

# **Influence of Alcohol-Based Hand Rub Format on Dry Time and Efficacy**

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## ABSTRACT

### Background / Objectives

Alcohol-based hand rubs (ABHRs) are one of the most important tools to prevent hospital acquired infections. They are available in a variety of formats including gels, rinses, and foams. A recent publication has suggested that foam ABHRs dry more slowly than ABHR gels and rinses, which encourages health care workers (HCWs) to use smaller, ineffective volumes.<sup>1</sup> However, analysis of ABHR gels and rinses was not included for comparison to the foams. The objective of this study was to determine whether there are significant dry time differences between rinse, gel, and foam ABHR formats. A secondary objective was to determine the antimicrobial efficacy of various formats of ABHRs at volumes which dry in 30 seconds.

### Methods

Dry times were determined for two ABHR rinses, two ABHR gels, and two ABHR foams by applying specific volumes, ranging from 0.5 ml to 3 ml, to subjects' hands and having them rub in the product until dry. A digital timer was used to record the interval from when the subject began rubbing to when the subject indicated that their hands felt dry. Linear regression analysis was performed to determine a slope (dry time per unit volume), and to calculate the volume drying in 30 seconds for each product. A subset of products, including a 90% ethanol gel, 80% ethanol rinse, and 70% ethanol foam, were evaluated for antimicrobial efficacy according to EN 1500, at the volume of product determined to dry in 30 seconds.<sup>2</sup>

### Results

For all ABHR tested, the mean product volumes which dried in 30 seconds ranged from 1.7-2.1 ml. The mean product volumes which dried in 30 seconds of identical 70% ethanol formulations, differing only in product format, were 1.7 ml, 1.9 ml, and 1.7 ml, for the foam, gel, and rinse, respectively, and were statistically equivalent. None of the products met the efficacy requirements of EN 1500 when tested at volumes which rub-in dry in 30 seconds.<sup>2</sup> However, all products tested according to EN 1500 were statistically equivalent to each other by repeated measures ANOVA ( $P > 0.05$ ), irrespective of alcohol concentration or product format.

### Conclusions

The results of this study demonstrate that product format does not significantly influence ABHR dry time. The data directly refutes previous speculations, showing that ABHR foams do not take longer to dry and will not encourage the use of inadequate volumes. In conclusion, product application volume was found to have a greater impact on efficacy than either product format or alcohol concentration. Further research is warranted to understand the impact of alcohol concentration, product formulation, and application volume on clinical efficacy and healthcare worker behavior and acceptance.

## MATERIALS AND METHODS

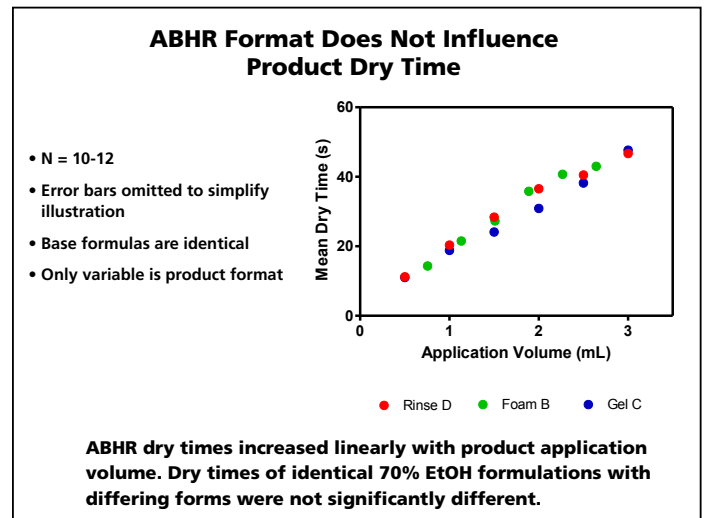
### Determining Quantity of Product that Dries in 30s:

Ten to thirteen volunteers were used to assess dry times for all products. Participants received doses of each ABHR and rubbed the product on their hands until they 'felt dry'. Dry times were closely monitored and recorded. Doses for each ABHR spanned 0.5-3.0 ml in 0.5 ml increments. Gel and rub formats were delivered via an automatic pipette set to the specific application volume. Foam formats were delivered via a bottle pump with an average output of 0.45 ml. All doses of a specific product were given on one day. Linear regression analysis using the mean dry times at each application quantity was used to determine the 30 second dry time amount for each test product.

### Antimicrobial Efficacy Testing:

Foam B, Rinse E, Gel F were tested according to EN 1500 in a randomized, crossover design, where hands were contaminated with *Escherichia coli* K12 NCTC 10538.<sup>2</sup> EN 1500 is the norm used in Europe to evaluate the antimicrobial efficacy of hand sanitizers. To meet the requirements of the norm the test product must demonstrate statistical non-inferiority to the reference product (two applications of 3 ml of 60% isopropanol for a 60 second total contact time). A total of 20 subjects were evaluated for each test product. Products were tested at the volume which was determined to dry in 30 seconds, however Foam B was tested at a conservative volume of 1.6 ml, as an output of 1.7 ml could not be achieved with existing pump outputs. Test products were applied and rubbed until dry.  $\log_{10}$  reductions were calculated for the test products and statistical comparisons were made to the reference product. A second EN 1500 study was conducted with only Foam B and Gel C using a volume of 3 ml for 30 seconds (typical test conditions).<sup>2</sup>

## RESULTS



**Quantities of Six ABHR Test Products Required to Keep Hands Wet for 30 seconds**

Test Product	Active Ingredient (v/v)	Quantity drying in 30s (95% CI)	
		mL	g
Foam A	62% EtOH	1.7 (1.4 – 1.8)	1.5 (1.3 – 1.6)
Foam B	70% EtOH	1.7 (1.5 – 1.8)	1.5 (1.3 – 1.6)
Gel C	70% EtOH	1.9 (1.7 – 2.0)	1.6 (1.4 – 1.7)
Rinse D	70% EtOH	1.7 (1.5 – 1.9)	1.5 (1.3 – 1.7)
Rinse E	80% EtOH	2.0 (1.9 – 2.2)	1.7 (1.6 – 1.9)
Gel F	90% EtOH	2.1 (1.9 – 2.3)	1.7 (1.6 – 1.9)

Amounts of various test products of different forms and alcohol concentrations required to keep hands wet for 30 seconds (95% CI) were not significantly different.

### ABHR Format Does Not Influence ABHR Efficacy

Test Product	Active Ingredient (v/v)	Application Instructions	Log <sub>10</sub> Reduction	Meets Norm?
Reference Product	60% IPA	2 x 3 ml for 60s	5.05	N/A
Foam B	70% EtOH	3 ml for 30s	5.06	Yes
Gel C	70% EtOH	3 ml for 30s	5.25	Yes

When tested under standard test conditions according to EN 1500, Foam B and Gel C met the efficacy requirements and were not significantly different from the internal reference.

### Product Application Volume Influences ABHR Efficacy

Test Product	Active Ingredient (v/v)	Application Instructions	Log <sub>10</sub> Reduction	Meets Norm?
Reference Product	60% IPA	2 x 3 ml for 60s	4.83	N/A
Foam B	70% EtOH	1.6 ml for 30s*	3.81**	No
Rinse E	80% EtOH	2.0 ml for 30s	4.03**	No
Gel F	90% EtOH	2.1 ml for 30s	4.02**	No

\* For Foam B, 1.7ml was not achievable using the existing pump, so a conservative volume of 1.6ml was used;

\*\* Log<sub>10</sub> reductions were statistically equivalent

When tested using an application volume which dries in 30s according to EN 1500, log<sub>10</sub> reductions for all test products were statistically equivalent regardless of form or alcohol content. All were inferior to internal reference.

## SUMMARY

- A single 70% ABHR formulation in three formats exhibited similar dry time profiles.
- ABHR volumes required to keep hands wet for 30 seconds did not differ significantly regardless of format or alcohol concentration.
- Foam B and Gel C met efficacy requirements (EN 1500 norm) when tested under standard test conditions.
- The antimicrobial efficacies of Foam B, Rinse E, and Gel F were statistically equivalent when tested at volumes drying in 30 seconds despite having different alcohol concentrations.

## CONCLUSIONS

- In contrast to speculations presented by Kampf et al. ABHR format does not influence product dry time or antimicrobial efficacy.
- Alcohol concentration alone is not a critical driver of ABHR efficacy.
- Product application volume is a key driver of ABHR efficacy.
- Further research is warranted to understand the relative impact of alcohol concentration, ABHR formulation, and product application volume on clinical efficacy and HCW behavior and product acceptance.

## References

1. Kampf, G et.al. 2010. Efficacy of ethanol-based hand foams using clinically relevant amounts: a cross-over controlled study among healthy volunteers. BMC ID. 10:78.
2. Comité Européen de Normalisation. 1997. EN 1500: Chemical disinfectants and antiseptics. Hygienic hand disinfection. Test method and requirement (phase 2, step 2). Comité Européen de Normalisation, Brussels.

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