

**CADTH RAPID RESPONSE REPORT:
SUMMARY WITH CRITICAL APPRAISAL**

Non-Alcohol Based Hand Rubs: A Review of Clinical Effectiveness and Guidelines

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Context and Policy Issues

Antisepsis that uses running water and an aqueous solution is usually referred to as a “scrub”. Scrubs are commonly used by surgical staff for hand antisepsis during pre-surgical preparation, and contain agents, such as chlorhexidine gluconate or povidone iodine. Scrubbing involves wetting the hands and forearms with water, systematically applying the scrub solution using hands or sponges and rinsing under running water. This process typically takes up to six minutes. The term “rub” usually refers to hand antisepsis procedures and products that do not require running water. The most commonly used rub products contain at least 60% alcohol (v/v).

Alcohol-based rubs have a well-established role in infection control strategy in healthcare settings for routine hand sanitization,¹⁻⁴ including hospitals, outpatient clinics, laboratory settings, community settings and for hand sanitization in surgical contexts.⁵⁻⁸ The ubiquitous usage of alcohol-based rubs is based on evidence for reduced infectious transmission, low cost, and their high acceptability and tolerability relative to other methods of sanitization.^{9,10} Nevertheless, there have been some concerns associated with the usage of alcohol-based hand sanitizers, such as religious objections, abuse potential, and flammability.³ These concerns, combined with a desire to optimize infection control and user acceptability, has led to the development of several non-alcohol based hand rub products. These products use antimicrobial agents such as triclosan, chlorhexidine, iodophors or quaternary ammonium compounds; various combinations and formulations have been developed (e.g., water-based, foams, gels, nanocapsules).^{11,12}

The purpose of this report is to review the evidence regarding the effectiveness of non-alcohol based hand sanitizer (rubs) for reducing infection rates and infection transmission in the healthcare setting for both healthcare workers and non-healthcare personnel. Another objective of this report is to summarize evidence-based guidelines regarding the use of non-alcohol based hand rubs.

Research Questions

1. What is the clinical effectiveness of non-alcohol based hand rubs?
2. What are the evidence-based guidelines regarding the use of non-alcohol based hand rubs?
3. What are the evidence-based guidelines regarding the discontinuation of alcohol-based hand rubs?

Key Findings

Two studies demonstrated the antimicrobial activity of a product containing chlorhexidine and a product containing polyhexamethylene guanidine. The impact on infection and infection transmission remains unknown. Four guidelines recommended the use of alcohol-based rubs in the healthcare setting, and two of these guidelines explicitly recommend against the use of non-alcohol based rubs.

Methods

Literature Search Methods

This report makes use of a literature search strategy developed for a previous CADTH report. For the current report, a limited literature search was conducted on key resources including Medline, PubMed, OVID, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. For research questions 1 and 2, no filters were applied to limit retrieval by study type. For research question 3 methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, and guidelines. Where possible, retrieval was limited to the human population. For all research questions the search was limited to English-language documents published between January 1, 2005 and February 14, 2017. Rapid Response reports are organized so that the evidence for each research question is presented separately.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients in the hospital and residential care setting (including common areas)
Intervention	Questions 1 and 2: Non-alcohol based hand rubs Question 3: Alcohol-based hand rubs Including gel or foam formulations.
Comparator	Question 1: Alcohol-based hand rubs Questions 2 and 3: No comparator required
Outcomes	Question 1: Clinical benefit (e.g., infection transmission, infection rate); Harms (e.g., rate of abuse, superficial skin infection or irritation) Question 2: Evidence-based guideline recommendations regarding the use of non-alcohol based hand rubs; Question 3: Evidence-based guideline recommendations regarding the discontinuation of alcohol-based hand rubs
Study Designs	Health technology assessments (HTAs), systematic reviews (SRs), or meta-analyses (MA), randomized controlled studies, non-randomized studies, guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2005.

This report did not examine the use of water-based scrub hand sanitizing. In the literature on this topic, antiseptics that use running water and an aqueous solution is usually referred to as a “scrub”. Antiseptics with an alcohol solution is often referred to as an alcohol rub or a waterless scrub. If studies used the term “scrub” or “wash” and did not indicate a waterless procedure, these interventions were deemed not relevant for the purposes of this report and were excluded. Studies that used a brush or sponge during the scrub application procedure were deemed not relevant for this report.

Critical Appraisal of Individual Studies

The non-randomized studies were critically appraised using the Downs and Black instrument¹³ and guidelines were assessed with the AGREE II instrument.¹⁴ Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described.

Summary of Evidence

Quantity of Research Available

A total of 536 citations were identified in the literature search. Following screening of titles and abstracts, 518 citations were excluded and 18 potentially relevant reports from the electronic search were retrieved for full-text review. 12 potentially relevant publications were retrieved from the grey literature search. Of these potentially relevant articles, 24 publications were excluded for various reasons, while six publications met the inclusion criteria and were included in this report. Appendix 1 describes the PRISMA flowchart of the study selection.

Additional references of potential interest are provided in Appendix 5.

Summary of Study Characteristics

Two studies^{11,15} and four guidelines²⁻⁶ met the inclusion criteria for this report. Detailed characteristics of the studies and a description of the guidelines can be found in Appendices 2,4.

Study Design

Both studies used non-randomized, open-label designs.^{11,15} Each study had two separate phases, and used crossover methodology in one of the phases.

All four guidelines used methods that included a systematic literature search and grading of the evidence or recommendations.²⁻⁶

Country of Origin

One study was performed in Finland,¹⁵ and the second study was performed in France.¹¹

The guidelines were written by experts based in Canada (Ontario-based or federally initiated),^{2,3} the United Kingdom^{5,6} or internationally (initiated in Switzerland by the World Health Organization WHO).⁴

Patient Population

One study was performed in hospital workers in acute or non-acute hospital wards (N=125) and in volunteers (N=20).¹⁵ The second study was performed in volunteers, but the setting and the source of the volunteers were not described (N=13).¹¹

Target Audience

The target audience of the guidelines included healthcare workers and personnel responsible for developing policies for hand hygiene in healthcare settings.²⁻⁶

Interventions and Comparators

One study compared alcohol-based hand disinfectant to a water-based hand disinfectant containing polyhexamethylene guanidine (Desisoft, Soft Protector).¹⁵ The second study compared 2-propanol 60% rub to chlorhexidine nanocapsules (Nanochlorex).¹¹

All four guidelines discussed the role of alcohol-based rubs. One guideline provided summary data from studies that used non-alcohol based hand sanitizers (rubs and scrubs).⁴

Outcomes

One study was designed to measure transepidermal water loss with a vapometer, monitor adverse effects, such as eczema, analysis of colony forming units (CFU) from fingerprints before and after water based disinfectant (no alcohol control was used for this CFU analysis).¹⁵ This study also applied a standardized European test method (EN 12791) for chemical disinfectants, which included CFU analysis. The second study measured impact of the hand rubs on CFU, distinguishing impact on aerobic and anaerobic bacteria, and comparing immediate (30 seconds after hand rub application) with delayed effects (3 minutes after hand rub application).¹¹

Summary of Critical Appraisal

Details regarding the critical appraisal can be found in Appendix 3.

The lack of randomization and blinding in both studies increases the risk of bias.^{11,15} One of the trials was sponsored by the manufacturer of the non-alcohol based hand rub and the first author was a consultant for the manufacturer.¹⁵ There was no justification for the sample size in either trial, which increases uncertainty in interpreting outcomes that showed similar effectiveness; where similar results were observed between the two hand rubs, it is unknown if this is related to inadequate sample size or is an indication that the two products are equally effective. Objective microbiological endpoints were utilized in both studies, but neither study was designed to evaluate clinical outcomes, such as disease transmission or infection rates.

All four guidelines had explicitly defined objectives, and the guideline authors included experts with relevant qualifications.²⁻⁶ All four guidelines used methodology that included a systematic literature review, though the criteria for study selection were not explicit in any of the guidelines. All four guidelines utilized a system of grading the supporting evidence and/or recommendations.

Summary of Findings

1. What is the clinical effectiveness of non-alcohol based hand rubs?

No clinical outcomes such as disease transmission or incidence of infection, were measured in either study.

In vitro antimicrobial effects

One study demonstrated that colonization of the fingertips was reduced after application of a guanidine-based product, based on in vitro CFU counts from a total of 268 fingerprint samples from healthcare workers (N=99, no comparator group).¹⁵ The authors also observed that after 3 minutes of disinfection using the invitro EN12791 test procedure (N=20 volunteers), the reduction in CFUs for the guanidine group was greater than the reduction in CFUs for the alcohol-based group. The authors concluded that the product met the European standard based on these results.

Another study showed that there were no significant differences between 2-propanol 60% and a chlorhexidine nanocapsular product for the change in resident skin flora after application of the hand rub (N=5).¹¹ Both products resulted in significant reductions in aerobic bacteria when pre and post values were compared but only the chlorhexidine product resulted in significant reductions in anaerobic bacteria counts, relative to pre-rub values. Application of 2-propanol 60% did not result in significant changes in anaerobic bacteria counts, relative to pre-rub values.

There were no significant differences in bactericidal activity 30 seconds following a hand rub with chlorhexidine nanocapsule product relative to 62% ethanol gel (N=8).¹¹ At 3 hours following a hand rub, the reduction in resident skin flora was greater with the chlorhexidine product relative to the 62% ethanol gel.

Ex vivo antimicrobial effects

An ex vivo test was used to study the rub activity against repeated contaminations of human skin by *S. epidermidis*.¹¹ Human skin specimens initially treated by either the chlorhexidine product or the 62% ethanol gel for 5 min and then were artificially contaminated. The chlorhexidine product had greater reductions in bacterial counts compared to the 62% ethanol gel up after 3 successive contaminations, up to 2 hours after the first contamination. After the fourth contamination at the 3 hour mark, there was no difference between the products in bacterial counts.

2. What are the evidence-based guidelines regarding the use of non-alcohol based hand rubs?

The “WHO Guidelines on Hand Hygiene in Health Care” (2009) recommended that alcohol-based rubs be used for routine hand antisepsis and the authors considered this a strong recommendation supported by good quality evidence.⁴ Alcohol-based rubs were considered by the authors to be “the gold standard for hand hygiene in health care.” Several studies on non-alcohol based rubs were individually mentioned in the guidelines, but there were no conclusions, quantitative summaries, systematic critical appraisal, or recommendations made regarding non-alcohol based rubs.

The Public Health Agency of Canada “Hand Hygiene Practices in Healthcare Setting” (2012) stated that alcohol preparations are more effective antimicrobials agents than chlorhexidine and povidone iodine, but the authors did not provide context for this statement and the statement does not appear to apply to “rub” products. The guideline also stated that “there are no efficacy data on [non-alcoholic rubs] and they should not be used for hand hygiene in healthcare settings.”² The authors

recommended alcohol-based hand rub as the preferred method of hand hygiene in all healthcare settings.

Public Health Ontario published the “Best Practices for Hand Hygiene in All Health care Settings” (2014).³ The authors recommended against using non-alcohol based waterless antiseptic agents for hand hygiene in health care settings. According to the ranking system used, this was based on moderate quality evidence “from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies, preferably from more than one centre, from multiple time series, or from dramatic results in uncontrolled experiments.”

The National Institute for Clinical Excellence (NICE) commissioned a 2008 guideline on prevention and treatment of surgical site infection.^{5,6} It covered a broad range of topics related to preoperative, intraoperative and postoperative infection prevention and treatment. It also included a short section on hand hygiene which recommended using alcohol-based rubs for hand sanitizing between procedures. The recommendation was based on a single study that compared an alcohol based rub with a chlorhexidine scrub.

3. *What are the evidence-based guidelines regarding the discontinuation of alcohol-based hand rubs?*

Even though no guidelines were identified whose objectives were to assess the discontinuation of alcohol-based hand rubs, this topic was mentioned briefly in the “WHO Guidelines on Hand Hygiene in Health Care” (2009). The guidelines stated that although alcohol-based hand rubs may not be effective against *C. difficile*, it has not been shown that they trigger the rise of *C. difficile*-associated disease.⁴ The authors, therefore, recommended against abandoning alcohol-based hand rubs because of the overall potential negative impact on infection rates, except in the context of outbreaks of spore-forming pathogens (e.g. *C. difficile*).

Limitations

The generalizability of the results of the two studies is limited. The two studies examined the effects of specific formulations of chlorhexidine and guanidine-based products and the generalizability of the study results to other chemicals or other formulations of the same chemicals is unknown.

The main limitation of the guidelines was that there was very little discussion on the evidence for non-alcohol based hand rubs. The WHO guideline provided the most extensive summary of relevant individual studies, but there was very little critical appraisal of the studies. As well, it was often not clear whether the non-alcohol based products mentioned were “rubs” or “scrubs”.

Conclusions and Implications for Decision or Policy Making

Low to moderate quality evidence from two non-randomized studies suggested that a guanidine-based rub and a nanocapsule chlorhexidine gel have antibacterial activity against flora found on the hands of healthcare workers and volunteers. The effectiveness of different formulations of these chemicals and the impact of these products on infection and infection transmission rates are unknown.

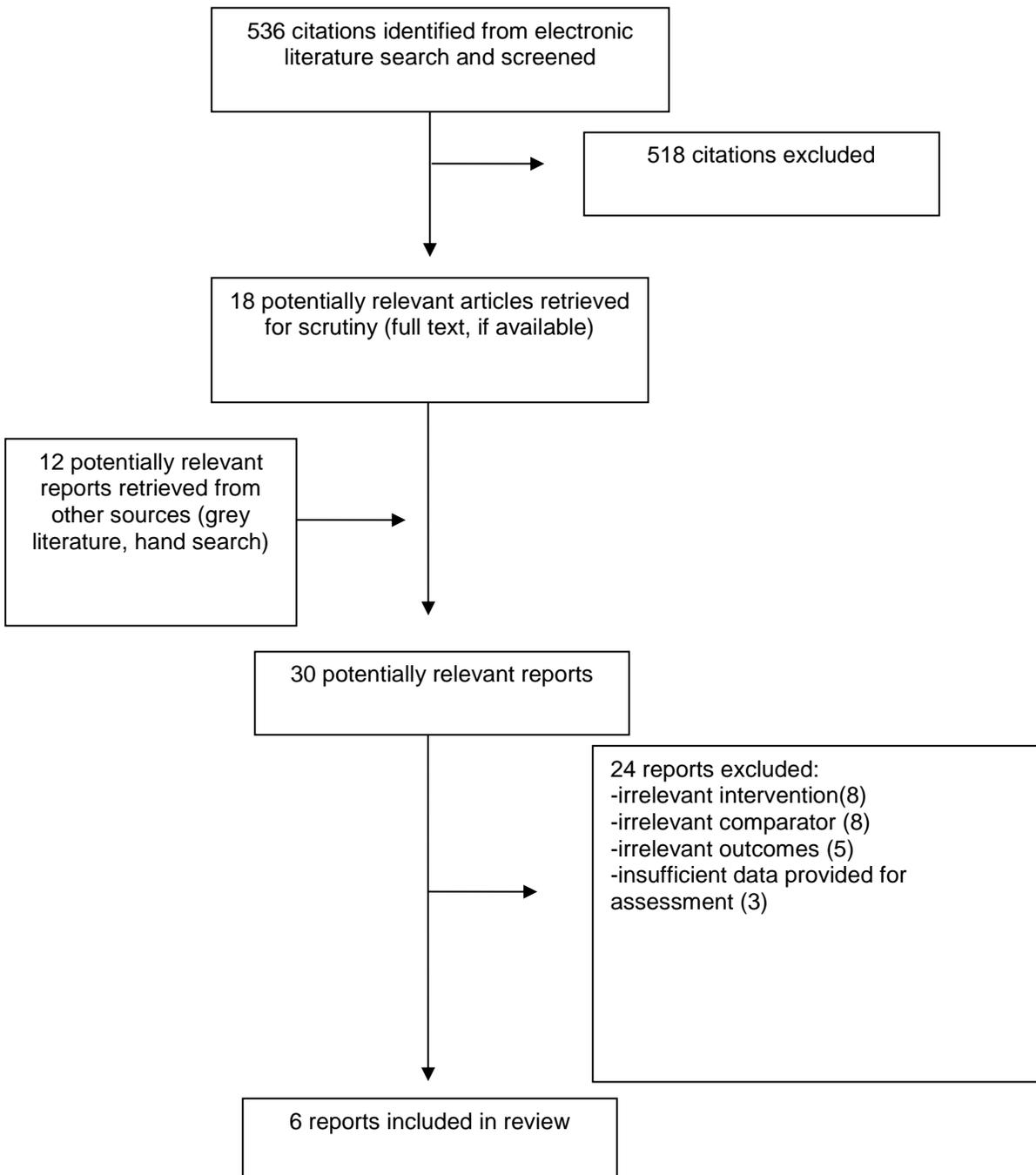
Four moderate-to-high quality evidence-based guidelines provided recommendations on selection of hand rub products in healthcare settings. None of the guidelines gave positive recommendations for use of non-alcohol based hand rubs. Two Canadian guidelines explicitly recommended against using non-alcohol based hand rubs.

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Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table A1: Characteristics of Included Clinical Studies

First Author, Year, Country	Study Design	Subject Characteristics	Intervention(s)	Comparator(s)	Outcomes
Agthe 2009 ¹⁵ Study was conducted in one hospital in Finland	Part 1. Non randomized, open-label, in hospital, included microbiological testing and skin observation Part 2. Invitro European standard #EN12791 microbiological testing, used a crossover design, open-label	Part 1. Water based disinfectant group (N= 99, healthcare workers in acute and non-acute care hospital wards) vs alcohol-based disinfectant group (N=26, healthcare workers in acute care ward) Part 2. N=20 volunteers	Part 1. Water based disinfectant (Desisoft, Soft Protector, polyhexamethylene guanidine) was introduced as the only disinfectant for 7 weeks for healthcare workers in acute and non-acute wards Part 2. Desisoft	Part 1. The regular alcohol-based disinfectant was used normally in one acute care ward (brand not stated) Part 2. 60% n-propanol was used	Part 1. Transepidermal water loss; skin inspection for eczema; CFU from fingerprint before versus after using water based disinfectant (no alcohol control was used for this CFU analysis) Part 2. Mean number of CFUs cultured from fingertips
Nhung 2007 ¹¹ France	Part 1: hand rub for 30 seconds, followed by complete drying, crossover design, open-label, non-randomized Part 2: hand rub for 30 seconds until completely dry, non- randomized, open-label	Part 1: N=5 Part 2: N=8	Part 1: One application of 1 mL of Nanochlorex rub (chlorhexidine nanocapsules); Part 2: 3 mL of Nanochlorex	Part 1: One application of 1mL of 2-propanol 60% rub; Part 2: 3 ml of Purell (62% ethanol gel)	Part 1: CFUs were counted for aerobic and anaerobic bacteria, after samples were incubated for 48 hours from the subjects' hands, Part 2: Outcomes obtained using the "glove-juice" technique. Post rub samples were taken at 30 seconds after rub and 3 hours after rub

CFU= colony forming unit

Table A2: Characteristics of Included Guidelines

Intended users/ target population	Interventions and practice considered	Outcomes considered	Evidence Collection, Selection, Synthesis	Recommendations development and evaluation	Guideline validation
WHO Guidelines on Hand Hygiene in Health Care (2009)⁴					
Healthcare workers, hospital administrators, health authorities	Behavioural changes, WHO-recommended hand antiseptics formulations, glove use and reuse, water quality for handwashing, religious and cultural aspects, advocacy/communication/campaigning	Healthcare associated infection, transmission of pathogens by hands, invitro culture growth,	Searches of MEDLINE, EMBASE, Cochrane Library	Four categories used to rank strength of recommendations and supportive evidence	Pilot tested the guidelines in several sites in different countries
PHAC Hand Hygiene Practices in Healthcare Settings (2012)²					
Professionals responsible for developing policies for hand hygiene in healthcare settings	Transmission of microorganisms by contaminated hands, impact of hand hygiene, hand hygiene programs, methods and products for hand hygiene, organizational barriers to effective hand hygiene	Efficacy, tolerability	Literature search from 1996	Used predefined criteria for rating evidence on which the recommendations were based (6 categories)	Not stated
Public Health Ontario: Best Practices for Hand Hygiene in All Healthcare Settings (2014)³					
Recommendations intended for use for health care providers, staff in any healthcare setting	Best practices for hand hygiene, products, hand sanitizing techniques, selection of hand hygiene products, behaviour, motivation, education, monitoring	Efficacy, tolerability	Systematic literature search	Used a 5-category system for grading strength of recommendation and 3 categories for grading the quality of evidence	Not stated
NICE: Surgical site infection prevention and treatment of surgical site infection (2008)^{5,6}					
Healthcare workers, healthcare managers, surgical patients	Guidance on the patient's journey throughout the preoperative, intraoperative and postoperative phases of surgery. There is one section on hand hygiene.	Efficacy, cost effectiveness	Systematic literature search including MEDLINE, EMBASE, Cochrane, CINAHL	Predefined levels of evidence and grades for recommendations.	Not stated

CADTH = Canadian Agency for Drugs and Technologies in Health; PHAC= Public Health Agency of Canada; RCT = randomized controlled trial; WHO= World Health Organization;

Appendix 3: Critical Appraisal of Included Publications

Table A3: Strengths and Limitations of Studies using Downs and Black¹³

Strengths	Limitations	Irrelevant Items
Agthe et al (2009) ¹⁵		
<p>Reporting</p> <ul style="list-style-type: none"> The objectives were described. The main outcomes were described. The interventions were described. The main findings were described. Estimates of the random variability in the data for the main outcomes were presented. Important adverse events were reported (e.g. impact on skin moisture). Actual probability values were reported. <p>Internal Validity - Bias</p> <ul style="list-style-type: none"> The study applied a test procedure using a standardized European test (EN 12791) for chemical disinfectants. 	<p>Reporting</p> <ul style="list-style-type: none"> The characteristics of the subjects were not well described. The distribution of potential confounders in each intervention group was not described. The characteristics of subjects lost to follow up were not described. <p>External Validity</p> <ul style="list-style-type: none"> It is unclear if the patients asked to participate in the study were representative of the entire population from which they were recruited. It is unclear if the patients who agreed to participate in the study were representative of the entire population from which they were recruited. It is unclear if the trial setting is representative of the setting in which the majority of patients will receive the intervention. No clinically important outcomes were measured (e.g. impact on infection and infection transmission). <p>Internal Validity - Bias</p> <ul style="list-style-type: none"> No attempt was made to blind subjects or those measuring outcomes, to the interventions the subjects received. It is not clear whether all the results reported were planned at the outset of the study. Statistical tests used to assess the main outcomes were not well described, therefore, not able to assess appropriateness. Compliance with the study interventions was not described. No alcohol-based control group was used for the microbiology testing during the phase of the study that was hospital based (Part 1). <p>Internal Validity – Confounding</p> <ul style="list-style-type: none"> Subjects were not randomized to intervention groups. The authors did not adjust the results for potential confounding variables. 	<p>Internal Validity/Reporting</p> <ul style="list-style-type: none"> Follow up was not part of the study design. <p>Internal Validity – Confounding</p> <ul style="list-style-type: none"> Part 1 of the study was a single arm design. Part 2 of the study was a crossover design, therefore the question regarding recruitment of intervention and control subjects from the same population at the same time does not apply. Subjects were not randomized; therefore, allocation concealment is not relevant.

Strengths	Limitations	Irrelevant Items
	<p>Power</p> <ul style="list-style-type: none"> There was no description of sample size estimation procedures. <p>Funding</p> <ul style="list-style-type: none"> The study received financial support from the manufacturer of the water-based intervention. The lead author was a consultant to the manufacturer. 	
<p>Nhung et al (2007)¹¹</p>		
<p>Reporting</p> <ul style="list-style-type: none"> The objectives were described. The main outcomes were described. The interventions were described. The main findings were described. Estimates of the random variability in the data for the main outcomes were presented. <p>Internal Validity - Bias</p> <ul style="list-style-type: none"> References were provided to support the choice of study design. 	<p>Reporting</p> <ul style="list-style-type: none"> Adverse events were not reported. Actual probability values were not consistently reported. The characteristics of the subjects were not well described. The distribution of potential confounders in each intervention group was not described. Follow up was not well described. <p>External Validity</p> <ul style="list-style-type: none"> It is unclear if the patients asked to participate in the study were representative of the entire population from which they were recruited. It is unclear if the patients who agreed to participate in the study were representative of the entire population from which they were recruited. It is unclear if the trial setting is representative of the setting in which the majority of patients will receive the intervention. No clinically important outcomes were measured (e.g. impact on infection and infection transmission). Nanochlorex is a uniquely formulated product. It is not known if the results can be extrapolated to other chlorhexidine rub products. <p>Internal Validity - Bias</p> <ul style="list-style-type: none"> No attempt was made to blind subjects or those measuring outcomes, to the interventions the subjects received. It is not clear whether all the results reported were planned at the outset of the study. Statistical tests used to assess the main outcomes were not well described, therefore, not able to assess appropriateness. Compliance with the study interventions was not described. 	<p>Internal Validity – Confounding</p> <ul style="list-style-type: none"> The study used a crossover design, therefore the question regarding recruitment of intervention and control subjects from the same population at the same time does not apply. Subjects were not randomized; therefore, allocation concealment is not relevant.

Strengths	Limitations	Irrelevant Items
	<p>Internal Validity – Confounding</p> <ul style="list-style-type: none"> Subjects were not randomized to intervention groups. The authors did not adjust the results for potential confounding variables. <p>Power</p> <ul style="list-style-type: none"> There was no description of sample size estimation procedures. 	

Table A4: Strengths and Limitations of Guidelines using AGREE II¹⁴

Strengths	Limitations
WHO Guidelines on Hand Hygiene in Health Care (2009) ⁴	
<p>Scope and Purpose</p> <ul style="list-style-type: none"> The objectives were described. The health questions were described. Target populations were described. <p>Stakeholder Involvement</p> <ul style="list-style-type: none"> The guideline was developed by individuals with relevant professional backgrounds. Target users were described. Views of the target population were sought. Pilot tested the guidelines in several sites in different countries. <p>Rigour of development</p> <ul style="list-style-type: none"> Systematic methods were used to search for evidence. Strengths and limitations of the evidence were described.’ Health benefits, side effects and risks were considered in formulating the recommendations. The guideline was externally reviewed by experts prior to its publication. A timeline for updating the guideline was provided (but appears to have not been followed). The link between recommendations and the supporting evidence was explicit. <p>Clarity of Presentation</p> <ul style="list-style-type: none"> The recommendations are specific and unambiguous. The different options for management of the health issue are clearly presented. Key recommendations are easily identifiable. <p>Applicability</p> <ul style="list-style-type: none"> The guideline provides advice on how the recommendations can be put into practice. The guideline described facilitators of and barriers to its application. The potential resource implications of applying the recommendations were considered. 	<p>Rigour of development</p> <ul style="list-style-type: none"> Systematic methods were used to search for evidence. Criteria for selecting the evidence were not fully described. Methods for formulating the recommendations were not clearly described. <p>Applicability</p> <ul style="list-style-type: none"> The guideline does not present full auditing criteria.

Strengths	Limitations
<p>Editorial Independence</p> <ul style="list-style-type: none"> This guideline was funded by the WHO. Authors stated competing interests. 	
<p>PHAC Hand Hygiene Practices in Healthcare Settings (2012)²</p>	
<p>Scope and Purpose</p> <ul style="list-style-type: none"> The objectives were described. The health questions were described. Target populations were described. <p>Stakeholder Involvement</p> <ul style="list-style-type: none"> The guideline was developed by individuals with relevant professional backgrounds. Target users were described. <p>Rigour of development</p> <ul style="list-style-type: none"> Authors stated that they performed a “thorough” literature search including citations after 1996 but no further details were given. Methods for formulating the recommendations were clearly described. Quality of evidence was assessed. Health benefits, side effects and risks were considered in formulating the recommendations. The guideline was externally reviewed by experts prior to its publication. The link between recommendations and the supporting evidence was explicit. <p>Clarity of Presentation</p> <ul style="list-style-type: none"> The recommendations are specific and unambiguous. The different options for management of the health issue are clearly presented. Key recommendations are easily identifiable. <p>Applicability</p> <ul style="list-style-type: none"> The guideline provides advice on how the recommendations can be put into practice. <p>Editorial Independence</p> <ul style="list-style-type: none"> This guideline was funded by the Public Health Agency of Canada. Authors stated competing interests. 	<p>Rigour of development</p> <ul style="list-style-type: none"> Criteria for selecting the evidence were not fully described. <p>Applicability</p> <ul style="list-style-type: none"> The guideline does not present full auditing criteria. The guideline did not describe facilitators of and barriers to its application. The potential resource implications of applying the recommendations were not discussed. There was no explicit analysis of studies that included non-alcohol based rubs.
<p>Public Health Ontario: Best Practices for Hand Hygiene in All Healthcare Settings (2014)³</p>	
<p>Scope and Purpose</p> <ul style="list-style-type: none"> The objectives were described. The health questions were described. Target populations were described. <p>Stakeholder Involvement</p> <ul style="list-style-type: none"> The guideline was developed by individuals with relevant professional backgrounds. Target users were described. <p>Rigour of development</p> <ul style="list-style-type: none"> Systematic literature search was performed. 	<p>Rigour of development</p> <ul style="list-style-type: none"> Criteria for selecting the evidence were not fully described. References in support of the recommendation were not always provided in the context of the recommendation. Methods for formulating the recommendations were not explicitly described. <p>Applicability</p> <ul style="list-style-type: none"> The guideline does not present full auditing criteria. The potential resource implications of

Strengths	Limitations
<ul style="list-style-type: none"> Recommendations were stated clearly and each was given a rank based on the strength of the recommendation and quality of the evidence. Health benefits, side effects and risks were considered in formulating the recommendations. External experts were involved in the development of the guideline. The guideline states that it will be updated when new evidence is available. <p>Clarity of Presentation</p> <ul style="list-style-type: none"> The recommendations are specific and unambiguous. The different options for management of the health issue are clearly presented. Key recommendations are easily identifiable. <p>Applicability</p> <ul style="list-style-type: none"> The guideline provides advice on how the recommendations can be put into practice. The guideline describes some facilitators of and barriers to its application. <p>Editorial Independence</p> <ul style="list-style-type: none"> This guideline was funded by the Public Health Ontario. 	<p>applying the recommendations were not discussed.</p> <p>Editorial Independence</p> <ul style="list-style-type: none"> Competing interests of the guideline developers were not stated.
<p>NICE: Surgical site infection prevention and treatment of surgical site infection (2008)^{5,6}</p>	
<p>Scope and Purpose</p> <ul style="list-style-type: none"> The objectives were described. The health questions were described. Target populations were described. <p>Stakeholder Involvement</p> <ul style="list-style-type: none"> The guideline was developed by individuals with relevant professional backgrounds and public membership. Target users were described. <p>Rigour of development</p> <ul style="list-style-type: none"> Systematic literature search was performed. Recommendations were stated clearly and the evidence was discussed in context. Health benefits, side effects and risks were considered in formulating the recommendations. External experts were involved in the development of the guideline. The guideline states that it will be updated every four years. <p>Clarity of Presentation</p> <ul style="list-style-type: none"> The recommendations are specific and unambiguous. The different options for management of the health issue are clearly presented. Key recommendations are easily identifiable. <p>Applicability</p> <ul style="list-style-type: none"> The guideline provides advice on how the recommendations can be put into practice. The guideline describes some facilitators of and barriers to its application. The potential resource implications of applying the recommendations were discussed. 	<p>Rigour of development</p> <ul style="list-style-type: none"> Criteria for selecting the evidence were not clearly described. Methods for formulating the recommendations were not explicitly described. <p>Applicability</p> <ul style="list-style-type: none"> The guideline does not present full auditing criteria. One section of the report was dedicated to the use of hand rubs. The recommendations for intraoperative use of alcohol hand rub were based on only one study.

Strengths	Limitations
Editorial Independence <ul style="list-style-type: none"> This guideline was funded by the National Institute for Clinical Excellence. Competing interests were stated by the contributors. 	

NICE= National Institute of Clinical Excellence; PHAC= Public Health Agency of Canada; RCT = randomized controlled trial; WHO= World Health Organization

Appendix 4: Main Study Findings and Author’s Conclusions

Table A5: Summary of Findings of Included Studies

Main Study Findings	Author’s Conclusion
Agthe 2009 ¹⁵	
<p>Part 1 (no comparator product used)</p> <p>CFUs recovered from hands of healthcare workers after the use of water based disinfectant, number of subjects(%)</p> <ul style="list-style-type: none"> • First sampling <ul style="list-style-type: none"> ○ Before disinfectant <ul style="list-style-type: none"> ▪ 0-10 CFUs: 32(50) ▪ 11-99 CFUs: 17(27) ▪ 100-199 CFUs: 11(17) ▪ ≥200 CFUs: 4(6) ○ After disinfectant <ul style="list-style-type: none"> ▪ 0-10 CFUs: 60(90) ▪ 11-99 CFUs: 3(4) ▪ 100-199 CFUs: 4(6) ▪ ≥200 CFUs: 0 • Second sampling <ul style="list-style-type: none"> ○ Before disinfectant <ul style="list-style-type: none"> ▪ 0-10 CFUs: 19(58) ▪ 11-99 CFUs: 7(21) ▪ 100-199 CFUs: 6(18) ▪ ≥200 CFUs: 1(3) ○ After disinfectant <ul style="list-style-type: none"> ▪ 0-10 CFUs: 29(88) ▪ 11-99 CFUs: 3(9) ▪ 100-199 CFUs: 1(3) ▪ ≥200 CFUs: 0 • Third sampling <ul style="list-style-type: none"> ○ Before disinfectant <ul style="list-style-type: none"> ▪ 0-10 CFUs: 23(55) ▪ 11-99 CFUs: 16(38) ▪ 100-199 CFUs: 3(7) ▪ ≥200 CFUs: 0 ○ After disinfectant <ul style="list-style-type: none"> ▪ 0-10 CFUs: 43(93) ▪ 11-99 CFUs: 3(7) ▪ 100-199 CFUs: 0 ▪ ≥200 CFUs: 0 • No statistically significant differences were observed for subjective assessments of dryness and eczema between the water-based (based on 174 observations) and alcohol-based (based on 43 observations) groups. • Users of the water-based hand disinfectant reported drying and itching of the skin more often than the control subjects (39% vs 17%; P=0.019) <p>Part 2 (alcohol-based comparator product was used)</p>	<p>Part 1</p> <ul style="list-style-type: none"> • Colonization of the fingertips was reduced based on the number of CFUs counted before disinfection compared to the number after disinfection (P<0.01). • The users of the water-based hand disinfectant reported dry skin more often than did control subjects, but visual inspection and the results of the moisture measurement showed no difference between the users of the water-based hand disinfectant and the control subjects. Transepidermal water loss measurement also showed no deterioration of skin condition. <p>Part 2</p> <ul style="list-style-type: none"> • The microbiological efficacy of the water-based hand disinfectant against bacteria was at least as good as that of alcohol-based hand disinfection product. • When tested in accordance with the European standard, the product met the requirements for short term and long-term efficacy.

Main Study Findings	Author's Conclusion
<ul style="list-style-type: none"> After 3 minutes of disinfection using the invitro EN12791 test procedure, the mean (\pmSD) log reduction factor in colony forming units for the water based group was 2.69 (\pm1.36) vs 3.18(\pm0.98) in the alcohol-based group. After 3 hours, the mean (\pmSD) log reduction factor in colony forming units for the water based group was 2.01 (\pm1.83) vs 2.59(\pm1.12) in the alcohol-based group. 	
Nhung et al (2007) ¹¹	
<p>Part 1: Immediate efficacy after 30 s hand rub on resident skin flora, N=5 (log₁₀ values\pmSD), * <0.05 compared to pre-values (t-test)</p> <ul style="list-style-type: none"> Aerobic bacteria <ul style="list-style-type: none"> Pre rub <ul style="list-style-type: none"> 2-propanol 60%: 6.64\pm0.23 Nanochlorex: 6.63\pm 0.21 Post rub <ul style="list-style-type: none"> 2-propanol 60%: 6.26\pm0.32* Nanochlorex: 6.33\pm0.14* Pre minus Post <ul style="list-style-type: none"> 2-propanol 60%: 0.38\pm0.55 Nanochlorex: 0.30\pm0.35 Anaerobic bacteria <ul style="list-style-type: none"> Pre rub <ul style="list-style-type: none"> 2-propanol 60%: 6.74\pm0.17 Nanochlorex: 6.67\pm0.13 Post rub <ul style="list-style-type: none"> 2-propanol 60%: 6.62\pm0.22 Nanochlorex: 6.42\pm0.19* Pre minus Post <ul style="list-style-type: none"> 2-propanol 60%: 0.12\pm0.39 Nanochlorex: 0.25\pm0.32 <p>Part2 Bacterial efficacy after 30 s hand rub on resident skin flora, N=8 (log₁₀ values\pmSD) * p<0.05 compared to pre-values (t-test) ** p<0.05 compared to Purell (t-test)</p> <ul style="list-style-type: none"> Immediate effect (30 seconds after rub) <ul style="list-style-type: none"> Pre rub <ul style="list-style-type: none"> 62% ethanol gel (Purell): 6.39\pm0.32 Nanochlorex: 6.39\pm0.32 Post rub <ul style="list-style-type: none"> 62% ethanol gel (Purell): 5.84\pm0.48 * Nanochlorex: 5.95\pm0.39* Pre minus Post <ul style="list-style-type: none"> 62% ethanol gel (Purell): 0.55\pm0.40 Nanochlorex: 0.44\pm0.20 Sustained effect (3 hours after rub) <ul style="list-style-type: none"> Pre rub <ul style="list-style-type: none"> 62% ethanol gel (Purell): 6.37\pm0.30 Nanochlorex: 6.37\pm0.30 Post rub 	<p>Part 1</p> <ul style="list-style-type: none"> Immediate efficacy on resident hand flora (N=5), Table 1: Nanochlorex and 2-propanol 60% reduced post-values of surviving aerobic bacteria on hands; Nanochlorex reduced bacteria by an average log₁₀ reduction factor, which was not significantly different from 2-propanol 60% (0.30 versus 0.38). However, a 30-s hand rub with 2- propanol 60% (v/v) was not found effective against anaerobic bacteria, whereas Nanochlorex achieved the required efficacy. <p>Part 2</p> <ul style="list-style-type: none"> Immediate antibacterial efficacy of Nanochlorex was not significantly different from Purell. However, Purell was not found effective to insure a significant decrease of bacterial post-values at 3 h. Sustained efficacy of Nanochlorex was shown against bacteria as evidenced by the comparable average log₁₀ reduction factors determined at 30 s and 3 h. <p>Overall</p> <ul style="list-style-type: none"> The results of these in-use tests showed that Nanochlorex had bactericidal efficacy similar to 2-propanol 60% (v/v) after a 30-s hand rub, but exhibited superior antibacterial and residual effect compared to 62% (v/v) ethanol-based hand gel.

Main Study Findings	Author's Conclusion
<ul style="list-style-type: none"> ▪ 62% ethanol gel (Purell): 6.08±0.37 ▪ Nanochlorex: 5.77±0.23* ○ Pre minus Post <ul style="list-style-type: none"> ▪ 62% ethanol gel (Purell): 0.29±0.33 ▪ Nanochlorex: 0.60±0.36** <p>Ex vivo testing An ex vivo test was used to study the rub activity against repeated contaminations of human skin by <i>S. epidermidis</i>. Human skin specimens initially treated by either the chlorhexidine product or the 62% ethanol gel for 5 min and then were artificially contaminated at time +5 min, +1 h, +2 h, and +3 h. A statistically significant difference in the log₁₀ CFU/ml was confirmed between chlorhexidine and the 62% ethanol gel at 1 hour (P < 0.001), 2 hours (P < 0.001) and 3 hours (P < 0.01), favouring the chlorhexidine product. After the fourth contamination, no significant difference in antibacterial activity was shown between the products.</p>	

CFU= colony forming unit; h=hours; RF=reduction factor; s=seconds; SD= standard deviation; v/v= volume/volume

Table A6: Summary of Evidence-based Guidelines

Guideline	Selected Recommendations
<p>Public Health Ontario: Best Practices for Hand Hygiene in All Healthcare Settings (2014)³</p>	<p>There is no evidence for the efficacy of non-alcoholic, waterless antiseptic agents in the health care environment. Non-alcoholic products have a quaternary ammonium compound (QAC) as the active ingredient, which has not been shown to be as effective against most microorganisms as ABHR or soap and water. QACs are prone to contamination by Gram-negative organisms. QACs are also associated with an increase in skin irritancy.</p> <p>Non-alcohol-based waterless antiseptic agents are not recommended for hand hygiene in health care settings and should not be used.</p> <ul style="list-style-type: none"> • Use 70 to 90% alcohol-based hand rub for hand hygiene in all health care settings. • Wash hands with soap and water if there is visible soiling with dirt, blood, body fluids or other body substances. If hands are visibly soiled and running water is not available, use moistened towelettes to remove the visible soil, followed by alcohol-based hand rub. • In all health care settings, provide hand hygiene products at point-of-care for use by staff and clients/patients/residents. • Dispense all hand hygiene and hand care products from a disposable dispenser that delivers an appropriate volume of the product. • Use single-use product dispensers that are discarded when empty. Do not “top-up” or refill containers. Clearly define responsibility for maintaining product dispensers. • Do not use bar soap for hand hygiene in any health care settings except for individual client/patient/resident use. • Do not use alcohol-free, waterless antiseptic agents as hand hygiene agents in any health care setting. • Consider user acceptability as a factor in hand hygiene product selection. • Choose hand hygiene and hand care products with low irritant potential. • Hand hygiene products must not interfere with glove integrity or with the action of other hand hygiene or hand care products. • Evaluate the dispenser system of product manufacturers to ensure that dispensers function adequately and deliver an appropriate volume of product. <p>(Source: pg 23)</p>
<p>NICE: Surgical site infection prevention and treatment of surgical site infection (2008)^{5,6}</p>	<p>Hands must be decontaminated immediately before every episode of direct patient contact/care and after any activity or contact that potentially results in hands becoming contaminated. Hands that are visibly soiled or potentially grossly contaminated with dirt or organic material must be washed with liquid soap and water. Hands should be decontaminated between caring for different patients or between different care activities for the same patient, including after removal of gloves. For convenience and efficacy, an alcohol-based hand rub is preferable unless hands are visibly soiled.</p> <p>(Source: Appendix H)</p>
<p>PHAC Hand Hygiene Practices in Healthcare Settings (2012)²</p>	<p>1.1. Alcohol-based hand rub is the preferred method of hand hygiene in all healthcare settings with the exceptions outlined in Part D, Section 1.2.</p> <p>1.2. Hand hygiene using soap and water, instead of alcohol-based hand rubs, should be performed as follows:</p> <p>1.2.1. To remove visible soil and/or organic material</p> <p>1.2.2. When a buildup of alcohol-based hand rub product feels uncomfortable on the hands after multiple applications. (Note: alcohol-based hand rub remains effective in this situation). Manufacturer’s recommendation</p> <p>1.2.3. At the point-of-care after caring for a patient with norovirus or <i>C. difficile</i> infection. If a designated handwashing sink is not available at the point-of-care, alcohol-based hand rub should be used and hands should be washed with soap and water as soon as a suitable handwash sink is available. (Note: Patients with norovirus or <i>C. difficile</i> infection are on</p>

Guideline	Selected Recommendations
	<p>contact precautions. This includes wearing gloves for the care of the patient and/or contact with the patient environment. Hand hygiene with soap and water should be performed following the removal of gloves at the point-of-care).</p> <p>1.2.4. During outbreaks or in settings with high transmission of norovirus or <i>C. difficile</i> infection</p> <p>1.2.5. With suspected or documented exposure to <i>B. anthracis</i>-contaminated items.</p> <p>1.2.6. Immediately after using toilet facilities</p> <p>1.3. Hand hygiene should be performed with alcohol-based hand rub preferably at the point-of-care in all healthcare settings</p> <p>1.4. Alcohol-based hand rubs with an alcohol (i.e., ethanol, isopropanol or <i>n</i> propanol) concentration above 60% and up to 90% should be used for clinical care</p> <p>1.4.1. Alcohol concentrations above 80% may be necessary for gels</p> <p>1.4.2. Alcohol concentrations with a minimum of 70% should be considered during outbreaks or in settings with a high transmission of norovirus</p> <p>1.4.3. Hand rubs that contain either no alcohol or alcohol in concentrations lower than 60% for hand hygiene should not be used.</p> <p>1.4.4. Hand hygiene products purchased for use in Canadian healthcare settings should be approved for professional use and have either a Health Canada Natural Product Number or a Drug Identification Number.</p> <p>(Source: Part D)</p>
<p>WHO Guidelines on Hand Hygiene in Health Care (2009)⁴</p>	<p>A. Wash hands with soap and water when visibly dirty or visibly soiled with blood or other body fluids or after using the toilet</p> <p>B. If exposure to potential spore-forming pathogens is strongly suspected or proven, including outbreaks of <i>Clostridium difficile</i>, hand washing with soap and water is the preferred means</p> <p>C. Use an alcohol-based hand rub as the preferred means for routine hand antisepsis in all other clinical situations described in items D(a) to D(f) listed below, if hands are not visibly soiled. If alcohol-based hand rub is not obtainable, wash hands with soap and water</p> <p>D. Perform hand hygiene:</p> <ul style="list-style-type: none"> a. before and after touching the patient b. before handling an invasive device for patient care regardless of whether or not gloves are used (IB); c. after contact with body fluids or excretions, mucous membranes, non-intact skin, or wound dressings d. if moving from a contaminated body site to another body site during care of the same patient e. after contact with inanimate surfaces and objects (including medical equipment) in the immediate vicinity of the patient f. after removing sterile or non-sterile gloves <p>(Source: pg 152)</p>

Appendix 5: Additional References of Potential Interest

British Columbia Guideline

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