GOJO

HAND HYGIENE TIMES

Your resource for the latest news in effective infection control program development and best practices.

Issue 3 Volume 2

Hand Hygiene in the Operating Room

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Hand hygiene in the Operating Room is a factor in decreasing health care associated infections (HAIs). Surgical wound infections can be caused by bacteria on the hands of the surgeon and their assistants. Healthcare associated infections can result in untoward outcomes such as escalating cost of care, increased morbidity and mortality, longer length of stay, as well as the pain and suffering a patient and their family may experience. When discussing surgical hand hygiene, it is important to understand the terminology.

Surgical Scrub Common Terms

- **Resident flora** – bacteria attached to deeper layers of skin and more resistant to removal. This bacteria is less likely to be associated with HAIs.
- **Transient flora** – bacteria which colonize on superficial layers of the skin, often acquired by Healthcare personnel (HCPs) during direct contact with patients and contaminated environmental surfaces. Transient flora is most likely to cause an HAI.
- **Persistence** – prolonged or extended antimicrobial activity that prevents or inhibits the proliferation and survival of microorganisms after application of a product.
- **Cumulative activity** – a progressive decrease in the numbers of microorganisms recovered after repeated application of a test product.[1]

FDA Regulations

The **purpose** of a surgical scrub is

- **to remove resident and transient microorganisms from the hands**
- **to reduce resident flora on the hands of the surgical team** for the duration of a procedure, reducing the risk of bacteria being released into the surgical field if gloves become punctured or torn.[2]

Surgical scrubs are considered an over-the-counter antimicrobial drug product and therefore must be regulated by the FDA. The FDA Topical Antimicrobial Drug Products for Human Use; Tentative Final Monograph (TFM) for Health Care Antiseptic Drug Products, published in 1994, defines a surgical hand scrub product as "an antiseptic containing preparation that significantly reduces the number of microorganisms on intact skin; it is broad spectrum, fast acting and persistent."[3]

There has been confusion around the suggestion that Chlorhexidine gluconate (CHG) must be an ingredient in a waterless Surgical Scrub. CHG is not required in formulations for surgical scrub to meet the FDA requirements. Water aided, traditional surgical scrubs often utilize CHG as the active ingredient, and some early alcohol based surgical scrubs utilized CHG as the secondary active ingredient to meet the antimicrobial efficacy requirements outline in the TFM, but surgical scrubs with alcohol as a single active ingredient do exist with documented persistent and cumulative activity that meet the US FDA regulatory requirements for surgical hand antisepsis is acceptable.[4]

AORN Recommended Practices

AORN Recommended Practices are developed by perioperative nurse specialists and provide guidance for clinical practice in the OR setting to ensure quality of care and patient safety. The AORN Perioperative Standards and Recommended Practices for Hand Hygiene in the Operative Setting issued a revised Recommendation III in July 2009 to account for the multiple regulatory paths related to hand hygiene products. Recommendation III was revised to state "A surgical hand scrub should be performed by healthcare personnel before donning sterile gloves for surgical or other invasive procedures. Use of either an antimicrobial surgical scrub intended for surgical hand antisepsis or an alcohol-based antiseptic surgical

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THAT'S a FACT!

According to the CDC's National Nosocomial Infections Surveillance (NNIS) system:[1]

- 38% of all nosocomial infections in surgical patients are SSIs
- SSI increases length of stay in hospital by an average of 7.5 days
- $2,734 to $26,019 extra cost per SSI (1985, US dollars)

1. http://www.ihi.org/ihi/Topics/PatientSafety/SurgicalSiteInfections/SurgicalSiteInfectionsCaseForImprovement

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HAND HYGIENE IN THE OPERATING ROOM

hand rub with documented persistence and cumulative activity that has met FDA regulatory requirements for surgical hand antisepsis is acceptable".[5] The term "FDA Approved" was removed from the AORN Hand Hygiene Recommended Practice because confusion surfaced over TFM compliant surgical scrubs, which are allowed by FDA criteria.

AORN Recommendation IV states that "surgical hand hygiene products and hand lotions should be approved by the organization's infection prevention and control committee or designated authority with specialized knowledge of hand products" [6] The Recommendation also states that "Antimicrobial surgical hand hygiene products should:

- Significantly reduce microorganisms on intact skin,
- Contain emollients and humectants to prevent skin irritation,
- Be broad spectrum,
- Be fast-acting and
- Have a persistent and cumulative effect.[7]

According to the CDC, bacteria on the hands of surgeons can cause wound infections if introduced into the operative field during surgery. Rapid multiplication of bacteria occurs under surgical gloves if hands are washed with non-antimicrobial soap. Bacterial growth is slowed after perioperative scrubbing with an antiseptic agent. Reducing resident skin flora on the hands of the surgical team for the duration of a procedure reduces the risk of bacteria being released into the surgical field if gloves become punctured or torn during surgery.[8]

CDC Hand Hygiene Guidelines

The CDC Hand Hygiene Guideline states that surgical hand scrubs should be evaluated for their ability to reduce the number of bacteria released from hands at different times including:

- Immediately after scrubbing
- After wearing surgical gloves for 6 hours (ie. Persistent activity). The TFM requires that bacterial cell counts on each hand do not exceed baseline within 6 hours on day one.
- After multiple applications over 5 days (ie. Cumulative activity). The TFM requires a 3-log reduction[10] of microbial flora on each hand within 1 minute of product use by the end of the fifth day when compared to with the established baseline.

Immediate and persistent activity are considered the most important in determining the efficacy of the product.[9]

It is vital that Infection Control professionals as well as OR staff and other members of a product selection committee maintain knowledge of current recommendations and guidelines when selecting operating room hand hygiene products. Infection Preventionists and other committee members need to review all the literature about products and ingredients and question test methods and product claims. A company who manufactures hand hygiene products should provide access to scientists who can provide evidence based studies to support the claims made about their product. Members of the Product Selection Committee should review products claims, and validate that the claims are science based. They should feel comfortable calling the manufacturing company to discuss concerns with the scientists.

OR Staff Skin Tolerance

Health care professionals have a higher prevalence of skin irritation than seen in the general population because of the necessity for frequent hand hygiene during patient care.[10] The tendency for some hand hygiene products to cause skin irritation and dryness has been a deterrent of product usage and acceptance by staff.[11] Some antimicrobial compounds can be irritating or sensitizing. When reviewing OR staff feedback and concerns with skin irritation, it is important to evaluate not just the hands, but the forearms for signs of skin irritation.

Education for Usage of Surgical Scrubs

Staff must be educated regarding the directions for usage of the product in order to ensure that the product is used effectively and achieves the goal of surgical hand antisepsis. When using alcohol based hand antiseptics, staff need to know the volume of product required and the length of time required for rubbing in the product, and how many applications of product are required to ensure hand antisepsis.

1,2, 8, 9 Boyce, J.M. & Pittet, D. (2002). Guideline for Hand Hygiene in Health-Care Settings. Center for Disease Control and Prevention. Recommendation of the Healthcare Advisory Committee ans the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002; 51(No. RR 16)
4,5,6,7 Association of perioperative Registered Nurses (2010). Perioperative Standards and Recommended Practices. Recommended Practices for Hand Hygiene in the Perioperative Setting.
3 Food and Drug Administration (1994). Tentative Final Monograph for Health-Care Antiseptic Drug Products [Docket No. 75N-183H].
10 ,11 Larson, E. et al. (2006). Skin reactions related to hand hygiene and selection of hand hygiene product. American Journal of Infection Control 34(10) 627-635.

Product Feature

PURELL WATERLESS SURGICAL SCRUB–

The Surgical Clean you need without the skin damage you don't.

PURELL® Waterless Surgical Scrub (PWSS) is designed to meet and exceed FDA and AORN surgical scrub requirements[1] without the addition of harsh ingredients. This advanced alcohol formulation provides the immediate kill and persistence you expect, but does it without CHG. Further, this unique advanced alcohol formulation uses alcohol as the only active ingredient together with patent-pending blend of inactive ingredients that make the alcohol work even harder. Requiring 2mLs of product per hand, PWSS provides the germ kill and persistent activity critical to the surgical environment.

- Designed to meet and exceed FDA and AORN requirements
- CHG Free Formulation
- Includes five skin conditioners that help maintain healthy skin
- Dye-free, fragrance-free formula
- **Compatible with latex, neoprene and polyisoprene gloves**
- **Requires only two applications and dries quickly**

Proven Antimicrobial Efficacy

PURELL® Waterless Surgical Scrub has been proven to reduce resident microorganisms and eliminate transient microorganisms from the hands of surgical team members. It slows microbial repopulation, which helps to reduce the potential transfer of microorganisms into a surgical wound while providing rapid antimicrobial kill of a broad spectrum of microorganisms. Table 1 shows the log reduction of microorganisms over a 3 day period for PWSS compared to a 4%CHG product, with reference to the FDA acceptance criteria.

Proven Persistent Activity

High alcohol content has been proven to kill both resident and transient bacteria immediately upon contact. When combined with a patent-pending blend of inactive ingredients, that alcohol weakens even the hardest-to-kill germs on contact, penetrates the skin more completely than alcohol alone to reach more resident bacteria, and creates a pH-balanced environment that inhibits germ recovery and regrowth.

Proven to Be Mild

It is essential for healthcare workers to maintain healthy skin on the job to reduce the probability of increased colonization and the spread of infectious agents. However, frequent scrubbing can lead to dry, irritated and damaged hands. PWSS has five conditioning agents that leave hands feeling soft and moisturized without any stickiness or residual buildup. And it evaporates quickly, allowing staff to quickly get into the OR.

IN VIVO SURGICAL SCRUB STUDY

Table 1.

		PURELL® Waterless Surgical Scrub		4% CHG Reference Product	FDA Acceptance Criteria
		Three applications of 2 mL	Two applications of 2 mL	Two 3-minute scrubs with 5 mL product and brush	
Day	**Sample**	**log_{10} Reduction**			
Day 1	Immediate	3.08	2.31	1.35	1
	3 Hour	2.53	2.58	1.19	N/A[1]
	6 Hour	2.30	2.19	0.49	>0[2]
Day 2	Immediate	3.39	2.93	2.34	2
	3 Hour	3.09	3.00	1.70	N/A
	6 Hour	2.51	2.47	1.33	N/A
Day 5	Immediate	3.02	3.15	3.77	3
	3 Hour	2.99	3.14	2.93	N/A
	6 Hour	2.64	2.88	2.75	N/A

[1] N/A: Not applicable [2] FDA acceptance criteria = bacterial cell count does not exceed baseline within 6 hours on the first day

CONCLUSION:

PURELL Waterless Surgical Scrub met or exceeded the FDA's in vivo efficacy criteria for surgical scrub products at all points measured with as little as two applications of 2 mL. In fact, when three applications of 2 mL were used, PURELL Waterless Surgical Scrub met the day five requirement of **99.9% reduction in microbial hand flora on day one.**

Product Feature

PURELL WATERLESS SURGICAL SCRUB

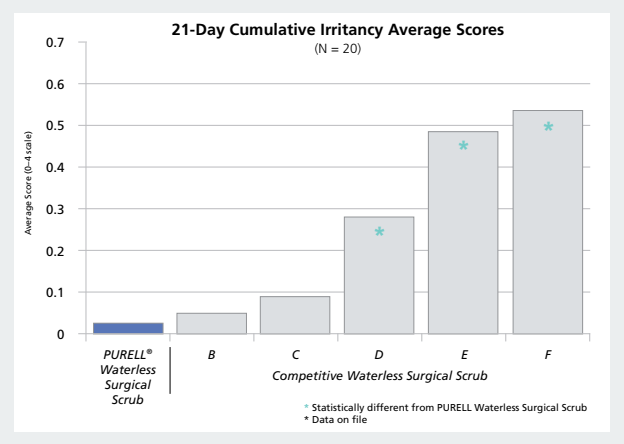
The Surgical Clean you need without the skin damage you don't.

PURELL® Waterless Surgical Scrub Dispensing Systems

At GOJO, we make it simple and easy to use our formulation with our state of the art dispensing systems. PURELL® Waterless Surgical Scrub (PWSS) dispensing systems are easy to use and maintain. Our 1200 mL refill bottles provide more scrubs than other dispensing bottles on the market. Our wall spacer accessory makes it easier to offset PWSS dispensing system from the wall to help prevent contamination from any germs, while our sink mount bracket enables the PWSS dispenser to be mounted on a sink to support a scrubbing environment that is familiar to OR staff.

The combined impact of PWSS with its advance alcohol formulation provides the immediate and lasting effects necessary for the surgical environment. For a surgical clean that's tough on germs but mild on skin, turn to PURELL – he brand healthcare workers and patients know and trust.

PROVEN TO BE MILD



CONCLUSION:

PURELL Waterless Surgical Scrub has a low potential for skin irritation and allergic contact dermatitis. Data for the first 21-Day Cumulative Irritation Test showed that PURELL Waterless Surgical Scrub is significantly less irritating than three of the five competitive products tested.

Description	Order Number	Case Pack
PURELL® Waterless Surgical Scrub		
TFX™ Dispenser	2785-12	12
1200 mL TFX Refill	5485-04	4
1000 mL TFX Refill	5483-04	4
2 fl oz bottle	9686-24	24
Dispensing Options /Accessories		
TFX™ Surgical Sink Bracket	2782-06	6
TFX™ Wall Spacer	2781-06	6
AT-A-GLANCE™ Service REFILL ALERT™	2101-24	24
PROVON® Nail Cleaners (150 Nail Cleaners per box; 6 boxes per case)	6180-06	6

A Look Ahead

next month's issue

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