

Clinical Research Response Apr 08, 2020

# Alcohol-Based Versus Non-Alcohol-Based Hand Sanitizers

## Hayes Viewpoint:

Based on an abstract review, although microbial contamination was reduced with alcohol-based hand rubs, results were conflicting. Furthermore, all studies used surrogate measures, including colony-forming units, time to kill in seconds, transepidermal water measurement, and subject's skin condition. No studies evaluated clinical outcomes of the incidence of infection or disease transmission.

## TABLE OF CONTENTS

At a Glance .....	2
Health Technology .....	3
Research Summary .....	4
Regulation and Guidance .....	9
Additional Information.....	14

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## At A Glance

### Technology

Alcohol-based versus non-alcohol-based hand sanitizers or hand rubs.

### Manufacturer

Many manufacturers make hand sanitizers.

### Focus of Report

The focus of this report is to compare the clinical effectiveness of alcohol-based with non-alcohol-based hand sanitizers in healthcare settings. This report is an update to the February 23, 2018, report of the same title, and this report also gives special attention to the efficacy of hand sanitizers for controlling coronavirus.

### Literature Summary

Five abstracts are summarized in this report: 1 randomized controlled trial (n=95 healthcare workers [HCWs], abstract #2); 3 prospective studies (n=25 healthy subjects, abstract #1, and n=20 healthy subjects, abstract #4, and n=125 HCWs, abstract #5), and 1 in vitro study (abstract #3).

### Regulatory Status

Topical antiseptic products are subject to Food and Drug Administration (FDA) regulation.

### Viewpoint

A review of abstracts did not identify a sufficient quantity of relevant studies reporting outcomes of interest to conclusively inform the comparative efficacy of alcohol base and non-alcohol-based hand sanitizers in healthcare settings. Only 1 identified abstract addressed the use of sanitizing hand rubs to kill viruses; coronaviruses were not specifically addressed by any study. Furthermore, all studies used surrogate measures (e.g., colony-forming units, time to kill in seconds, transepidermal water measurement, subject's skin condition) and none evaluated clinical outcomes (e.g., incidence of infection, disease transmission). In the setting of the novel coronavirus (COVID-19) pandemic, the U.S. Centers for Disease Control and Prevention (CDC) has recommended soap and water handwashing, with use of a > 60% alcohol rub when handwashing is not possible. A review of FDA content identified recommendations regarding alcohol-based but not non-alcohol-based sanitizing hand rubs.

## Health Technology

### Health Problem

Healthcare-associated infections (HAIs), also called hospital-acquired infections or nosocomial infections, refer to any infection acquired during a patient's stay at a hospital or other healthcare facility. The time frame for nosocomial infection onset is > 48 hours after hospital admission, or within 30 days of receiving health care. Healthcare facilities include acute care centers, ambulatory surgical centers, long-term care, dialysis centers, and home care ([Haque et al., 2018](#)).

The Center for Disease Control and Prevention identifies that nearly 1.7 million hospitalized patients acquire HAIs and that > 98,000 (1 in 17) of these patients die due to HAI. The Agency for Healthcare Research and Quality has stated that HAIs are the most common complication of hospital care ([Haque et al., 2018](#)).

Meticulous hand hygiene by healthcare workers (HCWs) using soap and water, an antiseptic, or an alcohol-based hand rub is a critical element in the prevention of HAIs.

Additional information about hand hygiene may be found in the [Related Hayes Reports](#) section.

### Technology Description

Hand sanitizers, sometimes also called hand rubs, are substances applied to the hands with the intent of preventing the transmission of infectious microbes, including bacteria and viruses. They are generally recommended for use when handwashing with soap and water is unavailable ([CDC, 2020](#)). Inclusion of alcohol in the sanitizer is common.

The composition and mechanism of action of alcohol-based hand sanitizers on microbes is described as follows ([Gold and Avva, 2020](#)):

Most alcohol-based hand antiseptics contain isopropanol, ethanol, n-propanol, or a combination of 2 of these products. The antimicrobial activity of alcohols can be attributed to their ability to denature and coagulate proteins. The microorganism's cells are then lysed, and their cellular metabolism is disrupted. Alcohol solutions containing 60% to 95% alcohol are most effective. Notably, higher concentrations are less potent because proteins are not denatured easily in the absence of water. Alcohol concentrations in antiseptic hand rubs are often expressed as percent by volume, but sometimes as percent by weight.

Alcohols such as ethanol are well-known antimicrobial agents and were first recommended for the treatment of hands in 1888. The highest antimicrobial efficacy can be achieved with ethanol (60% to 85%), isopropanol (60% to 80%), and n-propanol (60% to 80%). The activity is broad and immediate. Ethanol, the most common alcohol ingredient, appears to be the most effective against viruses; whereas, the propanols have a better bactericidal activity than ethanol.

Insight into the development of nonalcohol-based rubs is discussed in a rapid response report by the Canadian Agency for Drugs and Technologies in Health ([la Fleur and Jones, 2017](#)):

Alcohol-based rubs have a well-established role in infection control strategy in healthcare settings for routine hand sanitization, including hospitals, outpatient clinics, laboratory settings, community settings and for hand sanitization in surgical contexts....Nevertheless, there have been some concerns associated with the usage of alcohol-based hand sanitizers, such as religious objections, abuse potential, and flammability. 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...

Additional information about alcohol-based and non-alcohol-based hand sanitizers may be found in the [Online Resources](#) section.

### Intended Use

In healthcare settings, alcohol-based and nonalcohol-based hand sanitizers are intended to reduce the numbers of microbes on hands and consequent disease transmission among HCWs, non-HCWs, visitors, and patients.

## Research Summary

### Research Question

What is the evidence for the comparative clinical effectiveness of alcohol-based and non-alcohol-based hand sanitizers in healthcare settings?

### Viewpoint

It is widely recognized that adequate hand hygiene within healthcare settings is a critical component in preventing the transmission of microorganisms and disease risk from HCWs to patients and visitors and, thus, reducing the incidence of HAIs. The aim of this report was to compare the clinical effectiveness of alcohol-based versus non-alcohol-based hand sanitizers in healthcare settings.

There is a dearth of peer-reviewed evidence to evaluate alcohol-based and non-alcohol-based hand rubs in the healthcare setting. Based on a review of abstracts, although microbial contamination was reduced with alcohol-based hand rubs, results were conflicting. Furthermore, all studies used surrogate measures, including colony-forming units, time to kill in seconds, transepidermal water measurement, and subject's skin condition. No studies evaluated clinical outcomes of the incidence of infection or disease transmission. Furthermore, manufacturer involvement was reported for the authors of 2 studies.

In the setting of the coronavirus (COVID-19) pandemic, the U.S. Centers for Disease Control and Prevention (CDC) has recommended soap and water handwashing, with use of a > 60% alcohol rub when handwashing is not possible. The Food and Drug Administration (FDA) has issued [2 guidance documents](#) supporting the manufacture and creation of alcohol-based hand rubs and does not address other types of hand sanitizing rubs ([see Food and Drug Administration](#)).

### Search Strategy

Abstracts reviewed for this report were obtained from searches in the PubMed and Embase databases. Elsevier's Embase was searched using the search "free text" in all fields function.

Table 1. Literature Search Strategy for Alcohol-Based Versus Non-Alcohol-Based Hand Sanitizers

Database	Date of Search	Terms	Search Limits	Rationale	Results
PubMed	March 26, 2020	<b><i>alcohol AND (non-alcohol OR nonalcohol OR triclosan OR chlorhexidine OR iodophors OR water-based OR 'aqueous base') AND (hand OR handrub) AND (rub OR sanitizer OR disinfectant OR hygiene)</i></b>	Abstract, English language, published within last 15 years	Intervention, ingredients for non-alcohol-based rubs, various terms for intended use	148 citations
PubMed	March 29, 2020	<b><i>(alcohol OR ethanol) AND (nonalcohol OR non-alcohol) AND (rub OR sanitizer OR disinfectant)</i></b>	Abstract, English language, no date limit	Medical Subject Heading (MESH) term, various terms for intended use	15 citations
Elsevier's Embase	March 26, 2020	<b><i>alcohol AND (non-alcohol OR nonalcohol OR triclosan OR chlorhexidine OR iodophors OR water-based OR 'aqueous base') AND (hand OR handrub) AND (rub OR sanitizer OR disinfectant OR hygiene)</i></b>	Abstract, English language, published within last 15 years, articles, articles in press, reviews, Embase only	Intervention, ingredients for non-alcohol-based rubs, various terms for intended use	22 citations
Elsevier's Embase	March 29, 2020	<b><i>(alcohol OR ethanol) AND (nonalcohol OR non-alcohol) AND (rub OR sanitizer OR disinfectant)</i></b>	Abstract, English language, no date limit, articles, articles in press, reviews, Embase only	MESH term, various terms for intended use	0 citations

## Summary of Search Results

Searches for peer-reviewed literature comparing alcohol-based and non-alcohol-based hand sanitizing rubs in healthcare settings located a small body of evidence. Five abstracts were retrieved, including 1 randomized controlled trial (n=95 healthcare workers [HCWs], abstract #2); 3 prospective studies (n=25 healthy subjects, abstract #1, n=20 healthy subjects, abstract #4, and n=125 HCWs, abstract #5), and 1 in vitro study (abstract #3).

Abstracts of non-human studies, studies of soaps, studies of surgical site preparation, studies not comparing alcohol-based and non-alcohol-based rubs, studies of scrubs or handwashing, and studies addressing compliance were excluded.

Please refer to Table 2 for details of the study abstracts. For more details, please see the [Abstracts](#) section at the end of this report. Links to the full-text articles of abstracts #1, #2, #3, and #4 can be found under the [Online Resources](#) section.

**Table 2. Summary of Relevant Abstracts**

Key: BK, benzalkonium chloride; CFU, colony-forming unit; CHG, chlorhexidine gluconate; HCW, healthcare worker; N/A, not applicable

Abstract Number Author (Study Year) Country	Study Design	Population	Reported Outcomes	Conclusions
1. Bondurant et al. (2019) United States	Prospective comparative study  Ethanol 63% vs BK 0.12% formulation	n=24 healthy subjects	<b>Staphylococcus aureus</b> CFUs at 3 time points ≤4 hrs  BK produced a marked reduction in CFUs at each of the 3 time points tested (3.75-4.16 log <sub>10</sub> reductions), whereas the comparator produced less than 1 log <sub>10</sub> reduction over the same time. The differences were highly significant.	According to the authors:  These results show a major improvement in persistent antibacterial activity for the BK formulation compared with the comparator ethanol-based formulation.  <b>Conflicts:</b> 1 author was associated with BioSciences Laboratories Inc.
2. Therattil et al. (2015) United States	Randomized controlled trial  Ethyl alcohol-based sanitizer (Avagard D Instant Hand Sanitizer, 3M Health Care) vs BK (Soft <sup>^</sup> Shield, Bioderm Technologies Inc.) vs soap and water handwashing	n=36 alcohol-based sanitizer n=38 BK-based sanitizer n=21 soap and water handwashing	There was no difference between hand bacterial counts using the different methods at 4 hourly time points ( <b>P</b> >0.05). Hand bacterial counts increased significantly over the 3-hour clinic session with the ethyl alcohol-based sanitizer (9.24-21.90 CFUs; <b>P</b> <0.05), BK-based sanitizer (6.69-21.59 CFU; <b>P</b> <0.05), and soap-and-water handwashing (8.43-22.75 CFUs; <b>P</b> <0.05).	According to the authors:  There does not appear to be any difference in efficacy between single-use, long-acting sanitizer, and standard multiple-use hand hygiene methods. Hand bacterial counts increased significantly over the course of the 3-hour clinic session regardless of the hand hygiene measure used. Hand condition of subjects was improved with the ethyl alcohol-based sanitizer and the benzalkonium chloride-based sanitizer compared with soap-and-water handwashing.  <b>Conflicts:</b> None
3. Czerwinski et al. (2014)	In vitro study  Alcohol-based antiseptic vs water-based antiseptic lotion (both with 0.2% BK)	N/A (in vitro study)	The average 15-sec kill was 99.999% of the challenge organism for the alcohol-based antiseptic and 99.971% for the water-based antiseptic. The alcohol-based product demonstrated 100% of peak efficacy (60 seconds)	According to the authors:  A novel water-based antiseptic product demonstrated equivalent rapid, broad-spectrum antimicrobial activity to an alcohol-based sanitizer

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Alcohol-Based Versus Non-Alcohol-Based Hand Sanitizers

United States			within the first 15 seconds, whereas the water-based product showed 99.97%. The novel alcohol-based antiseptic reduced concentrations of 100% of organisms by 99.999%, whereas the water-based antiseptic lotion showed the same reduction for 96% of organisms.	and provided additional benefits of reduced irritation, persistent effect, and greater efficacy against common viruses. The combination of rapid, broad-spectrum immediate kill and persistent efficacy against pathogens may have significant clinical benefit in limiting the spread of disease.  <b>Conflicts:</b> The authors were associated with Innovative BioDefense Inc.
4. Barbadoro et al. (2014) Italy	Prospective comparative study  Alcohol-based hand rub (isopropyl alcohol 40%; N-propyl alcohol 25%; glycerin 1.74%; triethanolamine salt of carbomer <1%) vs chlorhexidine vs povidone-iodine	n=20 healthy subjects	The best results were achieved with the alcohol-based hand rub and these were sustained for a period of 3 hours. Some volunteers experienced skin peeling off the hands when using alcohol-based hand rub; in this group of participants, the bacterial count was reduced only by $0.91 \pm 1.67 \log_{10}$ compared with $2.86 \pm 1.22 \log_{10}$ in the group who did not show this phenomenon.	According to the authors:  Besides confirming the importance of alcohol-based hand rubs for surgical hand decontamination, the results suggest the value of assessing the characteristics, and response of healthcare workers' skin, that may contribute to the development of skin peeling, and the subsequent possibility of a paradoxical overcolonization of hands after surgical preparation with alcohol-based hand rub.  <b>Conflicts:</b> None
5. Agthe et al. (2009) Finland	Prospective comparative study	n=26 HCWs alcohol-based disinfectant  n=99 HCWs water-based disinfectant	Results of the fingerprint test showed that there was a statistically significant decrease in colonization of the fingertips before and after disinfection ( $P < 0.001$ ). 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.	According to the authors:  The water-based hand disinfectant was shown to be an effective hand disinfectant that caused relatively little skin irritation and can serve as a hand hygiene alternative in situations in which alcohol-based disinfectant cannot be used.  <b>Conflicts:</b> None

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## Ongoing Studies

A search of the [ClinicalTrials.gov](https://clinicaltrials.gov) database on March 25, 2020, using the term **hand sanitizer** located 11 studies. However, upon record review, none were found to address the research question of this report.

## Limitations of the Report

The Hayes Viewpoint in this report is based on a review of abstracts. No full-text articles were reviewed and a comprehensive Health Technology Assessment was not conducted.

## Regulation And Guidance

### Regulation

#### Food and Drug Administration (FDA)

The Food and Drug Administration has issued [2 guidance documents](#) on the production of alcohol-based hand sanitizer in the setting of the coronavirus (COVID-19) emergency.

[Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\)](#) (March 19, 2020)

Because of the public health emergency posed by COVID-19, FDA does not intend to take action against firms that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, provided the following circumstances are present:

1. The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:
  - a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20; or Isopropyl Alcohol (75%, v/v) in an aqueous solution.
  - b. Glycerol (1.45% v/v).<sup>10</sup>
  - c. Hydrogen peroxide (0.125% v/v).
  - d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

2. The firm pays particular attention to ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used. A simple record should be used to document key steps and controls to assure each batch matches the formula developed for the drug product.
3. The hand sanitizer is prepared under sanitary conditions and equipment utilized is well maintained and fit for this purpose.
4. The firm uses the most accurate method of analysis available at the site for verification of alcohol content in samples of the finished drug product before each batch is released for distribution. Methods can include gas chromatography (GC), alcoholmeter, hydrometer, or other chemical analysis of at least equivalent accuracy. The sample tested can be performed on in-process material before filling into the final containers to be distributed.
5. The hand sanitizer is labeled consistent with the attached labeling in Appendix A (Labeling for Ethyl Alcohol Formulation Consumer Use), Appendix B (Labeling for Isopropyl Alcohol Formulation Consumer Use), Appendix C (Labeling for Ethyl Alcohol Formulation Health Care Personnel Handrub Use), or Appendix D (Labeling for Isopropyl Alcohol Formulation Health Care Personnel Handrub Use).
6. Firms register their facility and list these products in the FDA [Drug Registration and Listing System](#) (DRLS). Upon completion of registration and listing, firms receive automatic confirmation from the FDA and do not need to wait for a further communication from FDA before they begin to manufacture and distribute these products. FDA relies on registration and listing information to help manage drug shortages, monitor safety issues that may arise with product distributed to the public, and manage product recalls, among other important FDA public safety activities.

[Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency](#) (March 14, 2020)

Because of the public health emergency posed by COVID-19, FDA does not intend to take action against compounders that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, provided the following circumstances are present:

1. The hand sanitizer is compounded using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:
  - a. Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20; or Isopropyl Alcohol (75%, v/v) in an aqueous solution.
  - b. Glycerol (1.45% v/v).<sup>7</sup>
  - c. Hydrogen peroxide (0.125% v/v).
  - d. Sterile distilled water or boiled cold water.

The compounder does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

2. The compounder pays particular attention to ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used.
3. The hand sanitizer is prepared under conditions routinely used by the compounder to compound similar nonsterile drugs.
4. The hand sanitizer is labeled consistent with the attached labeling in Appendix A (Labeling for Ethyl Alcohol Formulation Consumer Use), Appendix B (Labeling for Isopropyl Alcohol Formulation Consumer Use), Appendix C (Labeling for Ethyl Alcohol Formulation Health Care Personnel Handrub Use), or Appendix D (Labeling for Isopropyl Alcohol Formulation Health Care Personnel Handrub Use).

Prior to the above 2 emergency guidance documents, the FDA issued the following guidance [Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use](#) (December 20, 2017)

This final rule finalizes the 2015 Health Care Antiseptic PR. This final rule applies to health care antiseptic products that are intended for use by health care professionals in a hospital setting or other health care situations outside the hospital. Health care antiseptic products include health care personnel hand washes, health care personnel hand rubs, surgical hand scrubs, surgical hand rubs, and patient antiseptic skin preparations (i.e., patient preoperative and preinjection skin preparations).

In response to several requests submitted to the 2015 Health Care Antiseptic PR, FDA has deferred further rulemaking on six active ingredients used in over-the-counter (OTC) health care antiseptic products to allow for the development and submission to the record of new safety and effectiveness data for these ingredients. The deferred active ingredients are benzalkonium chloride, benzethonium chloride, chloroxylenol, alcohol (also referred to as ethanol or ethyl alcohol), isopropyl alcohol, and povidone-iodine. Accordingly, FDA does not make a GRAS/GRAE [generally recognized as safe/generally recognized as effective] determination in this final rule for these six active ingredients for use as OTC health care antiseptics. The monograph or nonmonograph status of these six ingredients will be addressed, either after completion and analysis of ongoing studies to address the safety and effectiveness data gaps of these ingredients or at a later date, if these studies are not completed.

This rulemaking finalizes the nonmonograph status of the remaining 24 active ingredients intended for use in health care antiseptics identified in the 2015 Health Care Antiseptic PR. No additional data were submitted to support monograph conditions for these 24 health care antiseptic active ingredients. Therefore, this rule finalizes the 2015 Health Care Antiseptic PR and finds that 24 health care antiseptic active ingredients are not GRAS/GRAE for use as OTC health care antiseptics. Accordingly, OTC health care antiseptic drugs containing any of these 24 active ingredients are new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(p)) for which approved applications under section 505 of the FD&C Act (21 U.S.C. 355) and part 314 (21 CFR 314) of the regulations are required for marketing and may be misbranded under section 502 of the FD&C Act (21 U.S.C. 352).

This final rule covers only OTC health care antiseptics that are intended for use by health care professionals in a hospital setting or other health care situations outside the hospital...

## Position Statements and Guidelines

Table 4. Clinical Guidelines/Practice Statements

Name of Organization	Date Searched	Guidance Identified
<a href="#">Ontario Health Technology Assessment Series</a>	March 24, 2020	No guidance located.
<a href="#">Scottish Intercollegiate Guidelines Network (SIGN)</a>	March 25, 2020	No guidance located.
<a href="#">U.S. Preventive Services Task Force (USPSTF)</a>	March 25, 2020	No guidance located.
<a href="#">Veteran Affairs/Department of Defense (VA/DoD)</a>	March 25, 2020	<a href="#">Hand hygiene poster</a> (undated)
<b>Centers for Disease Control and Prevention (CDC)</b>		
<a href="#">MMWR Recommendations and Reports</a>	March 24, 2020	No guidance located. See CDC.
<a href="#">CDC Healthcare Infection Control Guidelines</a>	March 24, 2020	<a href="#">How to protect yourself</a> (March 18, 2020) <a href="#">CDC statement for healthcare personnel on hand hygiene during the response to the international emergence of COVID-19</a> (March 14, 2020)
<b>National Institute for Health and Care Excellence (NICE)</b>		
<a href="#">NICE Guidance</a>	March 26, 2020	<a href="#">Healthcare-associated infections: prevention and control in primary and community care</a> (February 2017) <a href="#">Infection prevention and control</a> (April 2014)
<a href="#">NICE Pathways</a>	March 26, 2020	<a href="#">Prevention and control of healthcare-associated infections</a> (2020) (Based on the NICE 2017 guideline above.)

[How to protect yourself](#) (CDC, March 18, 2020)

Clean your hands often

If soap and water are not readily available, use a hand sanitizer that contains at least 60% alcohol. Cover all surfaces of your hands and rub them together until they feel dry.

[CDC statement for healthcare personnel on hand hygiene during the response to the international emergence of COVID-19](#) (CDC, March 14, 2020)

CDC recommendations reflect the important role of hand hygiene for preventing the transmission of pathogens in healthcare settings for a wide range of pathogens. The ability of hand hygiene, including hand washing or the use of alcohol-based hand sanitizers to prevent infections is related to reductions in the number of viable pathogens that transiently contaminate the hands. Hand washing mechanically removes pathogens, while laboratory data demonstrate that 60% ethanol and 70% isopropanol, the active ingredients in CDC-recommended alcohol-based hand sanitizers, inactivates viruses that are genetically related to, and with similar physical properties as, the 2019-nCoV.

[Healthcare-associated infections: prevention and control in primary and community care](#) (NICE, February 2017)

1.1.2.4 An effective handwashing technique involves three stages: preparation, washing and rinsing, and drying. Preparation requires wetting hands under tepid running water before applying liquid soap or an antimicrobial preparation. The handwash solution must come into contact with all of the surfaces of the hand. The hands must be rubbed together vigorously for a minimum of 10–15 seconds, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers. Hands should be rinsed thoroughly before drying with good quality paper towels....

1.1.2.5 When decontaminating hands using an alcohol handrub, hands should be free from dirt and organic material. The handrub solution must come into contact with all surfaces of the hand. The hands must be rubbed together vigorously, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers, until the solution has evaporated and the hands are dry....

1.1.2.6 An emollient hand cream should be applied regularly to protect skin from the drying effects of regular hand decontamination. If a particular soap, antimicrobial hand wash or alcohol product causes skin irritation an occupational health team should be consulted.

[Infection prevention and control](#) (NICE, April 2014)

An alcohol-based handrub should be used for hand decontamination before and after direct contact or care, except in the following situations when soap and water must be used:

- when hands are visibly soiled or potentially contaminated with body fluids or
- when caring for patients with vomiting or diarrhoeal illness, regardless of whether or not gloves have been worn.

In addition to the organizations listed in the table above, the websites of organizations relevant to infection control and the Internet were searched for guidelines pertinent to the use of alcohol versus non-alcohol-based hand sanitizers. The findings are presented below.

[Advice for everyone coronavirus \(COVID-19\)](#) (National Health Service, March 25, 2020)

- wash your hands with soap and water often—do this for at least 20 seconds
- use hand sanitiser gel if soap and water are not available
- wash your hands as soon as you get back home
- cover your mouth and nose with a tissue or your sleeve (not your hands) when you cough or sneeze
- put used tissues in the bin immediately and wash your hands afterwards

Clinical practice guidelines by the Infectious Diseases Society of America: 2018 update on diagnosis, treatment, chemoprophylaxis, and institutional outbreak management of seasonal influenza ([Uyeki et al., 2019](#)), Infectious Disease Society of America, ***Clinical Infectious Diseases***

This guideline does not refer to alcohol-based hand disinfectant.

Non-alcohol based hand rubs: a review of clinical effectiveness and guidelines ([la Fleur and Jones, 2017](#)), Canadian Agency for Drugs and Technologies in Health (CADTH)

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.

[Guide to hand hygiene programs for infection prevention](#) (Association for Professionals in Infection Control and Epidemiology, 2015)

A compendium of strategies to prevent healthcare-associated infections in acute care hospitals: 2014 updates ([Yokoe et al., 2014](#))

...Strategies to Prevent HAIs through Hand Hygiene...

4. Perform hand hygiene with an alcohol-based hand rub or, alternatively, an antimicrobial or nonantimicrobial soap for the following indications (quality of evidence: II)...

[Techniques and products for surgical hand antisepsis: a review of guidelines](#) (CADTH, 2014)

...Surgical hand antisepsis techniques and agents include surgical hand scrubs with antiseptic soap or alcohol-based hand rubs.

SHEA/APIC guideline: infection prevention and control in the long-term care facility ([Smith et al., 2008](#)), ***American Journal of Infection Control***

...Health care provider hand contamination is usually transient and amenable to hand hygiene, frequent hand hygiene would be expected to lower LTCF infection rates, and the availability of alcohol-based hand sanitizer dispensers enhances access to hand sanitizing agents.

## Additional Information

### Publication History

Date	Title	Status
February 23, 2018	Alcohol-Based Versus Non-Alcohol-Based Hand Sanitizers	New
April 9, 2020	Alcohol-Based Versus Non-Alcohol-Based Hand Sanitizers	Update

### Related Hayes Reports

[Electronic Hand Hygiene Monitoring Systems – Product Comparison](#)  
[Electronic Monitoring Versus Direct Observation of Hand Hygiene Compliance in Healthcare Settings](#)  
[Risk of Infection From Hospital Suction Regulators](#)  
[Steriplex SD](#)  
[Surgical Hand Disinfection - Product Comparison](#)

### Online Resources

Alcohol sanitizer ([Gold and Avva, 2020](#)), *Stat Pearls [Internet]*.

Demonstrating the persistent antibacterial efficacy of a hand sanitizer containing benzalkonium chloride on human skin at 1, 2, and 4 hours after application ([Bondurant et al., 2019](#)), *American Journal of Infection Control*. [Full text of abstract #1]

Skin antiseptics in healthcare facilities: is a targeted approach necessary? ([Wiemken T, 2019](#)), *BMC Public Health*.

Reported adverse health effects in children from ingestion of alcohol-based hand sanitizers—United States, 2011–2014 ([Santos et al., 2017](#)), *Mortality and Morbidity Weekly Report*.

Randomized controlled trial of antiseptic hand hygiene methods in an outpatient surgery clinic ([Therattil et al., 2015](#)), *Wounds*. [Full-text article for abstract #2]

To study the effect of hand sanitizers used in Kingdom of Saudi Arabia against the common bacterial pathogens ([Ali Y, 2015](#)), *International Research Journal of Natural and Applied Sciences*.

In vivo comparative efficacy of three surgical hand preparation agents in reducing bacterial count ([Barbadoro et al., 2014](#)), *The Journal of Hospital Infection*. [Full text of abstract #4]

Novel water-based antiseptic lotion demonstrates rapid, broad-spectrum kill compared with alcohol antiseptic ([Czerwinski et al., 2013](#)), *Journal of Infection and Public Health*. [Full-text article for abstract #3]

### Abstracts

1. Am J Infect Control. 2019 Aug;47(8):928-932. doi: 10.1016/j.ajic.2019.01.004.

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Demonstrating the persistent antibacterial efficacy of a hand sanitizer containing benzalkonium chloride on human skin at 1, 2, and 4 hours after application.

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**BACKGROUND:** Use of hand sanitizers has become a cornerstone in clinical practice or the prevention of disease transmission between practitioners and patients. Traditionally, these preparations have relied on ethanol (60%-70%) for bactericidal action.

**METHODS:** This study was conducted to measure the persistence of antibacterial activity of 2 preparations. One was a non-alcohol-based formulation using benzalkonium chloride (BK) (0.12%) and the other was an ethanol-based formulation (63%) (comparator product). The persistence of antibacterial activity was measured against *Staphylococcus aureus* using a technique modification prescribed in American Society for Testing and Materials protocol E2752-10 at up to 4 hours after application.

**RESULTS:** The test product (BK) produced a marked reduction in colony-forming units at each of the 3 time points tested (3.75-4.16-log<sub>10</sub> reductions), whereas the comparator produced less than 1-log<sub>10</sub> reduction over the same time. The differences were highly significant.

**DISCUSSION:** In the course of patient care or examination, there are instances where opportunities exist for the practitioner's hands to become contaminated (eg, key boards and tables). Persistent antibacterial activity would reduce the chances of transfer to the patient.

**CONCLUSIONS:** These results show a major improvement in persistent antibacterial activity for the BK formulation compared to the comparator ethanol-based formulation.

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2. Wounds. 2015 Dec;27(12):347-53.

Randomized Controlled Trial of Antiseptic Hand Hygiene Methods in an Outpatient Surgery Clinic.

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**INTRODUCTION:** Outpatient wound care plays an integral part in any plastic surgery practice. However, compliance with hand hygiene measures has shown to be low, due to skin irritation and lack of time. The objective of this trial was to determine whether single-use, long-acting antiseptics can be as effective as standard multiple-use hand hygiene methods in an outpatient surgical setting.

**MATERIALS AND METHODS:** A prospective, randomized controlled trial was performed in the authors' outpatient plastic surgery clinic at Rutgers New Jersey Medical School, Newark, NJ to compare the efficacy of an ethyl alcohol-based sanitizer (Avagard D Instant Hand Antiseptic, 3M Health Care, St. Paul, MN), a benzalkonium chloride-based sanitizer (Soft & Shield, Bioderm Technologies, Inc, Trenton, NJ, distributed by NAPP Technologies, Hackensack, NJ), and soap and- water handwashing. Subjects included clinic personnel, who were followed throughout the course of a 3-hour clinic session with hourly hand bacterial counts taken.

**RESULTS:** During the course of the trial, 95 subjects completed the clinic session utilizing 1 of the hand hygiene methods (36 ethyl alcohol-based sanitizer, 38 benzalkonium chloride-based sanitizer, and 21 soap-and-water handwashing). There was no difference between hand bacterial counts using the different methods at 4 hourly time points (P greater than 0.05). Hand bacterial counts increased significantly over the 3-hour clinic session with the ethyl alcohol-based sanitizer (9.24 to 21.90 CFU, P less than 0.05), benzalkonium chloride-based sanitizer (6.69 to 21.59 CFU, P less than 0.05), and soap-and-water handwashing (8.43 to 22.75 CFU, P less than 0.05).

**CONCLUSION:** There does not appear to be any difference in efficacy between single-use, long-acting sanitizer, and standard multiple-use hand hygiene methods. Hand bacterial counts increased significantly over the course of the 3-hour clinic session regardless of the hand hygiene measure used. Hand condition of subjects was improved with the ethyl alcohol-based sanitizer and the benzalkonium chloride-based sanitizer compared with soap-and-water handwashing.

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3. J Infect Public Health. 2014 May-Jun;7(3):199-204. doi:10.1016/j.jiph.2014.01.002.

Novel water-based antiseptic lotion demonstrates rapid, broad-spectrum kill compared with alcohol antiseptic.

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novel alcohol-based antiseptic and a novel water-based antiseptic lotion, both with a synergistic combination of antimicrobial ingredients containing 0.2% benzethonium chloride, were evaluated using the standard time-kill method against 25 FDA-specified challenge microorganisms. The purpose of the testing was to determine whether a non-alcohol product could have equivalent rapid and broad-spectrum kill to a traditional alcohol sanitizer. Both the alcohol- and water-based products showed rapid and broad-spectrum antimicrobial activity. The average 15-s kill was 99.999% of the challenge organism for the alcohol-based antiseptic and 99.971% for the water-based antiseptic. The alcohol-based product demonstrated 100% of peak efficacy (60s) within the first 15s, whereas the water-based product showed 99.97%. The novel alcohol-based antiseptic reduced concentrations of 100% of organisms by 99.999%, whereas the water-based antiseptic lotion showed the same reduction for 96% of organisms. A novel water-based antiseptic product demonstrated equivalent rapid, broad-spectrum antimicrobial activity to an alcohol-based sanitizer and provided additional benefits of reduced irritation, persistent effect, and greater efficacy against common viruses. The combination of rapid, broad-spectrum immediate kill and persistent efficacy against pathogens may have significant clinical benefit in limiting the spread of disease.

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4. J Hosp Infect. 2014 Jan;86(1):64-7. doi: 10.1016/j.jhin.2013.09.013. Epub 2013 Oct 16.

In vivo comparative efficacy of three surgical hand preparation agents in reducing bacterial count.

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**BACKGROUND:** Besides objective efficacy, the choice between an antiseptic-based liquid soap, or an alcohol-based hand rub for surgical hand preparation technique is based on personal preference. Glycerol is often added to the formulations in order to enhance tolerability; however, it has been recently reported as a factor reducing the sustained effect of surgical hand rubs.

**AIM:** To compare the efficacies of three commercial products for hand decontamination.

**METHODS:** The in vivo efficacy of an alcohol-based hand rub (isopropyl alcohol 40%; N-propyl alcohol 25%; glycerin 1.74%; triethanolamine salt of carbomer <1%) was compared with other widely used products in surgical hand antisepsis (chlorhexidine and povidone-iodine). All products were used according to the manufacturers' instructions.

**FINDINGS:** The best results were achieved with the alcohol-based hand rub and these were sustained for a period of 3h. Some volunteers experienced skin peeling off the hands when using alcohol-based hand rub; in this group of participants, the bacterial count was reduced only by  $0.91 \pm 1.67 \log_{10}$  compared with  $2.86 \pm 1.22 \log_{10}$  in the group who did not show this phenomenon.

**CONCLUSION:** Besides confirming the importance of alcohol-based hand rubs for surgical hand decontamination, the results suggest the value of assessing the characteristics, and response of healthcare workers' skin, that may contribute to the development of skin peeling, and the subsequent possibility of a paradoxical overcolonization of hands after surgical preparation with alcohol-based hand rub.

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5. Infect Control Hosp Epidemiol. 2009 Jul;30(7):685-90. doi: 10.1086/598239.

Microbiological efficacy and tolerability of a new, non-alcohol-based hand disinfectant.

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**OBJECTIVE:** Alcohol-based hand disinfectants are widely used in hospitals. Occasionally, there is a need for non-alcohol-based products, but alternatives have been scarce. We studied the microbiological efficacy and tolerability of a water-based hand disinfectant for healthcare workers.

**DESIGN:** A water-based hand disinfectant was introduced as the only hand disinfectant in 5 wards in Turku University Hospital, Finland. Ninety-nine healthcare workers participated in fingerprint sampling during the 7-week study period. In another ward, 26 healthcare workers who were using alcohol-based hand disinfectant acted as control subjects for the skin reaction studies. The water-based product was tested in the laboratory according to the European standard EN 12791. We obtained 292 fingerprint samples before disinfection and 302 after disinfection. The opinions of healthcare workers were collected by use of a questionnaire, and skin reactions were assessed subjectively by use of questionnaires and objectively by measuring moisture and transepidermal water loss.

**RESULTS:** When tested in accordance with the European standard, the product met the requirements for short-term and long-term efficacy. The results of the fingerprint test showed that there was a statistically significant decrease in colonization of the fingertips before and after disinfection ( $P < .001$ ). 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.

**CONCLUSIONS:** The water-based hand disinfectant was shown to be an effective hand disinfectant that caused relatively little skin irritation and can serve as a hand hygiene alternative in situations in which alcohol-based disinfectant cannot be used.

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