Final rinse water quality for flexible endoscopy to minimise the risk of post-endoscopic infection. Report from Healthcare Infection Society Working Party.

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1. Executive summary

Endoscopic procedures in diagnostic and surgical settings are performed routinely and the number of patients undergoing these procedures is progressively increasing. Outbreaks and sporadic cases of infection associated with the use of endoscopes have decreased due to improvements in endoscope decontamination. The majority of infections occur due to the failure in endoscope reprocessing; however, final rinse water has been implicated in some outbreaks and pseudo-outbreaks. The final rinse water should be free of bacteria and is an essential step in decontamination because it removes traces of disinfectants which could otherwise be hazardous to patients and staff. However, where the final rinse water has become contaminated by waterborne microorganisms this step carries the risk of contaminating the endoscope and subsequently potential transmission of these organisms into the patient, which could result in infections.

This evidence- and expert-based guidance document aims to improve patient safety and reduce risks of decontamination-related healthcare associated infections (HCAI) by standardising the interpretation of endoscopy final rinse water results through monitoring and assessing the risk of infection.

Summary of recommendations:

Evidence-based recommendations

EB1.1 Follow recommendations of national guidance to ensure endoscopes are appropriately reprocessed.

EB1.2 Control the presence of microorganisms in the water system which supplies the final rinse water to endoscope washer disinfectors.

EB1.3 Monitor the quality of the water system which supplies the final rinse water to the endoscope washer disinfectors.

EB 1.4 Change filters at frequencies indicated by the manufacturer.

EB1.5 Consider using water with a low bioburden for re-processing all endoscopes.

EB1.6 If reverse osmosis water is used, change membranes at frequencies indicated by manufacturer and ensure that appropriate self-disinfection is in place.

EB1.7 In endoscopy units performing a high number of procedures, consider changing membranes/filters more frequently.

Consultation draft

HIS RWQ for endoscopes guidance: main document.

Expert recommendations

Indicators

ER1.1 Monitor the final rinse water for total viable counts weekly (TVC) and test for the presence of environmental mycobacteria and *Pseudomonas aeruginosa* quarterly.

ER1.2 Consider testing for other microorganisms of significance, as based on local circumstances (e.g. *Legionella pneumophila* and other).

ER1.3 There is no need to monitor endotoxin levels routinely but consider doing so if the major water supply problem has been identified.

Testing methods

ER1.4 Use the methodology described in BS EN ISO 15883-1:2009+A1:2014 for total viable counts weekly (TVC) and endotoxins.

ER1.5 Use either culture-based or molecular methods to test for the presence of microorganisms of significance (e.g. *Pseudomonas aeruginosa,* environmental mycobacteria*, Legionella pneumophila* and other).

ER1.6 When molecular-based methods are used to detect the presence of microorganisms of significance, ensure that conventional methods for total viable counts weekly (TVC) and endotoxins are still in place.

ER1.7 Consider participating in an external quality assurance scheme for testing and interpreting results of the water quality.

Interpreting the results

ER2.1 Laboratories must provide the report of the final rinse water testing regardless of the results.

ER2.2 Upon receiving the final rinse water results, consider using a flow chart to assess the risk based on the traffic light system to decide which actions are required.

ER2.4 Collate total viable counts weekly (TVC) results to assess them for trends and to determine whether microbial counts are increasing.

ER2.3 When the water testing results are unsatisfactory or unacceptable, appropriate action must be taken by endoscope re-processing units to improve the quality of water.

Management of endoscopes and patients

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ER3.1 Following unsatisfactory final rinse water test results (TVC 10-100cfu/100ml), do not reprocess high-risk endoscopes in an affected endoscope washer-disinfector until satisfactory or acceptable result is obtained.

ER3.2 Where TVC is >100cfu/100ml or when microorganisms of significance are present, do not reprocess any endoscopes in an affected endoscope washer-disinfector.

ER3.3 Where TVC is >100cfu/100ml or when microorganisms of significance are present, recall and reprocess all unused reprocessed endoscopes.

ER3.4 Do not routinely trace and follow up patients with total viable counts weekly (TVC) counts >100cfu/100ml or when microorganisms of significance are present.

Non-microbial water contaminants

ER4.1 Ensure that the final rinse water meets other (non-microbial) standards of safety for potable water as set out in guidance.

Contamination after the final rinse

ER5.1 Ensure that actions are taken that minimise the risk of microbial contamination being re-introduced during the drying and storing of the endoscopes.

Good Practice Point: GPP5.1 For flushing the endoscope during the procedure, use sterile water if possible or use water which is at least the same quality as the final rinse water.

Roles and responsibilities

ER6.1 Ensure that an appropriate multidisciplinary team is involved in the management of the final rinse water.

ER6.2 Ensure that staff involved in endoscopy reprocessing are competent, understand the microbial risks associated with final rinse water and that training is assessed annually.

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2. Plain English summary

An endoscopy is a procedure where organs inside your body are looked at using an instrument called an endoscope. An endoscope is a long, thin, flexible tube that has a light and camera at one end. Images of the inside of your body are shown on a television screen. Because of their design, endoscopes are difficult to clean and therefore there is a risk that a person undergoing endoscopy may develop an infection. Harsh chemicals are used in cleaning the endoscopes, which means that they need to be rinsed off with water so that patients and staff avoid any adverse reactions. This is at the end of decontamination and hence is called the final rinse. However, where the final rinse water has become contaminated by waterborne bacteria or other organisms, this step carries the risk of re-contaminating the endoscope and possibly infecting a patient. Most infections occur due to the failure in endoscope reprocessing, (i.e., the process which cleans an endoscope and removes bacteria after it was used on a patient), but final rinse water has been implicated in some outbreaks and pseudo-outbreaks.

Infection rates associated with the use of endoscopes have decreased due to improvements in endoscope reprocessing. This document will help to improve patient safety and reduce risks of infections by providing advice to medical staff on how to deal with final rinse water. The glossary of terms used in this document is provided in Supplementary Materials file A.

3. Introduction

Since the Healthcare Infection Society's (HIS) Working Party report on the final rinse water for flexible endoscopy was published in 2002,[1] other guidance has become available, namely European Standards for endoscope washer disinfectors (EWDs) BS EN ISO 15883-1:2009+A1:2014[2] and the national guidance from the UK devolved nations (i.e., HTM 01-06,[3] WHTM 01-06,[4] NHS Scotland Guidance for the interpretation and clinical management of endoscope final rinse water[5]).

One of the most common issues with the use of EWDs is the quality of the final rinse water and actions to be taken if microbiological contamination is detected. Evidence shows that endoscopy final rinse water samples can fail the microbiological criteria required.[6,7] As a consequence, guidance that is based on action levels following the implementation of a risk assessment if it is necessary. This guidance provides practical recommendations on what actions to take in response to microbiological contamination of the final rinse water. Recommendations have been considered in the following areas: clinical management of patients, management of EWDs and water treatment systems and test methodology for microbiological assessment of final rinse water samples.

4. Guidance Development Team

4.1 Acknowledgements

Members of the Working Party represent UK professional societies i.e. Healthcare Infection Society (HIS), Infection Prevention Society (IPS), Central Sterilising Club (CSC), Institute of Decontamination Science (IDSc), Institute for Healthcare Estates and Engineering Management (IHEEM) and the British Society of Gastroenterology (BSG).

Consultation draft

4.2 Source of funding

The authors received no specific funding for this work. Financial support for time required to obtain the evidence and write the manuscript was provided by the authors' respective employing institutions.

4.3 Disclosure of potential conflict of interest

All conflicts of interest are disclosed in Supplementary Materials file B.

4.4 Relationship of authors with sponsor

HIS commissioned the authors to undertake this Working Party Report. The authors are members of the participating societies mentioned in section 4.1.

4.5 Responsibility for guidance

The views expressed in this publication are those of the authors and have been endorsed by HIS, IPS, BSG, CSC, IDSc, IHEEM and approved following a consultation with external stakeholders (Supplementary Materials file C).

Consultation draft

5. Working Party Report

5.1 What is the Working Party Report?

This report contains recommendations to minimise the risk of post endoscopic infection or pseudo-infection associated with contamination of final rinse water for flexible endoscopy. The Working Party recommendations represent examples of good practice; they have been developed systematically through a multi-professional group based on published evidence and professional experience. These recommendations may be used in the development of local protocols for all healthcare settings. Other aspects of decontamination and management of endoscopes are outside of the scope of these guidelines.

5.2 Why do we need a Working Party Report for this topic?

The previous guidelines relating to this topic were published in 2002. During this time there have been improvements in the endoscope decontamination protocols, including the quality of the final rinse water. However, the risk of healthcare-associated infections due to pathogens present on endoscopes remains and the guidance is still required. The European and the UK standards for the final rinse water quality exist, but they only provide information on methodology for testing and interpretation and do not make recommendations to the endoscope-processing units and endoscope suites on how to manage the unsatisfactory results. This guidance fills a clinical gap by providing recommendations on what actions need to be taken by endoscopy units when the final rinse water does not meet these standards.

5.3 What is the purpose of the Working Party Report's recommendations?

The recommendations describe measures that are practical for minimising the risk of post endoscopic infection or pseudo-infection related to final rinse water for flexible endoscopy when used by healthcare workers carrying out or advising on the decontamination of flexible endoscopes.

5.4 What is the scope of the guidance?

This guidance is intended for the decontamination of flexible endoscopes that do not undergo further reprocessing after decontamination in an EWD. While the focus of this guidance was the quality of the final rinse water in EWD, the Working Party acknowledge that some of these recommendations may also be relevant where endoscopes need to be processed manually due to their design or incompatibility with automated processes. Flexible endoscopes that are reprocessed in an EWD and then undergo a sterilization process are excluded from these guidelines. This guidance was developed by the UK-based experts and focusing on the UK-based standards; however, the Working Party believes that the recommendations can also be extrapolated to the settings outside the UK.

5.5 What is the evidence for this guidance?

In the preparation of these recommendations, systematic searches and systematic reviews of published literature were undertaken. Evidence was assessed for methodological quality and clinical applicability according to NICE protocols (more information is provided in the supplementary materials file B).[8] Where evidence was lacking, expert opinion was also derived from published guidelines, subjected to validated appraisal.[8]

5.6 Who developed this guidance?

The Working Party included medical microbiologists, microbiology scientists, infection control practitioners, water experts, decontamination leads and authorising engineers (decontamination).

5.7 Who is this guidance for?

Any healthcare practitioner can use this guidance and adapt it for local use. Users should include clinical medical, nursing, engineering and estates staff, decontamination leads as well as healthcare infection prevention and control teams in their decision-making process.

5.8 How is the guidance structured?

This guidance is divided into two sections. The first section includes the summary of available published evidence and provides rationale for evidence-based recommendations. The second section provides rationale for making expert-based recommendations. These were made where the published evidence was lacking. Instead, the knowledge and experience of the Working Party members were used to determine the best practice.

Consultation draft

5.9 How frequently is the guidance reviewed and updated?

The guidelines will be reviewed at least every four (4) years and updated if change(s) in the evidence are sufficient to require a change in practice.

5.10 How can this guidance be used to improve clinical effectiveness?

The guidance can be used to inform local infection prevention and control policies and to direct decision making. The recommendations provide a framework for audit tools aiming to achieve quality improvement in the quality of the final rinse water for endoscopy.

5.11 How much will implementation of this guidance cost?

In most areas there are no anticipated additional costs unless existing practice falls well below currently accepted best practice. Failure to implement the recommendations would result in greater costs both in terms of economics and quality of life.

5.12 Aim

The aim of this guidance is to provide advice on what is considered as adequate quality of the final rinse water, how to monitor the quality of the final rinse water and what actions to take in response to microbiological contamination of the final rinse water.

6. Methodology

6.1 Evidence search and appraisal

Topics for this guidance were derived from the initial discussions of the Working Party. To prepare these recommendations, the Working Party collectively reviewed relevant evidence from published sources. Methods were followed in accordance with the NICE manual for conducting evidence syntheses (described below and in supplementary file).[8]

6.2 Data sources and search strategy

Three electronic databases (Medline, Embase, CINAHL) were searched for articles published between 1st January 2000 and February 2021; search terms were constructed using relevant MeSH and free text terms (Appendix 1). Reference lists of identified articles were scanned for additional studies and forward reference searching (identifying articles which cite relevant articles) was performed. The searches were restricted to primary articles published in the English language.

6.3 Study eligibility and selection criteria

Any article presenting primary data relevant to final rinse water quality was included. Due to limited evidence, and the fact the principles of the final rinse water quality are similar, articles which used manual reprocessing of endoscopes were also included. This decision was made because the evidence on this topic remains limited. The Working Party recognised that the context and the setting for EWD

Consultation draft

and manual reprocessing may be different but that the principle that there is a risk of re-contaminating the endoscope with the final rinse water is the same.

Search results were downloaded to EndNote database and screened for relevance. One reviewer (AB) reviewed the title, abstracts, and full texts. A second reviewer (GM) checked at least 10% of the excluded studies at each sifting stage. Disagreements were discussed between the two reviewers. Any disagreements were discussed with a third reviewer. The results of study selection are shown in the PRISMA diagram in Appendix 2a. The list of the studies excluded at full text sift with a reason for this decision is provided in (Appendix 2b).

6.4 Data extraction and quality assessment

Included epidemiological studies (all outbreak studies) were appraised for quality using checklists recommended in the NICE guideline development manual. Pseudo-outbreaks as well as environmental and laboratory studies were not appraised for quality since no checklists exist for this type of studies. Critical appraisal and data extraction were conducted by one reviewer and checked by the second. The results are available in Appendix 3. Data from the included studies were extracted to create, study description, the summary of findings data extraction tables (Appendix 4).

6.5 Rating of evidence and recommendations

The strength of the evidence was defined by GRADE (Grading of Recommendations Assessment, Development and Evaluation) tables (Appendix 5) and using the ratings ‘high’, ‘moderate’, ‘low’ and ‘very low’ to construct the evidence statements, which reflected the Working Party’s confidence in the evidence. The strength of recommendation was adopted from GRADE and reflects the strength of each evidence statement. In instances where no evidence was identified from searches, the statement ‘No evidence was found in studies published so far…’ indicates that no studies have assessed this as an outcome. Where there was no evidence or a paucity of evidence, expert-based recommendations were made by experts’ experience. All disagreements were resolved by discussions and voting by members of the Working Party during the meetings.

When writing recommendations, the Working Party considered the following:

- Who should act on these recommendations?
- What are the potential harms and benefits of the intervention and any unintended consequences?
- What is the efficacy and the effectiveness of each intervention?
- Is it possible to stop another intervention because it has been superseded by the new recommendation?
- What is the potential effect on health inequalities?
- What is the cost-effectiveness of the intervention, including staff resources other economic concerns?

Consultation draft

- Can the recommended interventions be feasibly put into practice?

The wording of the evidence statements and the recommendations reflected the strength of the evidence and its classification. The following criteria were used:

- 'offer', 'measure', 'advise', 'refer', 'use' or similar wording was used if the Working Party believed that most practitioners/commissioners/service users would choose an intervention if they were presented with the same evidence: this usually means that the benefits outweigh harms, and that the intervention is cost-effective. This reflects a strong recommendation for the intervention. If there is a legal duty, or if not following a recommendation may have serious consequences, the word 'must' was used.
- 'do not offer' or similar wording was used if the Working Party believed that harms outweigh the benefits or if an intervention is not likely to be cost-effective. This reflects a strong recommendation against the intervention. If there is a legal duty, or if not following a recommendation may have serious consequences, the words 'must not' were used.
- 'consider' was used if the Working Party believed that the evidence did not support a strong recommendation, but that the intervention may be beneficial in some circumstances. This reflected a conditional recommendation for the intervention.
- The 'do not offer, unless…' recommendation was made if the Working Party believed that the evidence did not support the strong recommendation, and that the intervention was likely not to be beneficial, but could be used in some circumstances, for instance if no other options were available. This reflected a conditional recommendation against the intervention.
- Good Practice Point was made when the Working Party considered that despite lacking an evidence base, this advice could be considered beneficial to good clinical practice.

6.6 Consultation process

Feedback on draft guidance was received from the participating organisations and through consultation with relevant stakeholders. The draft report and standard comments form were placed on the HIS website for 14 days. The availability of the draft was advertised via email and social media. Stakeholders were invited to comment on format, content, local applicability, patient acceptability, and recommendations. The Working Party reviewed stakeholder comments, and collectively agreed revisions (Supplementary materials C). All reviews received from individuals with a conflict of interest or those who did not provide a declaration were excluded.

7. Results

The search identified a total of 1137 articles. After excluding duplicate and irrelevant studies and checking reference lists for related citations, a total of 20 were included, a further 28 articles were identified from backward and forward reference searching.

Of a total 48 articles which met the inclusion criteria, eleven described outbreaks[9-19] and one[20] described a case report when patients developed infections after endoscope procedures. Of the remaining 36 articles, 18 studies[21-38] described pseudo-outbreaks where endoscopes contaminated patient samples but where patients did not show any signs of colonisation or infection, ten articles[39-48] described the results of ongoing surveillance of endoscopes and/or the final rinse water, seven studies[49-55] reported the results of the survey where endoscopy services reported their practice for processing endoscopes, and one study described a laboratory experiment[56] where fungi were detected from different water sources. Two of the articles[54/55] describing the practice of reprocessing the endoscopes reported the same data and are further mentioned as one study.

8. Rationale for evidence-based recommendations

Consultation draft

Potential infection is one of the concerns following the endoscopic procedure. Contamination of final rinse water with water-borne microorganisms could lead to re-contamination of reprocessed endoscopes and subsequent infection in patients who were subjected to a procedure with a contaminated endoscope. Even in the absence of infection, pseudo-outbreaks may occur when patient samples become contaminated. Pseudo-outbreaks are still clinically important because patients who are involved may receive unnecessary therapy or may experience a delay in diagnosis or treatment while institutions may incur unnecessary costs and suffer from disruptions when investigations are undertaken. Previous guidance recommended that the institutions take steps to ensure the provision of bacteria-free water, which would require consideration of local circumstances. Additionally, it was recommended that once these steps are in place, institutions also monitor their final rinse water and take actions when the quality is shown to be unsatisfactory.

8.1 Outbreaks and sporadic infections

There was weak evidence from a total of eleven outbreak studies,[9-19] one case report[20] and one surveillance study[46] which considered the possibility of post-endoscopic infections arising from the contamination of the final rinse water. In three (21%) of these studies, involving a total of 32 patients (none were UK based),[15,19,46] water was found to be contaminated. Two of these studies reported reprocessing the endoscopes manually[15,19] and one reported disinfection using EWD.[46] In one of these studies,[15] a new nurse accidentally reversed the taps in the endoscope reprocessing room, resulting in the filtered water being used for handwashing and the tap water being used for rinsing the endoscopes. The authors reported that this resulted in transmission of *Legionella pneumophila* to three patients undergoing endoscope-assisted transoesophageal echocardiography. The second outbreak,[19] which resulted in 23 patients being infected with *Pseudomonas aeruginosa*, occurred in the urologist's office where endoscopes used for cystoscopy were processed manually. A number of breaches to the disinfecting procedure were identified, including shortening the duration of time the endoscopes were soaked in disinfecting solution, changing the final rinse water infrequently (every two weeks or when it became smelly), and using tap water for the final rinse.

Authors reported that the brushes used for manual cleaning and the rinse bath were contaminated with *Pseudomonas aeruginosa* implicated in this outbreak. Finally, one study[46] reported that surveillance of endoscopes, which was performed as a part of quality assurance, identified the contamination with one strain of *Pseudomonas aeruginosa*. The resulting testing of final rinse water performed twice weekly, showed contamination in two EWDs despite the water tanks, incoming tap water and EWD filters all testing negative. Authors reported that *Pseudomonas aeruginosa* were not detected in the samples obtained from the endoscopes but were still present in the final rinse water. Additionally, the authors reported that *Pseudomonas aeruginosa* re-emerged a few months later and that PFGE showed that these isolates were identical to the pseudo-outbreak strains. Thus, while endoscopes appeared to be decontaminated successfully, *Pseudomonas aeruginosa* was persistently present in the final rinse water samples until the concentration of the disinfectant and the disinfection running time were increased. Authors identified six bacteraemia cases which could potentially have been due to contaminated endoscopes, although they also stated that clinical isolates which had been obtained in the preceding six months did not match the strains found in the final rinse water samples. Thus, whilst the clinical and environmental strains did not match, it cannot be ruled out that the six cases were a result of contaminated final rinse water. Since the rate of the incidence of *Pseudomonas aeruginosa* bacteraemia did not increase comparing to the earlier data, authors did not consider these cases to be a result of an outbreak. None of the reported cases occurred in the UK. The remaining 11 studies reported that the final rinse water was not contaminated and thus was not the source of the outbreaks. Of these studies, seven reported that endoscopes were contaminated due to the failure in reprocessing.[8,11-14,16,20] There were further 34 outbreaks and case reports[57-90] (Appendix 6) which did not meet the inclusion criteria because they reported other sources of outbreaks such as reprocessing failure due to lapses in one or more steps in the disinfection,[59-61,63,68,71,77,79,82,85,86] or contamination involving faulty or inappropriately designed endoscopes,[62,63,66,72,78,79,83,87,91] and contaminated endoscopes when there were no evident lapses in reprocessing.[58,64,67,69,84,88]

Since the previous guidance was published, there were no outbreaks occurring in the UK where the final rinse water was implicated as a source. Furthermore, internationally, there was only one report which described an outbreak due to the final rinse water in EWD. This evidence demonstrates that, with appropriate controls put in place, there is now a very low risk of infection due to the final rinse water in EWDs. However, the Working Party concluded that the final rinse water remains a potential risk as a source of infection in patients undergoing endoscopic procedures and that the endoscope reprocessing suites must ensure that they continue to provide high quality final rinse water. The Working Party also acknowledge that the estimates of the risk may be underreported because not all

Consultation draft

infections associated with endoscopic procedures may be recognised and because some of the outbreaks may have not been published.

8.2 Pseudo-outbreaks

There was moderate evidence from a total of 18 articles which described pseudo-outbreaks where the final rinse water was found or was suspected to be contaminated.[21-38] These pseudo-outbreaks reported the patient samples to be contaminated but found that none of the patients were colonised or infected. All of the pseudo-outbreaks involved the contamination of bronchoscopes. One study also reported the involvement of ultrasound endoscopes which were used for pulmonology procedures[36] and another involving gastroscopes in addition to the bronchoscopes.[27] Pseudo-outbreaks were mostly due to microorganisms typically not transmitted between patients but found in the environment and occasionally infecting patients, e.g. environmental mycobacteria (8 out of 18 pseudo-outbreaks (44%) n=230 patients),[23-27,31-33] fungi (2/18 (11%), n=14),[21,29] *Pseudomonas putida* and *Stenotrophomonas maltophilia* (1/18 (6%), n=39),[22] or *Burkholderia cepacia complex* (1/18 (6%), n=3).[30] Together, these environmental microorganisms were responsible for 14 (78%) of pseudo-outbreaks, including all three pseudo-outbreaks which occurred in the UK,[21,26,37] and involved a total of 297 patient samples. The presence of these microorganisms suggests that the contamination occurred during or post-reprocessing, with the final rinse water as a potential contaminant. In total, 11/18 (61%) of the pseudo-outbreaks reported that the final rinse water contained microorganisms which were the cause of the pseudo-outbreaks,[22-24,,26,27,29-31,33,35,38] of which only one occurred in the UK.[26] The most common reason for contaminated water was a failure to replace filters on time,[24,31,33,35], other reasons included filters with an inappropriate pore size[27] and a missing filter.[30] Three reports did not provide the reason for contaminated filters,[22,29,38] however one of these reports mentioned that changing the filters did not successfully end the pseudo-outbreak, and that the microorganisms continued to contaminate the endoscopes until the water pipes which connected the sink to manual reprocessing cleaning equipment were changed.[38] One of the reports also stated that the frequency of filter changes according to manufacturers' instructions was not sufficient to prevent the pseudo-outbreak.[33] It was reported that an extremely high volume of water which was used in a busy endoscope unit required the filter to be changed monthly rather than quarterly. In two pseudo-outbreaks where either sterile water[37] or filtered water treated with UV light was used,[25] final rinse water was reported to be not contaminated, although one of these studies found a significant growth of contaminated pathogen on water filters.[25] The second study reported that the pseudo-outbreak was due to a design issue of the affected bronchoscopes which were immediately serviced and replaced.[37]

Consultation draft

Upon the review of the above evidence, the Working Party concluded that the environment rather than the failure in endoscope reprocessing is the most frequent reason for pseudo-outbreaks, with final rinse water as a potential environmental source. Only one of these pseudo-outbreaks occurred in the UK and this occurred before the guidance on final rinse water quality was published. Therefore, with appropriate monitoring and corrective actions in place, the risk of pseudo-outbreaks is now very low.

Furthermore, the Working Party concluded that unfiltered tap water, which is known to contain microorganisms is not suitable for the use of rinsing endoscopes after re-processing. The evidence suggests that even with filtration system in place, the water cannot be assumed to be safe (e.g. due to filter failure, inappropriately fitted filter etc.) and that additional measures (e.g. disinfection and monitoring) are needed to ensure adequate quality. Thus, monitoring of the final rinse water quality should remain an essential component of the infection prevention strategy in the endoscope reprocessing suites.

8.3 Surveillance

There was weak evidence from a total of ten surveillance studies[39-48] which assessed the benefit of monitoring of the final rinse water. Nine of these studies,[40-48] demonstrated the benefit of monitoring. Two studies[46,47] reported that environmental surveillance allowed them to promptly identify that the final rinse water was the source of contamination after the gastroscopes were found positive for *Pseudomonas aeruginosa*. Another study,[45] which reported the results of a 10-year surveillance, stated that that the annual endoscope and final rinse water sampling ensured that the contamination of endoscopes was uncommon. Three surveillance studies[40,43,44] reported that the final rinse water surveillance alerted them to a problem of contamination and therefore may have prevented potential outbreaks or pseudo-outbreaks. One of these studies[40] reported that filtering itself did not guarantee bacteria-free water and that monitoring (and remedial actions as needed) were necessary to minimise the risk to patients. Two studies[43,44] mentioned that the quality of water they obtained would have been sufficient for procedures such as gastrointestinal endoscopies but not for high-risk procedures such as ERCP, bronchoscopy or cystoscopy. There was only one study[39] which reported that surveillance of the final rinse water was not necessary. During an 80-week endoscope surveillance period, a small proportion (approximately 2%) of the endoscopes were contaminated with low-counts of microorganisms typically associated with being present in gastrointestinal and nasopharynx specimens. Authors stated that they did not monitor final rinse water, but they reported that there was no relationship between the contamination of re-processed endoscopes and the life cycle of the water filters. Authors reported that the filters which were used for purifying the water supplying the EWDs were changed at the mean frequency of 15.2 days, and

Consultation draft

the process appeared to sufficiently control the risk of introducing the microorganisms at the rinsing stage.

There was moderate evidence from two studies which reported that compliance with UK standards for water quality may be unattainable.[42,48] One study,[42] which described the experience of 5-year surveillance of final rinse water in three endoscope reprocessing units in the UK, reported that throughout the study period, *Pseudomonas aeruginosa* and environmental mycobacteria were occasionally grown from final rinse water samples. This would have been a trigger for action according to the UK standards, but the authors reported that no clinical cases were observed (*however, the Working Party notes that this does not mean that the infections did not occur*). Similarly, units frequently failed the 25EU/ml endotoxin threshold but were not able to identify the factors which would allow them to reduce the level of endotoxin to acceptable levels. Authors also reported that total viable counts (TVC) were consistently above the recommended 10 cfu/100ml, which resulted in service disruption and increased costs to hospitals. Instead, the authors recommended the monitoring of the final rinse water quality and using the natural variation limits (two and four lengths of standard deviation obtained from baseline data), as a safe and pragmatic approach to monitoring. Another study,[48] which described a four-month surveillance of EWDs final rinse water samples from twenty endoscopy units in the UK, reported that bacteria-free water was not possible to achieve and sustain. During this period, a total of 259 of 418 monitored final rinse water samples (62%) did not meet the criteria for bacteria free water despite using water filtration and disinfection (UV or ozone treatment). The authors also reported that none of the twenty units managed to sustain this standard throughout the duration of the study. The study recommended that, to avoid unnecessary impact on cost and staff time, units develop their own protocols with their own triggers for action to monitor the quality of the final rinse water. These protocols were based on natural variation from the baseline surveillance results, and authors reported that they had not recorded any clinical cases of colonisation or infection linked to final rinse water during the study period.

The Working Party concluded that the above studies provide additional evidence that monitoring of the final rinse water for microbial quality is essential. Monitoring can only be beneficial when safe but achievable levels of contamination are identified, and appropriate actions are taken to ensure these remain within limits When the safety are breached, these need to be corrected instantly. This will balance the risk to patients and also avoid unnecessary cost and service disruptions. These trigger points may be different depending on the level of risk associated with different types of endoscopy procedures and the type of microorganisms present. It would be pragmatic to expect that the final rinse water is free of waterborne pathogens such as Pseudomonas aeruginosa*,*

Consultation draft

environmental mycobacteria *and* Legionella *pneumophila but that other microorganisms are only present in small quantities. It appears that the 10 cfu/100ml threshold for TVC may be difficult to sustain although it may be necessary for some types of endoscopes or for high-risk patients.*

8.4 Risks associated with variance in qualities of final rinse water

There was weak evidence from six studies[49-55] of the benefit of using final rinse water of sufficient quality. One study,[50] which involved sampling the EWDs, reported that, in the first phase of the study, a total of nine out of 51 (17.6%) EWDs from 29 centres were contaminated, although only one (2%) had a final rinse water contaminated (with *Pseudomonas oleovorans*). The authors reported that a gastroscope which was reprocessed in this EWD and presented for examination in this study was also contaminated with this microorganism. In the second phase of the study conducted in the same 29 centres, 54 EWDs (not involved in phase 1) were sampled, and six (11.1%) EWD final rinse water samples were found to be contaminated (*Pseudomonas aeruginosa*, n=5; *P. oleovorans*, n=1). In three of six instances (50%) the associated gastroscopes were also contaminated with these microorganisms, thus providing the evidence that microorganisms from the final rinse water contaminated re-processed gastroscopes. One study[51] of gastroscope reprocessing methods in Chinese hospitals, reported that 180 of 280 (64%) endoscopes subjected to sampling were contaminated with different types of microorganisms. A total of 114 of 180 (63.3%) final rinse water samples were also contaminated, with the highest bacterial concentrations reaching as many as 91,000 cfu/100ml. In this study, the authors considered the final samples to be contaminated if bacterial counts were above 100cfu/100ml. The authors reported that there was no difference in the prevalence of contamination of the endoscopes based on whether they were re-processed manually or in EWDs but that they found a significant difference based on the type of water used. From a total of 59 endoscopes reprocessed using the tap water, 15 (25%) were found to be contaminated. On the other hand, only 18 of 168 (11%) endoscopes reprocessed using the purified water (achieved by using 0.2µm filters) were contaminated (OR 0.352 [CI95% 0.164-0.755] when compared to tap water) whilst the prevalence of the endoscopes reprocessed using filtered (> 0.2µm filters) water was similar to those reprocessed by tap water (14/53, 26%, OR 1.053 [CI95% 0.4252-2.455]). Another survey,[52] which was conducted in the UK, involved sampling of 63 gastrointestinal scopes routinely processed in EWDs in two hospitals. The authors reported that the overall prevalence of contaminated endoscopes was low (n=3, not possible to determine the number of samples). In this survey, sampling also included environmental sites, including the final rinse water from EWDs which authors considered important for potential disinfection failures. The authors reported that only 4% of the samples were contaminated (measured by the presence of microorganisms by dipslides) in one hospital and none in the other (denominator not reported) and concluded that the final rinse

Consultation draft

water was of good quality in both units and unlikely to be a source of contamination for the endoscopes in this study, which was in accordance with the British Society of Gastroenterology guidelines. One study conducted in Italy[49] found a high prevalence of endoscopes being contaminated and reported that of eleven endoscope suites of which only three (27%) used sterile water whilst other ones used demineralised water (5/11, 46%) or did not have a rinsing step at all (3/11, 27%). Conversely, a similar study reported in two separate articles,[54/55] involved 37 gastrointestinal endoscopy services and reported that final rinse water quality did not affect the rate of endoscope contamination. In 34 of 37 (91%) of these institutions at least one endoscope was contaminated. Of those services which used rinsing (n=33), one (3%) used bi-distilled water, six (18.2%) used filtered water, and 26 (78.8%) used tap water for rinsing. The results may not have been only due to the final rinse water quality because the also authors reported other breaches in disinfection procedures. In total, 33/39 (84.6%) of colonoscopes were contaminated, mostly with Gram-negative bacteria and 50/62 (80.6%) of gastroscopes were contaminated, mostly with intestinal flora, which strongly suggests failure in re-processing. Lastly, one survey[53] in which 66 hospitals in China were asked to describe their reprocessing methods and provide one endoscope (of any type) for examination under scanning electron microscope, reported that many of the scopes had the evidence of biofilm present (36/66, 54.6%). The authors reported that there was no significant difference in the use of sterile water for rinsing between the hospitals which had endoscopes with and without biofilm (61.1%, 22/36 vs 60.0%, 18/30, p=0.927).

There was weak evidence from one laboratory experiment[56] which aimed to establish whether solid phase cytometry was reliable in detecting fungi in water. Among other water samples, the authors collected ten final rinse water specimens from EWD. They reported that no fungi were detected on plates, but that four (40%) final rinse water samples had very low counts (2-5 cfu) of fungi detected via solid phase cytometry. It was not reported whether this contamination resulted in the contamination of endoscopes or if these low counts could have any clinical implications.

Upon the review of the above evidence, the Working Party emphasised that the rinsing stage is necessary to remove the toxic residue from chemical agents used during disinfection and it is essential that the environmental microorganisms found in water are not re-introduced at this stage. Therefore, using high quality final rinse water, while expensive, may help the endoscopic units to sustainably provide the continual service which will prevent infections and the need to trace the affected patients, including those who were exposed to high-risk endoscopes or are at the increased risk of developing infections. When reviewing the above evidence, it should also be noted that the sampling mechanisms for endoscopes varies greatly. For example, with respect to the sampling fluid for recovery tests, some evidence quotes the use of sterile saline solution or reverse osmosis water or

Consultation draft

sodium dodecyl sulphate (SDS) in water. These have been shown to produce different levels of recovery in comparison tests. In addition, some studies used a neutraliser while others did not. This may explain some of the differences in the relationship between contaminated final rinse water and contaminated endoscopes. The Working Party also recognise that the rinsing stage is one of the steps that are required in safe reprocessing of the endoscopes and would also like to emphasise the need to ensure previous stages of reprocessing are performed according to the national standards.

Evidence-based recommendations

EB1.1 Follow recommendations of national guidance to ensure endoscopes are appropriately reprocessed.

EB1.2 Control the presence of microorganisms in the water system which supplies the final rinse water to endoscope washer disinfectors.

EB1.3 Monitor the quality of the water system which supplies the final rinse water to the endoscope washer disinfectors.

EB 1.4 Change filters at frequencies indicated by the manufacturer.

EB1.5 Consider using water with a low bioburden for re-processing all endoscopes.

EB1.6 If reverse osmosis water is used, change membranes at frequencies indicated by manufacturer and ensure that appropriate self-disinfection is in place.

EB1.7 In endoscopy units performing a high number of procedures, consider changing membranes/filters more frequently.

9. Rationale for expert-based recommendations

9.1 Testing methods

Technical guidance for ensuring that the final rinse water is of sufficient quality has been provided by the European Standards BS EN ISO 15883-1:2009+A1:2014,[2] Health Technical Memorandum 01-06,[3] Welsh Health Technical Memorandum WHTM 01–06-part D[4] and the NHS Scotland Guidance for the interpretation and clinical management of endoscopy final rinse water.[5] These provide standardised methodology for the frequency and means for assessing the TVC and detecting microorganisms of significance in the final rinse water. All the above guidelines are in agreement that weekly testing of the final rinse water for TVC and a quarterly testing for the presence of environmental mycobacteria and *Pseudomonas aeruginosa* are required. The individual guidelines also recommend other quality

Consultation draft

indicators for which the final rinse water could be tested depending on local circumstances (evidence that some microorganisms of significance are present in the hospital water systems). These may include *Legionella pneumophila,* Enterobacterales and may need to be tested based on the results of a risk assessment rather than routinely.

In addition to microbial contamination, endotoxins, which are thermostable toxic compounds derived from the cell walls of bacteria, may be present in the water and may cause adverse reactions if they are introduced into the human body during endoscopic procedures. The national standards for Wales and England recommend that final rinse water is also tested for endotoxins.[3,4] The Working Party considered the evidence from one UK study which reported no additional benefit of testing the final rinse water for endotoxins,[42] however, taking into account the potential negative outcomes, they concluded that endotoxin levels may be beneficial in some circumstances because be indicative of an underlying problem with the water system. Thus, while routine endotoxin testing is not required, the evidence of a major water supply issue may be considered as a prompt for a temporary endotoxin monitoring.

The technical guidance documents referred to above[2-5] all suggest that a culture-based method utilising Middlebrook 7H10 agar is used for the detection of environmental mycobacteria. Unfortunately, this requires a 28-day incubation period before the final result is available. All these documents[2-5] suggest that alternative media can be used. HTM 01-06 states that the use of alternative media may allow for a shorter incubation time if validation data is available,[3] whilst BS EN ISO 15883[2] Part 4 states that " Equivalent media can be used if they can be shown to lead to the same results". Molecular methods such as Polymerase Chain Reaction (PCR) offer a significant time saving and present the results in a near real-time period and can therefore be a suitable alternative to Middlebrook 7H10 agar. If using molecular methods, consideration will also need to be given to possibility of failures due to remaining fragments of organisms that would not have been culturable using traditional methods. Anecdotally, Working Party members indicated that it is a common practice to use molecular methods at the commissioning stage of new installations. The connection of new EWDs to the new final rinse water supply ring is typically allowed upon the receipt of a molecular method pass. This practice speeds up the installation process averting the need to wait for the results of a 28-day Middlebrook agar test. Subsequent culture-based test may be undertaken on the supply from the EWD before allowing the processing of bronchoscopes within the machine. As the acceptance of molecular methods increases, wider adoption for routine monitoring of environmental mycobacteria may be possible. Similar principles can be applied for the detection of other microorganisms of significance.

Consultation draft

HIS RWQ for endoscopes guidance: main document.

The Working Party concluded that, for results to be standardised, all laboratories are required to follow the methodology described in BS EN ISO 15883-1:2009+A1:2014[2] for TVC testing. A summary of the recommended testing methodology is available in Table 1 and in Appendix 7, which has been adapted from BS EN ISO standards and provides rationale for each of the recommendations. If wishing to do so, laboratories can adopt molecular-based approaches to detecting microorganisms of significance. However, there are no molecular-based alternatives to TVC and endotoxin levels, and these must still be tested using the methodology specified in the BS EN ISO 15883-1:2009+A1:2014[2] standards.[2]

Additionally, the Working Party considered the value of using an external quality assurance scheme (such as NEQAS or the PHE EQA scheme, also known as proficiency testing) for the laboratories testing method for endoscope final rinse waters and concluded that participating in such a scheme may help the laboratories to improve their proficiency in water testing and interpretation of results.

Recommendations

ER1.1 Monitor the final rinse water for total viable counts weekly (TVC) and test for the presence of environmental mycobacteria and *Pseudomonas aeruginosa* quarterly.

ER1.2 Consider testing for other microorganisms of significance, as based on local circumstances (e.g. *Legionella pneumophila* and other).

ER1.3 There is no need to monitor endotoxin levels routinely but consider doing so if the major water supply problem has been identified.

ER1.4 Use the methodology described in BS EN ISO 15883-1:2009+A1:2014 for total viable counts weekly (TVC) and endotoxins.

ER1.5 Use either culture-based or molecular methods to test for the presence of microorganisms of significance (e.g. *Pseudomonas aeruginosa,* environmental mycobacteria*, Legionella pneumophila* and other).

ER1.6 When molecular-based methods are used to detect the presence of microorganisms of significance, ensure that conventional methods for total viable counts weekly (TVC) and endotoxins are still in place.

ER1.7 Consider participating in an external quality assurance scheme for testing and interpreting results of the water quality.

Consultation draft

Table 1: Summary of methodology recommended by different guidance documents for monitoring of the final rinse water quality

	BS EN ISO 15883 series	**HTM 01-06 series**	**WHTM 01-06 series**	**NHS Scotland guidance**
Quality indicators	TVC *Pseudomonas aeruginosa* Endotoxins	TVC *Pseudomonas aeruginosa* environmental mycobacteria Endotoxins	TVC *Pseudomonas aeruginosa* environmental mycobacteria Endotoxins	TVC *Pseudomonas aeruginosa*
Total Viable Counts (TVC)				
Frequency of test	Weekly, establish that water supply consistently within limits, then less frequent	Weekly	Weekly	Follow BS EN ISO 15883-1:2009+A1:2014 guidance
Volume sampled	100 ml in duplicate	100 ml in duplicate	100 ml in duplicate	
Sample transport	Process within 4 hrs or transport at 2-5°C & process within 48hrs	Process within 4 hrs or transport at 2-5°C & process within 48hrs		
Culture media	R2A	R2A, TSA or YEA	R2A, TSA or YEA	
Incubation temperature	28-32°C	28-32°C	28-32°C	
Incubation period	5 days	Examine after 48hrs, report if positive, final report after 5 days	Examine after 48hrs, report if positive, final report after 5 days	
Acceptable limit	<10 cfu/100ml	<10 cfu/100ml	<10 cfu/100ml	
Further advice	Tests for other organisms of clinical significance	Implement trend analysis, identify microorganisms if >10 cfu/100ml, risk assessment for positive samples		
Microorganisms of significance				
Pseudomonas aeruginosa				
Frequency of test	*no recommendation*	Quarterly	Quarterly	Follow BS EN ISO 15883-1:2009+A1:2014 guidance
Incubation temperature	*no recommendation*	35-37°C	*no recommendation*	

Consultation draft

Incubation period	*no recommendation*	2 days	*no recommendation*	
Culture media	*Pseudomonas aeruginosa*-selective medium	CN agar or alternative	*no recommendation*	
Volume sampled	*no recommendation*	100ml	*no recommendation*	
Sample transport	*no recommendation*	*no recommendation*	*no recommendation*	
Acceptable limit	0 cfu/100ml	0 cfu/100ml	*no recommendation*	
Further advice	*no recommendation*	If in doubt, subculture colonies on milk cetrimide agar for 1d	*no recommendation*	
Environmental mycobacteria				
Frequency of test	Quarterly	Quarterly	Quarterly	
Incubation temperature	28-32^{o}C	28-32^{o}C	28-32^{o}C	
Incubation period	examine weekly for total of 28 days	examine weekly for total of 28 days	examine weekly for total of 28 days	
Culture media	Middlebrook 7H10 agar or alternative	Middlebrook 7H10 agar or alternative	Middlebrook 7H10 agar or alternative	
Volume sampled	100 ml	100 ml	100 ml	*no recommendation*
Sample transport	Process within 4 hours or transport at 2-5^{o}C and process within 48 hours	Process within 4 hours or transport at 2-5^{o}C and process within 24 hours	Process within 4 hours or transport at 2-5^{o}C and process within 48 hours	
Acceptable limit	0 cfu/100ml	0 cfu/100ml	0 cfu/100ml	
Further advice	If growth is observed, identification by specialist laboratory	If growth is observed, identification by specialist laboratory	If growth is observed, identification by specialist laboratory	
Endotoxins				

Consultation draft

Acceptable limit	<0.25 EU against the LAL test	<30 EU/ml for non-invasive endoscopes, <0.25 EU/ml for scopes passed into sterile body cavities	<30EU/ml, not required routinely unless there is a major TVC problem	*no recommendation*
Other microorganisms of significance				
Recommended methods	Need for testing based on local circumstances	*no recommendation*	Need for testing based on local circumstances	*no recommendation*

EU – endotoxin units

Consultation draft

9.2 Interpreting the results

The above guidance documents,[2-5] which provide the recommendations on the standards of laboratory testing of the final rinse water, also provide recommendations on how the results should be interpreted and what actions should be taken if water is not considered to be of sufficient quality. The recommendations in all guidance documents are in an agreement that the water samples with TVC of <10cfu/100 ml are considered appropriate. This threshold is different to the previously recommended 'preferably sterile' standard set by the withdrawn HTM 2030[91] document and recommended in our previous guidance.[1] This new standard was adjusted following the emergence of the evidence that achieving and sustaining completely bacteria-free water from filtration and disinfection is challenging.[42,48] As a result, the guidance documents from England and Wales adapted the framework proposed by Willis, 2006[48] and suggested using a traffic light system, for interpretation of the results (Table 2). This framework recommends actions that need to be taken following the unsatisfactory final rinse water test results. Additionally, the guidance also states that laboratories are required to produce the final report regardless of the results.

Table 2: Interpretation of the results. Identification of any microorganisms of significance is considered an unacceptable result (red colour grade).

Aerobic colony count in 100ml	Interpretation	Action
<1cfu/100ml	Satisfactory (green)	No action required
1-9cfu/100ml repeatedly	Acceptable (yellow)	Indicates bacterial number are under reasonable level of control, no action required
10-100cfu/100ml	Unsatisfactory (orange)	Risk assessment required to investigate potential problems. Super-chlorinate or repeat EWD self-disinfect
>100cfu/100ml **OR** >0cfu/100 microorganisms of significance	Unacceptable (red)	Risk assessment required, consider taking EWD out of service until water quality improved

For microorganisms of significance such as *Pseudomonas aeruginosa,* environmental mycobacteria*, Legionella pneumophila* or Enterobacterales, all guidance documents retain the previous standard that these microorganisms should be absent from the final rinse water.

For endotoxins, revised limit of 30EU/ml is advocated in England for non-invasive endoscopes.[3] However the guidance also states that endoscopes which are introduced into sterile body cavities should be free of endotoxins. From this recommendation, a presumption must therefore be made that the previous limit derived from Sterile Water for Injection of 0.25EU/ml should apply in such cases. This infers that if an EWD is used for processing invasive endoscopes (which is a common practice for many endoscope reprocessing suites), the facility needs to apply a more stringent threshold for endotoxin level to ensure patient safety.

Consultation draft

Further evidence of the problem associated with maintaining sterile water was highlighted in the survey commissioned by the Working Party in 2017, which was sent to the laboratories in England, Ireland, Scotland, and Wales. The participating laboratories provided data on a total of 12,011 final rinse water samples (Table 3). The data showed that 35.8% of final rinse water samples had 0 cfu/100ml and 44.06% had <10 cfu/100ml, thus demonstrating that 80% of the samples were within an acceptable limit. However, there were also 14.14% where TVC were in 10-99 cfu/100ml range and 5.95% in >100 cfu/100ml range. Considering the most recent data published by the UK Joint Advisory Group on gastrointestinal endoscopy (UK JAG),[92] which reported that 2,133,541 gastrointestinal endoscopies were performed in 2019 in all four countries, this means that 426,708 gastrointestinal endoscopes may have been contaminated with unsatisfactory final rinse water. Although no outbreaks due to contaminated final rinse water were reported in the published literature in the UK since the previous guidance,[1] there is a concern that the final rinse water may still pose a risk to patients. The Working Party emphasised that the apparent absence of outbreaks in the UK is likely due to continued monitoring and the fact that actions are taken before the concentration of microorganisms reaches unsafe levels.

Table 3: Analysis of final rinse water test results from the laboratory survey commissioned by the Working Party in 2017

Number of cfu/100ml	Number of samples	Proportion of positive samples
0	4306	35.85%
1-9	5292	44.06%
10-100	1698	14.14%
>100	715	5.95%
Total	**12011**	**100%**

If water is found to be of insufficient quality, corrective action must be taken to remove bacterial contamination. The flow chart presented in Figure 1 summarises actions that are necessary to correct the unsatisfactory results.

Consultation draft

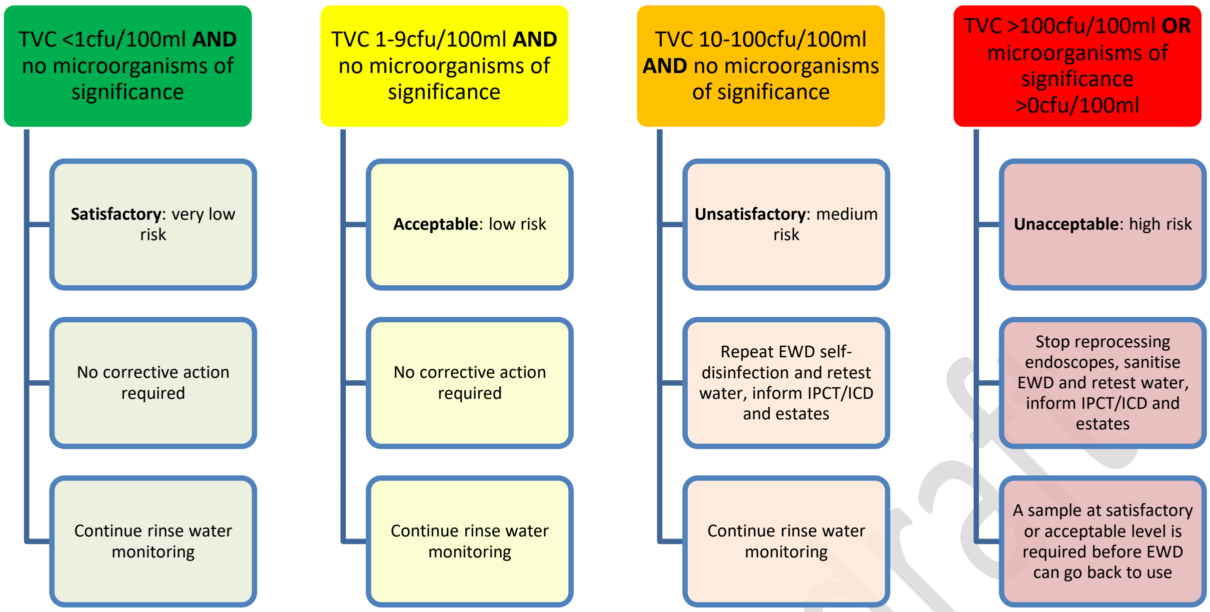

Figure 1. Actions required for EWD following the results of final rinse water testing.

Consultation draft

Recommendations

ER2.1 Laboratories must provide the report of the final rinse water testing regardless of the results.

ER2.2 Upon receiving the final rinse water results, consider using a flow chart to assess the risk based on the traffic light system to decide which actions are required.

ER2.4 Collate total viable counts weekly (TVC) results to assess them for trends and to determine whether microbial counts are increasing.

ER2.3 When the water testing results are unsatisfactory or unacceptable, appropriate action must be taken by endoscope re-processing units to improve the quality of water.

9.3 Actions for the management of endoscopes and patients

Some endoscopes are considered to present a higher risk than others, e.g. those used for more invasive procedures such as ERCP or endoscopies that breach the mucous membranes. Furthermore, some patients especially those who are immunosuppressed may be more susceptible to post-endoscopic infections.

According to the Scottish national guidance[5] endoscopes which are used in invasive procedures require different management where final rinse water quality was inadequate. For high-risk endoscopes, actions need to be considered upon receiving either unsatisfactory or unacceptable results. Table 4 provides information on the type of endoscopes that are considered high-risk. Similar to the actions recommended by Scottish national guidance,[5] the Working Party concluded that unsatisfactory quality of the final rinse water (10-100cfu/100ml) is not appropriate for reprocessing of high-risk endoscopes but may still be used for low-risk endoscopes during the time when the corrective actions are undertaken. However, the Working Party does not believe that there is a need for recalling the endoscopes which were already reprocessed. When the water quality test returns unacceptable results (>100cfu/100ml or microorganisms of significance are present), the EWD should be taken out of action for all endoscopes. Additionally, the Working Party concluded that with the unacceptable results, all endoscopes which were reprocessed since the last test need to be recalled and reprocessed in another EWD. This is similar to the action recommended in the Scottish national guidance document.[5]

The Scottish national guidance[5] also recommends action for ERCP patients when the quality of the final rinse water is at unacceptable level. However, patient tracing is expensive, resource-intensive, and potentially disruptive to endoscopy services. This Working Party has deliberately decreased the emphasis on patient follow up and lookback. This is because, firstly, there is now a better understanding of the real risk posed to patients by contaminated final rinse water. Secondly, there are now much more robust systems in place for the management of final rinse water, meaning that the possibility of final rinse water being contaminated to levels likely to cause clinical concerns (>1000 cfu/100ml), or the chance of high-risk endoscopes being processed in a machine with these counts are now reduced. The Working Party concluded that tracing and follow-up of patients may only be necessary when unusually high TVCs are detected, or a highly pathogenic microorganism is present in the final rinse water. The decision to do so needs to be carefully balanced and needs to take into consideration all potential negative effects (e.g. service disruptions, stress to patients). This is in line with the evidence from two UK surveillance studies,[42,48] which reported that no clinical cases were observed despite the final rinse water occasionally not meeting the recommended standards.

Consultation draft

Table 4: Categorisation of endoscopes and patients for consideration in endoscope management

	High risk for introducing microorganisms	**Low risk for introducing microorganisms**
Endoscopes	Bronchoscopes Cystoscopes Ureteroscopes Duodenoscopes used for ERCP	Gastroscopes Colonoscopes Scopes used for small intestines Naso-laryngoscopes ENT scopes Urethroscopes

HIS RWQ for endoscopes guidance: main document.

Recommendations

ER3.1 Following unsatisfactory final rinse water test results (TVC 10-100cfu/100ml), do not reprocess high-risk endoscopes in an affected endoscope washer-disinfector until satisfactory or acceptable result is obtained.

ER3.2 Where TVC is >100cfu/100ml or when microorganisms of significance are present, do not reprocess any endoscopes in an affected endoscope washer-disinfector.

ER3.3 Where TVC is >100cfu/100ml or when microorganisms of significance are present, recall and reprocess all unused reprocessed endoscopes.

ER3.4 Do not routinely trace and follow up patients with total viable counts weekly (TVC) counts >100cfu/100ml or when microorganisms of significance are present.

9.4 Non-microbial water contaminants

Aside from microbial contamination, there are other water contaminants that can cause concern or require monitoring. Water quality varies in different parts of the UK and can also vary depending on the level of the water table, and the source of water as determined by the various Water Boards to ensure adequate quantity of supplies to meet our needs. There are limits for contaminants in various European standards and NHS guidance of the UK. However, it is worth remembering that a full chemical analysis, while no longer an absolute requirement in most parts of the UK can still be of benefit. Both the HTM[3] and WHTM[4] documents refer to this as a subsequent test when conductivity levels are high, and it is often the only reliable method of determining the purity of final rinse water for substances other than dissolved ions. The non-microbial contaminants are important to preserve the life of EWD but are outside the scope of this guidance, thus no recommendations are proposed by the Working Party. Further information and Good Practice Points in relation to non-microbial water contaminants is included in Appendix 8.

Recommendation

ER4.1 Ensure that the final rinse water meets other (non-microbial) standards of safety for potable water as set out in guidance.

9.5 Contamination after the final rinse

The Working Party is aware that following the final rinsing, there remain the stages where microorganisms can be introduced if care is not taken. Potential failures in drying and storing or inadequate quality of water used during the endoscopic procedures all carry the risk of environmental bacteria re-contaminating a reprocessed endoscope. While this is outside the scope of this guidance and the evidence for these practices is scarce, there is a concern that due to the biofilm build-up in

Consultation draft

instruments, poor quality water would increase the bioburden of the endoscopes. The Working Party therefore suggests that appropriate actions are taken to ensure that the endoscopes are not re-contaminated during drying and storing. Additionally, the working Party suggests that the water used for flushing during the endoscopic procedure is at least of the same quality as the final rinse water used in EWDs or preferably sterile.

Recommendation

ER5.1 Ensure that actions are taken that minimise the risk of microbial contamination being re-introduced during the drying and storing of the endoscopes.

Good Practice Point: GPP5.1 For flushing the endoscope during the procedure, use sterile water if possible or use water which is at least the same quality as the final rinse water.

9.6 Roles and responsibilities

The importance of sufficient knowledge about endoscope reprocessing cannot be overstated and any staff working in endoscopy suite need to understand basic principles, including the quality of final rinse water. All staff must be given training, clear description of their responsibilities, and the outline of the accountability for their actions. Working Party recognises the importance of multidisciplinary team in the management of endoscopy final rinse water. At minimum, the team requires input from the individuals who have sufficient knowledge of decontamination and water safety and who also have an authority to act and an Authorising Engineer (decontamination) (AE(D)) who is accountable for appropriate actions. It is advisable that members of other disciplines are also involved, including Infection Control Consultant or Consultant Microbiologist, Decontamination Lead, Infection Control Lead, Decontamination Manager, Endoscope Decontamination Manager, Authorised Person (AP), Clinical/Nurse Management, Divisional Operational Manager and Estates Manager.

Recommendations

ER6.1 Ensure that an appropriate multidisciplinary team is involved in the management of the final rinse water.

ER6.2 Ensure that staff involved in endoscopy reprocessing are competent, understand the microbial risks associated with final rinse water and that training is assessed annually.

Consultation draft

10.Conclusions

Since the last publication of the guidelines on final rinse water quality,[1] there have been no published reports of outbreaks or sporadic infections associated with the final rinse water in the UK. These results demonstrate that the previously set recommendations were required to prevent the infections arising from the endoscopic procedures. Currently, the clinical risk arising from contaminated final rinse water is low because it has been mitigated by consistently improved final rinse water quality. Sudden increases in microbial burden are unlikely, therefore it is important that the process of weekly monitoring of the final rinse water and promptly improving the quality when testing shows unacceptable results continues. This practice will prevent the need for patient tracing and follow-up, which in turn will preserve resources and avoid delays in the endoscopy suites.

11. Further research

Research recommendations:

RR1 Studies assessing the diagnostic accuracy and the clinical effectiveness of molecular-based approaches as alternatives to culture-based approaches for testing the final rinse water quality.

RR2 Studies assessing the risk of endoscope recontamination and the risk of infection when using tap water for flushing during the procedures

Consultation draft

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HIS RWQ for endoscopes guidance: main document.

List of abbreviations

cfu – colony-forming unit

EWD – endoscope washer disinfectors

HIS – Healthcare Infection Society

TVC – total viable count

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