Australian Infection Control in Endoscopy Consensus Statements on Carbapenemase-producing Enterobacteriaceae

Abstract

Outbreaks of Carbapenemase-producing Enterobacteriaceae (CPE) clinical infections related to endoscopic transmission are well documented. The high morbidity and mortality associated with these infections emphasises the need to reassess endoscopic reprocessing protocols. The Gastroenterological Society of Australia (GESA) established a multi-society Committee to formulate evidence-based consensus statements on the prevention and management of endoscopic transmission of CPE. A literature search was undertaken utilising the MEDLINE database. Further references were sourced from published paper bibliographies. Nine statements were formulated. Using the Delphi methodology the statements were initially reviewed electronically by the committee members and subsequently at a face-to-face meeting in Melbourne, Australia. After further discussion, four additional sub-statements were added resulting in a total of 13 statements. Each statement was assessed for level of evidence, recommendation grade and the voting on recommendation was recorded. For a statement to be accepted, five out of six committee members had to “accept completely” or “accept with some reservation”. All 13 statements achieved consensus agreement. Eleven statements achieved 100% “accepted completely”. Two statements were 83% “accepted completely”, 17% “accepted with some reservation”. Of particular significance, automated flexible endoscope reprocessors (AFER’s) were mandated for high level disinfection and the use of forced-air drying cabinets was mandated for endoscope storage. These evidence-based statements encourage preventative strategies with the aim of ensuring the highest possible standards in flexible endoscope reprocessing thereby optimising patient safety. They must be considered in addition to the broader published guidelines on infection control in endoscopy.

Key words: Carbapenemase-producing Enterobacteriaceae, CPE, Endoscopy, infection, duodenoscope

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Introduction

The Gastroenterological Society of Australia (GESA) and the Gastroenterological Nurses College of Australia (GENCA) have a long and distinguished history in setting the highest standards in endoscopic instrument reprocessing. The first Australian guidelines, "Infection and Endoscopy"¹ were published in the early 1980's. The current document, "Infection Control in Endoscopy, Third Edition (updated in 2011)"² is a valuable resource utilised in endoscopy units throughout Australia and the Asia-Pacific region.

Carbapenemase-producing Enterobacteriaceae (CPE) confer broad resistance to most β -lactam antibiotics including "last-line" carbapenems³. The prevalence of CPE infection has increased over the past decade with 9000 health-care associated infections occurring each year in the United States of America³. Thus, CPE was labelled an "urgent public health threat" by the Centers for Disease Control (CDC) in that country³. Exposure to CPE can result in asymptomatic colonisation or clinically serious infections including intra-abdominal infection, pneumonia, urinary tract infections and device related infections⁴. As a result of very limited effective antimicrobial treatments, CPE infections are associated with a mortality of 18-48%⁴⁻⁶.

Patient to patient transmission of CPE by endoscopic instruments was first reported in 2010⁷⁻⁹. Whereas most attention has focussed on transmission by duodenoscopes during endoscopic retrograde cholangio-pancreatography (ERCP)⁷⁻¹⁵, positive (22/540 [4.2%]) microbiological cultures have been reported from linear echoendoscopes post high level disinfection¹⁶. There are also anecdotal reports of infectious transmission from linear echoendoscopes¹⁷. Duodenoscopes and linear echoendoscopes have complex instrument tips with an elevator mechanism. However, CPE transmission has also been associated with the use of endoscopic instruments without complex tips including gastroscopes^{18,19}, bronchoscopes¹⁵, cystoscopes²⁰ and ureteroscopes²¹. To date, no transmission has been reported with colonoscopes (Table 1).

The published estimated risk of iatrogenic infection during gastrointestinal endoscopy ranges from 1:27600²² to 1 in 10 million²³. A frequently quoted estimate is 1 in 1.8 million²⁴ which was published in a 1993 Technology Assessment Position Paper by the American Society for Gastrointestinal Endoscopy (ASGE)²⁵. However, it must be acknowledged that only a small number of endoscopically transmitted infections are detected and reported in the peer reviewed literature²⁶⁻²⁸. Kim and colleagues defined placement of a biliary stent, a diagnosis of cholangiocarcinoma and active inpatient status as risk factors for transmission of CRE when ERCP was performed using a contaminated duodenoscope. The observed transmission rate was 14.4%²⁹.

As a result of the increasing prevalence of CPE infections, the high mortality due to limited treatment options and the clear link with endoscopic procedures, GESA established a committee with GENCA, the Australian Society for Infectious Diseases (ASID) and the Australasian College for Infection Prevention and Control (ACIPC) to formulate evidence -based consensus statements on the prevention and management of endoscopic instrument transmission of CPE.

Methods

Based on a literature search through MEDLINE, BD formulated nine statements. These draft statements and relevant published literature were electronically despatched to the committee members who evaluated each statement and anonymously recorded their assessment of three parameters: Evidence level, recommendation grade and voting on recommendation (Table 2)³⁰ using an online voting platform (Mentimeter. www.mentimeter.com). Each statement was randomly assigned to two committee members to further review the available published literature. A face-to-face meeting was subsequently convened in June 2017 in Melbourne, Australia to review and discuss the evidence and revise the statement wording. At this time, four additional statements were added (5a, 7a, 7b, 8a), resulting in a total number of 13 statements (Table 3). Committee members judged each statement against the three parameters and voted anonymously for a second time using an electronic system. Consensus was achieved when 5 out of 6 committee members voted “accept completely” or “accept with some reservation”. A statement was rejected if 5 out of six members voted “reject completely” or “reject with some reservation”. All 13 statements achieved consensus acceptance.

Consensus Statements

1. 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.

Evidence level: IV

Recommendation grade: D

Voting on recommendation: Accepted completely: 100%

This global statement is an essential starting point in ensuring the highest reprocessing standards and focusses on facilities providing endoscopic procedures, irrespective of their physical infrastructure or case volume. Despite advances in endoscopic instrument reprocessing over the past 40 years, current reprocessing techniques remain sub-optimal^{17,31-34} as evidenced by recent outbreaks of CPE^{7-15,18-21}. Endoscopic units should be designed to facilitate patient flow minimising interaction of pre and post procedure patients and endoscope flow avoiding any contact between reprocessed (clean) and used (dirty) instruments. Facilities must provide appropriate equipment for endoscope reprocessing and adequate staff appropriately trained, supervised and reassessed in their adherence to reprocessing protocols as stipulated by instrument manufacturers. This is supported in a recently published study assessing the reprocessing of flexible endoscopes with an elevator mechanism as the quality of manual cleaning between reprocessing technicians showed variation³⁵. Compliance with this statement also requires attention to comprehensive infection control in endoscopy guidelines² and published standards for infection control in the unit's jurisdiction⁶.

2. The most important component of decontamination is timely and meticulous cleaning prior to disinfection.

Evidence Level: IIb

Recommendation Grade: B

Voting on Recommendation: Accepted completely: 100%

Reprocessing of endoscopic instruments requires adherence to nine sequential steps (Table 4).

Each of these steps must be completed to the highest standard consistent with manufacturers' instructions relevant to specific instruments. It cannot be over-emphasised that adequate cleaning of a used endoscope is essential if reprocessing is to be effective. If an instrument is not clean, it cannot then be high level disinfected or sterilised. Whereas there has been increased focus on the drying and storage phase of reprocessing over recent years, the importance of cleaning is paramount.

The importance of adequate cleaning has been highlighted in recent reports of outbreaks of CPE, as a result of difficulties cleaning the complex tips of duodenoscopes and linear echoendoscopes. The first known transmission of CPE at ERCP in the USA was attributed to insufficient cleaning practices^{8,9}. However, at least eight subsequent reported outbreaks have occurred despite apparent appropriate and optimal reprocessing technique³¹. In an analysis of linear echoendoscope cultures, Chapman et al reported 4.2% of primary cultures were positive for pathogenic gram-negative bacilli¹⁶.

It is essential that the cleaning process commences immediately after completion of the endoscopic procedure. The greater the time interval an instrument is left uncleaned, the greater the possibility of organic material drying in the channels and tips. This increases the difficulty of removal and the formation of microorganism-harboured biofilm. Pre-cleaning should be performed immediately after the instrument is withdrawn from the patient, with the insertion tube wiped clean and the channels lavaged with the suction of a detergent solution. After leak testing, the manual or more recently, the automated, brushless cleaning process should commence promptly. The French guidelines recommend that manual cleaning should commence within 10 minutes of completion of a procedure and automated flexible endoscope reprocessing (AFER) high level disinfection within 45 minutes³⁶⁻³⁸. In investigating an outbreak of KPC-K pneumoniae, Naas et al determined the cause to be delayed pre-wash cleaning and inadequate drying¹⁸. We recommend that after initial bedside pre-cleaning, instrument cleaning should commence within 15 minutes. If manual cleaning is performed, AFER HLD should commence within 45 minutes of completion of the procedure.

3. The use of a Therapeutic Goods Administration (TGA)-approved automated flexible endoscope reprocessor (AFER) is mandated for reprocessing in accordance with manufacturers' instructions.

Evidence Level: IIb

Recommendation grade: B

Voting on recommendation: Accepted completely: 100%

The Therapeutic Goods administration, a division of the Australian Department of Health, is the regulatory authority in Australia which regulates therapeutic goods, including medical devices. Endoscopy units in other jurisdictions will need to adhere to their regulatory authority's instructions on approved AFER's.

AFER's are already widely used in endoscopy units throughout the world. This statement refers to AFER's for HLD and not for automated cleaning. Automation enhances standardisation of reprocessing and compliance with reprocessing protocols. In a multi-site observational study comparing AFER reprocessing with manual reprocessing protocols, Ofstead et al reported 75.4% versus 1.4% compliance respectively³⁹. A multicentre Chinese study reported that the biofilm was detected in endoscope channels significantly more frequently from hospitals undertaking manual cleaning compared with those employing AFER's ($p=0.001$)⁴⁰. Whereas it has not been recommended that manual cleaning be replaced by automated cleaning in this consensus statement, the benefits of automation can similarly be applied to the cleaning phase of reprocessing. Alfa et al reported that automated cleaning resulted in 98.8% of surfaces and 99.7% of lumens meeting or surpassing cleaning endpoints for protein, haemoglobin and bioburden residuals⁴¹. Similar results have been reported with other automated cleaning machines⁴². The mandating of automated cleaning remains under review.

4. Quality control is fundamental to the delivery of efficient and safe endoscopic procedures and incorporates proof of process with adequate staff training (including education, professional development and assessment), documentation and microbiological surveillance cultures.

Evidence level: IIb

Recommendation grade: B

Voting on recommendation: Accepted completely 100%

Key to the performance of optimal endoscope reprocessing is monitoring and documentation of each step of the process, staff education and reassessment and microbiological cultures. Meticulous documentation not only focusses staff on compliance with reprocessing protocols, but also facilitates endoscope tracking should a root cause analysis be instigated in the investigation of a suspected endoscope transmission of an infectious agent. Protocol compliance remains inadequate as revealed in a Centres for Disease Control (CDC) pilot infection control audit reporting that 28% of 67 centres were not compliant with uniform endoscope reprocessing⁴³.

Microbiological surveillance culture of endoscopic instruments was mandated in Australia over twenty years ago². It is widely considered indispensable in monitoring reprocessing, reinforcing good practice and detecting instruments requiring maintenance. This was the conclusion of Saviuc et al in their retrospective series of 846 endoscope culture samples from a teaching hospital in France in which 118 (14%) were positive for indicator organisms³⁶. Microbiological cultures have not been universally adopted and are not mandated in the United States. The U.S. Food and Drug Administration however highlighted the importance of duodenoscope cultures in 2015 following a number of endoscopy related CPE outbreaks³⁴. In a recently published study, microbiological cultures were an essential component of optimising duodenoscope reprocessing protocols resulting in the withdrawal of duodenoscopes with a high rate of culture positivity and an overall decline in the high-level disinfection defect rate⁴⁴.

5. Patient-to-patient transmission of carbapenemase-producing Enterobacteriaceae (CPE) by endoscopic instruments can result in serious illness, and its prevention must be a priority of every endoscopic unit.

Evidence level: III

Recommendation grade: D

Voting on recommendation: Accepted completely: 100%

CPE are resistant to most antimicrobials. Patients colonised by CPE may remain asymptomatic and may be unaware of their potential to act as a transmission source of the bacteria. CPE blood stream infections are associated with a mortality of 18-48%⁴⁻⁶. Direct patient to patient transmission may occur in the health care setting or CPE may be transmitted by healthcare workers as a result of deficient hand hygiene practices or the presence of contaminated equipment including hand washing basins⁴⁵. Table 3 lists the reported series of endoscopy related CPE transmission. Kola and colleagues expertly tracked the transmission of CP *K pneumoniae* in a university hospital in Berlin between 2012 and 2013. The index patient, with asymptomatic colonisation, transmitted the organism to patients in the same ward, one of whom underwent an ERCP resulting in transmission to subsequent patients undergoing procedures with the same instrument. This was followed by further patient to patient transmission in another ward¹¹. These reports emphasise the central role endoscopic procedures can play in transmission of CPE.

5a. Informed consent for patients undergoing endoscopic procedures with duodenoscopes or linear echoendoscopes must include disclosure of the risk of CPE colonisation or infection.

Evidence level: IV

Recommendation grade: D

Voting on recommendation: Accept completely 100%

As detailed in Table 3, the majority of outbreaks of CPE related to endoscopic transmission were linked to duodenoscopes⁷⁻¹⁵. Further reports relate to linear echoendoscopes^{16,17}. As discussed in Statement 2, this is related to the difficulties in cleaning the complex tips of these instruments. Despite reported outbreaks being sporadic it is reasonable to conclude that the risk of transmission of a microorganism is present whenever these instruments are used. As a result of increased patient mobility with air travel, patients may move from a hospital in a high risk country to a country considered low risk and require hospital admission and endoscopic procedures¹⁸. Given the morbidity and mortality associated with CPE infection and the risk of transmission with duodenoscopes and linear echoendoscopes, it is considered mandatory that informed consent for these procedures includes a disclosure of the risk of CPE transmission³³.

6. Reported endoscopic transmission of CPE has been predominantly related to instruments with complex tips (e.g. duodenoscopes and linear echoendoscopes), but all endoscopes instruments may transmit CPE.

Evidence level: III

Recommendation grade: C

Voting on recommendation: Accept completely: 83%, Accept with some reservation: 17%

It is accepted that the complex tips of duodenoscopes and linear echoendoscopes are a source of transmission of CPE due to difficulties in achieving adequate removal of biologic material⁷⁻¹⁷. Other endoscopes, without complex tips have also been linked to patient-to-patient transmission of CPE^{15,18-21}. Six out of ten screened patients were colonised with KPC *K* pneumoniae and two developed clinical infections following gastroscopies using a colonised instrument¹⁸. Endoscopy was determined to be an independent risk factor in the acquisition of Ertapenam-resistant *K* pneumoniae in an outbreak published by Orsi and colleagues in 2011¹⁹. Viable microorganisms were recovered from 64% of endoscopic instruments after HLD in a series published in 2015⁴⁶ and bacteria were detected in 9/15 (60%) of patient ready endoscopic instrument in a study published by Ofstead et al including gastroscopes (n=2), colonoscopes (n=3) and bronchoscopes (n=4)⁴⁷. Therefore, an additional mechanism of bacterial retention and subsequent mobilisation must be present.

7. Instrument reprocessing and environmental management protocols need to be augmented in an effort to reduce the risk of CPE.

Evidence level: IIb

Recommendation grade: C

Voting on recommendation: Accept completely: 100%

Published studies have reported conflicting results on the adequacy of endoscope reprocessing with some reporting no or low levels of detectable bacteria after disinfection or sterilisation and

other reporting 35-60% of endoscopes growing organisms of concern⁴⁸. Improvements in instrument reprocessing and environmental protocols aimed at reducing the risk of CPE transmission will likely reduce the transmission of all microorganisms. Existing protocols predominantly target planktonic organisms. However, there is increased emphasis on targeting biofilm which develops in endoscope channels and may harbour bacteria. Biofilm represents a major challenge to endoscope reprocessing as it is very difficult to detect, monitor, and very difficult to remove. In addition to meticulous channel flushing and cleaning, it is increasingly appreciated that adequate instrument, and in particular, channel drying is essential in preventing its formation. Viable microorganisms in endoscope channel biofilm can survive reprocessing⁴⁹. A “build-up biofilm” model was developed which mimics the cumulative effect of reprocessing protocols on flexible endoscopes⁵⁰. Effective HLD may decrease if “build-up” biofilm develops within instrument channels as it is associated with the survival of a wide range of microorganisms⁵⁰. In a more recent study utilising an *E coli* and *P aeruginosa* biofilm model, it was reported that if biofilm accumulates within endoscope channels during repeated reprocessing, neither the detergent or HLD will provide the expected level of bacterial removal⁵¹. This was supported by a recent study where biofilm was detected by confocal laser scanning and scanning electron microscopy in all 39 endoscope channels examined after high level disinfection⁵². As yet, there is no practical technique available to assess for the presence of biofilm in endoscope channels. Borescopes are not widely available, are expensive and of unproven accuracy in the detection of biofilm. This remains under ongoing investigation, however. In a series by Thaker et al, endoscope channels were inspected using a borescope in 59 endoscopes. No biofilm was identified, but channel scratches were seen in 86% of inspections, with shredding in 59%, debris in 23%. No intra-channel moisture was seen in 74 inspections when the instrument was forced-air dried and stored vertically overnight compared with moisture being present in 28% of inspections after storage alone⁵³. Adenosine triphosphate (ATP) testing is effective in identifying residual organic material and improving quality of manual cleaning of endoscopes, including those with an elevator mechanisms³⁵. However, ATP assays are insufficiently sensitive or specific to warrant their routine clinical application for the assessment of instrument high level disinfection adequacy⁵⁴.

7a. All endoscopic instruments, except those in sterile packaging, should be stored in TGA-approved forced-air drying cabinets.

Evidence level: IIb

Recommendation grade: C

Voting on recommendation: Accept completely: 83%, Accept with some reservation: 17%

This statement represents one of the most significant recommendations in this consensus. It is important to emphasise that the recommendation for storage in forced-air drying cabinets is for all endoscopic instruments, not only those with complex tips. It is our understanding that this is the first time such a recommendation has been made in any jurisdiction. The basis for this recommendation is the acceptance 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 in preventing its formation. An early literature review in 2006 concluded that endoscope drying is as important to the prevention of disease transmission and nosocomial infection as cleaning and high level disinfection⁵⁵. As acknowledged in Statement 3, the Therapeutic Goods Administration is an Australian regulatory authority, and therefore approval for the use of any brand of forced-air drying cabinet will need to be sought in the readers' jurisdiction.

The importance of adequate drying in preventing bacterial overgrowth was highlighted in an early study in 1991, in which the concentration of bacteria and the ratio of gram-negative to gram-positive bacteria were significantly higher at 48 hours than at two hours in the group of duodenoscopes that were less thoroughly dried. None of 19 duodenoscopes that received an extra 10 minutes of forced-air drying showed any microbial growth at 48 hours whereas nearly half of non-dried duodenoscopes were contaminated at 48 hours⁵⁶. Utilising an in-vitro biofilm model, Kovaleva et al concluded that routine cleaning procedures do not remove biofilm reliably from endoscope channels if an adequate drying procedure is not performed⁵⁷. The use of forced-air drying cabinets have been shown to limit bacterial proliferation^{58,59}. In the multicentre Chinese series by Ren-Pei, it was also concluded that biofilm build-up may relate to inadequate

drying with the detection of biofilm in 36/66 (54.6%) of biopsy/suction channels and 10/13 (76.9%) of air/water channels in an analysis of 79 endoscope channels from 66 hospitals⁴⁰.

It is acknowledged that the installation of forced-air drying cabinets in all endoscopy units constitutes a significant capital expenditure and may pose challenges due to the space requirement. Therefore, in Australia a deadline for compliance has been set at January 2022. This allows sufficient time to attend to these challenges. All units however are immediately required to demonstrate that they have instituted a plan to meet this compliance date.

7b. Endoscopes stored in TGA-approved forced-air drying cabinets may be used for a period of up to 7 days without reprocessing, unless otherwise stated by the manufacturer.

Evidence level: IIb

Recommendation grade: C

Voting on recommendation: Accept completely 100%

A practical benefit of the use of forced-air drying cabinets is extended time instruments can be used for a procedure without the need for reprocessing. Schmelzer et al⁶⁰ summarised the proportion of contaminated endoscopes, defined as the presence of any pathogen and >10CFU/ml in seven studies that sampled all channels for length of time and type of storage. Drawing from these data, it is considered safe to use an endoscopic instrument for a period of seven days without the need for pre-procedure reprocessing. This will confer cost-savings to endoscopy units and health services. It is important to acknowledge that each forced-air drying cabinet manufacturer will have conducted studies specific to their cabinet and the safe re-use duration may need to be adjusted based on these results.

8. When endoscopic procedures are performed on known CPE-positive patients, specific environmental and instrument reprocessing protocols should be utilised.

Evidence level: III

Recommendation grade: C

Voting on recommendation: 100%

When considering management protocols for endoscopic procedures on patients known to be colonised with CPE, the first priority must be strict adherence to standard precautions with the addition of contact precautions to minimise the risk of others being exposed⁶¹. Safe work practices associated with these standard precautions must be applied to all patients and the environment⁶¹. Specific to CPE-positive patients, two main issues need to be addressed. The first is control of the environment ie the endoscopy unit and in particular the procedure room⁶. In the design of any endoscopy unit patient flow is important to minimise contact of pre and post-procedure patients. This is particularly important for CPE-positive patients. CPE-positive patients should be transported from admission, or their single room, directly into the procedure room, if possible. Alternatively, if available, place CPE positive patients into a single room within the endoscopy unit. These patients then return to this room following the procedure for recovery and transfer to the ward or discharge thereby minimising contact with other patients in the pre-procedure area. This room should be cleaned and disinfected following each patient use. If a single room in the endoscopy unit is not available, the patient can undergo routine post-procedure monitoring in the procedure room prior to return to the hospital ward or discharge from the unit. Fixtures in the room should be appropriately shielded to minimise droplet contamination. All non-essential equipment should be removed from the room. Only staff essential for the safe performance of the procedure and patient care should enter the room. Following the procedure, the room should undergo a comprehensive, “terminal” clean before further use⁶. The second main issue relates to the endoscopic instrument.

8a. Following an endoscopic procedure on a known CPE-positive patient, the instrument should undergo microbiological testing and be quarantined until a negative result is obtained at 48 hours.

Evidence level: III

Recommendation grade: C

Voting on recommendation: accept completely: 100%

Whereas CPE are concerning organisms due to their antimicrobial resistance, they are readily cultured as are other Enterobacteriaceae. 48 hours is a sufficient time interval to allow CPE to be

detected by routine culture methods if present. This is an important addition to reprocessing protocols as it provides strong reassurance that CPE will not be transmitted to subsequent patients via the endoscope. If cultures return a positive result, the instrument remains quarantined, undergoes a second reprocessing cycle and microbiological culture. If the second culture is negative the instrument can return to service. If the second culture is positive, the instrument should be sent for a comprehensive service and channel replacement. This 48 hour quarantine procedure was an important component of the effective resolution of the Seattle duodenoscope-related CPE outbreak⁶². The additional microbiological cultures will represent crucial data in the event of a CPE outbreak investigation with a suspected link to endoscopic procedures.

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

Evidence level: IV

Recommendation grade: D

Voting on recommendation: Accept completely: 100%

It is essential that each health service have in place a management procedure to definitively investigate a potential CPE outbreak. This is best undertaken by an outbreak management team incorporating, endoscopy staff, the microbiology department, infection control, hospital management and media relations. Whereas it is essential to determine the source of an outbreak and manage the source, it is also important that endoscopy units continue to function safely and that patients and the community are reassured of the safety of endoscopic procedures. Patient movement into and out of the endoscopy unit may have to be minimised⁶.

Conclusion:

These multi-society consensus statements offer specific guidance on the control of CPE transmission related to endoscopic procedures. They are in addition to broader published guidelines on infection control in endoscopy². These statements are evidence based and encourage preventative strategies with the aim of ensuring the highest possible standards in flexible endoscope reprocessing thereby optimising patient safety.

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