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Bacteria-free endoscopy rinse water – a realistic aim?

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SUMMARY

A number of outbreaks and pseudo-outbreaks have been associated with contaminated rinse water in endoscope washer-disinfectors. Health Technical Memorandum 2030 specifies that final rinse water should be 'bacteria-free'. In this study, results of rinse-water testing from 20 endoscopy units were reviewed over a 4-month period. Over 60% of samples were of an unsatisfactory quality (i.e. not bacteria-free) and none of the endoscopy units consistently achieved sterile water throughout the study period. Poor microbiology results caused anxiety to endoscopy staff and infection control teams who had to decide whether or not to take washer-disinfectors out of use, possibly resulting in delays to medical procedures. There was no common policy on how to react to poor results, with staff at each unit developing their own action levels. Here, it is suggested that future guidelines would be of more practical use if they specified a series of action levels of increasing severity based on the bacterial count in a water sample.

INTRODUCTION

Effective cleaning and disinfection of endoscopes between clinical procedures is essential in order to ensure that cross-contamination between patients does not occur. The cleaning regime generally involves a manual cleaning stage using a brush, to remove all organic matter and other debris, followed by disinfection and finally rinsing with clean water. The endoscopes may then be dried by either purging with dry air or flushing with 70% alcohol. Automated endoscope washer-disinfectors are widely used for the disinfection and rinsing stages since these machines are considered to be more effective than manual techniques and also have the advantage of protecting the user from the irritant effects of disinfectant chemicals such as glutaraldehyde [1].

There are a number of reports in the literature of outbreaks and pseudo-outbreaks amongst patients following endoscopy procedures, which were subsequently traced to improperly functioning washer-disinfectors or contaminated rinse water. For example, the source of a pseudo-epidemic of *Legionella pneumophila* serogroup 6 was identified as contaminated tap water used to rinse disinfected bronchoscopes [2]. More recently, an outbreak of multidrug-resistant *Pseudomonas aeruginosa* was attributed to a contaminated washer-disinfector that had not been adequately maintained during the year since it was purchased [3]. Furthermore, two cases of pseudo-infection with *Mycobacterium chelonae* were associated with contaminated rinse water in a washer-disinfector used to disinfect bronchoscopes [4]. Pseudo-infections may lead to misdiagnosis and inappropriate treatment of patients, which may be

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both costly and unpleasant for the patient [5]. However, compared to the total number of endoscopic procedures carried out, reports of associated infections are very low. In the United States, it was estimated that the incidence of pathogen transmission during gastrointestinal endoscopy procedures between 1988 and 1992 was ~1/1·8 million procedures [6]. In the latter study, each reported case of pathogen transmission was associated with a recognized breach of endoscope cleaning and disinfection guidelines or defective equipment.

In 1995, Health Technical Memorandum (HTM) 2030 [7] was produced by NHS Estates, providing guidance on operational management, design considerations and validation requirements of washer-disinfectors. This document states that the final rinse water used for invasive endoscopes should be sterile, and for non-invasive endoscopes 'it is preferable that it is sterile'. It suggests that weekly microbiological checks should be carried out, and that there should be no recovery of microorganisms from duplicate samples of 100 ml of rinse water. In addition, annual samples should be tested to ensure absence of environmental mycobacteria in 100 ml of water. A joint working group of the Hospital Infection Society and the Public Health Laboratory Service issued guidelines relating to the prevention of contamination of endoscope rinse water [8]. This document is in agreement with HTM 2030 that final rinse water should be bacteria-free, but suggests that a weekly to monthly programme of monitoring with regular review of results may be adequate.

Our laboratory routinely tests final rinse water from endoscope washer-disinfectors for 20 endoscopy units in the South of England. The aim of this study was to determine whether the majority of units were routinely able to achieve the level of sterility indicated in HTM 2030 and the Joint Working Group guidelines for final rinse water.

MATERIALS AND METHODS

Water samples

Final rinse water samples were submitted by staff from 20 endoscopy units in a variety of NHS and private hospitals in southern England. The frequency of sampling, the microbiological tests requested and the number of washer-disinfectors tested varied between units. Samples of 400–500 ml were collected from washer-disinfector outlets into sterile bottles containing sodium thiosulphate to neutralize any residual chlorine in the water (Bibby Sterilin, Stone, Staffordshire, UK). They were then transported to the laboratory in cold boxes maintained between 2 and 8 °C and were tested on the day of collection.

Determination of aerobic colony count

A membrane filtration technique was used, as described by the Standing Committee of Analysts [9]. Duplicate aliquots of 100 ml were filtered through sterilized funnels, using a membrane of pore size 0·45 μm. Following filtration, membranes were placed on yeast extract agar plates (Oxoid, Basingstoke, Hampshire, UK) and incubated at 37 °C for 48 h. The total number of colonies on each membrane was then counted. If the number of colonies was more than 100, it was not considered possible to accurately determine the total number, and the result was recorded as '>100'. If presumptive *P. aeruginosa* colonies were identified, their presence was reported to the customer. These were identified as blue/green, oxidase-positive colonies that fluoresced under ultra-violet light.

Detection of environmental mycobacteria

A single 100-ml aliquot of water was filtered onto a membrane as described above. The membrane was placed on a Middlebrook (7H11) agar plate (Becton Dickinson UK Ltd, Cowley, Oxfordshire, UK) and incubated at 30 °C for 7 days. Following incubation, suspect colonies were counted and the identity confirmed by performing an acid-fast stain [10]. Acid-fast bacilli were considered to be *Mycobacterium* spp.

Determination of staff policy on action levels and troubleshooting

Discussions were held with staff responsible for each endoscopy unit, either by telephone or by means of personal meetings, to determine their policies regarding when they responded to unsatisfactory results with corrective actions and what type of actions they would take.

RESULTS

A total of 418 samples from 20 endoscopy units were tested between 1 April and 31 July 2003. These were taken from a variety of models of washer-disinfectors

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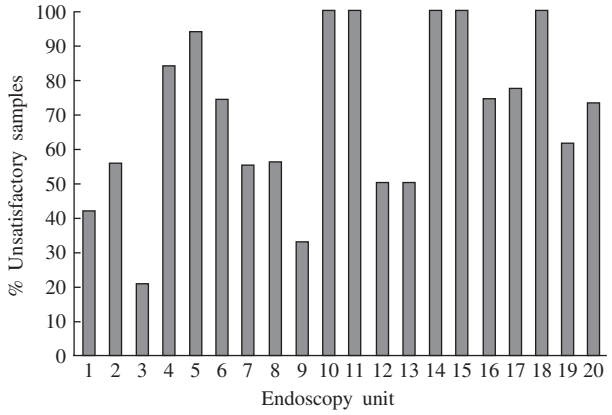

Fig. 1. Percentage of samples submitted from each endoscopy unit that gave unsatisfactory microbiology results (i.e. those that resulted in any growth of bacteria in the aerobic colony count or any growth of environmental mycobacteria).

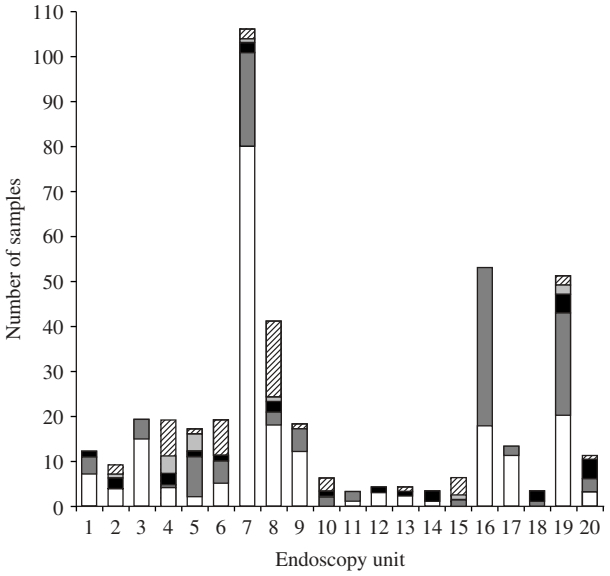

Fig. 2. Number of samples from each endoscopy unit giving aerobic colony counts of 0 (□), 1–9 (▩), 10–49 (■), 50–100 (▩) or >100 (▨).

including 13 machines produced by Labcaire (Clevedon, North Somerset, UK), in which water is treated by means of filtration (through filters with pore size of 5, 1 and finally 0·2 μm), two Medivator machines (based on filtration followed by treatment of water with ultra-violet light), two Bioquell machines (based on filtration followed by ozone treatment) and three QED machines in which water was not filtered, but was treated with 'superoxidized water' that contains a mixture of oxidizing species including hypochlorous acid and chlorine.

Overall, 62% of the samples tested were of an unsatisfactory quality according to HTM 2030 (i.e. there was presence of bacterial growth in duplicate 100-ml samples, and/or presence of environmental mycobacteria in 100 ml). None of the endoscopy units achieved sterility in all samples tested, and four units did not achieve any bacteria-free samples in the period studied (Fig. 1).

The unit with the highest proportion of satisfactory results was Unit 3, with only four out of 19 samples each giving 1 colony-forming unit (c.f.u.) in 100 ml (Fig. 2). Similarly, 12 out of 18 samples from Unit 9 were bacteria-free, and a further five gave aerobic colony counts (ACCs) of <10 c.f.u. in 100 ml. In contrast, samples from Units 4, 6, 8, 10 and 15 frequently gave ACCs of >100 c.f.u. in 100 ml.

There appeared to be little correlation between the ACC and the level of mycobacteria detected. Whilst some samples gave an ACC of zero and a mycobacteria count of >100, others had an ACC of >100, but mycobacteria were not detected.

Staff at different units followed different policies regarding action levels for unsatisfactory results. For example, the Infection Control Team responsible for Units 16 and 17 was not overly concerned by the relatively frequent ACCs of <10 c.f.u., but investigated the presence of environmental mycobacteria at any level. Investigations included testing the incoming water to ensure that the bacterial load was within the level that could be removed by the biocide, Sterilox, and superchlorinating the incoming water supply when the bacterial load was found to be elevated (>1000 c.f.u./ml). *Mycobacterium* isolates were also tested for sensitivity to the biocide, and swabs were taken from inside the washer-disinfectors to ensure that surfaces above the normal water level were not harbouring a biofilm. Where possible, washer-disinfectors were taken out of use if *Mycobacterium* spp. were detected. However, if no alternative washer-disinfector was available, those machines giving only one or two *Mycobacterium* colonies per 100 ml of rinse water continued to be used, but with increased vigilance for microbiological problems in any bronchoscopy patients affected.

A second infection control team was responsible for Units 10–15. If an ACC of >100 c.f.u. was obtained from one of these units, a repeat sample was submitted. If the level was still >100 c.f.u., the machine was shock-dosed with hypochlorite. Repeated counts of >100 c.f.u. led to the washer-disinfector being taken

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out of use until the problem was corrected. From these six units, only the washer-disinfectors used for bronchoscopes were tested for *Mycobacterium* spp. If mycobacteria were detected, the clinical microbiology laboratory covering the relevant hospitals was consulted to determine whether any false-positive *Mycobacterium* results had been obtained recently from bronchial aspirate samples.

The staff responsible for Units 2, 4, 5, 6, 9 and 18 reacted to elevated ACCs by carrying out a risk assessment. The severity of corrective actions depended on the outcome of this assessment, with machines used to rinse bronchoscopes being considered a higher risk than those used for cystoscopes or colonoscopes. In general, however, a bacterial count of >100 c.f.u. resulted in the relevant machines being taken out of use. The presence of *P. aeruginosa* in a number of samples also resulted in investigations and increased disinfection procedures. A series of ACCs of >100 c.f.u. from one washer-disinfector in particular resulted in closure of the unit until the problem was resolved. The bacteriological quality of incoming water was tested, but found to be satisfactory, and repeated dosing with chlorine dioxide failed to remove the problem. Eventually, the pipework within the washer-disinfector was replaced, following which counts dropped to an undetectable level.

Staff at Unit 19 requested that a specific test for *P. aeruginosa* in 100 ml be routinely carried out on their samples as well as the ACC in 100 ml. Conversations with staff at this endoscopy department indicated that action was only taken if *P. aeruginosa* was detected; there was little concern about generally elevated bacterial counts.

DISCUSSION

It can be seen from the results of this study that the majority of endoscopy units were unable routinely to meet the guideline criteria set for microbiological quality of final rinse water. This was despite running daily disinfection cycles in the washer-disinfectors, changing filters regularly (usually every 3 months) and servicing machines on a regular basis (also every 3 months in many of the units) to ensure compliance with manufacturer's specifications. Where staff from our laboratory were involved in investigating persistent contamination of rinse water, problems that were identified included elevated bacterial counts in incoming water and a build up of biofilm in pipework within the washer-disinfector.

Whilst the recommendation for the bacterial quality of final rinse water is that bacteria should be absent in 100 ml [7, 8], it is unclear at what level of contamination the machines should be considered unfit for use. Since it was impractical for busy hospital endoscopy departments to take washer-disinfectors out of use each time bacteria were detected in water samples, staff responsible for the units had each developed their own policy for when, and to what extent, to react. Action levels varied depending on risk assessments and local experience. However, there was little understanding of what level of contamination might constitute a significant risk to patients.

Implementation of the final rinse-water testing programme specified in HTM 2030, and resulting investigations of contamination problems, proved to be a significant burden on hospitals, both financially and in terms of staff time. For example, the cost to one NHS Trust of water testing over the 4-month period described here was approximately £1200 (covering laboratory reagent and staff costs only). During this period, there were numerous re-tests, additional disinfection treatments of the washer-disinfector and lengthy telephone consultations between Infection Control and laboratory staff. Therefore, there were considerable additional costs in terms of the time of endoscopy nurses and Infection Control staff as well as disinfectants and other equipment for treating the rinse water. On one occasion during this time, an ACC of >100 c.f.u. in 100 ml from one of the washer-disinfectors within this Trust resulted in the closure of the endoscopy unit for 5 working days (with a resulting loss of income) while an investigation was carried out and remedial action put in place. Meanwhile, patients due to undergo endoscopy procedures at this unit were transferred to clinics in other local departments, resulting in extra work for the staff involved. In addition to the time spent by Infection Control staff, microbiologists and endoscopy staff individually addressing this problem, a series of emergency meetings were held to deal with the incident, involving approximately 15 members of hospital staff for a total of 1½ h. Remedial action included replacing the filters and pipework in the washer-disinfector, which had a significant additional cost.

It is, therefore, important that action levels and remedial actions are clearly identified, in order to avoid unnecessary expenditure of time and money on inappropriate responses to microbiology results.

Whilst there is a clear need for guidance on the expected quality of final rinse water, it appears that

Table. *Example of how future guidelines might be produced consisting of a series of action levels of increasing severity*

Aerobic colony count in 100 ml	Interpretation/action
0	Satisfactory
1–9 (achieved on a regular basis)	Acceptable – indicates that bacterial numbers are under a reasonable level of control
10–100	Unsatisfactory – investigate potential problems and super-chlorinate
>100	Unacceptable – take washer-disinfector out of use until water quality improved

current guidelines may be unhelpfully rigid, leaving endoscopy staff unclear about how urgently to react to even low numbers of bacteria in water samples. The guidelines issued by the joint working group of the Hospital Infection Society and the Public Health Laboratory Service [8] give detailed guidance on remedial actions to be taken on finding contaminated rinse water, but do not identify a level of bacteria above which the washer-disinfector should be taken out of use. Thus, it is tempting for staff to repeatedly carry out remedial actions and re-test water samples whilst still using the washer-disinfector. It is suggested by Muscarella [11] that low numbers of bacteria remaining on an endoscope after washing may become problematic if the endoscope is subsequently stored wet and in a moist environment for several hours, but that a few bacteria per millilitre of final rinse water may be considered acceptable if the endoscope is dried thoroughly using 70% alcohol followed by forced air after cleaning and before storage. As part of our local investigations of elevated bacterial numbers in rinse water, Infection Control teams checked microbiological records for patients on whom affected endoscopes may have been used. None of these checks revealed any cases of nosocomial infection likely to be due to endoscopy rinse-water contaminants. Therefore, in most instances, it seems reasonable to view low numbers of bacteria in final rinse water as undesirable but not necessarily a cause for immediate alarm. We would suggest that guidelines consisting of a series of action levels of increasing severity would be of more practical use to hospital staff than the current single guideline of 'bacteria-free' water. The Table shows an example of how action levels might be set; these reflect the current policies of local Infection Control teams that have been developed from their experiences to date. However, it should be noted that there are certain situations where a more stringent interpretation of results may be appropriate, such as bronchoscopy of immunosuppressed patients.

It is considered that *Mycobacterium* spp. are undesirable in any numbers. However, results should be addressed by means of a risk assessment, with presence of mycobacteria in water used to rinse bronchoscopes being viewed as more significant than in rinse water for other types of endoscope.

It is clear from our liaison with Infection Control teams and other hospital staff that the introduction of more practical guidelines such as those suggested here would be an important step in helping staff to address microbiological contamination problems in an efficient and appropriate manner. One year after introducing these guidelines locally, the proportion of 'non-sterile' samples tested in our laboratory had reduced from 62 to 39%. We believe that this was partly because the more structured interpretation of results helped hospital staff to focus their efforts on the problems that really needed attention, and therefore, resulted in an overall improvement in washer-disinfector maintenance.

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DECLARATION OF INTEREST

None.

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