e249.

156. Thaker AM, Kim S, Sedarat A, et al. Inspection of endoscope instrument channels after reprocessing using a prototype borescope. Gastrointest Endosc 2018; 88: 612-619.

157. Quan E, Mahmood R, Naik A, et al. Use of adenosine triphosphate to audit reprocessing of flexible endoscopes with an elevator mechanism. Am J Infect Control 2018; 46: 1272-1277.

158. Olafsdottir LB, Wright SB, Smithey A, et al. Adenosine triphosphate quantification correlates poorly with microbial contamination of duodenoscopes. Infect Control Hosp Epidemiol 2017; 38: 678-684.

159. Standards Australia. AS 1668.2-2012: The use of ventilation and airconditioning in buildings – mechanical ventilation in buildings, 2012.

160. Jensen PA, Lambert LA, Iademarco NF, Ridzon R. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. MMWR Recomm Rep 2005; 54: 1-141.

161. Centres for Disease Control and Prevention, Healthcare Infection Control Practices Advisory Committee. Guidelines for environmental infection control in health-care facilities. Atlanta, Ga: US Department of Health and Human Services, 2003, updated 2019. https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf (accessed 5 May 2021).

162. Australasian Health Infrastructure Alliance. Australasian Health Facility Guidelines: Part B - Health Facility Briefing and Planning. 0270 - Day Surgery / Procedure Unit. Sydney: AHIA, 2022.

163. Australian Commission on Safety and Quality in Health Care. Optimising ventilation for infection prevention and control in healthcare settings. Sydney: ACSQHC, 2022. https://www.safetyandquality.gov.au/publications-and-resources/resource-library/optimising-ventilation-infection-prevention-and-control-healthcare-settings (accessed 5 May 2025).

164. Ofstead CL, Wetzler HP, Snyder AK, Horton RA. Endoscope reprocessing methods: a prospective study on the impact of human factors and automation. Gastroenterol Nurs 2010; 33: 304-311.

165. Visrodia K, Petersen BT. Borescope examination: is there value in visual assessment of endoscope channels? Gastrointest Endosc 2018; 88: 620-623.

166. Ofstead CL, Hopkins KM. Sterilization central: the value of borescopes in detecting damage, soil, fluid, and foreign objects in flexible endoscopes. Biomed Instrum Technol 2020; 54: 146-152.

167. Barakat MT, Girotra M, Huang RJ, Banerjee S. Scoping the scope: endoscopic evaluation of endoscope working channels with a new high-resolution inspection endoscope (with video). Gastrointest Endosc 2018; 88: 601-611.e1.

168. Communicable Disease Section. Infection control guidelines: cleaning and waste disposal procedures. Melbourne: Victorian Department of Health and Human Services, 2015. https://www2.health.vic.gov.au/public-health/infectious-diseases/infection-control-guidelines/cleaning-waste-disposal (accessed 6 May 2021).

169. Hanson PJ, Gor D, Jeffries DJ, Collins JV. Elimination of high titre HIV from fibreoptic endoscopes. Gut 1990; 31: 657-659.

170. Chu NS, McAlister D, Antonoplos PA. Natural bioburden levels detected on flexible gastrointestinal endoscopes after clinical use and manual cleaning. Gastrointest Endosc 1998; 48: 137-142.

171. Gillespie EE, Kotsanas D, Stuart RL. Microbiological monitoring of endoscopes: 5-year review. J Gastroenterol Hepatol 2008; 23: 1069-1074.

172. Deva AK, Vickery K, Zou J, et al. Detection of persistent vegetative bacteria and amplified viral nucleic acid from in-use testing of gastrointestinal endoscopes. J Hosp Infect 1998; 39: 149-157.

173. Wang P, Xu T, Ngamruengphong S, et al. Rates of infection after colonoscopy and osophagogastroduodenoscopy in ambulatory surgery centres in the USA. Gut 2018; 67: 1626-1636.

174. Alfa MJ, Olson N, Murray BL. Comparison of clinically relevant benchmarks and channel sampling methods used to assess manual cleaning compliance for flexible gastrointestinal endoscopes. Am J Infect Control 2014; 42: e1-e5.

175. Visrodia KH, Ofstead CL, Yellin HL, et al. The use of rapid indicators for the detection of organic residues on clinically used gastrointestinal endoscopes with and without visually apparent debris. Infect Control Hosp Epidemiol 2014; 35: 987-994.

176. International Organization for Standardization. ISO 15883-1-2024: Washer-disinfectors. Part 1: General requirements, terms and definitions and tests, 2024.

177. Veltman S, Mutowo M, Jones D, et al. Transforming endoscope reprocessing: a new model. Clin Serv J 2024; 24 (4): 42-45.

178. Moses FM, Lee JS. Current GI endoscope disinfection and QA practices. Dig Dis Sci 2004; 49: 1791-1797.

179. Reynolds CD, Rhinehart E, Dreyer P, Goldmann DA. Variability in reprocessing policies and procedures for flexible fiberoptic endoscopes in Massachusetts hospitals. Am J Infect Control 1992; 20: 283-290.

180. Rex DK, Sieber M, Lehman GA, et al. A double-reprocessing high-level disinfection protocol does not eliminate positive cultures from the elevators of duodenoscopes. Endoscopy 2018; 50: 588-596.

181. Snyder GM, Wright SB, Smithey A, et al. Randomized comparison of 3 high-level disinfection and sterilization procedures for duodenoscopes. Gastroenterology 2017; 153: 1018-1025.

182. Beilenhoff U, Biering H, Blum R, et al. ESGE-ESGENA technical specification for process validation and routine testing of endoscope reprocessing in washer-disinfectors according to EN ISO 15883, parts 1, 4, and ISO/TS 15883-5. Endoscopy 2017; 49: 1262-1275.

183. Barakat MT, Huang RJ, Banerjee S. Comparison of automated and manual drying in the elimination of residual endoscope working channel fluid after reprocessing (with video). Gastrointest Endosc 2019; 89: 124-132.e2.

184. Association for the Advancement of Medical Instrumentation. AAMI ST91:2015: Flexible and semi-rigid endoscope processing in health care facilities, 2015.

185. Pineau L, Philippe E. Evaluation of endoscope cleanliness after reprocessing: a clinical-use study. Zentralsterilisation (Wiesb) 2013; 21: 22-27.

186. Shimono N, Takuma T, Tsuchimochi N, et al. An outbreak of *Pseudomonas aeruginosa* infections following thoracic surgeries occurring via the contamination of bronchoscopes and an automatic endoscope reprocessor. J Infect Chemother 2008; 14: 418-423.

187. Kovach SM. Understanding the sonic cleaning process. HealthVIE.com 2011; (June): 70-92.

188. Kovach SM. Improving the quality of the sonic cleaning process. Manag Infect Control 2006; (July): 84-97.

189. Kovach SM. Ensuring cavitation in a medical device ultrasonic cleaner. Biomed Instrum Technol 2019; 53: 280-285.

190. Standards Australia. AS 2773:2019 Ultrasonic cleaners for health service organisations, 2019.

191. Ren W, Sheng X, Huang X, et al. Evaluation of detergents and contact time on biofilm removal from flexible endoscopes. Am J Infect Control 2013; 41: e89-e92.

192. Alfa MJ, Singh H, Nugent Z, et al. Simulated-use polytetrafluorethylene biofilm model: repeated rounds of complete reprocessing lead to accumulation of organic debris and viable bacteria. Infect Control Hosp Epidemiol 2017; 38: 1284-1290.

193. National Standards Authority of Ireland. EN 16442: Controlled environment storage cabinet for processed thermolabile endoscopes, 2015.

194. Ofstead CL, Wetzler HP, Johnson EA, et al. Simethicone residue remains inside gastrointestinal endoscopes despite reprocessing. Am J Infect Control 2016; 44: 1237-1240.

195. Ofstead CL, Heymann OL, Quick MR, et al. Residual moisture and waterborne pathogens inside flexible endoscopes: evidence from a multisite study of endoscope drying effectiveness. Am J Infect Control 2018; 46: 689-696.

196. Perumpail RB, Marya NB, McGinty BL, Muthusamy VR. Endoscope reprocessing: comparison of drying effectiveness and microbial levels with an automated drying and storage cabinet with forced filtered air and a standard storage cabinet. Am J Infect Control 2019; 47: 1083-1089.

197. Singh H, Duerksen DR, Schultz G, et al. Evaluation of an overnight non-culture test for detection of viable Gram-negative bacteria in endoscope channels. Endosc Int Open 2019; 7: E268-E273.

198. Kovaleva J, Degener JE, van der Mei HC. Mimicking disinfection and drying of biofilms in contaminated endoscopes. J Hosp Infect 2010; 76: 345-350.

199. Saliou P, Le Bars H, Payan C, et al. Measures to improve microbial quality surveillance of gastrointestinal endoscopes. Endoscopy 2016; 48: 704-710.

200. Pineau L, Villard E, Duc DL, Marchetti B. Endoscope drying/storage cabinet: interest and efficacy. J Hosp Infect 2008; 68: 59-65.

201. Ren-Pei W, Hui-Jun X, Ke Q, et al. Correlation between the growth of bacterial biofilm in flexible endoscopes and endoscope reprocessing methods. Am J Infect Control 2014; 42: 1203-1206.

202. Schmelzer M, Daniels G, Hough H. Safe storage time for reprocessed flexible endoscopes: a systematic review. JBI Database System Rev Implement Rep 2015; 13: 187-243.

203. Graham DY, Alpert LC, Smith JL, Yoshimura HH. Iatrogenic *Campylobacter pylori* infection is a cause of epidemic achlorhydria. Am J Gastroenterol 1988; 83: 974-980.

204. Wilson SJ, Everts RJ, Kirkland KB, Sexton DJ. A pseudo-outbreak of *Aureobasidium* species lower respiratory tract infections caused by reuse of single-use stopcocks during bronchoscopy. Infect Control Hosp Epidemiol 2000; 21: 470-472.

205. Beecham HJ, 3rd, Cohen ML, Parkin WE. *Salmonella typhimurium*. Transmission by fiberoptic upper gastrointestinal endoscopy. JAMA 1979; 241: 1013-1015.

206. Doherty DE, Falko JM, Lefkovitz N, et al. *Pseudomonas aeruginosa* sepsis following retrograde cholangiopancreatography (ERCP). Dig Dis Sci 1982; 27: 169-170.

207. Gamble HP, Duckworth GJ, Ridgway GL. Endoscope decontamination incidents in England 2003–2004. J Hosp Infect 2007; 67: 350-354.

208. Dirlam Langlay AM, Ofstead CL, Mueller NJ, et al. Reported gastrointestinal endoscope reprocessing lapses: the tip of the iceberg. Am J Infect Control 2013; 41: 1188-1194.

209. Ofstead CL, Hopkins KM, Buro BL, et al. Challenges in achieving effective high-level disinfection in endoscope reprocessing. Am J Infect Control 2020; 48: 309-315.

210. Griffiths H, Dwyer L. What every endoscopist should know about decontamination. Frontline Gastroenterol 2019; 10: 167-170.

211. Healthcare Infection Control Practices Advisory Committee. Essential elements of a reprocessing program for flexible endoscopes – recommendations of the Healthcare Infection Control Practices Advisory Committee. Atlanta: CDC, 20167, updated 2017. https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html (accessed 5 May 2021).

212. The FDA Group. A basic guide to IQ, OQ, PQ in FDA-regulated industries. Westborough, Mass: The FDA Group, 2019. https://www.thefdagroup.com/blog/a-basic-guide-to-iq-oq-pq-in-fda-regulated-industries (accessed 6 May 2021).

213. McCarthy M. "Meticulous" cleaning of duodenoscopes may not eliminate infection risk, US watchdog warns. BMJ 2015; 350: h997.

214. Higa JT, Choe J, Tombs D, et al. Optimizing duodenoscope reprocessing: rigorous assessment of a culture and quarantine protocol. Gastrointest Endosc 2018; 88: 223-229.

215. Buss AJ, Been MH, Borgers RP, et al. Endoscope disinfection and its pitfalls--requirement for retrograde surveillance cultures. Endoscopy 2008; 40: 327-332.

216. Tunuguntla A, Sullivan MJ. Monitoring quality of flexible endoscope disinfection by microbiologic surveillance cultures. Tenn Med 2004; 97: 453-456.

217. Moses FM, Lee J. Surveillance cultures to monitor quality of gastrointestinal endoscope reprocessing. Am J Gastroenterol 2003; 98: 77-81.

218. Leung J, Vallero R, Wilson R. Surveillance cultures to monitor quality of gastrointestinal endoscope reprocessing. Am J Gastroenterol 2003; 98: 3-5.

219. Phillips L. Identification and resolution of contamination causes found in flexible endoscopes. Gastroenterol Nurs 1997; 20: 9-11.

220. Saviuc P, Picot-Guéraud R, Shum Cheong Sing J, et al. Evaluation of the quality of reprocessing of gastrointestinal endoscopes. Infect Control Hosp Epidemiol 2015; 36: 1017-1023.

221. Chomel De Varagnes S, Brulebois A, Shum J, et al. Results of 4 years of microbiological testing of bronchoscopes. Rev Mal Respir 2009; 26: 283-290.

222. Fröhlich E, Muller R, Kimmig JM, Funke G. [Quality-agreement colonoscopy: an outcome evaluation from the district of North-Württemberg, Germany, 2003 – 2007] [German]. Z Gastroenterol 2009; 47: 203-208.

223. Machado AP, Pimenta AT, Contijo PP, et al. Microbiologic profile of flexible endoscope disinfection in two Brazilian hospitals. Arq Gastroenterol 2006; 43: 255-258.

224. De Wolfe TJ, Safdar N, Meller M, et al. A prospective, randomized comparison of duodenoscope reprocessing surveillance methods. Can J Gastroenterol Hepatol 2019; 2019: 1959141.

225. FDA/CDC/ASM Working Group on Duodenoscope Culturing. Duodenoscope surveillance sampling & culturing: reducing the risks of infection. US Food & Drug Administration, Centers for Disease Control and Prevention, American Society for Microbiology, 2018. https://www.fda.gov/media/111081/download (accessed 6 May 2021).

226. Gastroenterological Nurses College of Australia, Gastroenterological Society of Australia. Endoscopy: standards for endoscopic facilities and services. Melbourne: GESA, 2006.

227. Centre for Healthcare Related Infection Surveillance and Prevention (CHRISP). Endoscope reprocessing audit. Brisbane: Queensland Government, 2011.

228. Banerjee S, Nelson DB, Dominitz JA, et al. Reprocessing failure. Gastrointest Endosc 2007; 66: 869-871.

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

230. Newsom SWB. La Scandale du CIDEX®. La santé et l'état belges contaminés par un désinfectant [book review]. J Hosp Infect 2002; 50.

231. Vanhems P, Gayet-Ageron A, Ponchon T, et al. Follow-up and management of patients exposed to a flawed automated endoscope washer-disinfector in a digestive diseases unit. Infect Control Hosp Epidemiol 2006; 27: 89-92.

232. Nelson DB. Hepatitis C virus cross-infection during endoscopy: is it the "tip of the iceberg" or the absence of ice? Gastrointest Endosc 2007; 65: 589-591.

233. SA Health Medicines and Technology Policy and Programs and Workforce Health. Safe handling – cytotoxic drugs and related waste – a risk management guide. Adelaide: SA Health, 2015. https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/resources/cytotoxic+drugs+and+related+waste+a+risk+management+guide+for+south+australian+health+services+2015 (accessed 6 May 2021).

234. Connor T, McLauchlan R, Vandenbroucke J. ISOPP standards of practice. Safe handling of cytotoxics. J Oncol Pharm Pract 2007; 13 Suppl: 1-81.

235. Korczowska E, Crul M, Tuerk J, Meier K. Environmental contamination with cytotoxic drugs in 15 hospitals from 11 European countries—results of the MASHA project. Eur J Oncol Pharm 2020; 3: e24.

236. Easty AC, Coakley N, Cheng R, et al. Safe handling of cytotoxics: guideline recommendations. Curr Oncol 2015; 22: e27-e37.

237. Sunshine Coast Hospital and Health Service. Homecare information chemotherapy: information for patients and their families, 2016. https://www.health.qld.gov.au/__data/assets/pdf_file/0028/388900/2016-fs-chemotherapy.pdf (accessed 6 May 2021).

238. Hristov V, Pavlovic S. Assessment of the cytotoxic waste management in Western Balkan countries. Rotterdam: International Solid Waste Association, 2020.

239. Australian Technical Advisory Group on Immunisation. Australian immunistion handbook. Canberra: Australian Government Department of Health, 2018. https://immunisationhandbook.health.gov.au (accessed 6 May 2021).

240. Safe Work Australia. Hazardous Chemical Information System (HCIS). http://hcis.safeworkaustralia.gov.au (accessed 8 June 2021).

241. National Occupational Health and Safety Commission. Approved criteria for classifying hazardous substances [NOHSC:1008(2004)], 3rd ed. Canberra: Commonwealth of Australia, 2004.

242. Safe Work Australia. Classifying chemicals.: https://www.safeworkaustralia.gov.au/classifying-chemicals (accessed 8 June 2021).

243. Safe Work Australia. Managing risks of hazardous chemicals in the workplace: code of practice. Canberra: Safe Work Australia, 2020. https://www.safeworkaustralia.gov.au/doc/model-code-practice-managing-risks-hazardous-chemicals-workplace (accessed 6 May 2021).

244. Gastroenterological Nurses College of Australia and Queensland Health. Endoscope reprocessing modules, updated 2017. https://www.genca.org/education/endoscope-reprocessing-modules/ (accessed 6 May 2021).


GESA
Gastroenterological
Society of Australia


GENCA
est.1978