The Influence of ABHR Product Format on *In Vivo* Efficacy: A Meta Analysis

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ABSTRACT

Background / Objectives

Alcohol-based hand rubs (ABHR) are the primary form of hand hygiene in healthcare settings. ABHR are available in a number of different formats including rinse, spray, gel, and foam. In U.S. healthcare facilities the most common formats are gel and foam. Currently, there are conflicting data regarding the relative efficacy of gel versus foam ABHR. The objective of this study was to determine whether product format influences ABHR efficacy through a meta-analysis of multiple studies comparing both gel and foam products.

Methods

The test products were commercial ABHR formulations based on 70% ethanol and differing only by the addition of "gelling" ingredients (Gel A) or "foaming" ingredients (Foam B). Data from a total of 18 studies which were executed at different times of the year, by different laboratories, where the efficacy of Gel A and Foam B were evaluated were included in the analysis. Standard test methodologies were used in each study and included the U.S. Food and Drug Administration Health Care Personnel Handwash (HCPHW) method, ASTM E1174-06, ASTM E2755-10, and ASTM E2784-10. All methods measure test product efficacy after both a single use and after 10 consecutive uses. Two meta-analyses were conducted, one based on single use data and one based on data after 10 consecutive product uses. The Hedges' *g* value was calculated based on the log reduction from baseline for each product for each study. The model used was a complete random effects model with subgroups (Gel A and Foam B) evaluated.

Results

After a single test product use mean log reductions ranged from 2.32-4.48 and 2.43-4.57, for Gel A and Foam B, respectively. After 10 product uses, log reductions ranged from 3.11-5.24 and 2.61-5.19, for Gel A and Foam B, respectively. Based on the meta-analysis both products were highly effective after a single use (Hedges' $g = 11.746$ and 12.174 for Gel A and Foam B, respectively) and after ten product uses (Hedges' $g = 11.164$ and 10.844 for Gel A and Foam B, respectively). Because the Hedges' *g* 95% confidence intervals for Gel A and Foam B overlapped, there was no difference in efficacy between Gel A and Foam B after a single use or after ten consecutive uses.

Conclusions

This was the first example of applying meta-analysis to compare the *in vivo* efficacy of different ABHR products or product formats (gel vs. foam). The results of this meta-analysis indicate that ABHR format does not significantly influence efficacy. Previously published results suggest that other attributes, including product formulation and product application volume, are more predictive of ABHR efficacy.

MATERIALS AND METHODS

A total of 17 studies were run for each product: Gel A (PURELL Advanced Instant Hand Sanitizer, GOJO Industries) and Foam B (PURELL Advanced Instant Hand Sanitizer Foam, GOJO Industries). These studies were executed over approximately 18 months, from June 2010 to December 2011, at 2 different laboratories. Test methodologies included the U.S. FDA Healthcare Personnel Handwash (HCPHW) method (ASTM E 1174-94), ASTM E1174-06 (Test Method for Evaluation of Effectiveness of HCPHW Formulations), ASTM E2755-10 (Test Method for Determining the Bacteria-Eliminating Effectiveness of Hand Sanitizer Formulations Using Hands of Adults), and ASTM E2784-10 (Test Method for Evaluation of the Effectiveness of Handwash Formulations Using the Paper Towel (Palmar) Method of Hand Contamination). Products were applied to the hands and rubbed in until dry, and product application volume was based on real world dosing of 1.1-2.0 ml (see table for details). Log_{10} reductions from baseline were calculated after a single use (Wash 1) and ten consecutive uses (Wash 10).

A meta-analysis evaluation was conducted by separating the data into two analyses (Application 1 and Application 10). A Hedges' *g* value was calculated1 based on the log_{10} reduction for each product for each study at Application 1 and Application 10. This calculation standardizes the values and allow products from different studies to be compared. A complete random effects model was used because the products were tested with different methods, at different dosages, and on different days.

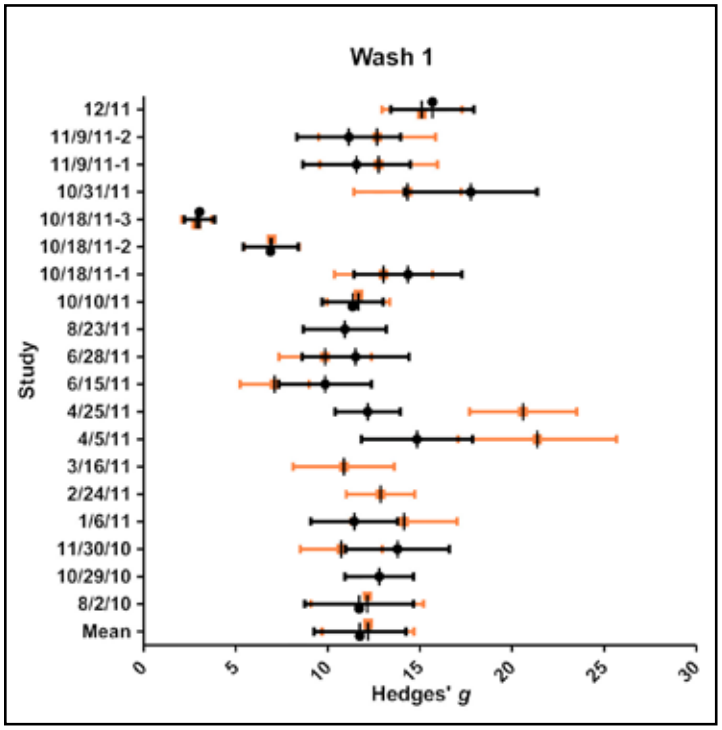
RESULTS

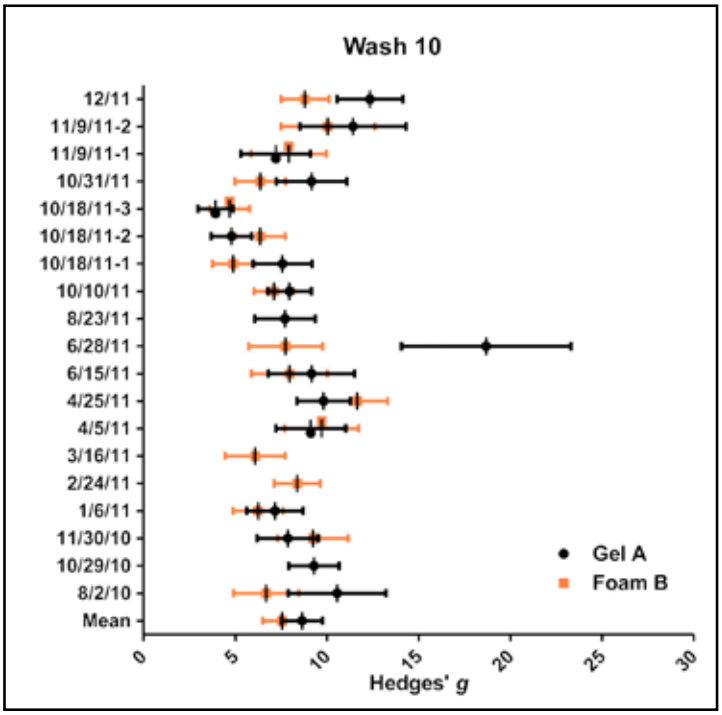
Summary of Data used in Meta-analysis:

Product	Method	Dose (mL)	N	App1 LR	App1 95% CI	App10 LR	App 95% CI
Gel A	HCPHW	2	16	3.03	2.66-3.40	3.40	3.01-3.79
		2	48	3.20	3.04-3.37	3.60	3.37-3.82
		2	24	3.58	3.32-3.84	3.50	3.07-3.93
		2	24	3.35	3.14-3.56	4.09	3.78-4.40
		2	16	3.96	3.56-4.36	4.67	4.29-5.04
		2	16	3.65	3.28-4.02	4.78	4.60-4.96
		2	24	3.57	3.31-3.83	4.22	3.87-4.56
		2	24	3.34	3.17-3.51	3.77	3.44-4.11
		2	16	3.61	3.26-3.97	4.79	4.33-5.24
		2	16	3.83	3.50-4.15	4.76	4.52-5.00
		1.3	48	3.10	2.91-3.29	3.11	2.87-3.35
		1.2	48	3.39	3.17-3.61	4.18	3.91-4.45
		1.1	48	2.85	2.71-2.99	3.28	3.11-3.45
	E 1174-06	2	24	2.54	2.13-2.95	3.91	3.50-4.32
	E 2784-10	2	24	4.48	4.07-4.89	5.24	4.83-5.65
	E 2755-10	2	24	3.32	2.91-3.73	5.06	4.65-5.74
		1.2	24	2.32	2.08-2.57	3.78	3.43-4.13
Foam B	HCPHW	2	16	3.25	2.92-3.58	4.26	3.75-4.76
		2	48	3.62	3.48-3.77	4.06	3.84-4.28
		2	24	3.55	3.34-3.77	4.00	3.53-4.47
		2	24	3.48	3.34-3.61	4.41	4.41-4.69
		2	16	3.90	3.53-4.27	4.62	4.04-5.20
		2	16	3.84	3.27-4.40	5.00	4.60-5.39
		2	16	4.44	4.07-4.80	5.16	4.76-5.56
		2	24	3.37	3.13-3.61	4.48	4.04-4.92
		2	16	4.03	3.73-4.34	5.19	4.80-5.57
		2	16	3.96	3.64-4.27	4.81	4.47-5.15
		1.3	49	3.06	2.96-3.17	3.26	3.07-3.45
		1.2	48	3.48	3.28-3.67	4.27	3.99-4.55
		1.1	48	2.86	2.71-3.01	3.02	2.75-3.28
	E 1174-06	2	24	2.69	2.28-3.10	4.35	3.94-4.76
	E 2787-10	2	24	4.57	4.16-4.98	5.06	4.65-5.47
	E 2755-10	2	24	3.29	2.88-3.70	4.06	3.65-4.47
		1.2	24	2.43	2.11-2.76	2.61	2.22-2.99

App=Application, LR=Log_{10} Reduction, CI=Confidence Interval

Hedges' *g* Values Calculated from Log Reductions:





Gel A and Foam B were statistically equivalent as the 95% confidence intervals of the calculated Hedges' *g* overlapped at Application 1 for gel (9.26-14.23) and foam (9.681-14.67), and at Application 1 for gel (7.22-9.38) and foam (6.48-8.63).

CONCLUSIONS

The meta-analysis of this data indicates that product format does not significantly influence efficacy. Foam and gel ABHR based on the same technology achieve equivalent antimicrobial efficacy when tested at real world volumes.

References

1. Borenstein et al, (2009) An introduction to MetaAnalysis, John Wiley & Sons, Ltd.

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