GOJO

HAND HYGIENE TIMES

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

Issue 6 Volume 3

Hand Sanitizer Efficacy: Formulation Matters

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Infection Preventionists, purchasing agents, and materials management staff are often involved in the selection of alcohol based hand rubs (ABHR) for the healthcare facility. Although the Technical Bulletins and the Material Safety Data Sheets (MSDS) tell us that the products are safe and effective, do we really understand the testing process that a product goes through before they are labeled as such? Do we understand the terminology related to the reported results?

In the United States, alcohol based hand sanitizers are classified as over the counter drugs and are regulated by the FDA under the 1994 Tentative Final Monograph for Health-Care Antiseptic Drug Products (TFM).[1] The FDA has classified ethyl alcohol concentrations between 60–95% as generally safe and effective for use in antiseptic hand hygiene products. It is important to note that ethyl alcohol is the only active ingredient the FDA has recognized as both safe and effective for use as a "leave-on" hand antiseptic.

The TFM specifies antimicrobial testing and performance requirements for ABHR, requiring both *in vitro* and *in vivo* testing of the finished product. *In vitro* or **laboratory methods**, including time-kill assays, are used to demonstrate the speed of kill and the spectrum of activity of products. *In vivo* studies using **human subjects** are used to simulate clinical efficacy. The Healthcare Personnel Handwash (HCPHW) method, American Society for Testing and Material (ASTM) E 1174, is the current recognized standard for the *in vivo* evaluation of ABHR.[1,2] This method was originally designed in the 1970's to evaluate antimicrobial hand washing agents, which are lathered with the aid of water and then rinsed off. In the absence of a method specifically designed to evaluate ABHR, the HCPHW method has become the default method for in vivo ABHR evaluation. While ASTM approval is an important step in changing regulatory testing guidelines for ABHR, HCPHW is currently the only FDA recognized method to test ABHR antimicrobial efficacy *in vivo.*

During the ASTM testing process, the desired outcome is a measurable reduction in the quantity of test bacteria that remains on the hands. This measurement is expressed as a $\log_{10}$ reduction. A $\log_{10}$ reduction is calculated by subtracting the quantity of bacteria recovered post product usage from the quantity recovered at baseline. The hand contamination and product application procedures are then repeated for a total of ten product applications and the hands are sampled for bacterial recovery after the final product application. FDA requirements are a 2 $\log_{10}$ reduction (99%) after the first product application and a 3 $\log_{10}$ reduction (99.9%) after the tenth and final product application.[1]

Log Reduction Calculator:

Log_{10} Reduction from Baseline	Percent Reduction of Bacteria from Baseline
1	90.000%
2	99.000%
3	99.900%
4	99.990%
5	99.999%

FDA HCPHW Test Requirements:

Handwash Application	FDA TFM Log_{10} Reduction Requirement
1	2
10	3

The antimicrobial efficacy of ABHR cannot be assumed based solely on the inclusion of ethyl alcohol at levels between 60 and 95%. Differences in efficacy can be attributed to variation in product formulation to create specific attributes including skin tolerance, skin moisturization, and aesthetic properties.

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THAT'S a FACT!

In one study, approximately 25% of nurses reported symptoms or signs of dermatitis on their hands, and 85% gave a history of skin problems.[3] The variable potential of detergents to cause skin irritation can be reduced by adding emollients and humectants.[3]

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These additional ingredients can in some cases either improve or inhibit the formulation's antimicrobial efficacy. In addition, the volume or quantity of product applied to hands in the HCPHW test will influence the test results; with increasing application volumes directly correlating to increased *in vivo* efficacy. Therefore, critical examination of product literature, especially HCPHW application 1 and 10 data, must be performed to determine and compare antimicrobial efficacy of products. Infection preventionists and others involved in product selection should feel comfortable asking to review the scientific data supporting ABHR products and not just rely on advertisement materials.

Practical considerations regarding product availability, dispenser systems, and cost should also be assessed during a product selection period.[3] For example, ABHR supply must be continuously available and dispenser systems should be functional and reliable. Cost is always a consideration when selecting products, but the costs associated with treating preventable HAI clearly suggest that proper hand hygiene is a cost effective strategy.

The ultimate purpose of the chosen ABHR is to interrupt the spread of pathogens and the acquisition of HAI through the reduction of transient bacteria and the promotion of hand hygiene compliance. While there are many factors to evaluate and consider when selecting the proper AHBR, efficacy and end user acceptance is of utmost importance. Critical evaluation of product efficacy data, namely HCPHW, should be completed because total product formulation, not just alcohol level, dictates product efficacy. Product trials should be conducted to verify product acceptance and dermal tolerance. Proper ABHR selection can drive hand hygiene compliance, resulting in decreased HAI rates and ultimately lead to a safer hospital environment for patients and staff.

1 Food and Drug Administration. Tentative final monograph for healthcare antiseptic drug products; proposed rule. Federal Register 59, 31441-31450 (2004).
2 ASTM International. E-1174-06: Standard test method for evaluation of the effectiveness of health care personnel or consumer handwash formulations. 2006. West Conshohocken, PA, ASTM International.
3 Larson, E., Girard, R., Pessoa-Silva, C. L., Boyce, J., Donaldson, L. and Pittet, D. Skin reactions related to hand hygiene and selection of hand hygiene products. Am. J. Infect. Control 34, 627-635 (2006).

Product Feature

PRODUCTS AND PROGRAMS TO HELP IMPROVE HAND HYGIENE COMPLIANCE

With PURELL®, America's # 1 instant hand sanitizing brand, GOJO offers a diverse selection of hand sanitizing solutions and educational tools to meet a variety of needs in healthcare settings. PURELL® helps build hand hygiene compliance and sends a clear message that infection control is important.

Specifically, GOJO offers the following:

1) **New PURELL Advanced Formulations**
2) **Handwashing Solutions**
3) **Green Certified Hand Hygiene Solutions**
4) **Wall and Bottle Dispensing Systems**
5) **Point of Care Solutions**
6) **Compliance Monitoring**
7) **Healthcare Worker(HCW) and Patient Hand Hygiene Training Tools**

GOJO OFFERS:

PURELL® ADVANCED INSTANT HAND SANITIZER FORMULATIONS

*Unprecedented germ kill – in **every** ounce.*

This next generation formulation of PURELL offers highly efficacious antimicrobial activity while maintaining optimal skin health, all with only 2 mL of product. PURELL® Advanced Skin Nourishing Formulations are clinically proven to improve skin condition in 14 days.[1,]

Ounce for ounce, PURELL Advanced formulations out perform other hand sanitizers.[2,3]

HANDWASHING SOLUTIONS

With our PROVON®, GOJO offers a broad range of handwashing products. Antimicrobial or non-antimicribial, liquid or foam, PROVON handwashing products are effective, yet mild and gentle to the skin and help build hand hygiene compliance.

GREEN CERTIFIED HAND HYGIENE SOLUTIONS

GOJO offers a full line of green certified hand sanitizers and hand washing solutions that help support community and environmental wellness throughout a healthcare facility.

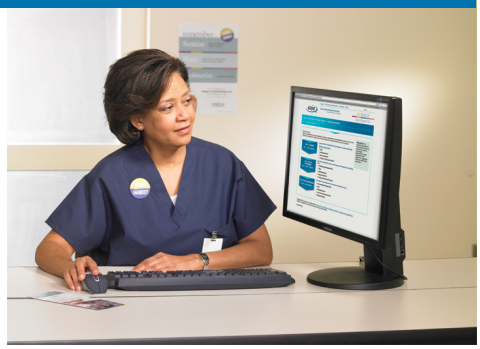
WALL AND BOTTLE DISPENSING OPTIONS

With our state-of-the art dispensing systems, GOJO offers a variety of practical, reliable, accessible, and attractive touch free, manual and bottle dispensing options to help provide easy access to hand hygiene solutions and improve compliance.

POINT OF CARE SOLUTIONS

PURELL® Point of Care Solutions offer flexible, small, convenient and portable hand hygiene solutions for optimal hand hygiene compliance always within reach.

COMPLIANCE MONITORING



In support of the Joint Commission and CDC Hand Hygiene Guideline, GOJO has a suite of compliance monitoring and measuring tools and resources which track, measure, monitor and benchmark compliance. These tools provide the training and support for HCWs to motivate them to practice good hand hygiene.

PATIENT EDUCATIONAL TOOLS AND HEALTHCARE WORKER IN-SERVICE PROGRAMS

In order to help increase compliance within the healthcare setting and adhere to the CDC guidelines, GOJO continues to provide patient educational programs and HCW in-service programs such posters, videos and brochures that offer constant reminders on the importance of hand hygiene.

Product Feature

PRODUCTS AND PROGRAMS TO HELP IMPROVE HAND HYGIENE COMPLIANCE (continued)

For further information on helping healthcare facilities fight the spread of infections that may cause illness and improving hand hygiene compliance, contact GOJO at healthcare@gojo.com or visit us at healthcare.gojo.com.

Description	Size & Dispensing	Order Number
PURELL® Advanced Instant Hand Sanitizer Formulations		
FOAM		
PURELL Advanced Instant Hand Sanitizer Foam	TFX™ 1200ml Refill	5392-02
PURELL Advanced Instant Hand Sanitizer Foam	TFX™ 1000ml Refill	5592-02
PURELL Advanced Instant Hand Sanitizer Foam	FMX™ 1200 mL Refill	5192-03
PURELL Advanced Instant Hand Sanitizer Foam	FMX™ 1000 mL Refill	5190-03
PURELL Advanced Instant Hand Sanitizer Foam	535 mL Pump Bottle	5792-04
PURELL Advanced Instant Hand Sanitizer Foam	45 mL Pump Bottle	5692-24
PURELL Advanced Skin Nourishing Instant Hand Sanitizer Foam	TFX 1000ml Refill	5399-02
PURELL Advanced Skin Nourishing Instant Hand Sanitizer Foam	FMX™ 1000ml Refill	5199-03
PURELL Advanced Skin Nourishing Instant Hand Sanitizer Foam	535 mL Pump Bottle	5798-04
PURELL Advanced Skin Nourishing Instant Hand Sanitizer Foam	45 mL Pump Bottle	5698-24
Gel		
PURELL Advanced Instant Hand Sanitizer	TFX™ 1200ml Refill	5456-04
PURELL Advanced Instant Hand Sanitizer	2 fl oz PERSONAL Flip-Cap Bottle	9605-24
PURELL Advanced with Aloe Instant Hand Sanitizer	TFX 1200mL Refill	5457-04
PURELL Advanced Skin Nourishing Instant Hand Sanitizer	NXT 1000mL Refill	2151-08
PURELL Advanced Skin Nourishing Instant Hand Sanitizer	2 fl oz Pump Bottle	9648-24

Description	Size & Dispensing	Order Number
Hand Washing Solutions		
PROVON Medicated Foam Handwash with Advanced Moisturizers and Triclosan	TFX 1200mL Refill	5388-02
PROVON Green Certified Foam Hand Cleaner	TFX 1200mL Refill	5382-02
PROVON Foaming Antimicrobial Handwash with Moisturizers	FMX 1250mL Refill	5186-03
Green Certified Solutions		
PURELL Green Certified Instant Hand Sanitizer Foam	TFX 1200mL Refill	5391-02
PURELL Green Certified Instant Hand Sanitizer	TFX 1200mL Refill	5491-04
Wall and Bottle Dispensing Solutions		
PURELL TFX Touch-Free		2720-12
PURELL FMX-12		5120-06
535mL Pump Bottle Bracket		5700-06
PURELL PAL™		9600-PL1
PURELL CLASSIC™ Holder		9614-12
PURELL HOOK-ON Holder: 12 fl oz		9007-12
PURELL HOOK-ON Holder: 535 mL		5701-12
Point of Care Solutions		
PURELL VERSAHOLD™ Point of Care Bracket		5704-06-BLU
PLACES™ Holder		9008-12
PURELL PERSONAL Gear Retractable Clip		9608-24
PURELL Dispenser: 8 fl oz		9601-12
Compliance Monitoring		
www.CleanHands.com		
Patient Educational Tools and Healthcare Worker In-Service Programs		
Visit: healthcare.gojo.com – available in the Reference Tools section		

1. Acute Moisturization Analysis Study #110212-301, April 25, 2011, BioScience Laboratories, Bozeman, MT.
2. Healthcare Personnel Handwash Study #110103-101, April 5, 2011, BioScience Laboratories, Bozeman, MT.
3. Healthcare Personnel Handwash Study #100907-101, January 6, 2011, BioScience Laboratories, Bozeman, MT.

A Look Ahead

next month's issue

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