Soap: the science behind it and tools and tips for selecting a hand soap that's right for your facility.

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GOJO

Introduction

Hand hygiene is the primary measure to prevent transmission of pathogens in healthcare facilities[1] and alcohol-based hand rub (ABHR) is designated as the preferred method for performing hand hygiene by the 2002 Centers for Disease Control and Prevention (CDC) and the 2009 World Health Organization (WHO) hand hygiene guidelines. However, soap and water also plays a critical role in hand hygiene, namely when hands are visibly soiled or contaminated with blood or other bodily fluids and when there are outbreaks of *Clostridium difficile* or norovirus.[2]

Because ABHR has been the primary focus for hand hygiene, soap has received less attention in recent years, and due to limited data around soap, many healthcare facilities have given less thought to the type of soap they are using. When soap does become the focus, it is often when healthcare facilities are faced with changing their soap products, and they look for technical information to assist them in their decision-making that typically does not exist.

The purpose of this paper is to educate infection preventionists and other key decision makers on the science of soap, help explain the regulatory pathways of soaps used in healthcare settings, and provide guidance on how to evaluate soap products to support a facility's decision on which soap is best.

Background

Prior to publication of the 2002 CDC hand hygiene guidelines, soap was the predominant hand hygiene product. Today, ABHR represents about two-thirds of all hand hygiene product sales in healthcare.[3] While ABHR is the primary pillar of hand hygiene due to its many proven advantages such as superior efficacy, speed of procedure, better compliance, and skin health benefits,[4] soap remains an important aspect of the hand hygiene regimen that is not always given as much consideration as it deserves.

The Science of Soap

Soap's Mechanism of Action

When selecting the type of soap for a healthcare facility, it's important to first understand how soap works. The general mechanism of action is lifting and suspending oil, dirt, and other organic substances from hands so they can be rinsed down the drain, much like cleaning a dirty dish. Alkali metal salts of fatty acids, such as sodium laurate and potassium cocoate, are traditionally used as soaps. Soaps are classified as surfactants (surface active agents) as they possess both polar (ionic/hydrophilic) and non-polar (long hydrocarbon/hydrophobic) groups. When soap is added to water, tiny clusters called micelles are formed due to aggregation of hydrophobic segments. The ionic segments of surfactants orient outward of the core aggregates/micelles. Hydrophobic segments of micelles have strong affinity towards oil-type dirt and germs, and the hydrophilic segments of micelles attract toward the water-soluble materials. As a result, soaps are capable of cleaning skin and other substrates by removing both water soluble and water-insoluble dirt from the substrates and suspending them in aqueous solutions.

In recent decades, detergents have also been used as soaps. Detergents have similar functional groups as soaps but their hydrophilic groups can be of various types including anionic, non-ionic, cationic, or amphoteric, instead of carboxylic salts. Examples of detergents include sodium laureth sulfates, alkyl polyglucosides, cocamidopropylbetaine and fatty alkyl amine oxides.

With plain or non-antimicrobial soaps, organic substances and some microorganisms on the skin are removed, but the commensal resident organisms that are reduced quickly regrow to a normal level. The target organisms for removal are transient, non-resident organisms that may cause illness. Antimicrobial soaps also contain an antibacterial active ingredient that interacts with and kills bacterial cells. Some actives (e.g. chlorhexidine gluconate or CHG) may deposit on the skin's surface in low levels, which keeps the number of microorganisms to a reduced level by static activity for an extended period of time. There are several active ingredients that are used in antimicrobial soap formulations in healthcare, and their spectrum of activity and efficacy against microorganisms varies and can be greatly affected by the other non-active ingredients in the formula **(Table 1)**.

variables, cost, and reasons of practicality. However, studies of germ reduction on the hands support that ABHR is most efficacious, followed by antimicrobial soap, followed by non-antimicrobial soap as least efficacious **(Table 2)**.[1] That said, healthcare facilities are permitted the choice between antimicrobial and non-antimicrobial soap, or may use a combination of the two.

A good way to approach the decision of whether to choose an antimicrobial or a non-antimicrobial soap is to consider risk reduction. **Table 3** shows comparisons of the average $\log_{10}$ reductions against bacteria after a single hand wash using water, non-antimicrobial soap, and antimicrobial soap. The greatest risk reduction will be achieved by using an antimicrobial soap. For example, if a healthcare

Table 1. Active Ingredients Commonly Used in Soaps and Sanitizers Today and Their Spectrum of Activity

Product Type	Active Ingredient	Gram + activity	Gram – activity	Viral activity Enveloped/ Non-enveloped	Fungal activity	Current Monograph Ingredient
Sanitizer	Ethyl alcohol	+++	+++	+++/++	+++	Yes
Soap	Triclosan	+++	+	+/?	±	No
	Chloroxylenol (PCMX)	+++	+	+/±	+	Yes
	Quaternary ammonium compounds (quat)	++	+	+/?	±	Yes
	Chlorhexidine gluconate (CHG)	+++	++	++/+	+	No; requires New Drug Application

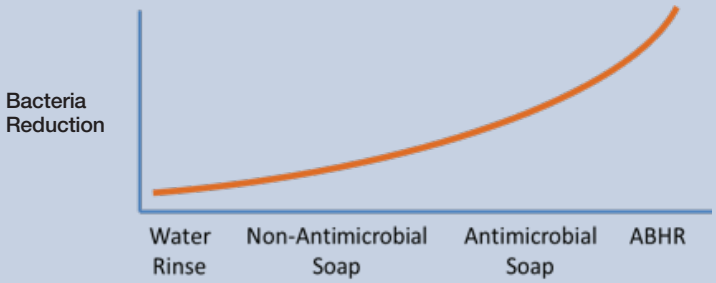
Good = +++, moderate = ++, poor = +, variable = ±, none = –, unknown=?

Adapted with permission from Pittet, Allegranzi & Sax, 2007. WHO Guidelines on Hand Hygiene in Health Care: First Global Patient Safety Challenge Clean Care Is Safer Care. Geneva: World Health Organization; 2009.

Lack of Consensus around Antimicrobial versus Non-antimicrobial Soap

Both CDC and WHO hand hygiene guidelines allow the use of either an antimicrobial or a non-antimicrobial soap, and due to a lack of evidence demonstrating clinical benefit (i.e. resulting reduction of infection rates), do not recommend one over the other. Clinical data are lacking due to complexity of designing such a study, difficulty eliminating confounding

Table 2. Relative Efficacy of Different Hand Hygiene Preparations



Centers for Disease Control and Prevention. Guidelines for hand hygiene in health-care settings—2002. Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51 (RR-16):1-45.

worker's (HCW) hands are contaminated with 10,000 bacteria and he or she were to wash with plain water only, a 1 log_{10} reduction would be achieved, leaving 1,000 bacteria behind. Traditional non-antimicrobial soap would result in around a 2 log_{10} reduction and would leave 100 bacteria behind. Washing with an antimicrobial soap would result in around a 2.5 to 3 log_{10} reduction, resulting in between 10 and 30 bacteria remaining on the hands. Depending on the organism, the difference between exposure to 10 to 30 bacteria versus 100 bacteria could potentially mean the difference between acquiring an infection or not. Therefore, facilities seeking the highest level of risk reduction should choose an antimicrobial soap.

In addition, HCW often failed to cover all surfaces of their hands and fingers highlighting the fact that there is a need for education around proper technique.

Soap's Effects on Skin

Even though ABHR is positioned as the most efficacious and mildest hand hygiene approach, ABHR are not intended or effective at removing visible soil from hands.

Table 3. Average Log_{10} Reductions of Different Hand Washing Preparations

Product Type	Average Log Reductions Against Bacteria	If 10,000 Bacteria on Hands, How Many CFU* Remain on Hands	If 1,000 Bacteria on Hands, How Many CFU* Remain on Hands
Water	1.00	1,000	100
Traditional Non-Antimicrobial Soap	~2.00	100	10
Antimicrobial Soap	2.50-3.00	10-30	1-3

*CFU, Colony-forming units

Handwashing Technique

While there's a lack of consensus on type of soap, there's more consensus around handwashing technique. The CDC recommends wetting hands first with water, applying a manufacturer-recommended volume of product to hands, and rubbing vigorously for at least 15 seconds, covering all surfaces of the hands and fingers, followed by rinsing and drying thoroughly with a disposable towel. The WHO recommends a similar method, although they provide more specifics when it comes to vigorously rubbing all surfaces of hands and fingers, separating the process into very specific steps such as palm to palm, fingers interlaced, rotational rubbing of thumb and so forth. Despite published recommendations, HCW have been observed not rubbing for an adequate amount of time. In ten observational studies, the duration of handwashing ranged on average from as little as 6.6 seconds to as much as 30 seconds.[5]

Soap is still a critical component of a hand hygiene program and should be used when hands are visibly soiled or contaminated with blood or other bodily fluids, before eating, and after using the restroom.

HCW skin health is an important factor affecting hand hygiene compliance and there is a perception that ABHR cause skin damage. But, if ABHRs are properly formulated, soap and water use is generally the main factor affecting skin condition with current hand hygiene products today.

It is well known that washing with soap, specifically surfactants, can damage the skin's barrier. The stratum corneum (SC) is the very top layer of skin and it can be described using a "brick and mortar" model. Under a microscope, the skin barrier, when healthy, looks like a brick wall. The "bricks," are called corneocytes, which are really dead skin cells. They are held in place by a lipid bilayer and moisture which is the "mortar." The lipid bilayer is composed of two layers of fatty acids. Its role is to help "lock in" moisture.

There is a science to properly formulating soap, and poorly formulated soaps will be very harsh on the skin. As they lift the dirt, they will also remove natural components of the skin (corneocytes and lipids) that help keep skin healthy. This sets up a vicious dry skin cycle that worsens with each soap wash.

Finally, any insult to the SC barrier then leads to an increase in epidermal nerve density that can cause sensations of stinging, burning, itching, tingling and tightness. This is often recognized during contact with ABHR, but it is the soap, specifically surfactants, that created the condition. In addition, environmental stressors such as low relative humidity, using hot water, and low quality of paper towels can also affect the skin.[6] Therefore, it is critical to provide the right product formulation to minimize damage and keep the "bricks and mortar" intact. These tightly packed "bricks" help restore the skin's natural protection against the environment, chemicals, and pathogens.

As discussed earlier, antimicrobial soaps remove dirt, oil, and organic substances from the skin; however, they also have the addition of an active ingredient to help kill germs.

Traditionally, antimicrobial soaps have been less mild to skin than non-antimicrobial soaps; however, the latest generation of antimicrobial soaps can provide antimicrobial efficacy as well as improved skin mildness.

Choosing a well-formulated soap with low potential for irritation can help mitigate skin health issues and will be discussed later in this paper. But first, it's important to understand the regulatory pathways for soap.

The Regulatory Landscape

The Food and Drug Administration (FDA) Division of Over-The-Counter (OTC) Drug Products regulates the use of topical antiseptic drug products used in healthcare. Antimicrobial soaps used in healthcare settings fall under this category. There are two regulatory pathways for these products; one is the New Drug Application (NDA) and the other is the Monograph process.

The Healthcare Monograph

The Healthcare OTC Monograph Final Rule represents the regulatory standards for the marketing of antimicrobial soaps not covered by a New Drug Application. The Monograph establishes conditions under which certain OTC active ingredients are generally recognized as safe and effective. The Monograph is a "recipe book" that specifies allowed ingredients, doses, product form, indications for use, warnings and also provides a set of labeling and testing requirements for manufacturers.[7]

Alternative Regulatory Pathway – New Drug Application

Products that contain active ingredients not included in the Monograph or combinations of active ingredients follow a different regulatory pathway. The New Drug Application (NDA) pathway is the vehicle through which drug sponsors (the person or entity who assumes responsibility for the marketing of a new drug) formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.[8] The FDA reviews the application to determine whether the drug is safe and effective when used as proposed, whether the drug's labeling is appropriate, and whether the drug was manufactured in a way that maintains the quality of the drug. If the NDA is approved, then the drug may be marketed and sold in the U.S. This is how prescription drugs are brought to market.
As an example, chlorhexidine gluconate (CHG) is an active ingredient used in a variety of applications in healthcare today, including hand washes, patient bathing, pre-operative skin preparation, impregnated dressings and a variety of other antiseptic uses to prevent colonization and infection by bacteria. CHG is not an active ingredient covered by the Monograph and therefore requires a NDA.

Choosing a Soap for Your Healthcare Facility

With all of the considerations around soap, selecting the right product can be confusing. Additionally, there can be reluctance to changing hand hygiene products in healthcare facilities due to the many considerations that go along with it, such as potential for a period of adjustment among HCW, the logistics involved with switching dispensers, and disruptions to the clinical workflow. When considering a product change or if you're currently using a soap active ingredient with an uncertain future, it's important to carefully select the right product and right dispensing solution for your facility.

As previously discussed, soap has not been given as much consideration as ABHR when healthcare facilities have chosen hand hygiene products.

Poorly formulated soap can have profound negative effects on HCW skin condition and can contribute to a cycle of skin damage that is reinforced by avoidance of ABHR and continued over-use of soap. Therefore, selecting well-formulated products is an important foundational aspect of a hand hygiene and an infection prevention and control program.

How to Select the Right Soap for Your Facility

Factors to consider when selecting soap for your healthcare facility are summarized in **Table 4**. Deciding whether to use an antimicrobial or a non-antimicrobial soap is often the first decision. Many healthcare facilities take a risk-reduction approach by utilizing an antimicrobial soap for added protection, while some choose a hybrid approach and deploy antimicrobial soap to high acuity areas such as intensive care units, hematology-oncology areas, and surgical areas. Others use non-antimicrobial soaps throughout the facility. While the evidence around whether antimicrobial soaps result in better clinical outcomes remains elusive, it is estimated that as much as two-thirds of the soaps sold into healthcare today is antimicrobial.[3]

Key Factors to Consider When Selecting a Soap

Developing a truly mild, yet effective soap that can be used multiple times during a HCW's shift is a significant technical challenge, so it's important to carefully assess products under consideration. It can be very helpful to evaluate soaps within the context of three important factors: efficacy, skin health, and aesthetics (skin feel). It is important to note that more sensitive skin often undergoes a period of adjustment during which the skin's natural defenses must adapt to any product change that is made. As a result, trialing products for a minimum of two-to-three weeks is essential since the stratum corneum renewal time or "turnover" typically occurs in that timeframe.[9] If there are skin adjustment issues that occur during the beginning of a trial period, they should also subside within that two-to-three week window. It is also advisable that if trialing more than one product back-to-back, a washout period of around one week between

products is scheduled during which time the previous product is re-implemented. The WHO provides two protocols for evaluation of tolerability and acceptability of ABHR which can be adapted fo soap evaluations.[10]

Efficacy. For antimicrobial soaps, it is not only important to consider different active ingredients, but also evaluate the efficacy of finished formulations. The Healthcare Personnel Handwash Test is the only FDA-accepted test for healthcare hand wash products and it measures the reduction of a transient market organism (*Serratia marcescens*) on the hands of adult subjects after a single product use and after 10 consecutive product uses. The FDA requires antimicrobial hand wash and hand rub agents achieve a 2-$\log_{10}$ reduction at Application 1 and a 3-$\log_{10}$ reduction at Application 10.[11] Product manufacturers should supply customers with this data for products being sold into healthcare.

Skin health. How a product affects the skin health of end-users is especially important in environments such as healthcare where repeated use scenarios are common. While the OTC Monograph does not specify irritancy testing requirements, ensuring skin tolerance of products is critical to maximizing HCW acceptance and hand hygiene compliance.[1] Industry standard is a 14-day human cumulative irritancy assay with delayed challenge. This type of study is designed to assess the irritation potential of test product and involves daily, consecutive application of product in "patches" to the forearm of human subjects for 14 days. A control material or product is also included in the study. Dermal reactions, including erythema, edema, and other features indicative of irritation, are scored by expert visual assessments using a standard scale. A mean cumulative irritation score on a scale of 0-4 is reported with lower numbers indicating lower potential for skin irritation and allergic contact dermatitis. Forearm controlled application tests are also used to determine irritation or skin improvement effects of products under more "real world" conditions over an extended period of time. The most important tests, however, are field or clinical tests that determine irritation or skin improvement effects of products with realistic conditions and behaviors in clinical settings.

Aesthetics/Skin Feel. Product aesthetics and skin feel are focused towards end-user acceptance. Aesthetic considerations can begin with how the product looks (color), the product form (foam or liquid), and the sensory experience during use which it lathers and rinses. The bottom line is that if HCW do not like a product, they are less likely to use it,[12] so aesthetic and skin feel considerations should not be minimized.

Balancing efficacy, skin health, and skin feel can be difficult to accomplish, but with proper formulation, of both ABHRs and soaps, it is possible to achieve this balance.

Table 5. Factors to Consider when Selecting a Soap for a Healthcare Facility

Factor	Considerations
Antimicrobial vs. Non-Antimicrobial Soap	• Determine level of "risk tolerance" o For greatest risk reduction, choose an antimicrobial soap • Consider a single soap product approach or a hybrid approach (e.g. antimicrobial in high acuity areas only) o A hybrid approach can add complexity for Environmental Services (EVS)
Efficacy (Antimicrobial Soaps)	• Product should meet FDA efficacy requirements defined in OTC Monograph o Solicit product manufacturer for technical bulletin
Skin Health/ Mildness	• Maintains skin condition with repeated use • Solicit skin health testing data from product manufacturer o 14 day irritancy test is used to determine exaggerated irritant potential that may be cumulative with repeated exposure of a material. o Forearm controlled application test is used to determine irritation or skin improvement effects of products under more "real world" conditions over an extended period time. As part of this test, skin hydration, TEWL, skin erythema, redness and dryness and other measures may be conducted to evaluate product performance. • Field or home-use tests are used to determine irritation or skin improvement effects of products with realistic conditions & behaviors
Aesthetics (Skin Feel)	• Color o Color can be used to connote or visually depict features and benefits of the product (ex. aloe-containing products are often green and perceived as soothing) o Some facilities prefer dye-free products whenever possible • Format (foam vs. liquid) - this is purely a preference • Lather - product should have an acceptable lather • Rinse - product should rinse easily and leave behind a "clean feeling" • Scent/odor/fragrance o Fragrance can be a positive aspect of the sensory experience, and in one study had a positive effect on hand hygiene compliance.[13] o Some facilities have a fragrance-free policy. o Fragrance is often used to minimize the base odor of raw ingredients and active ingredients which can often have an unpleasant odor. o Fragrance can either be synthetic or natural (e.g. essential oils). o If carefully selected, fragrance can be used in levels appropriate for the healthcare environment.

Table 5. Factors to Consider when Selecting a Soap for a Healthcare Facility (conti.)

Factor	Considerations
Dispensing Solutions	• Touch-free o In one study, touch-free dispensers were used significantly more than manual dispensers and were associated with an increased hand hygiene compliance rate[14] o Believed to reduce cross-contamination by multiple users[15] • Manual o Allows for adjustment of amount of product dispensed, which may impact efficacy[15] • Sealed container - products used in healthcare should come in sealed containers. Refilling bottles or "topping off" product is not acceptable practice in healthcare facilities.[1] • Environmental considerations – inquire with product manufacturer as to whether empty refill containers are recyclable. • Compatibility with Electronic Compliance Monitoring (ECM) technology – determine if dispensers are ECM-ready should upgrading to this technology be of future interest
Other Value Added Programs	• Education – inquire if the vendor offers education around their product in the form of in-services, peer-reviewed publications, or other materials.
HCW acceptance	• Both the CDC and the WHO recommend soliciting input from HCW when selecting hand hygiene products to maximize acceptance. Ideally, HCW should be given the opportunity to trial products at minimum for two weeks. The WHO provides two product trial protocols for consideration.[10]
Product Compatibility and Known Interactions	• Solicit information from product manufacturer on product compatibility. Inquire about known interactions between products used to clean hands, skin care products, and type of gloves used.[1]
Cost	• While cost is an important consideration for most healthcare facilities, it should not be the overriding factor when selecting a product.[1] If a product is not of acceptable quality, well-formulated, and liked by HCW, then it may not be used.

Conclusion

When faced with the challenge of choosing a new soap, it is important for key decision makers to be armed with as much knowledge around soap as possible. Although ABHR should remain the primary method for performing hand hygiene, soap continues be an important piece of the hand hygiene regimen. Careful consideration should be given when selecting soap due to its potential for adverse skin effects if not properly formulated. Evaluating soap and ABHR in terms of efficacy, skin health, aesthetics/skin feel, and regulatory stability can be helpful. As always, allowing HCWs the opportunity to trial products and provide input is a critical aspect of product acceptance. While selecting the right soap may not be easy, being well-informed about the options and key selection factors can help make the process easier.

Reference List

1. Centers for Disease Control and Prevention. Guidelines for hand hygiene in health-care settings—2002. Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51 (RR-16):1-45.
2. Dubberke ER, Carling P, Carrico R, et al; Society for Healthcare Epidemiology of America. Strategies to prevent Clostridium difficile infections in acute care hospitals: 2014 update. Infect Control Hosp Epidemiol. 2014;35(6):628-645.
3. Market share information derived through Global Healthcare Exchange, LLC dataset, 2015.
4. Widmer AF. Replace and washing with use of a waterless alcohol hand rub? Clin Infect Dis. 2000;31:136-43.
5. World Health Organization. WHO guidelines on hand hygiene in health care. First global patient safety challenge: clean care is safer care http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf. Published 2009. Accessed March 13, 2018.
6. Larson E, Girard R, Pessoa-Silva CL, Boyce J, Donaldson L, Pittet D, et al. Skin reactions related to hand hygiene and selection of hand hygien products. Am J Infect Control. 2006;34:627-635.
7. Over-the-counter drug Monograph process. U.S. Food and Drug Administration Web site. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm317137.htm Updated January 7, 2015. Accessed March 13, 2018.
8. New Drug Application (NDA). U.S. Food and Drug Administration Web site. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm Updated March 29, 2016. Accessed March 13, 2018.
9. Baker H. Technique for estimating turnover time of human stratum corneum. J Am Med Assoc. 1967;95(4):408-411.
10. Clean care is safer care: tools for evaluation and feedback. Centers for Disease and Prevention Web site. http://www.who.int/gpsc/5may/tools/evaluation_feedback/en/ Accessed March 13, 2018.
11. Department of Health and Human Services Food and Drug Administration (FDA). Tentative final monograph for health-care antiseptic drug products; proposed rule. Federal Register. 1994;59(116):31402-31452.
12. The Joint Commission. Measuring hand hygiene adherence: overcoming the challenges. Oakbrook Terrace, IL: The Joint Commission; 2009.
13. Birnbach DJ, King D, Vlaev I, Rosen LF, Harvey PD. Impact of environmental olfactory cues on hand hygiene behaviour in a simulated hospital environment: a randomized study. J Hosp Infect. 2013;85(1):79-81.
14. Larson EL, Albrecht S, O'Keef M. Hand hygiene behavior in a pediatric emergency department and a pediatric intensive care unit: comparison of use of 2 dispenser systems. Am J Crit Care Nurses. 2005;14:304-311.
15. Landers T. Hand hygiene products. In: Association of Professionals in Infection Control. Guide to Hand Hygiene Programs for Infection Control. 1st ed. Washington, DC: APIC; 2015.

Biography

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