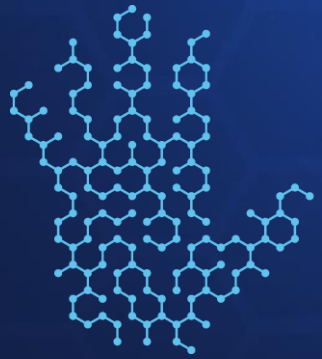
Navigating the New Soap Landscape in Healthcare
FDA Final Rule, Science of Soap & Best Practices for Skin Health



Tracy Clark, MSN, RN, CPPS

Learning Objectives

1. Explain the purpose of the FDA Monograph and summarize recent changes.

2. Describe how the FDA and the healthcare facility will ensure safety from a nurse/healthcare worker and patient safety standpoint.

3. Review available antimicrobial ingredients and their future statuses.

4. Define important attributes of a hand hygiene product, including efficacy, skin health, and aesthetics needed to drive hand hygiene compliance.

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Why Is This an Important Topic?

- Current guidance around soap is limited
- Regulatory changes affecting soap have taken place and may be confusing for healthcare workers
- Product availability has been affected
- Soap is an essential part of an effective hand hygiene program
- Healthcare facilities may need assistance in interpreting the changes and making adaptations as needed

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EFFICACY AND RECOMMENDATIONS AROUND SOAP

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Hand Hygiene Overview

Soap and Water:

- When hands are **visibly soiled or contaminated** with blood or other bodily fluids
- In outbreaks of *C. difficile*
- Before eating
- After using the restroom

Alcohol-Based Hand Rub (ABHR):

- **In all other clinical situations** if hands are not visibly soiled

Hand sanitizing with alcohol-based hand rub is the gold standard in all situations when hands are not visibly soiled

Visibly soiled = Hands on which dirt or body fluids are readily visible

- Hand washing represents approximately **15%** of hand hygiene events in acute care facilities

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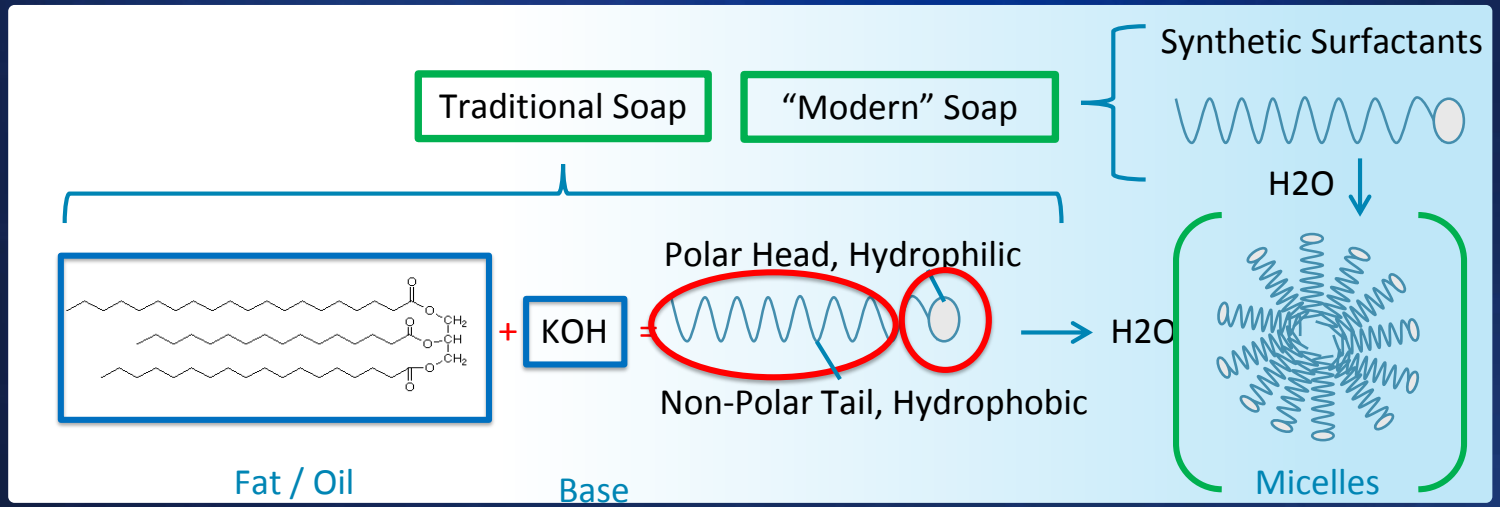
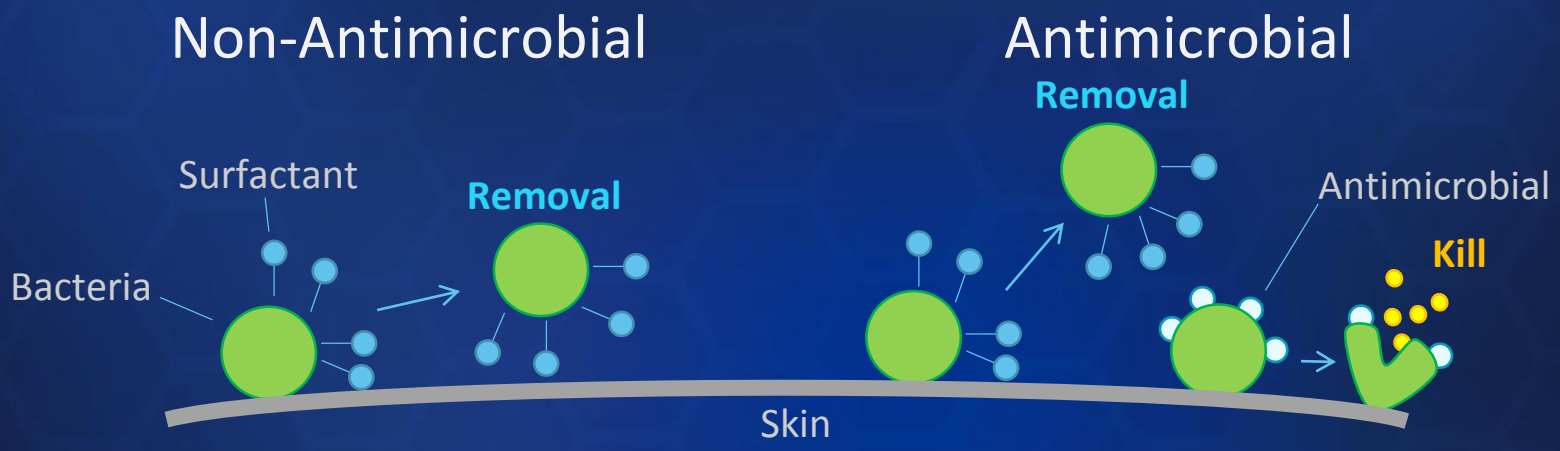
History and Science of Soap

- A soap-like material found in clay cylinders during the excavation of ancient Babylon is evidence that soap making was known as early as 2800 B.C.
- Records show that ancient Egyptians bathed regularly
- The first of the famous Roman baths, supplied with water from their aqueducts, was built about 312 B.C.



Mechanism of Action of Soap



Product	Average Log Reductions Against Bacteria After Single Wash	Average Log Reductions Against C. *difficile* Spores After Single Wash
Water	1.00	0.75
Plain	~2.00	0.75-1.25
Antimicrobial	2.50-3.00	0.75-1.25

*Edmonds et. al. Infection Control and Hospital Epidemiology, March 2013, Vol. 34, No. 3

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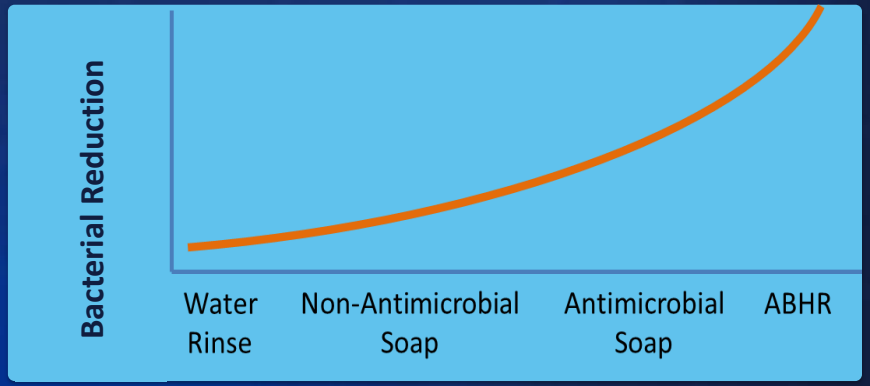
Non-Antimicrobial vs. Antimicrobial Soap

- **CDC and WHO recommend the use of either antimicrobial or non-antimicrobial soap**
  - **There is** no clinical data demonstrating a clinical benefit of antimicrobial soaps
    - Studies are complex, expensive, long-term, difficult to control
  - Selection based on risk profile/tolerance
    - **Estimated 60+% of soap sold in healthcare is antimicrobial**



Centers for Disease Control and Prevention. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002:51 [pg 27]

Product	Average Log Reductions Against Bacteria After Single Wash	If 10,000 Bacteria on Hands, How Many CFU Remain on Hands After Hand Wash?	If 1,000 Bacteria on Hands, How Many CFU Remain on Hands After Hand Wash?
Water	1.00	1,000	100
Plain	~2.00	100	10
Antimicrobial	2.50-3.00	10-30	1-3

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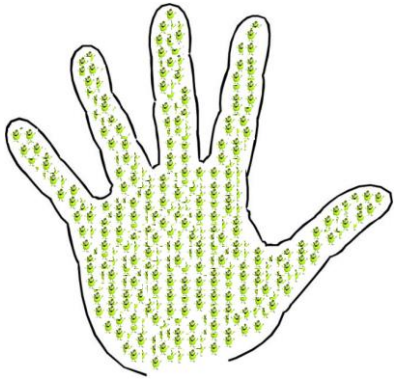
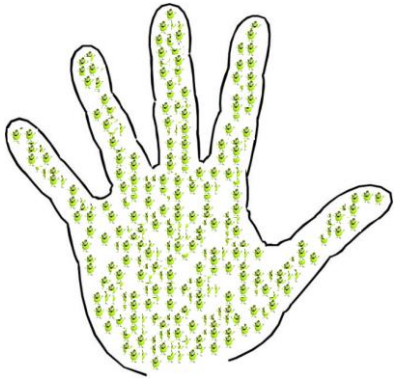
The Effects of Different Hand Hygiene Regimens on the Reduction of Bacteria from Hands

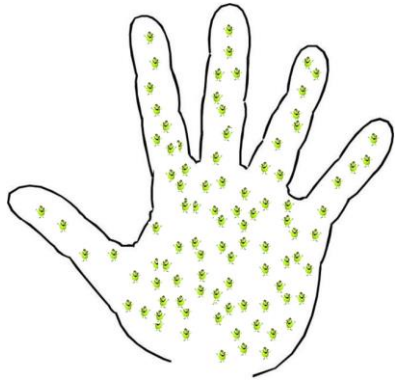
Baseline =
10,000 Bacteria



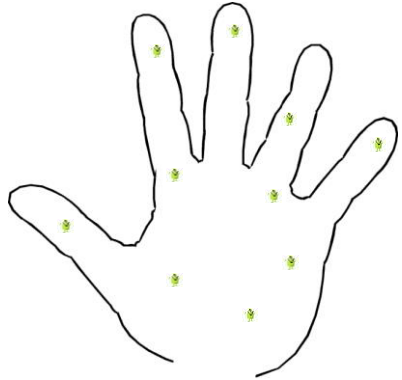
After water =
1000 Bacteria
(1 log= 90%)



After plain soap =
100 Bacteria
(2 log= 99%)



After antimicrobial soap =
10 Bacteria
(2.5-3 log = 99.9%)



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FDA HEALTHCARE ANTISEPTIC MONOGRAPH

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Over-the-Counter (OTC) Drug Monograph

- OTC Drug Monograph Review initiated in 1972
- > 200,000 OTC drug products
  - 700 active ingredients
  - 52 therapeutic categories
- Tentative Final Monograph 1994

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
21 CFR Parts 333 and 369
[Docket No. 75N-183H]
RIN 0905-AA06

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Prouducts

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice of proposed rulemaking

Federal Register / Vol. 59, No. 116 / Friday, June 17, 1994 / Proposed Rules

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1994 Over-the-Counter Drug Monograph System

A drug monograph establishes conditions under which an OTC drug is GRASE

(Generally Recognized as Safe and Effective)

- Dosage strength
- Dosage forms
- Labeling
  - Indications
  - Warnings
  - Directions
- **Efficacy testing**
  - Category I – GRASE
  - Category II – Not safe or not effective
  - Category III – Not enough data to determine safety or effectiveness

Products containing Category I and Category III actives can be sold into the market under a Tentative Final Monograph

In the Final Rule: Categories are replaced by terms "monograph" and "non monograph"

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Monograph Changes

Federal Register / Vol. 59, No. 116 / Friday, June 17, 1994 / Proposed Rules

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ACTION: Notice of proposed rulemaking

Active Ingredient	Hand Wash Application
Benzalkonium Chloride (BAK)	III
Benzethonium Chloride (BEC)	III
Chloroxylenol (PCMX)	III
Triclosan	III
Chlorhexidine Gluconate (CHG)	New Drug Process

*Category III: Not enough data to make a final decision on safety and effectiveness, but sufficient data for sale of products until monograph is finalized

August 03, 2010

NRDC Sues FDA for Failing to Take Action on Triclosan and Triclocarban

November 28, 2013

FDA Enters Into Consent Decree; Agrees to Timely Complete Triclosan OTC Drug Antiseptic Monographs

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Soap Active Ingredients

- Today
  - Category III (safety and efficacy) active ingredients; Still permitted to use
- Final Monograph
  - In order for an active ingredient to make the final monograph any safety / efficacy data gaps would need to be addressed (see below)
- **Deferrals submitted for BAK, BEC, PCMX**
  - These actives have been given additional time to complete required testing

Table 10. Safety Studies Available for Health Care Antiseptic Active Ingredients[1]

Active Ingredient[2]	Human Pharmaco - kinetic (MUsT)	Animal Pharmaco - kinetic (ADME)	Oral Carcino-genicity	Dermal Carcino-genicity	Reproductive Toxicity (DART)	Potential Hormonal Effects	Resistance Potential
Benzalkonium Chloride			○				○
Benzethonium Chloride		○		●	○		○
Chloroxylenol	○	○			○		○
Triclocarban	○	○	●		○	○	
Triclosan	○[4]	○	●		●	○	○

Active Ingredient	Hand Wash Application
Benzalkonium Chloride (BAK)	III
Benzethonium Chloride (BEC)	III
Chloroxylenol (PCMX)	III
Triclosan	III

14Empty cell indicates no data available; "○" indicates incomplete data available; "●" indicates available data are sufficient to make a GRAS / GRAE determination.

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Monograph vs New Drug Application (NDA) Process

MONOGRAPH

- A “rule book” listing **ingredients** for each therapeutic category
- Lists Generally Recognized As Safe and Effective (GRASE) Active ingredients:
  - Dosage strength
- Form
- Labeling:
  - Uses (indications)
  - Warnings
  - Directions
- **Final formulation testing for some categories**

NEW DRUG APPLICATION (NDA)

- Data demonstrating that a **specific formulated drug product** is safe and effective for use as directed for its approved indication
- FDA reviews sponsor’s submitted safety and efficacy data and approves the product before it can be legally sold
- Changes to formulation, manufacturing process, or other approved specifications must also be FDA reviewed and approved before marketing

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Chlorhexidine Gluconate (CHG) and the New Drug Application (NDA) Process

- Chlorhexidine Gluconate introduced into the market after 1972 and therefore not “eligible” for inclusion in the monograph process
- Several CHG containing products approved for sale via NDA process for various indications
- Products approved through the NDA process are not subject to monograph review
- Safety of NDA approved products monitored through active post-marketing surveillance programs

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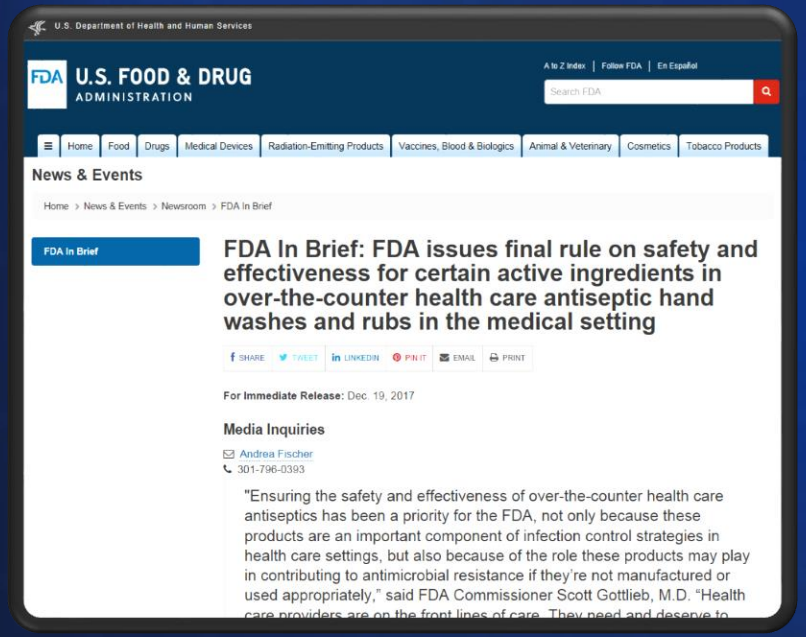
FDA Announces a Final Rule for Healthcare Skin Antiseptics: What Does It Mean?

Food and Drug Administration: Final Rule December 19, 2017


U.S. Department of Health and Human Services

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FDA In Brief

FDA In Brief: FDA issues final rule on safety and effectiveness for certain active ingredients in over-the-counter health care antiseptic hand washes and rubs in the medical setting

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For Immediate Release: Dec. 19, 2017

Media Inquiries

Andrea Fischer

301-796-0393

"Ensuring the safety and effectiveness of over-the-counter health care antiseptics has been a priority for the FDA, not only because these products are an important component of infection control strategies in health care settings, but also because of the role these products may play in contributing to antimicrobial resistance if they're not manufactured or used appropriately," said FDA Commissioner Scott Gottlieb, M.D. "Health care providers are on the front lines of care. They need and deserve to

Triclosan cannot be used as an active ingredient in skin antiseptic products used in "health care settings."

- Category I – GRASE
- Category II – Not safe or not effective
- Category III – Not enough data to determine safety or effectiveness

Categories I, II and III have been replaced with "Monograph" and "Non-monograph"

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What does “health care setting” mean?

- Outpatient medical and surgical facilities
- Dental clinics
- Skilled nursing or nursing homes
- Adult medical day care centers
- Public health clinics
- Imaging centers
- Oncology clinics
- Infusion centers, dialysis centers
- Behavioral health clinics
- Physical therapy
- Rehabilitation centers
- In private homes

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Monograph Implications for Healthcare Soaps

Current Actives	Current Status
Triclosan	Banned
Ethyl Alcohol (Ethanol)	Deferrals granted
Isopropyl Alcohol	Deferrals granted
Povidone-iodine	Deferrals granted
Benzalkonium Chloride (BAK)	Deferrals granted
Benzethonium Chloride (BEC)	Deferrals granted
Chloroxylenol (PCMX)	Deferrals granted
CHG (New Drug Application)	Not affected by Monograph changes

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FDA Final Rule: Effective December 20, 2018

- "Any OTC health care antiseptic drug product containing an ingredient that the FDA has found in this Final Rule to be non-monograph cannot be introduced or delivered for introduction into interstate commerce unless it is the subject of an approved NDA."
  - Manufacturers will have until December 20, 2018, to stop manufacturing and distribution of products containing triclosan--or reformulate those soaps.
- Deferred active ingredients will not be subject to the Final Rule and will be given extensions to allow for the submission of new safety and effectiveness data.
  - FDA requires Industry to provide ongoing progress reports to ensure the process moves forward.

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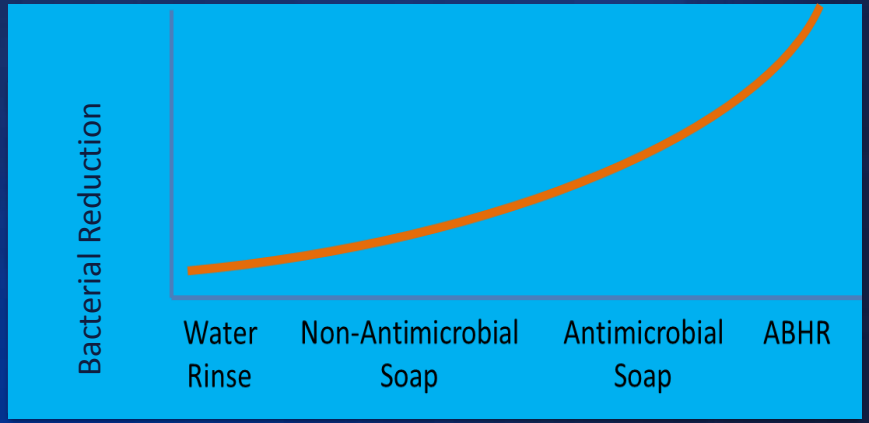
Non-Antimicrobial vs. Antimicrobial Soap

- **CDC and WHO guidelines allow the use of either antimicrobial or non-antimicrobial soap**
  - There is no definitive data demonstrating a clinical benefit of antimicrobial soaps over non-antimicrobial soaps
    - Studies are complex, expensive, long-term, difficult to control
  - Selection based on risk profile/tolerance



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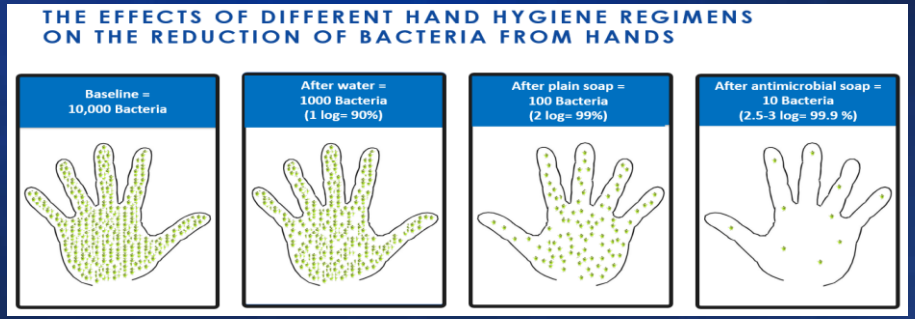

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Summary

- Handwashing is an essential part of an effective hand hygiene regimen
- CDC and WHO do not have recommendations for the type of soap used in healthcare facilities
- Antimicrobial soaps provide the greatest risk reduction
- The FDA has finalized the monograph; triclosan is now considered non- monograph
  - BAK, BEC and PCMX have uncertain futures
  - **CHG is a regulatory stable option because products have been proven safe and effective by FDA**
- Ultimately there are several critical factors that need to be considered when choosing the right soap formulation for your hospital

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SOAP FORMULATION AND EFFECTIVE BEHAVIORS FOR SUPERIOR SKIN HEALTH

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Skin Health Overview

- Anatomy of skin
- Impact of soap vs. ABHR on skin
- The cyclical effects of hand hygiene on skin
- Solutions to help break the cycle of skin damage
- Benefits of a well-formulated product
- Factors to consider when choosing soap

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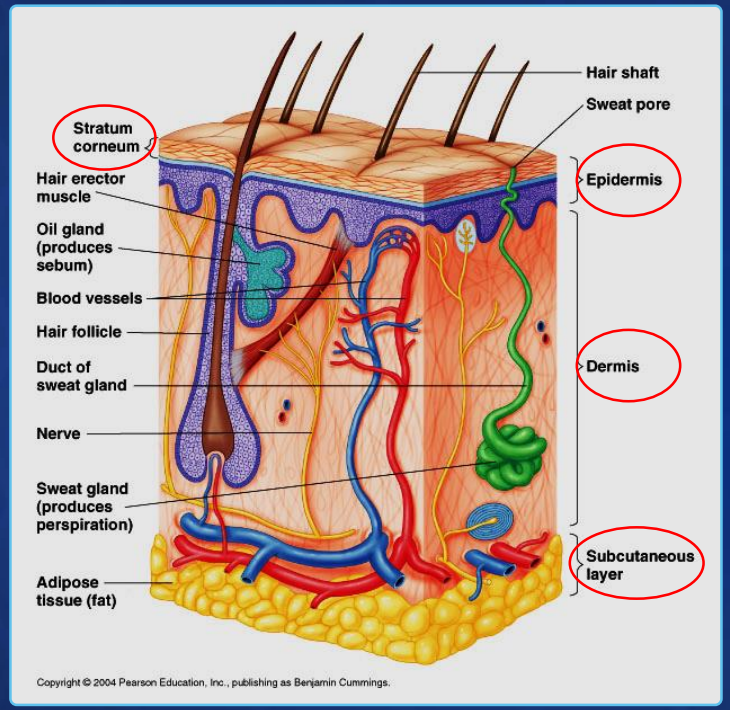
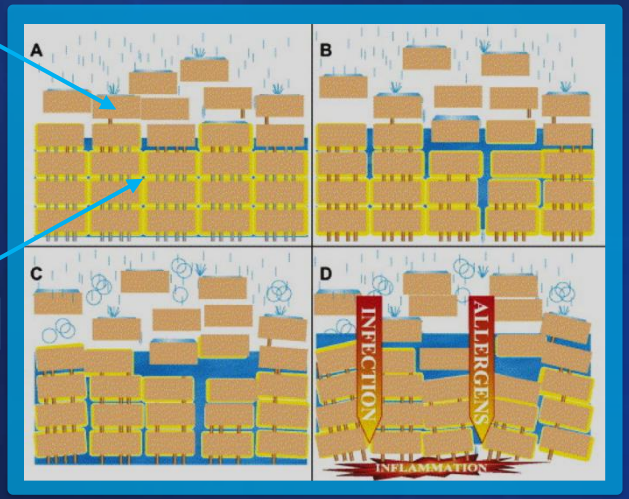
Anatomy of the Skin

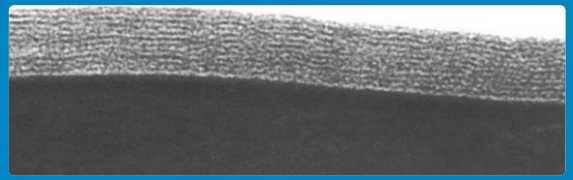


Effects on Stratum Corneum

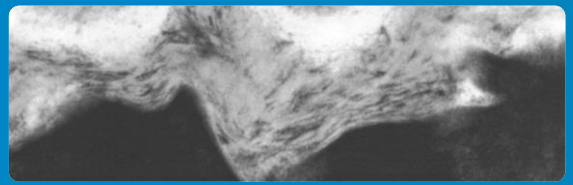
Corneocytes/Bricks

Lipids/Butter





Normal Stratum Corneum Lipid Structure



Disrupted Stratum Corneum Lipid Structure

- Moisture leaves the skin drying →
- Allergens and pathogens enter skin → dermatitis, infection

http://www.reamin.co.uk/en-gb/wp-content/uploads/2013/01/Infection.png

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Repetitive Exposure to Soap and Water

Soap has twofold effect

1. Removes some protective natural oils with each washing
2. Once oils are removed soap reaches living cells and damages them, leading to inflammation and reduced oil production

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The Cyclical Effects of Hand Hygiene On Skin

Workplace screening for hand dermatitis: a pilot study., Occup Med. 2016 Jan; Epub 2015 Sep 26., Nichol K, et. al. Hand hygiene compliance and irritant dermatitis: a juxtaposition of healthcare issues., Int J Cosmet Sci. 2012 Oct, Epub 2012 Jul 5, Visscher MO1, Randall Wickett R.

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Not all Soaps are Created Equal

- Soap is never meant replace ABHR
- But when used, it is important to select the right one
- It is possible to formulate a mild soap that is also efficacious

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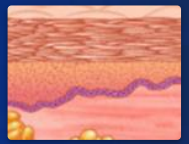
The Benefits of a Well-Formulated Product

Antimicrobial Efficacy
(Skin Microbiology)

Skin Health
(Maintain, Protect & Repair)

Skin Feel
(Aesthetics) **User Acceptance**



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Skin Feel: Aesthetics and Acceptability

User experience - chronic use

- Lather
- Odor (scent/fragrance)
- Rinsability
- Skin feel after use
  - Soft, conditioned, dry, irritated, facilitates easy gloving, etc.

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Breaking the Cycle of Skin Damage
Best Practices for Skin Care

1. Minimize handwashing with soap and water except when hands are visibly soiled or contaminated and when specified by your hospital policy
   - **In all other instances, use ABHR**
2. Always wet hands before applying soap to skin
3. The cooler the water the better – lukewarm at most
4. Rinse thoroughly
   - Surfactant residue is the primary cause of skin irritation
   - Don't forget all areas of the hands: finger webs / knuckles
5. Dry hands by patting, not rubbing with towels
6. Do not don gloves when hands are still wet with ABHR or water
7. Use facility-approved lotion frequently during shift
8. Don't forget skin care when not at work

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Key Conclusions

- Soap choice matters!
- Antimicrobial soaps provide the greatest risk reduction and have a history of safe use in healthcare settings
- Regulatory changes will force many health care facilities to transition to a new hand soap
- Soap can contribute to skin damage, but this can be minimized with proper formulation and using soap only when indicated
- The “best” hand hygiene products are those that achieve at least a threshold of antimicrobial efficacy while optimizing product acceptance elements to ensure maximum product usage.

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QUESTIONS AND DISCUSSION