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

David R. Macinga, PhD; Sarah L. Edmonds, MS; Esther Campbell, BS; David J. Shumaker, BS; James W. Arbogast, PhD

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 activation.

**Infect Control Hosp Epidemiol 2013;34(3):299-301**

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 activation.

**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 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.\textsuperscript{a, b} 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 contaminations 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 dispensers 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

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

* 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.

** Manual dispenser with touch-free adaptor.

** 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; Table 1) and to meet US FDA log<sub>10</sub> reduction criteria (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, 2 or more actuations of these dispenser/formulation combinations would be required to meet efficacy requirements. The dispenser output for foam F, which also failed previously to meet efficacy requirements at 2 mL, 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.

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.” 11(p182) 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.” 11(p182) 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.

** ACKNOWLEDGMENTS **

Financial support. All studies were funded by GOJO Industries.

Potential conflicts of interest. D.R.M., S.L.E., D.J.S., and J.W.A. report that they are full-time employees of GOJO Industries in research and develop-
ment. All other authors report no conflicts of interest relevant to this article. All authors submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest, and the conflicts that the editors consider relevant to this article are disclosed here.

Affiliations: 1. GOJO Industries, Akron, Ohio; 2. Department of Integrative Medical Sciences, Northeastern Ohio Medical University, Rootstown, Ohio; 3. Bioscience Laboratories, Bozeman, Montana.

Address correspondence to David R. Macinga, PhD, GOJO Industries, One GOJO Plaza, Suite 300, Akron, OH 44311 (macingad@gojo.com).

Received September 3, 2012; accepted November 7, 2012; electronically published January 22, 2013.

© 2013 by The Society for Healthcare Epidemiology of America. All rights reserved. 0899-823X/2013/3403-001$15.00. DOI: 10.1086/669514

REFERENCES
