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Literature review

Hand Hygiene: Products

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ARHAI Scotland
Antimicrobial Resistance and Healthcare Associated Infection

Key information

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Document information	Description
Description	This literature review examines the available professional literature on hand hygiene products in the health and care setting.
Purpose	To inform the hand hygiene section in the National Infection Prevention and Control Manual in order to facilitate the prevention and control of healthcare associated infections in NHSScotland health and care settings.
Target Audience	All NHS staff involved in the prevention and control of infection in NHSScotland.
Update/review schedule	Updated as new evidence emerges with changes made to recommendations as required. Review will be formally updated every 3 years with next review in 2026.
Cross reference	National Infection Prevention and Control Manual.
Update level	Practice – Changes include additional question on legislation and standards required for hand hygiene products. Change in recommendation allowing use of ABHR and non-alcohol-based hand rub if they meet the specified standards. Additional recommendations added on consecutive use and constraints of hand hygiene products. Research – Further high-quality research, including well conducted randomised controlled trials evaluating the efficacy of hand hygiene products is required. There is a large evidence gap relating to efficacy of hand washing emollients.

Contact

ARHAI Scotland Infection Control team:

Telephone: 0141 300 1175

Email: **NSS.ARHAIinfectioncontrol@nhs.scot**

Version history

This literature review will be updated in real time if any significant changes are found in the professional literature or from national guidance/policy.

Version	Date	Summary of changes
5.0	January 2024	Three-year update of Hand Hygiene Products Literature Review. Research questions and recommendations modified: • What is a hand hygiene product and what is its purpose? A hand hygiene product is a cleansing agent designed to remove or reduce pathogens from the hands (for example non-antimicrobial soap, antimicrobial soap, antimicrobial hand rub, and hand wipes). • What are the minimum requirements for microbiological efficacy of hand hygiene products for health and care settings? Hand hygiene products intended for use in health and care settings should have broad-spectrum antimicrobial activity (for example bactericidal, virucidal, yeasticidal, fungicidal). Alcohol-based hand rub (ABHR) products should have a minimum of 60% alcohol concentration. • When should a hand rub product be used for hand hygiene? A hand rub is the preferred product for hand hygiene in health and care settings. A hand rub can be alcohol-based or non-alcohol based if the product has met the required BS EN standards.

Version	Date	Summary of changes
		Addition of new questions and recommendations: • Are there any legislative requirements and/or standards that hand hygiene products must adhere to? Hand hygiene products intended for use in health and care settings should meet the obligatory and additional BS EN standards. For a hand rub product this is bactericidal activity (BS EN 13727 phase 2, step 1 & BS EN 1500 phase 2, step 2) and yeasticidal activity (BS EN 13624 phase 2, step 1). Consideration should also be given to BS EN 17430 2022 (phase 2, step 2) for hand rub products. For a hand wash product this is bactericidal activity (BS EN 13727 phase 2, step 1 & and EN1499 phase 2, step 2). Additional BS EN standards for both hand rub and hand wash products include: tuberculocidal/mycobactericidal activity (BS EN 14348 phase 2, step 1) and virucidal activity (BS EN 14476 phase 2, step 1). • How often can a hand rub product be used consecutively in place of hand washing? There is no maximum number of times a hand rub product can be used consecutively in place of handwash. If hands become sticky/tacky with any notable product build-up, they should be washed with liquid soap and water to remove residue. Manufacturer's instructions should be followed. • Are there any constraints to the use of hand hygiene products? A risk assessment should be conducted when placing hand rub dispensers to consider the risk of ingestion/unintended use.

Version	Date	Summary of changes
		Single-use hand hygiene product containers should not be refilled to reduce the risk of product contamination. Question removed as covered in hand hygiene indications review: • What is the correct technique when using antimicrobial hand wipes for hand hygiene?
4.0	July 2020	Update of the Hand Hygiene: products literature review v3.0 using the two-person NIPCM methodology. Research questions modified. Addition of the following recommendations: When should antimicrobial soap be used for hand hygiene in health and care settings? Hands should be washed with antimicrobial soap and water before performing an invasive procedure. When should alcohol-based hand rub (ABHR) be used for hand hygiene in health and care settings? ABHR solutions containing 62-90% alcohol by volume is the preferred product for hand hygiene in health and care settings unless hands are visibly contaminated/soiled, or when there is likely to be exposure to spore forming organisms (C. difficile or B. anthracis) or infectious diarrhoeal diseases (Norovirus). What is the correct technique when using antimicrobial hand wipes for hand hygiene? Manufacturer's instructions should be followed for correct technique when using hand wipes for hand hygiene. Recommendations regarding surgical scrubbing removed for inclusion in the Hand Hygiene –

Version	Date	Summary of changes
		Surgical hand antisepsis in the clinical setting literature review.
3.0	August 2015	Updated after review of current literature
2.0	April 2014	Updated after review of current literature
1.0	January 2012	Defined as final

Approvals

Version	Date Approved	Name
5.0	December 2023	NPGE Working Group, CIPC Working Group
4.0	July 2020	NPGE Working Group, CIPC Working Group
3.0	August 2015	Steering (Expert Advisory) Group for SICPs and TBPs
2.0	April 2014	Steering (Expert Advisory) Group for SICPs and TBPs
1.0	January 2012	Steering (Expert Advisory) Group for SICPs and TBPs

Contents

1. Objectives

The aim is to review the extant scientific literature regarding hand hygiene products in health and care settings to inform evidence-based recommendations for practice. The specific objectives of the review are to determine:

- What is a hand hygiene product and what is its purpose?
- Are there any legislative requirements and/or standards that hand hygiene products must adhere to?
- What are the minimum requirements for microbiological efficacy of hand hygiene products for health and care settings?
- When should a hand rub product be used for hand hygiene?
- When should a hand wash product be used for hand hygiene?
- How often can a hand rub product be used consecutively in place of hand washing?
- When should a hand wipe product be used for hand hygiene?
- Are there any constraints to the use of hand hygiene products?

2. Methodology

This targeted literature review was produced using a defined two-person systematic methodology as described in the National Infection Prevention and Control Manual: Development Process.

In addition to the exclusion criteria outlined in the NIPCM: Development Process the following exclusion criteria were used in this review.

- Surgical hand antisepsis products
- Skin care studies
- Modified hand products (COVID-19 pandemic response to shortages)
- Studies testing chemicals not measured within a hand product formula

A PRISMA flowchart is presented in **Appendix 3**. Adapted from: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097.

3. Discussion

3.1 Implications for practice

What is a hand hygiene product and what is its purpose?

Five pieces of guidance were identified from the literature providing evidence on what a hand hygiene product is and its purpose. This included four expert opinion guidance documents graded as SIGN 50 level four evidence.[1,2,3] Two guidance documents were graded as 'recommend' using the AGREE tool. [4,5]

A hand hygiene product is a cleansing agent designed to remove or reduce pathogens from the hands.[1] These cleaning agents include non-antimicrobial soap, antimicrobial soap, antimicrobial hand rub, and hand wipes.

Non-antimicrobial soap (commonly referred to as 'plain soap') is available in bar, leaflet, tissue, powder, and liquid formats.[3,4] The detergent properties of non-antimicrobial soap enables the physical removal of transient microorganisms along with dirt and organic matter from the hands.[1-5] However, unlike antimicrobial hand hygiene products, non-antimicrobial soaps do not contain antimicrobial agents. Antimicrobial soap is a generic term for soap products that contain antimicrobial active ingredients, such as chlorhexidine gluconate (CHG), triclosan (bacteriostatic activity), hexachlorophene (inactivation of essential enzymes), chloroxylenol (inactivation of bacterial enzymes and alteration of cell walls) and quaternary ammonium compounds, for example benzalkonium chloride (BK).[2,4,5,7]

Antimicrobial hand rubs are commercially available as liquid solutions, gels and foams. The active ingredients may be alcohol (ethanol, isopropanol, n-propanol), CHG and BK. [1-6] The antimicrobial activity of alcohols can be attributed to their ability to denature proteins.[1,3,4] Non-alcohol-based hand rubs such as those containing CHG are thought to have antimicrobial activity due to the ability of the chemical to attach and disrupt cytoplasmic membranes of microorganisms.[3,4,7] BK is thought to disrupt the intermolecular interactions, resulting in compromised physical and biochemical properties of an organism.[4,7] There is significant variation in the properties of available antimicrobial hand rubs, with some containing mixed formulas with more than one active ingredient.[4]

Antimicrobial hand wipes consist of a disposable, soft material impregnated with antimicrobial agents for example BK, chloroxylenol and/or alcohol.[3,5]

Are there any legislative requirements and/or standards that hand hygiene products must adhere to?

Fourteen pieces of evidence were identified from the current literature including eight British/European (BS EN) standards [8-15] and six guidance documents, [1-5, 16] 11 graded as SIGN50 level 4 [1-3,8-15] and three graded 'recommend' using the AGREE tool.[4,5,16] No legislative requirements were identified for hand hygiene products in Scottish health and care settings in the literature.

The BS EN standards refer to a collection of documents outlining a methodological process for testing the minimum microbiological efficacy of hygienic hand products. There are eight standards that have relevance for products intended to be used in health and care settings; these include BS EN 1500, 13727, 1499, 13624, 14476, 17430, 14348 and 14484 (see appendix 1). These standards cover testing against the following microorganisms: viruses (murine norovirus, poliovirus, adenovirus, vaccinia virus) within BS EN 14476 and 17430, bacteria (*Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Enterococcus hirae*, *Mycobacterium avium* and *Mycobacterium terrae*) within BS EN 1500, 13727, 1499 and 14348, and yeast (*Candida albicans*) within BS EN 13624. The standards are comprised of two phases: in vitro testing and simulation of practical conditions using the hands of participants in a controlled setting. At the time of writing, the discussed standards were the most recent versions available. It should be noted, however, that these are subject to amendment and that the standards discussed here do not represent all standards which apply to hand hygiene products.

According to BS EN 14885, obligatory standards to be passed for hygienic hand rub and hand wash in the medical area include bactericidal and yeasticidal activity, with additional consideration given to tuberculocidal/mycobactericidal activity, and enveloped viruses. The range of pathogens (obligatory and additional) in the BS EN methodology is limited when compared to the multiple organisms present in health and care settings, therefore wider evidence of efficacy against further pathogens

than is specified in the standards would be advantageous. Further limitations include the lack of applicability of the standards to health and care settings specifically that in vitro testing does not reflect use on human skin, the use of murine norovirus instead of human norovirus which has been successfully cultivated in other methodologies, [17,18] and the lack of a power calculation/small sample size stated in the methodology when recruiting participants for practical simulation.

Despite limitations, the BS/EN standards provide a consistent, rigorous, and transparent methodology for testing a hand hygiene product. In practice the standards are used by manufacturers to inform buyers of the antimicrobial properties of their product, but manufacturers may state further evidence on efficacy tested by different means. However, there is the potential for publication bias as manufacturers are not required to report which standards their product does not meet. Due to the heterogeneity across the evidence base on hand hygiene product efficacy testing, the BS EN standards allow for accurate synthesis and comparison of products, minimising the introduction of bias. Although the BS EN standards are not mandatory, national UK guidance from NICE and epic3 state that hands should be decontaminated with hand rubs that comply with a British Standard,[5,16] particularly BS EN 1500 (NICE).[16] Extant international guidance (CDC, WHO, Australian National Hand Hygiene Initiative (ANHHI)) state that hand rubs should comply with a recognised standard. [1,2 3,4]

What are the minimum requirements for microbiological efficacy of hand hygiene products for health and care settings?

In total, 50 pieces of evidence were identified providing evidence on the minimum requirements for microbiological efficacy of a hand hygiene product for health and care settings. From the previous review (version 4.0) there were 18 before and after studies (graded SIGN50 level 3),[19-37] three laboratory studies (graded SIGN50 level 3),[38-40] five randomised controlled trials (RCTs) (graded SIGN50 level 1+), [41-45] and three guidance documents (two graded AGREE 'recommend' [4,5] and one expert opinion).[3] In this current update, 21 additional pieces of evidence were added.

Twelve laboratory studies [46-56] and four before and after studies, [17,57-60] all graded as SIGN50 level 3 were included, along with four expert opinion guidance documents, graded as SIGN50 level 4.[1,2,61,62]

There is a considerable variety of microorganisms present in the health and care setting, so it is important that a hand hygiene product has broad-spectrum effectiveness against bacteria, viruses, yeast, and fungi. However, variation in how this microbiological efficacy is measured creates challenges when synthesising the evidence base. As previously discussed, (**question two**), microbiological efficacy of a hand hygiene product can be assessed via the implementation of a specific standard (**appendix 1**)**.** Additional assessment measures include primary research studies and manufacturers specific data. In vitro studies commonly measure antimicrobial activity by assessing the log reduction of a pathogen before and after contact with a hand hygiene product via a suspension test. The BS EN standards require a hand rub product to provide at least a four or five decimal log reduction (pathogen specific) in vitro, and a hand wash product must demonstrate at least a two to five decimal log reduction (**appendix 1**). When simulating practical conditions, the mean log reduction of the release of the test organism achieved by the hygienic hand rub or wash should be at least not inferior to that achieved by the control product (60% propan-2-ol for bacteria and 70% ethanol for viruses). This is predominately measured via evaluating remaining viable pathogen or colony forming units on the fingertips/pads of participants hands. Other less common measurements of microbial efficacy in the primary literature include the minimum inhibitory concentration (in vitro) and total colony forming units' load reduction (in vivo).

Alcohol-based hand rub (ABHR)

There are many different ABHR formats (for example gel, foam, or liquid), and formulations (alcohol type, alcohol concentration, additional ingredients) and it is unclear which provides the optimum microbicidal properties. In the available literature, hand hygiene products with alcohol (ethanol, isopropanol) as the main active ingredient (60-95% concentration) have demonstrated log/load reductions and inhibitory properties against gram positive and gram negative bacteria (*Pseudomonas aeruginosa, E. coli, Salmonella enteritidis, S. aureus, Enterococcus faecalis,* methicillin resistant *S. aureus,* vancomycin resistant *enterobacteria,*

gentamicin-resistant *enterococcus, Serratia marcescens*),[21,22 25,31,32, 34,37,38,39,40,45,51,59,60] yeast (*Candida* species),[23] viruses (rotavirus, hepatitis B, SARS-CoV-2, influenza A, enterovirus) [20,25,29,37,38,39,45,47,48-52,56] and generally lowers the number of colony forming units on contaminated hands. [26,28,30,32,33,41-44] Only five of the primary research studies implemented a BS EN standard (BS EN 1500 & BS EN 14476) and all those tested against BS EN 1500 were inferior to the reference ABHR product, therefore not adequately passing the requirements of the standard.[22,31,32,37,59]

The activity of ABHR may vary depending on alcohol formulation**.** Isopropanol was found to elicit greater bactericidal efficacy against *Escherichia coli* K12 when compared to ethanol. [22] However, other studies have found no difference between alcohol type and bacterial reduction.[30,31] ABHR may not demonstrate sufficient antibacterial or antiviral activity against all pathogens, and this has been reported in a small number of studies. These pathogens include hepatitis E virus,[47] rhinovirus,[27] adenovirus, [56] norovirus and *Clostridioides difficile*.[19,35] This is important to consider when managing outbreaks involving these pathogens in health and care settings.

Additional active ingredients such as hydrogen peroxide, CHG, triclosan and organic acids have been added to some ABHRs. There is mixed evidence on the effectiveness of these formulations compared to 'plain' ABHR with some studies showing additive formulations to result in greater residual activity than alcohol alone,[44,45,38,] some to be equally effective, [29] and some not.[56] Guidance states that the combined activity of CHG with ABHR could be applied in settings with higher risk individuals or when performing invasive procedures.[1,2,3,5] It is unclear from the identified evidence if there are any risks/benefits associated with the routine and long-term use of ABHR containing additional antimicrobial agents. Due to the heterogeneity in the evidence base it is challenging to summarise the literature, although it is evident from the large number of primary studies that ABHR solutions containing at least 60% alcohol have antimicrobial activity against microorganisms. However, precise recommendations on formulation and the addition of other active ingredients that can contribute to the efficacy cannot be established.

Non-alcohol-based hand rub

There is less available evidence on the microbiological efficacy of non-alcohol-based hand rubs. Hand rubs containing BK (~0.1% concentration) have demonstrated antimicrobial efficacy using various measurements (log reduction, colony count reduction, minimum inhibitory concentration) against gram-positive and gram-negative bacteria [45,46,60], yeast (*Candida*) [23] and viruses (SARS-CoV-2 and influenza A).[54] Further hand rubs with active ingredients such as epigallocatechin-3-gallate-palmitate (EC16) (a food additive) have demonstrated in vivo virucidal activity against murine norovirus and herpes simplex one virus.[53]

As ABHR has been globally implemented for hand hygiene in health and care settings, comparison studies with different active ingredients are important to assess for antimicrobial efficacy. Few studies were identified in the literature. One study found BK to have greater bactericidal activity against *S. aureus* when compared to ABHR. Throughout the study period, healthcare workers had reduced colony counts on their hands suggesting that BK has sustained antibacterial activity.[57] However, BK (0.1%) based hand rub did not have sufficient virucidal activity against human norovirus when compared to 60% ethanol.[17] Activity of BK against gram-negative bacteria is limited, and it has been reported that BK based products have been contaminated with gram-negative bacteria due to lack of efficacy, with *Burkholderia cepacia* reportedly having resistance to this agent.[3,4,62] These findings indicate hand hygiene products with BK as the main active ingredient may not be suitable for use in health and care settings. Using the BS EN standard to provide evidence of effectiveness of a hand rub product requires comparison against a reference alcohol (60% propan-2-ol for bacteria and 70% ethanol for viruses), therefore if a hand rub meets the minimum requirements of the standard, then the results can provide evidence of superiority or equal effectiveness to an alcohol-based rub.

Hand wash

Generally, ABHR has been found to have greater efficacy than non-antimicrobial soap against certain pathogens (Rhinovirus, MRSA) [4,21,24] and more generally when reducing colony forming units on the hands of participants in vivo. [24,28,42,43] However, there are instances when the detergent properties of hand washing with soap and water are beneficial, for example, the physical removal of spores (for example

C. difficile)[19,35] which are resistant to the effects of alcohol; or when hands are visibly soiled.[25,26,27] Evidence is limited on whether the microbicidal properties of ABHR are better than those of antimicrobial soap: some evidence indicates that ABHR is better against certain pathogens [21,25,40,41,58] some evidence indicates that antimicrobial soap is better; [19,35,38] and some evidence indicates that there is no difference.[23,40] The available extant guidance considers ABHR to be more effective than both non-antimicrobial and antimicrobial soap.[1,2,4,5,61] Evidence for the effectiveness of other active ingredients when compared to both non-antimicrobial and antimicrobial soap was not available. Minimal evidence was found on the microbiological efficacy of hand wash alternatives, with one study finding an emollient based hand wash to be effective against SARS-CoV-2.[55]

Hand wipes

There is limited evidence for the minimum microbial efficacy of hand wipes. Hand wipes differ in active ingredients and formulation which make direct comparison challenging.[36-38] Hand wipes have been found to be ineffective at reducing bacteriophage MS2 (a surrogate for a nonenveloped human virus) on artificially contaminated hands [38] and are less effective at reducing microbial hand contamination than either antimicrobial [52] or non-antimicrobial soaps. [35,38] In comparison to ABHR, hand wipes have been found to be more effective at removing *C. difficile* spores, [35] *S. marcescens and Geobacillus*. *stearothermophilus*.[36] No evidence was found on the comparison between hand wipes and other non-alcohol-based hand rubs.

Several limitations exist within this body of evidence on microbiological efficacy of all hand hygiene products. In vitro studies are inherently limited in their methodologies which impacts on their applicability and transferability to health and care settings, particularly due to inconsistency in hand hygiene product contact/exposure times, dose, formulations, and type/strain of pathogen utilised in the studies. Similar inconsistencies are apparent with in-vivo studies, including variation in the method used to recover the test organism from the skin and hand hygiene technique. Furthermore, in several of the included studies, manufacturers are involved in funding of the studies or employ authors. Using a standard methodology as demonstrated in the BS EN standards would allow for greater synthesis of the

evidence base and more robust recommendations regarding minimum microbiological requirements for a hand hygiene product. There is also a need for well conducted clinical trials measuring hand hygiene product effectiveness in real life health and care settings and further investigation on yeasticidal and fungicidal activity of hand hygiene products. Other factors to consider in the selection of a hand hygiene product include: the wider scientific evidence base on the composition and active ingredients of a product, manufacturer's product specific data and evidence of broad-spectrum activity against common healthcare associated pathogens.

When should a hand rub product be used for hand hygiene?

In total, nine guidance documents were identified providing evidence for when a hand rub product should be used for hand hygiene. From the current update, this included four guidance documents graded as SIGN50 level 4 evidence.[1,2,61,62]
A further five guidance documents were included from the previous review (version 4.0), three of these were assessed as 'recommend' using the AGREE tool [4,5,16] and two were expert opinion and graded as SIGN50 level 4.[3, 63]

As previously mentioned, the available evidence suggests that ABHR has superior efficacy when compared to non-antimicrobial soap, but poorer effectiveness against spore forming organisms (see question three). Therefore, the existing guidance consistently recommends that ABHR of at least 60% alcohol concentration should be the preferred method for hand hygiene (Public Health Agency of Canada (PHAC), ANHHI, CDC, SHEA), with some guidance stating a maximum concentration of 90-95% (CDC, ANHHI, PHAC). Reasons for preferable use of ABHR include easy accessibility (for example being able to place ABHR stations at entrances to clinical environments, close to where direct care is being delivered or being able to carry in transport) leading to increased hand hygiene compliance, reduced cost, and efficacy against a broad spectrum of microorganisms.[1-5,16,61,62] However, much of the guidance fails to cite high quality or relevant evidence in support of this recommendation, along with lack of a transparent and robust methodology. The available guidance consistently recommends that ABHR should not be used if hands

are visibly contaminated/soiled, or when there is likely to be exposure to spore forming organisms (for example *C. difficile, B. anthracis*) or infectious diarrhoeal diseases (for example norovirus). [1-5,16,61-63] The use of hand rub may also be important when health and care settings are experiencing water quality issues, or water system related outbreaks.

Extant guidance recommends against the use of non-alcohol-based hand rubs in health and care settings.[1-5,61] However, the available guidance lacks sufficient appraisal of available evidence on non-alcohol-based hand rubs and international bodies such as the WHO and CDC acknowledge that the use of non-alcohol-based hand rub in health and care settings is an unresolved issue, with limited primary data on efficacy being reported.[61] There is also limited available evidence on the sporicidal activity of other active ingredients other than alcohol. As previously discussed, implementing the BS EN standards for any hand rub product (ABHR or non-alcohol based) can provide a benchmark for demonstrating sufficient microbiological efficacy against numerous pathogens, and this is not limited to those only containing alcohol as the active ingredient.

When should a hand wash product be used for hand hygiene?

Nine guidance documents contributed to the evidence on when a hand wash product should be used for hand hygiene in health and care settings. From the current update, this included four guidance documents graded as SIGN50 level 4 evidence.[1,2,61,62] A further five guidance documents were included from the previous review (version 4.0), three of these were graded as 'recommend' using the AGREE tool [4,5,16] and two were expert opinion and graded as SIGN50 level 4. [3, 63]

Existing guidance from the WHO, CDC, NICE, SHEA, EPIC3, PHAC and ANHHI recommend that hand washing with non-antimicrobial soap is the preferred method of hand hygiene when hands are visibly contaminated/soiled (with dirt, blood, body fluids) or when providing care to individuals with suspected/confirmed infection with a spore forming organism (for example *C. difficile, B. anthracis*) or gastrointestinal (GI)

infection (for example norovirus) due to ABHR being ineffective against spores.[1-5,16,19,35,61,62]

CDC guidance states that either non-antimicrobial soap or antimicrobial soap is appropriate for washing visibly contaminated/soiled hands or when there is exposure to spore forming organisms or infectious diarrhoea.[3] However, most of the extant guidance (CDC, WHO, ANHHI, CPHA) do not recommend the routine use of antimicrobial soaps for hand hygiene, noting that plain soap and water is sufficient and prolonged use of antimicrobial soap can lead to skin complaints.[1,3,4,61]

How often can a hand rub product be used consecutively in place of hand washing?

Where hand rubbing is the preferred method for hand hygiene, consecutive use is likely and there is the possibility of product build-up on the hands. [61] Three expert opinion-based guidance documents, graded SIGN 50 level 4 were identified.[2,3,61] One guidance document (ANHHI) states that there is no maximum number of times the hands can be decontaminated with hand rub before washing with soap and water. However, this guidance lacked information on evidence sources that informed the recommendations.[2] In practice, any notable product build-up or sticky/tacky residue on the hands may indicate that a hand wash is required. Similarly, CDC (2002) suggest that if health and care staff feel an accumulation of emollient from ABHR on their hands after repeated use, washing hands with soap and water after five to 10 applications of a products is recommended by certain manufacturers.

When should a hand wipe product be used for hand hygiene?

Four guidance documents were identified providing evidence for the use of hand wipe products in health and care settings. All were graded SIGN 50 level 4 evidence. One guidance document from the Royal College of Nursing (RCN) [63] was from the

previous literature review (version 4.0), with three additions from the current update (SHEA, PHAC, ANHHI).[1,61,62]

The consensus among the guidance (RCN, SHEA, CPHA, ANHHI) is that hand wipes should not be routinely used for hand hygiene but can be beneficial for hand hygiene in situations where there is no access to hand washing facilities, for example in community care when there is no access to running water or hand rub, or when handwashing facilities are unsuitable due to contamination.[1,61,63] Hand wipes may also be useful when hands are visibly soiled, there is no access to running water or for bedbound individuals. SHEA guidelines do not recommend hand wipe use due to the lack of available data and recommend the need for further research in this area.[61, 62]

Are there any constraints to the use of hand hygiene products?

Ten pieces of evidence were identified in the literature providing evidence for the constraints to the use of hand rub products. This included one sampling study,[64] two case reports [65,66] and seven guidance documents.[1-5,62,67] In accordance with SIGN 50 methodology, the sampling study and case reports were graded as SIGN 50 level 3. Three guidance documents were assessed using the AGREE tool and rated 'recommend' [4,5,67] and the other four guidance documents graded as SIGN 50 level 4.[1-3,62]

The risks associated with ABHR identified in the literature predominantly focus on the ingestion of these products, whether that be intentional or unintentional. Three known cases of ABHR consumption in hospital settings were reported in the literature, two of which were in NHS England [66] and one in a South Korean hospital.[65] These cases emphasise the need for risk assessment to be undertaken in the clinical setting when placing ABHR dispensers.[65,66] Furthermore, many hand hygiene guidance documents (SHEA, WHO, CDC, AORN, ANHHI) acknowledge the risk of ingestion of ABHR, although state this is uncommon in health and care settings. [1,- 5,62,67] There is consistency in the recommendations, again emphasising the need for a point of care risk assessment to be undertaken when deemed

appropriate. It is important to note that not all ABHR ingestion incidents will be available in published research/case reports due to patient confidentiality. Therefore, there is a risk of underreporting.

Other considered constraints in the literature include the refilling and cleaning of hand hygiene product dispensers and the potential for these to become contaminated, for example the risk of introducing a pathogenic organism into the container from an external source. It is important that manufacturer's instructions are followed when refilling or replacing hand hygiene product containers/dispensers and that single use products are not refilled (rubs and soaps).[2,5,64] A study based in China sampled the nozzles of 50 automatic hand rub dispensers in clinical and non-clinical settings and reported the identification of gram-positive and gram-negative bacterial species, predominantly *Bacillus cereus, Staphylococcus* species and *Enterobacter cloacae*. Three of the *B. cereus* isolates survived treatment with 70% ethanol, indicating hand rub dispensers to be a potential transmission source.[61] It must be noted that this study failed to mention if the bacterial isolates came from the clinical or non-clinical hand dispensers and evidence on frequency of use and cleaning protocols was not available. However, this study highlights the need for appropriate cleaning of dispensers to minimise the risk of transmission in health and care settings.

Religious factors have also been considered as a constraint in the use of alcohol-based hand hygiene products due to alcohol consumption being prohibited in certain religions, however guidance from WHO states that studies have demonstrated insignificant rates of cutaneous alcohol absorption after ABHR use.[1,4] No further constraints to the use of hand hygiene products in health and care settings were identified in the literature (See skin care literature review for further information).

3.2 Implications for research

There continues to be uncertainty around the efficacy of antimicrobial hand wipes, non-alcohol-based hand rubs and hand washing emollients in the primary literature base therefore further high-quality research including randomised controlled trials in these areas is still required. Although there is sufficient consistency in the evidence base to allow synthesis and development of recommendations, there is considerable conflicting evidence on the effectiveness of the different hand hygiene products against different classes of microorganisms, specifically when comparing the effectiveness of different product classes. This is due to the heterogeneity of the included studies in terms of the product formulations, test organisms, hand decontamination protocols and the influence of different study designs. The validity of many of the included studies is limited by small sample sizes, in addition the techniques used for hand hygiene and the training of participants for many studies were poorly described or not described at all increasing the risk of bias in their conclusions. Following a common methodology when undertaking research such as BS EN standards for testing hand hygiene products would allow for homogeneity across the evidence base, providing a more robust evidence base and allow for greater translation of findings into recommendations.

4. Recommendations

This review makes the following recommendations based on an assessment of the extant scientific literature on hand hygiene products in the health and care setting.

What is a hand hygiene product and what is its purpose?

A hand hygiene product is a cleansing agent designed to remove or reduce pathogens from the hands (for example non-antimicrobial soap, antimicrobial soap, antimicrobial hand rub, and hand wipes).

(No recommendation)

Are there any legislative requirements and/or standards that hand hygiene products must adhere to?

Hand hygiene products intended for use in health and care settings should meet the obligatory and additional BS EN standards.

For a hand rub product this is bactericidal activity (BS EN 13727 phase 2, step 1 & BS EN 1500 phase 2, step 2) and yeasticidal activity (BS EN 13624 phase 2, step 1). Consideration should also be given to BS EN 17430 2022 (phase 2, step 2) for hand rub products.

For a hand wash product this is bactericidal activity (BS EN 13727 phase 2, step 1 & and EN1499 phase 2, step 2).

Additional BS EN standards for both hand rub and hand wash products include: tuberculocidal/mycobactericidal activity (BS EN 14348 phase 2, step 1) and virucidal activity (BS EN 14476 phase 2, step 1).

(Category C)

No legislative requirements for hand hygiene products were identified.

(No recommendation)

What are the minimum requirements for microbiological efficacy of hand hygiene products for health and care settings?

Hand hygiene products intended for use in health and care settings should have broad-spectrum antimicrobial activity (for example bactericidal, virucidal, yeasticidal, fungicidal).

Alcohol-based hand rub (ABHR) products should have a minimum of 60% alcohol concentration.

(Category B)

When should a hand rub product be used for hand hygiene?

A hand rub is the preferred product for hand hygiene in health and care settings.

A hand rub can be alcohol-based or non-alcohol based if the product has met the required **BS EN standards**.

A hand rub should not be used when hands are visibly contaminated/soiled, or when providing care to an individual with suspected/confirmed infection with a spore forming organism (for example *C. difficile* or *B. anthracis*) or infectious diarrhoeal disease (for example norovirus).

(Category C)

When should a hand wash product be used for hand hygiene?

Hands should be washed with non-antimicrobial liquid soap and water when visibly contaminated/soiled or when providing care to individuals with suspected/confirmed infection with a spore forming organism (for example *C.difficile*, *B.anthracis*) or gastrointestinal (GI) infection (for example norovirus).

If performing a hand wash before a clean/aseptic procedure and hand rub cannot be used, hands should be washed with antimicrobial liquid soap and water.

(Category C)

How often can a hand rub product be used consecutively in place of hand washing?

There is no maximum number of times a hand rub product can be used consecutively in place of handwash. If hands become sticky/tacky with any notable product build-up, they should be washed with liquid soap and water to remove residue.

Manufacturer's instructions should be followed.

(Category C)

When should a hand wipe product be used for hand hygiene?

Hand wipes should not be used for hand hygiene by staff, patients and service users in health and care settings unless there is no water (for example due to an estates issue). In these instances, staff, patients, and service users may use hand wipes followed by a hand rub (if available) and should perform hand hygiene at the first available opportunity.

(Category C)

Are there any constraints to the use of hand hygiene products?

A risk assessment should be conducted when placing hand rub dispensers to consider the risk of ingestion/unintended use.

Single-use hand hygiene product containers should not be refilled to reduce the risk of product contamination.

(Category C)

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Appendices

Appendix 1: BS EN Standards

This appendix provides a non-exhaustive list of standards pertaining to topic hand hygiene products. The standards listed represent the most recent versions available at the time of publication. Please note, however, standards are subject to amendments and the most recent versions should always be sourced and used in practice.

Standard	Title	Description	Hand hygiene product	Test pathogen(s)	Requirement to pass
BS EN 13727:2012+A2:2015	Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity in the medical area — Test method and requirements (phase 2, step 1)	Standard applies to hygienic hand rub, hygienic handwash and other surgical antisepsis products used in hospitals. In vitro testing.	Hand rub and wash	*P. aeruginosa* *S. aureus* *E. hirae* *E. coli K12*	The hand rub shall demonstrate at least a 5 decimal log reduction and for hygienic hand wash at least a 3-log reduction, when tested against test pathogen

Standard	Title	Description	Hand hygiene product	Test pathogen(s)	Requirement to pass
BS EN 1500:2013	Chemical disinfectants and antiseptics — Hygienic hand rub — Test method and requirements (phase 2/step 2)	Standard provides a test method for "simulating practical conditions for establishing whether a product for hygienic hand rub reduces the release of transient microbial flora on hands when rubbed onto the artificially contaminated hands of volunteers." The standard is specific for settings where disinfection is medically indicated, including hospitals.	Hand rub	*E. coli* K12	the mean reduction of the release of the test organism achieved by the hygienic hand rub with the product under test shall be at least not inferior to that achieved by a specified reference hygienic hand rub (60 % volume concentration of propan-2-ol)

Standard	Title	Description	Hand hygiene product	Test pathogen(s)	Requirement to pass
BS EN 14476-2013 plus A2-2019	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)	Standard describes a suspension test for establishing minimum requirements for a chemical disinfectant or an antiseptic against the test viruses. Phase 2, step 2 in vivo testing should also be complied with to demonstrate sufficient evaluation of the product being tested.	Hand rub and wash	Poliovirus Adenovirus Murine Norovirus Adenovirus Murine Vacciniavirus	The product shall demonstrate at least a decimal log reduction of 4 in virus titre when tested against pathogen
BS EN 17430 2022	Chemical disinfectants and antiseptics - Hygienic handrub virucidal - Test method and	Standard describes a test for establishing minimum requirements for hygienic handrub when applied to the	Hand rub	Murine norovirus	The mean reduction of the test organism achieved by the hygienic hand rub shall be at least not inferior to that

Standard	Title	Description	Hand hygiene product	Test pathogen(s)	Requirement to pass
	requirements (phase 2, step 2)	artificially contaminated hands of volunteers against the test virus – murine norovirus.			achieved by a specified reference hygienic hand rub (70 % concentration of ethanol)
BS EN 1499-2013	Chemical disinfectants and antiseptics — Hygienic handwash — Test method and requirements (phase 2/step 2)	Standard applies to hygienic hand rub using practical conditions for establishing whether the hygienic handwash reduces the release of transient microbial flora on hands when used to wash the artificially contaminated hands of volunteers.	Hand wash	*E. coli* K12	the mean reduction of the release of the test organism achieved by the hygienic handwash with the product under test shall be larger than that achieved by a specified reference hygienic handwash (unmedicated liquid soap)

Standard	Title	Description	Hand hygiene product	Test pathogen(s)	Requirement to pass
BS EN 13624:2022	Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area — Test method and requirements (phase 2, step 1)	specifies a test method and the minimum requirements for fungicidal or yeasticidal activity of chemical disinfectant and antiseptic products that form a homogeneous, physically stable preparation when diluted with hard water, or - in the case of ready-to-use products - with water.	Hand rub and wash	*Candida albicans*	The hand rub shall demonstrate at least a 4 decimal log reduction and for hygienic handwash at least a 2-log reduction, when tested against test pathogen
BS EN 14348	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of	Standard documents the method for assessing the minimum requirement of a	Hand rubs and wash	*Mycobacterium avium* and *Mycobacterium terrae*	If a product has at least a 4-log reduction compared to the control with *Mycobacterium*

Standard	Title	Description	Hand hygiene product	Test pathogen(s)	Requirement to pass
	mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants – test methods and requirements (phase 2, step1)	chemical disinfectant, including hand rubs and hygienic hand washes, against *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755.			*terrae* it is considered as possessing tuberculocidal activity
BS EN 14885: 2022	Chemical disinfectants and antiseptics. Application of European Standards for chemical disinfectants and antiseptics.	Standard can be described as a master document referring to all the procedures across the standards and providing information on the processes.	ALL	N/A	N/A

Appendix 2: Grades of recommendation

Grade	Descriptor	Levels of evidence
Mandatory	'Recommendations' that are directives from government policy, regulations, or legislation	N/A
Category A	Based on high to moderate quality evidence	SIGN level 1++, 1+, 2++, 2+, AGREE strongly recommend
Category B	Based on low to moderate quality of evidence which suggest net clinical benefits over harm	SIGN level 2+, 3, 4, AGREE recommend
Category C	Expert opinion, these may be formed by the NIPC groups when there is no robust professional or scientific literature available to inform guidance.	SIGN level 4, or opinion of NIPC group
No recommendation	Insufficient evidence to recommend one way or another	N/A

Appendix 3: PRISMA Flow Diagram