Health Protection Scotland

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Literature Review and Practice Recommendations:

Existing and emerging technologies used for decontamination of the healthcare environment

Electrolysed Water

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Contents

Topic

The use of electrolysed water (EW) for decontamination of the healthcare environment.

Background

Current microbiological and epidemiological evidence indicates that contaminated surfaces in hospital settings can contribute to the transmission of nosocomial pathogens.[1] In particular, there appears to be a risk of pathogen acquisition from prior room occupants for methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), *Clostridium difficile* and *Acinetobacter baumannii*.[2] Accordingly, existing research implies that improved surface cleaning and disinfection can reduce healthcare-associated infections.[3]

The NHSScotland National Infection Prevention and Control Manual[4] currently recommends the use of a disinfectant solution at a dilution of 1,000 parts per million (ppm) available chlorine for routine and terminal room cleaning under transmission-based precautions. However, it is well-recognised that hypochlorite-based cleaning products are potentially harmful to healthcare workers and similarly detrimental to environmental surfaces over long-term use, due to their corrosive properties.[5] Electrolysed water (EW) has been proposed as an alternative cleaning product, offering a record of no adverse effects on healthcare workers in the published literature and a lack of need to wear personal protective equipment during use.[6] In addition, it is claimed that EW products are inexpensive and naturally degrade into harmless water.[6]

Despite these clear benefits, there are concerns that EW products have a relatively poor shelf-life and may be mistakenly used once no longer active, or that significant wastage might occur if the product is not completely consumed before its use-by date.[7] Although EW has been evaluated for use as an environmental disinfectant, there have been few attempts to determine its capacity to safely disinfect communal reusable medical equipment.[8] This is particularly the case with regard to sensitive clinical equipment that may be compromised by direct contact with traditional hypochlorite-based cleaning products.[8]

It has been reported that EW products are capable of significant sporicidal activity, indicating their applicability for the terminal cleaning of rooms following the discharge of patients under contact precautions.[6] For this reason, it would be pertinent to evaluate the potential use of EW products as an acceptable alternative to the current standard recommended for use within NHSScotland.[4] This review intends to assess the evidence base on the appropriateness of using EW for both routine cleaning and terminal cleaning in the healthcare environment.

Aim

To review the evidence base for using electrolysed water (EW) for decontamination of the healthcare environment.

Objectives

- To provide a generic description of EW, including the proposed or actual mechanism of action and the procedure for use.
- To assess the scientific evidence for effectiveness of EW.
- To explore practical and safety considerations related to the use of EW.
- To explore the costs associated with EW.
- To produce a concise evidence summary for EW to assist the Equipment and Environmental Decontamination Steering Expert Advisory Group in making practical recommendations on the use of EW for NHSScotland.

Research Questions

The following research questions will be addressed:

1. Is EW currently in use in UK healthcare settings?
2. What is the actual or proposed mechanism of action of EW?
3. What is the procedure for using EW?
4. What is the scientific evidence for effectiveness of EW for decontamination of the healthcare environment?
5. Are there any safety considerations associated with using EW in the healthcare setting?
6. Are there any practical or logistical considerations associated with using EW in the healthcare setting?
7. What costs are associated with using EW in the healthcare setting?
8. Has EW been assessed by the Rapid Review Panel?

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/)
- Health Technology Assessment (HTA) database (http://www.crd.york.ac.uk/CRDWeb/)
- Database of Abstracts of Reviews of Effects (DARE) (http://www.crd.york.ac.uk/CRDWeb/)
- National Patient Safety Agency (NPSA) (http://www.npsa.nhs.uk/)
- National Institute for Health and Care Excellence (NICE) (http://www.nice.org.uk/)
- Medicines & Healthcare products Regulatory Agency (MHRA) (http://www.mhra.gov.uk/)
- Rapid Review Panel (RRP): product evaluation statements (http://www.gov.uk/government/groups/rapid-review-panel/)

Search terms were developed and adapted to suit each database/website. Initial literature searches were run between 24/06/2014 and 01/07/2014. For the update, the literature search was performed on 18/08/2016. Different search strategies were applied in each year. See Appendix 1 for an example of the search run in the MEDLINE database in 2014 and Appendix 2 for an example of the updated search conducted in 2016.

Exclusion Criteria

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

- Article was released before 2004
- Article was not published in the English language
- Article does not concern decontamination using EW in the healthcare environment (off-topic)
- Article is an opinion piece, a non-systematic review or a conference abstract

- Article does not present evidence compatible with the McDonald-Arduino evidentiary hierarchy[9]
- Article concerns a study that did not have an appropriate comparison in the form of standard cleaning methods

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.[10] The McDonald-Arduino evidentiary hierarchy was used as a framework for assessing the evidence.[9]

Results

The original search found 94 articles. After the first stage of screening this was reduced to 12 articles, and after the second stage there were five articles to critically appraise.[11-15] The update search retrieved a further 55 articles, of which 6 passed the first stage of screening, but none met the inclusion criteria. In the original search, the study by Stewart *et al.*[15] was included as containing a non-concurrent comparison group. However, during the update a second opinion was sought and, since there was no statistical analysis performed in this comparison, a consensus was reached that the study would be excluded in the update. The four included studies used two different types of EW: two studies used acidic EW,[11;14] and two studies used neutral EW.[12;13] One of the four studies were conducted in the United Kingdom (UK),[13] one study was undertaken in Japan,[11] another in the Republic of Korea (South Korea),[14] and the last study was situated in Spain.[12]

Standard cleaning methods in the studies differed considerably. One study used a quaternary ammonium compound disinfectant[13] and three of the studies used solutions of sodium hypochlorite as a comparison.[11;12;14] All of the EW products had different available chlorine concentrations (ACC), pH levels and oxidation reduction potentials (ORP), all of which may have had an impact on

their effectiveness. Three of the studies were laboratory-based[11;12;14] and one was carried out in a care home.[13]

Two studies demonstrated that EW and sodium hypochlorite solution had similar levels of effectiveness.[11;12] Another two studies showed that EW was more effective than standard cleaning methods, including sodium hypochlorite solution[14] and quaternary ammonium compound disinfectant.[13]

Research Questions

Is EW currently in use in UK healthcare settings?

There is no mention of EW products in The NHSScotland National Cleaning Services Specification,[16] the National Patient Safety Agency (NPSA) Revised Healthcare Cleaning Manual,[17] the Association of Healthcare Cleaning Professionals (AHCP) Revised Healthcare Cleaning Manual[18] or the NHSScotland National Infection Prevention and Control Manual.[4]

These findings suggest that EW is not widely in use within UK healthcare settings.

What is the actual or proposed mechanism of action of EW?

EW is formed by the process of electrolysis, which involves passing an electric current through a diluted salt solution.14;19;20 This process is considered to provide a higher level of available hypochlorous acid than can be delivered using chemical forms.[13] There are three different types of EW available:

- Acidic electrolysed water
- Alkaline electrolysed water
- Neutral electrolysed water

Acidic EW is the product of negatively-charged ions being attracted to the anode (positive electrode), resulting in the formation of hypochlorous acid and a weak solution of hydrochloric.[19;20] Strongly acidic EW has a pH of 2.2 − 2.7 and is formed in a generator where the cathode and anode chambers are separated by a membrane. Weakly acidic EW has a pH of 5 – 6 and can be produced in generators where there is no separating membrane.[14]

Alkaline EW is the product of positively-charge ions being attracted to the cathode (negative electrode), resulting in the formation of a weak solution of sodium hydroxide.[19;20] Alkaline EW has a pH of 8 – 14.

Neutral EW is produced in a similar way to acidic EW, except it has additional hydroxide ions introduced to produce a neutral solution with a pH of 6 – 8.[12;15]

The antimicrobial effect of EW is based on the combined action of the pH, ORP and ACC.[11;14;21-23] A low pH may sensitise the outer membrane of bacterial cells, allowing the chlorine compounds to inactivate the cell.[14;23] Most micro-organisms do not survive well in acidic solutions, as a pH of below 3 impacts on their ability to grow and multiply. The chemical process of oxidation occurs when oxygen interacts with other compounds, causing loss of electrons and breakdown of the compound. In the case of microbes, the ORP is thought to damage cell membranes and create disruption in metabolic processes, thereby destroying micro-organisms.[14] In addition, the bactericidal activity of EW increases with a higher ACC. The chlorine compound in EW can be free chlorine, hypochlorous acid, hypochlorite ions, or a combination of these. At an acidic pH, available chlorine is usually in the form of hypochlorous acid, which is reported as significantly more effective than an equivalent concentration of hypochlorite ions.[11]

Acidic EW has a lower pH and a higher ACC than neutral or alkaline EW. This increases its potency but also makes it more corrosive and unstable, with a shorter shelf-life. Alkaline EW has a higher pH but a lower ACC, so it unlikely to be as efficacious as acidic EW.[21]

What is the procedure for using EW?

The EW used by Meakin et al.[13] was provided in ready-to-use spray bottles and did not require any special instructions for use. They report that the spray bottles dispensed approximately 1.5 mL of product per trigger spray and that surfaces were wiped with a microfibre cloth afterwards. Stewart et al.15 used EW provided by Aqualution® and state that each site was sprayed with 1.5 mL of product, wiped clean with detergent wipes 10 to 15 seconds later and then allowed to dry naturally.

What is the scientific evidence for effectiveness of EW for decontamination of the healthcare environment?

One before-and-after study[13] and three laboratory-based non-randomised trials[11;12;14] evaluated the efficacy of EW for decontamination of the healthcare environment. It was demonstrated that this intervention could reduce environmental surface contamination in laboratory and clinical settings.

As detailed in the methodology, the McDonald-Arduino evidentiary hierarchy[9] was used as a framework for assessing the evidence relevant to this research question.

Level V – Demonstration of reduced microbial pathogen acquisition (colonisation or infection) by patients via *non-outbreak* surveillance testing and clinical incidence:

No evidence identified.

Level IV – Demonstration of reduced microbial pathogen acquisition (colonisation or infection) by patients via *outbreak* surveillance testing and clinical incidence:

No evidence identified.

Level III – Demonstration of in-use bioburden reduction that may be clinically relevant:

No evidence identified.

Level II – Demonstration of in-use bioburden reduction effectiveness:

Meakin *et al.*[13] compared the cleaning efficacy of a quaternary ammonium compound disinfectant and neutral EW in an English residential care home using a before-and-after study. They demonstrated that EW was more effective; however, it is worth noting that this was a small-scale study in a single care home, and that the results may not be similar in a busy hospital environment. The rooms in the care home received a high standard of disinfectant-based cleaning in general, as reflected by the relatively low microbial counts retrieved from sampling. It is also significant that the study used quaternary ammonium compounds rather than hypochlorite solution, the current standard recommended within NHSScotland.[4]

Level I – Laboratory demonstration of bioburden reduction efficacy:

Issa-Zacharia *et al.*[11] investigated the *in vitro* inactivation of *E. coli*, *S. aureus* and *Salmonella* spp. using weakly acidic EW and compared this to strongly acidic EW and sodium hypochlorite solution. The results showed that strongly acidic EW had the greatest bactericidal effect, with weakly acidic EW and sodium hypochlorite showing similar levels of bactericidal effects, despite the hypochlorite solution having more than five times more available chlorine. This is thought to be due to the greater ORP and lower pH of strongly acidic EW. A longer treatment time was also associated with a greater effect. It is relevant to highlight that the study took place in Japan and that the concentration of sodium hypochlorite used was not specified: the study only stated that a 10 % solution was diluted with distilled water. This study produced the EW in-house using a generator.

Quan *et al.*[14] evaluated the bactericidal activity of weakly acidic EW on *Vibrio vulnificus* and *Vibrio parahaemolyticus* and compared it to that of sodium hypochlorite solution. Weakly acidic EW was able to kill organisms more quickly than sodium hypochlorite, even at an equivalent ACC. Weakly acidic EW maintained its bactericidal activity for one week under open storage conditions, and for more than five weeks under closed storage conditions, demonstrating that it has a relatively stable shelf-life. This study was conducted in the Republic of Korea (South Korea).

Deza *et al.*[12] compared the efficacy of neutral EW at inactivating *Escherichia coli*, *Listeria monocytogenes*, *Pseudomonas aeruginosa* and *Staphylococcus aureus* with a sodium hypochlorite solution of the same ACC, and similar pH levels and ORP. Neutral EW and sodium hypochlorite had similar efficacy in reducing bacterial populations on surfaces, with neutral EW having the advantage of being safer to handle. This study was located in Spain.

To summarise the evidence, it can be concluded that there is **low-quality evidence** to support the use of EW for routine and terminal cleaning procedures in the healthcare environment. In accordance with SIGN methodology, the before-and-after study and the three laboratory-based non-randomised trials were designated **level 3 evidence**.

Are there any safety considerations associated with using EW in the healthcare setting?

Chlorine-releasing agents are considered easy-to-use and the least expensive environmental disinfection method available. However, they do feature a number of limitations such as the release of irritating vapours and toxic gases which may affect the eyes and respiratory tracts of healthcare workers at high concentrations (i.e. 10,000 ppm available chlorine), and personal protective equipment (PPE) is recommended for this reason. Sodium hypochlorite-based products can be corrosive to various materials and potentially cause damage to environmental surfaces. This has led to a renewed interest in alternative methods of environmental decontamination.[5;24;25]

EW is considered to be more environmentally-compatible and safer than traditional cleaning agents, as it is less corrosive than standard hypochlorite-based cleaners. This means that no PPE or barrier protection is required, there are no chlorine fumes released and that contact with the skin does not pose a concern. EW can be mildly corrosive after long-term contact with metal surfaces.[11;19]

Meakin *et al.*[13] used a product manufactured by Aqualution® that has undergone sensitivity and toxicology studies to demonstrate that it is non-toxic to mammals and safe for the environment. The product is supplied in ready-to-use spray bottles, unlike some quaternary ammonium disinfectants which need to be diluted *in situ* and require the wearing of PPE during the dilution process.

Deza *et al.*[12] report that neutral EW is safer than acidic EW because no chlorine gas is produced at a neutral pH, making it safer for anyone using it, as well as for the environment. They also report that it is stable, has a good shelf-life and is less corrosive than its acidic counterpart.

Are there any practical or logistical considerations associated with using EW in the healthcare setting?

Different types of EW require different considerations in terms of shelf-life; acidic EW is more unstable and has a much shorter shelf-life than neutral EW.[12;21] Studies have shown that weakly acidic EW is able to maintain its pH, ORP and ACC if stored in closed conditions for a few days, making it a useful product in areas where on-site production is not practical.[11]

Meakin et al.[13] used Aqualution® products, which can be supplied in ready-to-use bulk containers, or generated on-site. On-site generation requires water, salt, electricity and electrolysing equipment, and can be useful in situations where the transport, delivery and storage of large volumes of liquid is costly and impractical. The ready-to-use products have a shelf-life of 12 months, and the manufacturers state that the product remains stable without compromising its effectiveness.26 Dancer et al.8 also used an Aqualution® product, Salvesan®, in which the hypochlorous acid has been stabilised: this allows the EW to be stored for periods in excess of 12 months.

Meakin *et al.*[13] also state that EW is able to provide the same level of cleaning efficacy as conventional biocides with a significantly shorter contact time, thereby improving the cleaning efficiency. Stewart *et al.*[15] suggest the use of EW to clean areas between patients in outpatient settings as the shorter time required for disinfection would be useful in busy healthcare settings. As EW products can be used in the same way as standard cleaning products, there is no need to purchase special personnel or train existing personnel.[19;21]

What costs are associated with using EW in the healthcare setting?

Sun *et al.*[19] state that the use of EW products involves a lower cost than traditional cleaning agents, but fail to provide any details. Landa-Solis *et al.*[21] also consider the use of EW to be an inexpensive option, and state that the end-product is non-flammable and has no special requirements for handling or disposal. This means that there are no additional costs for the disposal of EW.

Has EW been assessed by the Rapid Review Panel?

The Rapid Review Panel[27] (RRP) is a panel of UK experts established by the Department of Health to review new technologies with the potential to aid in the prevention and control of healthcare-associated infections.

No EW products have been reviewed by the RRP to date.

Discussion

This systematic review incorporated the results of four studies into its findings. The quality of included studies was solely of **level 3 (low-quality) evidence**, concerning the in-use or laboratory reduction of bioburden (level II and I, respectively). The study design of choice was either a before-and-after study or a laboratory-based non-randomised trial. The findings identified by the review were used to develop the following recommendations for clinical practice.

Recommendations for Clinical Practice

This review makes the following recommendations based on an assessment of the extant professional literature on electrolysed water (EW) for environmental decontamination:

- There is currently insufficient evidence to support the use of EW as an alternative to a chlorine-releasing agent as recommended by the National Infection Prevention and Control Manual.
  (Grade D recommendation)
- Whilst there is some evidence demonstrating effectiveness of EW, there have been insufficient studies to assess practical considerations.
  (Grade D recommendation)
- Consideration needs to be given to the type of EW used, the method of storage (if purchased in spray bottles) and its application.
  (Grade D recommendation)
- EW purchased must be stored appropriately, and effective stock rotation must be in place. A potential short life-span for EW products in comparison to regular cleaning products could result in use of deactivated EW or wastage of out-of-date stock.
  (Grade D recommendation)
- A detailed SOP must be established to ensure there is clarity on when and how EW is used.
  (Good Practice Point)
- EW products supplied in spray bottles must be discarded when empty and must **not** be reused.
  (Good Practice Point)
- Manufacturers' instructions for use of EW products must be followed for method of storage and use of product, especially regarding contact time and method of wiping surfaces, e.g. with microfibre wipe or detergent wipe (manufacturers' instructions must be cross-checked

for compatibility with EW).

(Grade D recommendation)

If NHS boards use EW production units, the following must also be considered:

- EW production units must be developed and built in accordance with national guidance.
  (Good Practice Point)
- A monitoring system must be in place for EW production quality, and processes in place should this fail.
  (Good Practice Point)
- A planned programme of maintenance must be in place for the production unit for estates staff.
  (Good Practice Point)
- Staff involved in the production of EW must be trained in the process of EW production and quality assurance testing.
  (Good Practice Point)
- Systems (SOPs) must be developed for the storage and proposed use of EW (e.g. will it be provided in spray bottles? Will these be sterile before use? Are they brought in ready-for-use or recycled?).
  (Good Practice Point)
- Locally produced EW must have a use-by date incorporated into the production programme appropriate for the type of EW produced.
  (Grade D recommendation)

Implications for Research

The review identified several gaps in the literature in relation to EW. Many of the relevant studies identified could not be included in this review as they did not make a suitable comparison in the form of standard cleaning as recommended for NHSScotland in the National Infection Prevention and Control Manual.[4] These studies variously compared the use of EW products with sodium hypochlorite solution and quaternary ammonium compound disinfectants. Future studies assessing the clinical effectiveness of EW for decontamination should include suitable comparison groups to enable the results to be transferable to clinical practice within NHSScotland.

There was also significant variability in the formulation of EW products, including differences in available chlorine concentration (ACC), pH level and oxidation reduction potential (ORP). These factors may all impact upon the effectiveness of the product. For the purposes of evaluating comparability, the optimal values of these factors should be determined before subsequent analyses measuring the effect of EW against appropriate comparison groups. In accordance, Meakin *et al.*[13] advocate the establishment of standardised benchmarking measures for the evaluation of environmental surface disinfectants.

The extant research focussed exclusively upon the efficacy of EW products in reducing environmental bioburden, whether clinically-based or laboratory-based. Extrapolating the findings of such studies to the prevention of nosocomial infections may not be valid under normal clinical working conditions. It is therefore necessary to conduct further studies demonstrating the effect of EW on the reduction of healthcare-associated infections and patient acquisition of nosocomial pathogens before conclusions on the efficacy of EW can be reached.

Finally, very few studies thus far have evaluated the cost-effectiveness of EW. Of the few that have, most have appealed to the inexpensive ingredients required for the production of EW and the low disposal costs for the harmless waste products that result from its degradation. It can therefore be seen that a comprehensive cost-effectiveness evaluation for the use of EW in NHSScotland would be timely.

Conclusion

The contribution of environmental contamination in healthcare settings to the cross-transmission of nosocomial infections has been thoroughly demonstrated: firstly, by interventional studies in which improved surface cleaning has reduced the incidence of HAIs;[1] and secondly, by observational studies which have evidenced the higher risk of pathogen acquisition in patients admitted to rooms where the prior occupant was known to be infected or colonised.[2] Electrolysed water (EW) provides an example of a novel technology that may supplement standard cleaning practices and potentially further reduce the transmission of nosocomial pathogens. This review aimed to provide a concise evidence summary outlining: the evidence of effectiveness for, the practical and safety considerations of, and the costs associated with, the use of EW.

The review found that there was a larger quantity of evidence supporting the use of acidic and neutral EW products than alkaline EW products, although this evidence was of low-quality. Of the three studies comparing EW to sodium hypochlorite solution, one found weakly acidic EW to be more effective, a second determined that neutral EW showed similar effectiveness to hypochlorite, and the third study identified strongly acidic EW as more effective and weakly acidic EW as only similarly effective to hypochlorite solution. However, all three studies were conducted within laboratory settings and used microbial bioburden as an outcome measure. A final study compared the use of neutral EW in a clinical setting with the use of a quaternary ammonium compound disinfectant, recognising EW to be more effective. Yet, this comparison group does not reflect current best practice recommended for use in NHSScotland.

If EW products are to be adopted within NHS healthcare settings, it is recommended that consideration should be given to the methods of application and storage of EW products. The reuse of EW spray bottles poses a significant risk of cross-infection and, therefore, spray bottles must be discarded once the product has been depleted. In addition, EW products feature a relatively short-life span in comparison to traditional cleaning products, necessitating the need for effective stock rotation. Otherwise, there is a risk that deactivated EW products will continue to be used or that out-of-date stock will be wasted. There has also been little in the way of cost-effectiveness evaluations of EW products in the UK.

The Rapid Review Panel (RRP) has not yet evaluated any EW products. If NHS Boards wish to adopt EW products, they must be aware that these products have not been reviewed or approved by the RRP.

Appendix 1: MEDLINE Search (2014)

Ovid MEDLINE(R) 1946 to present with daily update

AND

Ovid MEDLINE(R) In-process & other non-indexed citations

Search dates

24/06/2014 and 25/06/2014

1 (all "OR")		2 (all "OR")
electroly?ed water.mp. electroly?ed oxidizing water.mp. electrochemically activated water.mp. electro-chemically activated water.mp.	AND	Sterilization/ Decontamination/ Disinfection/ Housekeeping, Hospital/ clean*.mp.

Limits

English Language

Publication Year 2004 – 2014 Results: 36

Appendix 2: MEDLINE Search (2016)

Ovid MEDLINE(R) 1946 to present with daily update

Search dates

18/08/2016

1 (all "OR")		2 (all "OR")
Electrolysis/ (electroly?ed adj2 water).mp. electrochemically activated water.mp. (electrochemically activated adj2 solution*).mp.	AND	Sterilization/ Decontamination/ Disinfection/ Housekeeping, Hospital/ clean*.mp.

Limits

English Language

Publication Year 2014 – Current Results: 17

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