Literature Review and Recommendations: Management of Dental Unit Waterlines

PLEASE NOTE:

This literature review is currently under review in consultation with the Chief Dental Officer specifically in relation to Appendix 2.

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Contents

Topic

The appropriate management (including decontamination) of dental unit waterlines (DUWLs) for the prevention of healthcare-associated infections

Background

In 2012, a case report published in The Lancet confirmed that an 82-year-old woman in Italy had died from Legionnaires' disease associated with a strain of *Legionella pneumophila* genetically identical to one isolated from the dental unit waterlines (DUWLs) of a dental practice she had attended in the past 10 days.[1] Following heightened awareness of the infectious risk from contaminated DUWLs, Health Protection Scotland (HPS) has been asked by NHS boards to provide guidance for healthcare workers on the appropriate disinfection of DUWLs within the dental chair unit (DCU) – a reusable medical device.

The main purpose of DUWLs is to supply water for dental instruments connected to DCUs, including 'three-in-one' air/water syringes, ultrasonic scalers, high-speed turbine handpieces and slow-speed conventional handpieces.[2] This water is used to irrigate and cool tooth surfaces during dental treatment, preventing the harmful effects of heat generation on both dental instruments and vital tissues.[3] In addition, DUWLs may provide water for oral rinsing via the cup filler outlet, and washing out the DCU spittoon via the bowl-rinse outlet.[4]

The DUWLs in a DCU consist of approximately 6m of narrow-bore (2 mm internal diameter) flexible polyurethane or polyvinyl chloride (PVC) plastic tubing connected by brass or non-flexible plastic couplings.[5] The high surface area-to-water volume ratio and the intermittent use of DUWLs, leading to stagnation of water for extended periods during the day, promotes the formation of microbial biofilm within DUWLs. For a new unused dental unit system connected to mains water supply, biofilm formation can occur within 8 hours.[6] Since fluids moving through DUWLs assume a laminar pattern of flow, frictional forces along the tubing wall decrease the velocity of fluid travel and produce a hydrodynamic boundary layer conducive to biofilm proliferation.[7] Microorganisms may access DUWLs through incoming municipal water, contaminated independent water reservoirs (e.g. water bottles) or retrograde movement of output water and saliva into dental handpieces.[8] Despite the requirement of dental handpieces incorporating anti-retraction valves, clogging can occur due to biofilms deposition and fatigue of the product. Once the biofilm has been established, individual microorganisms and pieces of biofilm can detach and seed into dental output water.[9]

The first evidence of microbial contamination in dental output water was recognised by Blake in 1963;[10] following this seminal publication, further studies have identified a wide variety of bacterial, fungal and protozoan microorganisms colonising DUWLs, including nosocomial pathogens: *Legionella pneumophila*, non-tuberculous *Mycobacterium* spp. and *Pseudomonas aeruginosa*.[11] The primary route of transmission for most of these pathogens from DUWLs is aerosolisation of the output water via dental handpieces, and

subsequent inhalation of airborne droplets.[12] However, more rarely, microorganisms may be transmitted by imbibing or contamination of wounds.[13]

A number of European surveys confirm that dentists have poor awareness of DUWL contamination and an inadequate understanding of how the microbial risk should be managed, although dentists are positively seeking more information and help in this regard.[14-16] Evidence-based clinical guidelines are therefore necessary to resolve the situation and provide assurance measures to improve the safety of dental care provided for patients.

Aim

To produce evidence-based recommendations for the appropriate management (including decontamination) of dental unit waterlines (DUWLs) in general dental practices, community dental clinics and dental hospitals.

Objectives

- To summarise the risk of DUWL contamination to patients and staff, and identify measures that may be taken to prevent contamination of DUWLs.

- To assess the scientific evidence for the effectiveness of DUWL decontamination agents in general dental practices, community dental clinics and dental hospitals.

- To review dental chair unit (DCU) manufacturers' guidance on their recommendations for effective decontamination of DUWLs.

Research Questions

The following research questions will be addressed:

1. How prevalent is microbial contamination of DUWLs in the UK and which pathogens are implicated?

2. What are the risks to patients and staff from DUWL contamination and how should these risks be assessed?

3. What infection control measures can be implemented to minimise contamination of DUWLs?

4. What DUWL chemical agents (i.e. biocides) are effective for decontamination of DUWLs?

5. What measures should be in place to monitor DUWL water quality and what subsequent action should be taken?

6. What in-surgery DUWL monitoring tests are available and how accurate are they?

Methodology

Search Strategy

The following databases and websites were searched to identify relevant academic and grey literature:

- MEDLINE

- CINAHL

- EMBASE

- NHS Evidence (http://www.evidence.nhs.uk/)

- NICE (http://www.nice.org.uk/)

- National Patient Safety Agency (http://www.npsa.nhs.uk/)

Search terms were developed and adapted to suit each database/website. Literature searches were run on 12/10/2016. See Appendix 1 for an example of the search terms used in the MEDLINE database.

Exclusion Criteria

Academic and grey literature was excluded from the review on the basis of the following exclusion criteria:

- Article was published before 2000

- Article was not published in the English language

- Article does not concern the microbial contamination of DUWLs (off-topic)

- Article is a conference abstract or an opinion piece

- Article measures prevalence of microbial contamination outside of the UK

- Article does not evaluate infection control measures independently (i.e. evaluates multiple infection control measures in combination)

- Article does not make a comparison between DUWL chemical agents (i.e. only evaluates a single agent)

- Article does not report on the efficacy of chemical agents in operational DUWLs (i.e. only tested in model systems)

Screening

There was a two-stage process for screening the items returned from the literature searches. In the first stage, the title/abstract was screened against the exclusion criteria by the lead reviewer. Items that were not excluded at the screening stage progressed to the second screening stage. In the second stage of the screening process, the full text of remaining items was screened against the exclusion criteria by the lead reviewer. Items that were not excluded at the second screening stage were included in the review.

Critical Appraisal

Critical appraisal of the studies included in this review and considered judgement of the evidence was carried out by the lead reviewer using the Scottish Intercollegiate Guidelines Network (SIGN) methodology.[17] Evidence-based clinical guidelines were appraised using the AGREE II instrument.[18]

Results

The literature search identified 295 articles following de-duplication. After the first screening stage (by title/abstract), 160 proceeded to the subsequent stage. Following the second screening stage (by full text), 46 were included for critical appraisal. No articles were excluded on the basis of critical appraisal. Of the 46 articles, there remained: three legislative guidance documents,[19-21] one evidence-based guideline,[22] one randomised controlled trial,[23] 11 non-randomised controlled trials,[24-34] 15 cross-sectional studies,[35-49] two interrupted time series,[50;51] three before-and-after studies,[52-54] one international legislative guidance document,[55] six non-systematic literature reviews[2-4;12;13;56] and three case reports.[1;57;58]

Research Questions

1. How prevalent is microbial contamination of DUWLs in the UK and which pathogens are implicated?

Eight cross-sectional studies evaluated the prevalence of microbial contamination of DUWLs in the UK.[36-44] Of these studies, three were conducted in Scotland (general dental practices, one study; dental hospitals, two studies).[36;42;43] Those studies performed outside Scotland were carried out in countries with a broadly similar climate (e.g. air temperature) and similar existing legislation regarding mandatory measures to control *Legionella* spp. in water supplies. Throughout the UK, the majority of dental units use independent reservoirs, with the exception of a few dental hospitals and general dental practices in which water storage tanks are used.

While four of the studies[36;38;39;42] were performed in a dental hospital (England, two studies; Scotland, two studies), the remaining four[37;40;41;43;44] were carried out in general dental practices (England, three studies; Northern Ireland, one study; Scotland, one study) with one study over England and Northern Ireland.[40;41] The latter studies included a sample size of between 21 and 270 general dental practices, including dental units supplied by municipal water, independent reservoirs or header tanks.[37;40;41;43;44] Samples were typically collected from the following outlets: air-water syringes, high-speed turbine handpieces, cup fillers and wash-hand basin taps (as a non-DUWL control sample). Sample collection techniques varied (usually using sodium thiosulphate as a neutraliser to deactivate residual chlorine, and transferring samples to the laboratory within three hours), as did incubation methods by temperature (either 22 °C or 37 °C), period (typically 24 hours to 7 days) and media (usually Reasoner's 2A agar or yeast extract agar for total viable count (TVC) estimation, and selective media, e.g. cetrimide agar base, for identification of specific pathogens).

The results of the studies were largely in agreement with one another. There did not appear to be any significant variations by country (England, Northern Ireland or Scotland), clinical setting (dental hospitals or general dental practices), water supply (municipal, independent reservoir or header tank), DCU manufacturer (Castellini, Belmont, A-dec or Kavo) or age of dental unit (old or new). However, results consistently demonstrated that most DUWL water samples featured greater microbial contamination than control water samples (i.e. wash-hand basin taps) or had contamination of greater than 200 colony forming units per millilitre (CFU/ml).[36-44]

The European Union (EU) standard for potable water sets a threshold of an aerobic colony count no greater than 100 colony-forming units per millilitre (CFU/ml) after 72 hours of incubation at 22°C, or 20 CFU/ml after 24 hours incubation at 37°C.[59] While the former defines the level of water contamination, the latter is used as an initial screening test. The studies included in this review used various combinations of incubation period and temperature, with the consequence that their results cannot be used to judge compliance with EU standards. An incubation temperature of 37°C was most commonly adopted; hence, results recorded under these conditions were chosen to indicate the prevalence of microbial contamination nationally.

TVCs from DUWL water samples in dental hospitals (England, two studies; Scotland, two studies), incubated aerobically at 37°C, typically ranged from 186 to 320,000 CFU/ml, while biofilm TVCs were broadly comparable and varied from 190 to 7,762 CFU/ml.[36;38;39;42] In one study, DUWL water samples had a significantly higher level of contamination ($p < 0.05$) than cold water tap outlets.[36]

TVCs from DUWL water samples in general dental practices (England, three studies; Northern Ireland, one study; Scotland, one study), incubated aerobically at 37°C, ranged from 43 to 35,607 CFU/ml.[37;40;41;43;44] There was a significant correlation between the number of bacteria recovered from DUWL biofilms and water samples ($p < 0.05$), indicating seeding of bacteria from the biofilm into dental output water.[44] Age of a DCU did not appear to be associated with level of microbial contamination.[43] One study reported no association between water quality and the water supply or type of water;[37] however another reported greater contamination from distilled water when compared with hard, soft or deionised water and greater contamination in units supplied by bottles when compared with those supplied by mains or tanks.[44]

Studies succeeded in isolating the following pathogens from DUWL water samples: *Pseudomonas* spp.[38;39;41;44] including *P. aeruginosa*,[41] *Burkholderia cepacia*,[41] *Legionella pneumophila*,[40;44] *Mycobacterium* spp.[41;44] and fungi[41;44] including *Candida* spp.[44] However, the prevalence of *L. pneumophila* was low (< 2%). The prevalence of *Pseudomonas* spp. was found in 16 to 49% of samples, whereas between 5 and 26% were positive for *Mycobacterium* species. Across general dental practices, *P. aeruginosa* was significantly more prevalent in rural Northern Ireland ($p = 0.011$), while *Mycobacterium* spp. and fungal pathogens were significantly more prevalent in urban England ($p < 0.0001$).[41] The presence of oral streptococci in one study indicates possible back-siphonage and failure of anti-retraction valves.[44]

2. What are the risks to patients and staff from DUWL contamination and how should these risks be assessed?

Two legislative guidance documents,[19;20] two cross-sectional studies,[40;41] two non-systematic reviews[12;13] and three case reports[1;57;58] considered the risks to patients and staff from DUWL contamination or outlined how these risks should be assessed. Of the two studies and five non-legislative articles, none of them were conducted or described cases in Scotland. Many took place in countries or states where the climate is warmer and may be more suitable for microbial growth in water systems (e.g. Italy, California and Georgia (USA)).

The theoretical risk of harm to patients and staff is recognised to be very low, based on the microbial load of specific pathogens required to produce infections in healthy individuals being much higher than that typically found in DUWLs.[40] However, there is a growing population of individuals with compromised immune systems (e.g. extremes of age, those with immunodeficiencies or taking immunosuppressants) who may experience infections with lower microbial loads.[12;13] In addition, exposure to dental treatment is not universally considered a risk factor for infections such as legionellosis, and so, notified cases may not be linked back to DUWL contamination. Similarly, isolated cases of infection due to *P. aeruginosa* or nontuberculous mycobacteria following dental treatment are likely to be under-reported.

Risk assessment for DUWL water quality in the UK is legislated by the Health and Safety at Work Act (1974) and the Management of Health and Safety at Work Regulations 1999.[60;61] A suitable and sufficient risk assessment must be carried out for all water systems to identify and assess the risk of exposure to *Legionella* spp. from work activities and water systems on the premises and any precautionary measures needed.[19]

The following are all criteria used to judge whether there is a foreseeable risk of legionellosis from a water system:

(1) Water is stored or re-circulated as part of the system (e.g. water may be retained overnight in DUWLs or may be stored in a water tank);

(2) The water temperature in all or some part of the system is between 20 and 45°C (e.g. a DCU water heating unit or a temperature rise in DUWLs following continuous use over several hours);

(3) There are deposits that can support bacterial growth, such as rust, sludge, scale and organic matter (e.g. DUWL biofilm);

(4) It is possible for water droplets to be produced and, if so, they can be dispersed (e.g. aerosol from high-speed turbine handpiece or scaler);[20]

Risk identified from meeting any of the criteria points (1), (2) and (3) alongside droplet transmission risk in point (4) highlight that employees, contractors, visitors, etc. could be exposed to contaminated water droplets (e.g. patients and dental care staff within the dental surgery setting), thus, there could be a foreseeable risk of legionellosis.[20]

It is therefore important to control risks by introducing measures which do not allow proliferation of the organisms in the water systems and reduce, so far as is reasonably practicable, exposure to water droplets and aerosol. This will reduce the possibility of creating conditions in which the risk from exposure to *Legionella* spp. is increased. Appendix 2 provides a checklist of the key requirements for a risk assessment of hot and cold water systems in dental practices/services for legionella control based on BS 8580 'Water quality, Risk assessments for *Legionella* control'.[19;62]

The dutyholder is responsible for ensuring the risk assessment is carried out. The dutyholder may be either: the employer, where the risk from their undertaking is to their employees or others; or a self-employed person, where there is a risk from their undertaking to themselves or others; or the person who is in control of premises or systems in connection with work, where there is a risk from systems in the building.[19]

A responsible person must be appointed to ensure that all operational procedures are carried out in a timely and effective manner. If the dutyholder is self-employed or a member of a partnership, they may appoint themselves as the responsible person; however, they must have sufficient authority, competency and knowledge of the installation.[19]

The risk assessment must be reviewed regularly and specifically when there is reason to believe that the original risk assessment may no longer be valid e.g. changes to the water system or a significant *Legionella* spp. breach/risk arises. Where there are five or more employees, the significant findings of the risk assessment and the steps taken to prevent exposure to substances hazardous to health must be recorded as a statutory duty; however, it is still advisable to keep a record if there are fewer than five employees. Records must be retained for the period they remain current and for at least two years afterwards, with the exception of records kept for monitoring purposes and inspection, which should be kept for at least five years.[19]

If the dutyholder assesses, after completion of the risk assessment, that legionella risks within the dental practice/service are able to be controlled or mitigated, all risks and actions taken must be documented as part of the written control scheme. When control of *Legionella* spp. cannot be achieved the legionella written control scheme must be formulated to include additional control measures being taken to minimise the risk of legionellosis.[19] Appendix 3 provides a checklist of the key requirements of a legionella written control scheme.

3. What infection control measures can be implemented to minimise contamination of DUWLs?

One evidence-based guideline,[22] two non-randomised controlled trials,[24;34] two interrupted time series,[50;51] three before-and-after studies,[52-54] one international legislative guidance document[55] and three non-systematic reviews[2-4] provided evidence for infection control measures that may be implemented to minimise DUWL contamination. Of the seven prospective studies, none were conducted in Scotland; these studies were performed in Brazil,[52] Jordan,[50] Denmark,[24;34] Italy[54] and the USA.[51;53]

Such countries are likely to have different climates and water quality regulations, and often use DCUs designed by different manufacturers from UK dental clinics. Therefore, the findings are not necessarily applicable to Scotland.

In particular, DCUs in the prospective studies were manufactured by Flex and Castellini, while dental output water was provided either directly from the municipal supply or via independent bottle reservoirs. The evidence-based guideline was developed by the Centers for Disease Control and Prevention (CDC) in the USA,[22] while the international legislative guidance document was formulated by the Department of Health in England and Wales.[55]

The recommended infection control measures included anti-retraction devices, pre-treated water (e.g. sterile, distilled or deionised), in-line filtration, and flushing or drying of DUWLs. Most of the measures recommended by these articles were based solely on expert opinion; the exception being those on flushing or drying DUWLs and filtration of output water. The studies on flushing DUWLs found that applying this measure for 30 seconds reduced the contamination of output water and continued to further reduce levels when applied for three to four minutes, although using this measure in isolation did not maintain water quality at recommended standards and only impacted on water delivered at the beginning of the treatment session.[50-53] In contrast, drying DUWLs with compressed air or the use of filtration systems were not effective in improving DUWL output water quality.[24;34]

DCU design is now being accorded a much greater significance in the prevention of biofilm formation within DUWLs. There is a burgeoning literature on the development of novel DUWL tubing composed of antimicrobial materials such as *N*-halamine[63;64] and polyvinylidene fluoride (PVDF).[65;66] New DCUs increasingly have automated, or semi-automated, DUWL cleaning systems integrated into the unit; by example, the Poseidon-S disinfectant system,[67] the Autosteril unit[68] and the Planmeca Waterline Cleaning System.[69;70]

4. What DUWL chemical agents (i.e. biocides) are effective for decontamination of DUWLs?

One randomised controlled trial[23] and nine non-randomised controlled trials[25-33] provided evidence for the effectiveness of different DUWL biocides in the decontamination of DUWLs. Of the 10 clinical trials, all were conducted outside Scotland. Nine of the trials were performed in single countries: Denmark,[25] the USA,[23;26] India,[27;33] France,[28] Italy,[29] Turkey[31] and Malaysia.[32] The multi-country trial was conducted across seven European countries: Denmark, Germany, Greece, Ireland, Spain, the Netherlands and England.[30]

Since the trials were situated across a very broad range of countries, ranging over Europe, North America and Asia, the findings are broadly suitable for generalisation. Unfortunately, most were carried out in dental teaching hospitals or community dental clinics, rather than general dental practices – the sole exception being the Europe-wide trial. All 10 trials used TVCs from DUWL output water samples to evaluate the

effectiveness of DUWL biocides,[23;25-33] while two studies (the Europe-wide trial and the randomised controlled trial) also used TVCs from DUWL biofilm samples to assess their efficacy.[23;30]

By improving the quality of DUWL output water and minimising DUWL biofilm formation, the risk to patients and staff presented by waterborne microbial pathogens can be reduced. While it is well established that a DUWL biocide should be used routinely to decontaminate DUWLs, it is unclear whether certain types of biocide are more effective than others and whether specific regimens allow the water quality to be consistently maintained. The manufacturers of DCUs are required to provide instructions on the use of DUWL biocides for their units under the EU Medical Devices Directive;[71] however, dental practitioners may need to choose between different commercially available products to achieve this end. Comparisons between different products under the same clinical conditions should inform this decision.

The DUWL biocide products evaluated in these studies often combined multiple chemical agents, most typically one or more agents with antimicrobial activity (e.g. sodium hypochlorite or chlorhexidine gluconate) and a chelating agent (e.g. citric acid or ethylenediaminetetraacetic acid (EDTA)). In addition, the cleaning regimen for each product often varied. Some products required an initial 'shock' application with a high chemical concentration (e.g. 1-2% sodium hypochlorite) followed by continuous application with a lower concentration of the same, or different (e.g. <0.2% tosylchloramide sodium and <0.2% polyhexamethylene biguanide), agent along with a chelating agent (e.g. EDTA). Other products required intermittent application, either daily or regularly throughout the week, of a higher chemical concentration (e.g. 0.25-5% hydrogen peroxide or 0.26% peracetic acid and hydrogen peroxide). Other DUWL biocides have only been evaluated *in vitro* or without a concurrent comparison group (e.g. electrolysed water); therefore, there is weaker evidence to recommend the use of these agents.

Some studies concluded that all DUWL biocides were equally effective, although different application regimens influenced their efficacy, whereas other studies found a significant difference between various DUWL biocides following the same regimen. Four studies demonstrated that continuous application of DUWL biocides is more effective than intermittent application,[28-30;32] although one study demonstrated comparable effectiveness of continuous and daily intermittent applications.[27]

The evidence was strongest for DUWL biocide products based on peroxide compounds (e.g. hydrogen peroxide and sodium percarbonate), bisbiguanides (e.g. chlorhexidine gluconate) and chlorine compounds (e.g. tosylchloramide sodium and chlorine dioxide):

- Two studies demonstrated superior effectiveness of hydrogen peroxide (0.014-0.02% hydrogen peroxide combined with silver) over an alternative agent,[29;30] another two studies demonstrated comparable effectiveness (<1% and 1.4% hydrogen peroxide alone)[23;25] and one study demonstrated inferior effectiveness (0.0235% hydrogen peroxide alone).[32]

- One study demonstrated superior effectiveness of sodium percarbonate (<10% sodium percarbonate combined with <0.5% silver nitrate) over an alternative agent.[32]

- Two studies demonstrated superior effectiveness of chlorhexidine gluconate (0.12% chlorhexidine gluconate combined with 12% ethanol) over an alternative agent,[26;30] although two studies demonstrated comparable effectiveness (0.12% chlorhexidine gluconate combined with 12% ethanol, and 0.2% chlorhexidine gluconate alone).[23;33]

- Two studies demonstrated superior effectiveness of tosylchloramide sodium (<0.2% tosylchloramide sodium combined with <0.2% polyhexamethylene biguanide; accompanied by either a 'shock' application with 1-2% sodium hypochlorite or intermittent application of 15-30% polyaminopropyl biguanide) over an alternative agent.[28;30]

- One study demonstrated superior effectiveness of chlorine dioxide (0.22% chlorine dioxide) over an alternative agent,[29] although another study demonstrated inferior effectiveness.[32]

There have been various issues concerning the use of DUWL biocides reported in the published literature. Notably, some DCUs may be incompatible with certain DUWL biocides. Adverse effects have been observed, including obstruction of waterlines, corrosion of couplings, and discolouration of output water and equipment surfaces.[30;69] The manufacturer of the biocide Sterilex Ultra advises against the use of non-polypropylene bottles for this reason.[30] It has been suggested that the use of DUWL biocides based on iodine or chlorine compounds might increase the release of mercury from amalgam in dental unit waste-water.[72;73] Specific components of DUWL biocides may also be harmful to patients; for example, phenylalanine is listed on the safety data sheet of the biocide Alpron and is contraindicated for individuals with phenylketonuria.[28] Anaphylactic reactions following the use of chlorhexidine gluconate mouthwash have also been occasionally reported.[74] In addition, it has been found that some DUWL biocides may have an adverse effect on enamel- and dentine-bonding agents.[75-77] Finally, long-term use of a specific DUWL biocide may lead to selective overgrowth of microorganisms and an elevated TVC, as can been seen in the overgrowth of catalase-positive bacteria following long-term use of hydrogen peroxide-based biocides.[69]

5. What measures should be in place to monitor DUWL water quality and what subsequent action should be taken?

Three legislative guidance documents,[19-21] one evidence-based guideline[22] and one international legislative guidance document[55] provided evidence on the measures that should be in place to monitor DUWL water quality and corresponding actions that should be taken. Three of the documents, including the Health and Safety Executive (HSE) Approved Code of Practice on control of *Legionella* spp. in water systems and the Scottish Health Technical Memorandum (SHTM) 04-01, provide guidance on legislation directly applicable to Scotland.[19-21] These address the requirements of healthcare

premises to monitor water systems for contamination with *Legionella* spp.; however, they do not offer specific guidance on DUWLs. In contrast, the evidence-based guideline from the CDC and the international guidance on legislation applicable to DUWLs in England and Wales, Health Technical Memorandum (HTM) 01-05, describe measures to be taken for the management of DUWLs, but they are not directly applicable to Scotland and may only be used as a source of expert opinion.[22;55]

Routine monitoring of DUWL water quality could allow dental practitioners to recognise an unacceptable standard of water quality and instigate the necessary measures for remediation. However, a TVC will not inform the practitioner as to whether DUWL output water is contaminated with nosocomial pathogens – rather, it will only provide a measure of overall bio-burden which may indicate a greater likelihood of significant pathogenic microorganisms being present. It is therefore debatable whether such measures justify the additional costs entailed.

There were two sources of conflict in the available evidence: firstly, while CDC guidance recommends following manufacturers' instructions on whether routine in-surgery TVC testing is required, English and Welsh guidance recommends against the use of in-surgery test kits. Secondly, the threshold for an acceptable TVC in the USA is higher (< 500 CFU/ml) than in England and Wales (100-200 CFU/ml).[22;55] This difference reflects the regulatory standard for potable water in the USA required by the Environmental Protection Agency (EPA), in that no more than 5% of water samples should be contaminated with coliforms and there should be no more than 500 CFU/ml heterotrophic water bacteria.[78] In 1995, the American Dental Association (ADA) had previously recommended a standard of no more than 200 CFU/ml heterotrophic water bacteria, based upon the standard established for fluid delivery systems in haemodialysis.[79] Following publication of the CDC guidance in 2003, which advocated the EPA's standard of < 500 CFU/ml, the ADA subsequently adopted the CDC's new recommendation in 2004.[22] Within the European Union, the regulatory standard for potable water is the absence of *Escherichia coli*, or any other faecal coliforms, and an aerobic colony count of less than 100 CFU/ml after 72 hours of incubation at 22°C;[59] this standard has been adopted as a more stringent measure of water quality in some European studies.[29;37]

SHTM 04-01 states that microbiological testing of water systems for TVCs is only considered necessary where there are taste or odour problems. Although routine testing is not necessary, if it is adopted then it should be conducted quarterly. The purpose of the testing procedure is to provide an early warning system whereby an elevated TVC triggers some form of action to determine the identity of the microorganism and implement the appropriate treatment.[21]

The HSE Approved Code of Practice mandates that monitoring for *Legionella* spp. should be carried out where there is doubt about the efficacy of the control regime or it is known that recommended temperature, disinfectant concentrations or other precautions are not being consistently achieved throughout the system.[19] Collection of water samples (Appendix 4) for microbiological analysis of *Legionella* spp. must follow the Code of Practice BS 7592: 2008, as required by SHTM 04-01.[21;80] Action levels (Appendix 5)

following sampling for *Legionella* spp. in healthcare premises must be followed, as outlined by the HSE Approved Code of Practice.[19]

6.   What in-surgery DUWL monitoring tests are available and how accurate are they?

One evidence-based guideline,[22] six cross-sectional studies,[35;45-49] one non-systematic review[56] and one international legislative guidance document[55] provided evidence for the availability and suitability of in-surgery DUWL monitoring tests that may be used to screen for, and monitor, microbial contamination of DUWLs. The six cross-sectional studies were performed in the USA,[35;45;46;48] Japan[49] and England;[47] these studies evaluated a range of in-surgery test kits, not all of which are commercially available in Scotland. The studies were performed across a relatively limited range of countries, most often in the USA, where current guidance on DUWL management advocates compliance with the DCU manufacturers' instructions on the use of in-surgery test kits.[22] Compliance with TVC thresholds in the USA is typically judged by the standard of < 500 CFU/ml in water samples;[22;78] therefore, in-surgery test kits tend to be evaluated in the USA with less stringency than in the UK.

In-surgery test kits have the potential to allow dental practitioners in primary care to monitor the water quality of their DUWLs, without the use of expensive specialist equipment, and take appropriate infection control measures should excessive levels of microbial contamination be detected.[56] For this reason, the manufacturers of some DCUs recommend their use on a periodic basis. Over the past 10 years, various products using culture-based in-surgery testing have been developed, although many of these are no longer commercially available. Despite being based on similar technical components, there appears to be significant variability in the accuracy of different products in measuring TVCs. In addition to this, studies evaluating their accuracy have used a wide range of microbiological techniques, not all of which are available to general dental practitioners, including: incubation above room temperature, serial dilutions and electronic colony counting. These variations led to a difficulty in making direct comparisons between standard laboratory methods and in-surgery testing kits used clinically.

The findings were generally consistent across the studies, in that culture-based in-surgery test kits were judged to have variable sensitivity and specificity values, yet were found to be broadly reliable across repeated tests.[45] In-surgery test kits tend to underestimate TVCs in comparison to standard laboratory procedures.[35;46;48] Specificity values for these kits were typically higher than corresponding sensitivity values, although both were highly variable: sensitivity values were 21.0-98.3% and specificity values were 77.3-100%. Both values tended to increase with longer incubation periods (e.g. seven days). Although they underestimated TVCs, the systematic nature of this undercounting allowed them to be considered suitable for monitoring compliance over time, so long as the optimal counting range included the recommended threshold for compliance. In contrast, adenosine triphosphate (ATP) bioluminescence tests only showed a correlation with relatively high TVCs in water samples and were found to be inaccurate in measuring

low TVCs; therefore, they are only suitable to use when screening for gross contamination.[47;49]

Discussion

This systematic review incorporated the results of 46 articles into its findings. The included articles were predominantly of low to moderate quality.

HPS Recommendations for Clinical Practice

This review makes the following recommendations based on an assessment of the extant literature on the management of dental unit waterlines (DUWLs):

Risk Assessment

- A risk assessment must be undertaken in all general dental practices, community dental clinics and dental hospitals to evaluate the risk to patients and staff from microbial contamination of water supplies (including DUWLs) with *Legionella* spp. **(Mandatory)**

- The risk assessment should include an evaluation of the risk of harm to immunocompromised patients due to contamination of DUWLs with nontuberculous mycobacteria (e.g. *Mycobacterium abscessus*) and *Pseudomonas aeruginosa*. **(Good Practice Point (GPP))**

- Following completion of the risk assessment, where there is *Legionella* spp. risk suspected or confirmed, the key requirements (outlined in Appendix 2) must be incorporated into the risk assessment and a legionella written control scheme (Appendix 3) must be prepared, implemented and properly managed for preventing or controlling legionella. **(Mandatory)**

Technical Requirements Water Supply Management

- If dental chair units (DCUs) are directly connected to a municipal water supply, an air gap must be incorporated into the system to prevent backflow into the mains supply. **(Mandatory)**

- Water supplies for dental hospitals and large dental clinics, particularly those using cold water storage tanks, may require a pre-treatment system. This can include water softening units, sediment pre-filters, activated carbon filters and/or kinetic degradation fluxion (KDF) filters. If required, an integrated backwash facility should be available to prevent biofilm formation. **(Good Practice Point (GPP))**

- Dental instruments connected to DUWLs, or the DCU itself, should be equipped with anti-retraction devices (e.g. valves). These should be tested for efficacy on a regular basis, at least annually, and appropriately maintained. **(AGREE rating: Recommend)**

- Disposable in-line or point-of-use filters may be fitted to DUWLs to improve the quality of output water (if water has been identified as poor quality) but they should be replaced at the appropriate frequency as recommended by manufacturers (e.g. daily).
  (Good Practice Point (GPP))

- DCUs should not be fitted with water heaters.
  (Good Practice Point (GPP))

- DCUs may be equipped with integrated and automated, or semi-automated, DUWL cleaning systems to improve compliance with cleaning regimens and reduce the frequency of handling errors.
  (Good Practice Point (GPP))

Infection Control Management

- Only sterile saline or sterile water should be used for irrigation during oral surgical procedures. This should be delivered using devices specifically designed for sterile fluids (e.g. a single-use disposable syringe or autoclavable tubing).
  (AGREE rating: Recommend)

- Sterile, distilled or deionised water may be used to improve the quality of DUWL output water if other measures are taken to prevent formation of DUWL biofilm. Equipment used for water treatment should be regularly maintained and the water should be appropriately stored to ensure water quality.
  (Good Practice Point (GPP))

- Independent water bottle reservoirs should be handled with personal protective equipment (e.g. gloves) when refilling, and disinfected on a regular basis. Multiple bottles should be available to allow adequate time for reprocessing. After disinfection, these should b**e left open to the air for** drying overnight and stored inverted.
  (Good Practice Point (GPP))

- DUWLs should be drained until dry at the end of each working day.
  (Good Practice Point (GPP))

Flushing Management

- DUWLs should be flushed with water for two to four minutes at the beginning and end of a treatment session to improve the quality of DUWL output water.
  (Grade D recommendation)

- DUWLs should be flushed with water for 30 seconds between patients to improve the quality of DUWL output water.
  (AGREE rating: Recommend)

Decontamination

- Manufacturers' instructions on appropriate decontamination of DUWLs should be followed to avoid invalidation of the DCU's warranty as a reusable medical device. **(Good Practice Point (GPP))**

- The safety data sheet for a DUWL biocide provided by the manufacturer should be consulted to assess the risk of harm to certain groups of patients (e.g. phenylalanine in some DUWL biocides is harmful to individuals with phenylketonuria). **(Good Practice Point (GPP))**

- DCUs should be monitored for any signs of damage due to the use of DUWL biocides (e.g. obstruction of tubing, corrosion of couplings, and discolouration of equipment surfaces). **(Good Practice Point (GPP))**

- DUWL biocides should be applied continuously, or at least daily, to minimise levels of microbial contamination in DUWL output water and biofilm formation in DUWLs. **(Grade C recommendation)**

- DUWL biocides based on peroxide compounds (e.g. hydrogen peroxide and sodium percarbonate), bisbiguanides (e.g. chlorhexidine gluconate) or chlorine compounds (e.g. tosylchloramide sodium and chlorine dioxide) should be used to effectively improve the quality of DUWL output water and minimise biofilm formation in DUWLs. **(Grade C recommendation)**

- DUWL biocides based on electrolysed water may be used to improve the quality of DUWL output water. **(Grade D recommendation)**

- If DCUs are directly connected to a municipal water supply, the connection must be turned off prior to treatment with an intermittent or 'shock' application of DUWL biocide to prevent contamination of mains water with the treatment agent. **(Mandatory)**

- After treatment with an intermittent or 'shock' application of DUWL biocide, the DUWLs should be flushed thoroughly with water before DCUs are used for patient treatment. **(Good Practice Point (GPP))**

Microbiological Requirements

Legionella

- Monitoring for *Legionella* spp. must be carried out where, following risk assessment, there is doubt about the efficacy of the control measures to mitigate or eliminate risk or it is known that recommended temperature, disinfectant concentrations or other precautions are not being consistently achieved throughout the water system. **(Mandatory)**

- Collection of water samples ([Appendix 4](#)) for microbiological analysis of *Legionella* spp. must follow the Code of Practice BS 7592: 2008, as required by SHTM 04-01.
  (Mandatory)

- Microbiological analysis of water samples for *Legionella* spp. must be performed in a United Kingdom Accreditation Service (UKAS)-accredited laboratory with the current ISO standard methods for the detection and enumeration of *Legionella* spp. included within the scope of accreditation.
  (Mandatory)

- Action levels ([Appendix 5](#)) following sampling for *Legionella* spp. in healthcare premises must be followed, as outlined by the Health and Safety Executive (HSE) Approved Code of Practice.
  (Mandatory)

- Should a medical practitioner notify the employer of a case of legionellosis in a dental employee, this must be reported to HSE under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 2013.
  (Mandatory)

Total Viable Counts (TVCs)

- Manufacturers of DCUs may recommend the use of routine microbiological testing for TVC in DUWL output water, in which case their advice should be followed.
  (AGREE rating: Recommend)

- Microbiological testing for TVC in DUWL output water must be performed if there are associated taste or odour problems.
  (Mandatory)

- Where monitoring of DUWL water quality is undertaken, the TVC should not exceed 500 colony-forming units per millilitre (CFU/ml) and ideally should be lower than 200 CFU/ml.
  (AGREE rating: Recommend)

Monitoring and Testing Kits

- Culture-based test kits, or dip slides, may be used to measure the TVC of water samples from DUWLs, although in-surgery test kits tend to underestimate TVC in comparison to standard laboratory procedures.
  (AGREE rating: Recommend)

- If in-surgery test kits are used to monitor compliance with recommended TVC thresholds (e.g. < 200 CFU/ml), the optimal counting range for the system should lie below, or overlap, the chosen threshold (e.g. 0-200 CFU/ml).
  (Good Practice Point (GPP))

- In-surgery test kits with an optimal counting range in excess of recommended TVC thresholds should only be used on an occasional basis to detect gross contamination

of DUWLs and should not be used on a periodic basis for monitoring compliance.
(Good Practice Point (GPP))

- Since adenosine triphosphate (ATP) bioluminescence does not correlate significantly with microbial contamination at low TVC counts, it should only be used on an occasional basis to detect gross contamination and should not be used on a periodic basis for monitoring compliance.
(Grade D recommendation)

Implications for Research

The available research concerning microbial contamination of DUWLs was primarily of low to moderate quality, especially with regard to the risk posed by contamination with nosocomial pathogens. In particular, existing evidence often takes the form of isolated case reports or occupational health risk assessments for dental healthcare workers.

Since infections caused by *Pseudomonas aeruginosa* and nontuberculous mycobacteria are non-notifiable under the Public Health etc. (Scotland) Act 2008,[81] incidents and outbreaks resulting from these pathogens are unlikely to be recognised as arising from contaminated DUWLs unless the infections are severe enough to require hospitalisation (e.g. the 2015 *Mycobacterium abscessus* outbreak in the USA). Considering the very low likelihood that a dose of infectious agent sufficient to cause infection in an immunocompetent individual could be delivered via DUWLs, future research in this area will require the use of national surveillance and administrative datasets providing a large sample size.

Few clinical trials have compared different DUWL biocides concurrently on in-use DCUs. Of these, all were conducted over a short time-frame (e.g. 8 weeks) and only a few measured the effect on DUWL biofilms in addition to dental output water. Only one study was a randomised controlled trial, while the non-randomised controlled trials failed to make any adjustment for the influence of confounding factors such as age of the DCU or differences in water supply. Adverse effects of DUWL biocides on DCUs, e.g. obstruction of tubing and corrosion of couplings, are relatively widespread and merit greater attention in future evaluations of these products.

Recently, interest has grown in the design of DCUs to ensure that microbial contamination of DUWLs is minimised. Novel DUWL tubing composed of antimicrobial materials, such as *N*-halamine and polyvinylidene fluoride (PVDF), has only been evaluated in laboratory studies and should be assessed in clinical trials before it is more widely adopted. Compliance with cleaning regimens has been noted to be a problem, particularly with regard to those biocides requiring daily application. Automated DUWL cleaning systems have shown promising results by obviating the need for user compliance, but there have been no direct comparisons with manually applied DUWL biocides or comparisons between different systems.

It is currently contested whether in-surgery microbiological monitoring tests offer a suitable way for dental practitioners to maintain dental unit water quality at an acceptable standard. While the CDC advocates that guidance provided by DCU manufacturers with

respect to monitoring kits should be followed, the Department of Health in England and Wales explicitly recommends against the use of these products. Culture-based in-surgery test kits (e.g. dip slides) have been shown to have variable sensitivity and specificity values, compared with the gold standard of cultivation in a UKAS-accredited microbiology diagnostic laboratory. Until the accuracy of these tests has been improved and evaluated through further research, it is unclear whether routine in-surgery monitoring is beneficial as a form of screening for gross contamination or maintaining dental unit output water at an acceptable standard.

Conclusion

A consequence of raised awareness regarding the infectious risk from contaminated dental unit waterlines (DUWLs) has been the call by NHS boards that Health Protection Scotland (HPS) provides guidance for healthcare workers on the appropriate disinfection of DUWLs. To meet these requests, HPS has developed evidence-based clinical guidelines with recommendations on the appropriate management of microbial contamination of DUWLs for use in general dental practices, community dental clinics and dental hospitals. This guidance should aid dental practitioners in improving the safety of dental care provided for patients.

The risk of contaminated DUWLs in Scotland is most significant for *Legionella* spp., nontuberculous mycobacteria (e.g. *Mycobacterium abscessus*) and *Pseudomonas aeruginosa*, especially for immunocompromised patients. A risk assessment for *Legionella* spp. in water supplies of healthcare premises is mandatory by law. However, there is only slight evidence of a risk that appears to be very low; hence, the precautionary principle should be applied, in that the consequences of the risk are such that full scientific certainty should not be used as justification for postponing cost-effective measures to prevent future infections.

As a reusable medical device under the European Union Medical Devices Directive, dental chair units (DCUs) must be maintained according to the manufacturer's instructions. Accordingly, DCU manufacturers may endorse a specific commercial product to disinfect DUWLs; however, unless a DUWL biocide is considered incompatible with the unit, a variety of products are likely to be available for this purpose. The limited evidence available from published research supports the recommendation that continuous agents should preferably be used, based on peroxide compounds (e.g. hydrogen peroxide and sodium percarbonate), bisbiguanides (e.g. chlorhexidine gluconate) or chlorine compounds (e.g. tosylchloramide sodium and chlorine dioxide).

Appendix 1: MEDLINE Search

Initial Search

Ovid MEDLINE(R) 1946 to present with daily update

Search date

12.10.2016

1 (all "OR")

(dent* adj3 water line*).mp.

(dent* adj3 waterline*).mp.

(dent* adj3 water system*).mp.

(dent* adj3 water quality).mp.

dent* treatment water.mp.

Limits

English Language

Publication Year 2000 – Current

Results: 224

Appendix 2: Checklist of Key Requirements for a Risk Assessment of Hot and Cold Water Systems in Dental Settings for *Legionella* Control

Legionella Risk Assessment Checklist
for Hot and Cold Water Systems in Dental Settings
Key requirements (derived from BS 8580 'Water quality, Risk assessments for Legionella control')[62]

In sections 1-2 Confirm Yes (Y), No or N/A

Section 1: Roles and Responsibilities	Y/N N/A
1.1 Are details of management personnel involved in legionella risk assessment documented? Check names, job titles and contact information for dutyholder, appointed responsible person(s), deputies, service providers (e.g. water treatment suppliers, cleaning and disinfection service providers) are included.	
1. 2 Are competency assessments and training records available for those associated with legionella risk assessment and control?	
1.3 Are roles and responsibilities for employees, contractors and consultants clearly identified and documented?	

Section 2: Legionella Water System Risks and Controls	Y/N N/A
2.1 Is water stored or re-circulated as part of the system? (e.g. check water is not retained overnight in DUWLs or stored in a water tank)	
2.2 Is water temperature in all or some part of the system between 20 and 45°C? (e.g. a DCU water heating unit or a temperature rise in DUWLs following continuous use over several hours)	
2.3 Are deposits that support bacterial growth, such as rust, sludge, scale and organic matter (e.g. DUWL biofilm visible)?	
2.4 Are the following actions being taken to minimise legionella transmission as part of the Legionella Control Scheme?	
• Assessment of the water system for any potential risk of contamination with *Legionella* spp. and other material and implementation of control measures	

Section 2: Legionella Water System Risks and Controls	Y/N N/A

• Assessment of the potential for *Legionella* spp. to grow within the system and planning, implementation and evaluation of controls such as:
   o   chemical and physical water treatment measures
   o   disinfection and cleaning regimes
   o remedial work and maintenance	

• Regular monitoring of the effectiveness of the control measures and implementation of corrective actions where necessary	

In section 3 Tick box ✓ to Confirm action

Section 3: Legionella Water System Risks and Controls where additional control measures are required as part of the legionella control scheme*	✓
3.1 The scope of the assessment (i.e. the details and entirety of the plant being assessed) is described	
3.2 Assessment of the validity of the schematic diagram which should include all parts of the system where water may be used or stored has been undertaken	
3.3 Details of the design of the system, including an asset register of all associated plant, pumps, strainers, outlets and other relevant items are recorded	
3.4 Evidence of the competence of those involved in control and monitoring activities is available	
3.5 A review of the legionella written control scheme, including management procedures and site records or logbooks, which include: system maintenance records; routine monitoring data; water treatment and service reports; cleaning and disinfection records; and *Legionella* spp. and other microbial analysis results are complete	

*applicable where risk is not mitigated e.g. changes to the water system or a significant legionella breach arises

Appendix 3: Key Requirements for Legionella Control Schemes

The key requirements when preparing a legionella written control scheme include:

(1) The purpose and scope of the control scheme;

(2) A summary of the legionella risk assessment;

(3) The management structure, including: dutyholder; responsible person(s) and communication pathways; training; and, allocation of responsibilities;

(4) The correct and safe operation of the system;

(5) Precautions in place to prevent or minimise risk associated with the system;

(6) Analytical tests, including microbiological testing, other operational checks, inspections and calibrations to be carried out, their frequency and any resulting corrective actions;

(7) Health and safety information, including details on storage, handling use and disposal of any chemical used in both the treatment of the system and testing of the system water;

(8) An incident plan, which should cover the following situations: major plant failure, e.g. chemical system failure; very high levels or repeat positive water analyses for *Legionella* spp.; an outbreak of legionellosis, suspected or confirmed as being centred at the site; an outbreak of legionellosis, the exact source of which has yet to be confirmed, but which is believed to be centred in an area which includes the site.

(9) Locally, if risk is identified that is unable to be controlled or mitigated an up-to-date schematic plan showing the layout of the system(s) and its location within and around the premises – this should identify piping routes, storage and header tanks, calorifiers and relevant items of plant, especially water softeners, filters, strainers, pumps and all water outlets is required to inform/assist further controls;

(10) Remedial action to be taken in the event that the scheme is shown not to be effective, including control scheme reviews and any modifications made;

Appendix 4: Water Sample Collection for *Legionella* spp. Sampling

The following procedure must be adopted when collecting water samples for *Legionella* spp. sampling in healthcare premises, as outlined by Code of Practice BS 7592: 2008:[80]

(1) Where possible, ensure that the water outlet is in good condition with no leaks.

(2) Clean the outlet thoroughly with a clean disposable cloth (using detergent if necessary).

(3) Disinfect the outlet with either sodium hypochlorite solution (prepared on the day of use to provide 1% available chlorine) or chlorine dioxide foam. Disinfection may be carried out by preparing a solution of sodium hypochlorite in a container and suspending it under the outlet such that it is immersed in the solution for two to three minutes. Alternatively, a wash bottle containing sodium hypochlorite solution may be used to spray the solution on both the outside and inside of the outlet, leaving it for two to three minutes before rinsing.

(4) Turn on the water outlet gently to avoid unnecessary aerosol production and operate for two to three minutes.

(5) A one litre sterile plastic bottle (or two 500 ml bottles) should be used containing a pre-dosed standard volume of neutraliser (e.g. 18 mg/L sodium thiosulphate) to deactivate any residual disinfectant in the water.

(6) Aseptically open the labelled bottle, fill to almost the brim with water, replace and tighten the lid, and shake the bottle to distribute the neutraliser.

(7) The water sample should be transported to the laboratory within 24 hours (ideally within 2 hours). If transport is delayed, the water samples should be stored between 6 and 18°C.

(8) United Kingdom Accreditation Service (UKAS) or ISO 9002 accredited laboratories must always be used for analysis.

Appendix 5: Action Levels for *Legionella* spp. Sampling

The following action levels must be adopted for *Legionella* spp. sampling in healthcare premises, as outlined by the HSE Approved Code of Practice:[19]

(1)   Up to 100 CFU/L. Any detection of *Legionella* spp. should be investigated and, if necessary, the system re-sampled to aid interpretation of the results in line with the monitoring strategy and risk assessment.

(2)   > 100 and up to 1000 CFU/L. If the minority of samples are positive, the system should be re-sampled. If similar results are found again, a review of the control measures and risk assessment should be carried out to identify any remedial actions necessary. If the majority of samples are positive, the system may be colonised, albeit at a low level. An immediate review of the control measures and risk assessment should be carried out to identify any other remedial action required. Disinfection of the system should be considered.

(3)   > 1000 CFU/L. The system should be re-sampled and an immediate review of the control measures and risk assessment carried out to identify any remedial actions, including possible disinfection of the system. Re-testing should take place a few days after disinfection and at frequent intervals afterwards until a satisfactory level of control is achieved.

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