CONCISE COMMUNICATION

Efficacy of Novel Alcohol-Based Hand Rub Products at Typical In-Use Volumes

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In vivo efficacies of 2 alcohol-based hand rub (ABHR) products (gel and foam) were evaluated at a volume of 1.1 mL. Both met US Food and Drug Administration $\log_{10}$ reduction requirements after a single application and 10 consecutive applications. This is the first study to identify ABHR formulations capable of meeting efficacy requirements with a single-dispenser actuation.

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Alcohol-based hand rub (ABHR) is recommended as the primary means of hand hygiene in healthcare settings on the basis of demonstrated superiority to hand washing with respect to antimicrobial efficacy, skin tolerance, usage convenience and compliance, and clinical effectiveness.[1,2] Most of the previous studies evaluating the efficacy of ABHR products have used application volumes of 3–5 mL or more.[3] However, such large volumes are seldom used in clinical practice in US healthcare settings. The efficacies of several ABHR products commercially available in US healthcare systems and 2 World Health Organization (WHO)–recommended formulations were recently reported when tested at a more realistic volume of 2 mL.[4] Two ABHR products based on 70% ethanol, a gel and a foam formulation, met US Food and Drug Administration (FDA) efficacy requirements. In contrast, 7 additional commercial ABHR products and the 2 WHO-recommended formulations failed to meet the same efficacy standard, suggesting that the majority of ABHRs used in US hospitals may have substandard efficacy at realistic volumes.

Most US acute care hospitals use wall-mounted dispensers, and the prevalence of automated touch-free dispensers is increasing. At least 2 published reports suggest that touch-free dispensers can improve hand hygiene compliance rates.[5,6] Because touch-free dispensers deliver a predetermined volume, healthcare workers may assume that the manufacturer has chosen the dispenser output that would meet US FDA efficacy requirements with a single activation. As a result, healthcare workers likely activate the dispenser a single time per hand hygiene episode. The objectives of our study were to determine the output volumes and ABHR dry times of touch-free dispensers marketed to US healthcare facilities and to evaluate the efficacy of 2 commonly-used ABHR formulations at the volume dispensed from a touch-free dispenser (ie, "in-use volume").

METHODS

ABHR test products and dispensers. Commercial ABHRs and corresponding touch-free dispensers used in this study were purchased online or through medical supply distributors and are described in Table 1.

Dispenser output determination. Each dispenser/ABHR combination was primed, and then 10 actuations were collected and weighed on a calibrated analytical balance. The mean mass per actuation was converted to mean volume per actuation by dividing by the product density. Product densities were measured using an Anton Paar DMA 4500 density meter at 15.6°C (60°F).

ABHR dry-time determination. Ten subjects evaluated each product/dispenser combination. A single actuation from each dispenser was dispensed onto the hands, and subjects rubbed test product onto all surfaces of the hands up to the wrists. The time interval from when a subject began rubbing to when the person indicated that his or her hands felt dry was recorded using a calibrated digital timer.

In vivo efficacy determination. Test products were evaluated according to the US FDA Healthcare Personnel Handwash Method (ASTM E1174), which has been described in detail elsewhere.[4,7,8] In brief, E1174 measures the reduction of a transient marker organism (*Serratia marcescens*; ATCC 14756) on the hands of subjects after a single test product use and after 10 consecutive hand contamination and product use cycles. Institutional review board approval was obtained prior to enrolling study subjects. All subjects were at least 18 years of age and were of mixed sex and race. Fifty study subjects (25 for gel A and 25 for foam F) completed the study. A neutralizer assay was conducted according to ASTM E1054-08, which demonstrated that test products were effectively neutralized during hand sampling (data not shown).

RESULTS

Dispenser output and ABHR dry time. Mean product outputs and dry times for 8 commercially available ABHR product/dispenser combinations are illustrated in Table 1. Gel dispenser outputs ranged from 0.9 to 1.3 mL. Mean ABHR gel dry times for single-dispenser actuations ranged from 17 to 26 seconds. Foam dispenser outputs ranged from 0.6 to 1.1 mL. Mean ABHR foam dry times for single-dispenser actuations were somewhat shorter and ranged from 12 to 21 seconds.

Efficacy of ABHRs at dispensed volumes. When evaluated at an output of 1.1 mL, mean $\log_{10}$ reductions for gel A and foam F were 2.85 and 2.86, respectively, after 1 application and were 3.28 and 3.02, respectively, after the tenth application (Table 2). Both test products met current US FDA

TABLE 1. Touch-Free Dispenser Outputs and Mean Alcohol-Based Hand Rub (ABHR) Product Dry Times

ABHR	ABHR active (vol/vol)	Product name	Dispenser part no.	Manufacturer	Mean dispenser output, mL	Mean ABHR dry time, s
Gel A	70% ethanol	Purell Advanced Instant Hand Sanitizer	1920-04	GOJO Industries	1.2	22
Gel B	62% ethanol	Endure 320 Advanced Care Waterless Antimicrobial Hand Rinse with Moisturizers	92022510	Ecolab	1.3	25
Gel C	68% ethanol[a]	Avagard D Instant Hand Antiseptic with Moisturizers	3M-9240	3M	1.3	26
Gel D	63% isopropanol	Cal Stat Plus Antiseptic Handrub with Enhanced Emollients	STE-1307Q5/ STE-1303Q0[b]	Steris	0.9	21
Gel E	90% ethanol[a]	Sterillium Comfort Gel	LXT10AUTO	BODE	1.0	17
Foam F	70% ethanol	Purell Advanced Instant Hand Sanitizer Foam	1920-04	GOJO Industries	1.1	21
Foam G	70% ethanol	Quik-Care Foam Waterless Hand Sanitizer	92021121	Ecolab	0.6	12
Foam H	70% ethanol	Avagard Foaming Instant Hand Antiseptic	3M-9240	3M	0.6	15

[a] Ethanol concentration on product label reported as weight per weight (wt/wt); volume per volume (vol/vol) concentration was determined analytically in the authors' laboratory.

[b] Manual dispenser with touch-free adaptor.

efficacy requirements at both the first and the tenth application.

DISCUSSION

This is the first report to demonstrate that well-formulated ABHR can meet US FDA efficacy requirements at a volume achievable with a single-dispenser actuation (ie, in-use volumes; Table 2). It highlights the importance of both product formulation and dispenser output for determining ABHR efficacy. The touch-free dispenser for gel A and foam F dispensed a volume that was sufficient to keep hands wet for at least 20 seconds (consistent with WHO usage guidance;[2] Table 1) and to meet US FDA $\log_{10}$ reduction criteria[8] (Table 2). Dispenser outputs for gels B, C, and E were 1.3, 1.3, and 1.0 mL, respectively, and produced similar product dry times (Table 1). However, because each of these ABHRs failed to meet efficacy requirements at 2 mL in a previous study,[4] 2 or more actuations of these dispenser/formulation combinations would be required to meet efficacy requirements. The dispenser output for foam H, which also failed previously to meet efficacy requirements at 2 mL,[9] was 0.6 mL, suggesting that 4 or more actuations would be required to meet efficacy requirements. For these products needing multiple dispenser actuations to meet efficacy requirements, dry times would likely be in excess of 40 seconds. Such lengthy dry times may negatively impact healthcare worker compliance.[2,10] Alternatively, if a single-dispenser actuation were used, efficacy would be suboptimal per US FDA standards and could compromise the clinical effectiveness of hand hygiene.

TABLE 2. In Vivo Efficacy of Alcohol-Based Hand Rub Tested at the Volume Dispensed from a Touch-Free Dispenser

Test product	Application volume, mL	$\log_{10}$ reduction (95% CI)	
		Application 1	Application 10
Gel A	1.1	2.85 (2.67–3.04)	3.28 (3.04–3.53)
Foam F	1.1	2.86 (2.65–3.07)	3.02 (2.63–3.40)
FDA requirement	NA	2	3

NOTE. Efficacy was evaluated according to the US Food and Drug Administration (FDA) Healthcare Personnel Handwash Method.[7,8] CI, confidence interval; NA, not applicable.

The Centers for Disease Control and Prevention hand hygiene guidelines do not provide specific recommendations regarding ABHR use volumes but instead defer to the "manufacturer's recommendations regarding volume of product to use."[1(p32)] Furthermore, in the section preceding the recommendations, the guidelines state that "the ideal volume of product is not known and may vary for different formulations."[1(p11-12)] The data presented in this study clearly validate that statement and demonstrate that product dry time cannot be used as an indicator of ABHR "efficacy." Instead, manufacturers should provide recommendations for product usage volumes based on efficacy data generated using standard in vivo methods.

In conclusion, both product formulation and application volume are critical variables influencing ABHR efficacy. ABHRs should be expected to meet efficacy requirements at volumes that are consistent with dispenser output and that do not require excessive dry times. Further studies are warranted to better understand the influence of these variables on end-user product acceptance, hand hygiene compliance, and clinical outcome.

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