Balancing acceptability with efficacy in Hygienic hand rub testing.

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Martyn A.C. Wilkinson[1], Christina R. Bradley[1], John D. Hines[2], Adam P. Fraise[1]. [1]Hospital Infection Research Laboratory, Queen Elizabeth Hospital Birmingham. [2]Deb Group Ltd.

INTRODUCTION

Hygienic hand rubs are widely used in healthcare to reduce the likelihood of pathogens being disseminated via the hands. International standards such as EN 15001 have been published to assess the efficacy of hand rubs claiming antimicrobial action. This standard compares 2 x 3 ml applications of 60 % v/v isopropanol (IPA) with a test product. However, as WHO guidelines2 recommend that drying times of alcohol-based hand rubs (ABHRs) be limited to 20-30 seconds, and given that >98 % of healthcare-based hand hygiene events involved 1.5 ml or less of ABHR3, it is unclear whether the standard reflects what happens in practice.

METHODS

Drying time and acceptability as a function of volume: Fifteen volunteers (eight female, seven male) were recruited to test six volumes of 60 % IPA, ranging from 0.5 ml to 3 ml, in 0.5 ml increments. The alcohol was applied to volunteers' hands with a calibrated pipette, and rubbed in using the standard hand rub procedure as described in EN 1500 (the Ayliffe technique). Volunteers self-reported when their hands were dry; the time from application was recorded. At the end of the test, the volunteers were asked to rate the time taken to dry on a three point scale: too short, OK, too long.

Antimicrobial efficacy: Five of the volunteers (two female, three male) subsequently applied the same six volumes of 60 % IPA in the manner of an EN 1500 test. This involved washing the hands in a non-microbicidal standard soft soap, followed by immersion to the mid-metacarpal level in an overnight broth culture of Escherichia coli K12 (mean CFU/ml = 4.53x108) for 5 seconds. The hands were then allowed to air dry for 3 minutes. Subsequently, the hands were sampled for pre-counts by massaging the fingertips in sterile Petri dishes containing 10 ml tryptone soya broth (TSB) for 1 minute. The requisite volume of 60 % IPA was then added to the volunteers' hands with a calibrated pipette, and rubbed in using the standard hand rub procedure as described in EN 1500 for 30 seconds; the volunteers self-reported when their hands were dry. At the end of the rubbing procedure, the hands were sampled for post-counts by massaging the fingertips in sterile Petri dishes containing 10 ml TSB for 1 minute. All samples were plated onto tryptone soya agar (TSA) and incubated at 37°C for 18 hours. Reduction factors were calculated by subtracting mean $\log_{10}$ post-values from mean $\log_{10}$ pre-values.

RESULTS

Figure 1 displays the time taken to dry vs the volume of 60 % IPA applied. The graph contains regression lines and 95 % confidence intervals. The data were broken down by gender, to see if hand size affected the results. The drying time significantly increased as the volume increased ($p<0.0001$, Kruskal-Wallis test), but was not associated with gender ($p=0.8397$, Mann-Whitney U test). Figure 2 depicts the same data broken down by user acceptability. The user comments displayed a significant relationship with volume/drying time ($p<0.0001$, Kruskal-Wallis test), with >70 % of comments negative for 3 ml. The volume that scored highest for acceptability was 1.5 ml. This volume had a mean drying time of 27.07 seconds. Figure 3 displays the $\log_{10}$ reduction factors from the five volunteers vs volume of IPA. The $\log_{10}$ RF increased significantly as the volume increased ($p=0.00218$, Kruskal-Wallis test). The volume applied significantly affected the likelihood of drying: only the 0.5 ml and 1 ml applications dried during the 30 seconds (in all 5 volunteers, and in 2 volunteers, respectively - $p=0.0001297$, Mann-Whitney U test). There was no significant difference between genders ($p=0.1508$, Mann-Whitney U test), though this may be due to the small sample size. Figure 4 displays historical data from more than 12 years' worth of EN 1500 tests at the Hospital Infection Research Laboratory. This shows the distribution of the $\log_{10}$ RF's produced by the reference product - 2 x 3 ml applications of 60 % IPA over 60 seconds. The mean $\log_{10}$ RF of these 554 samples is 5.16. The dotted horizontal line on Figure 3 represents this mean of 5.16.

Figure 1

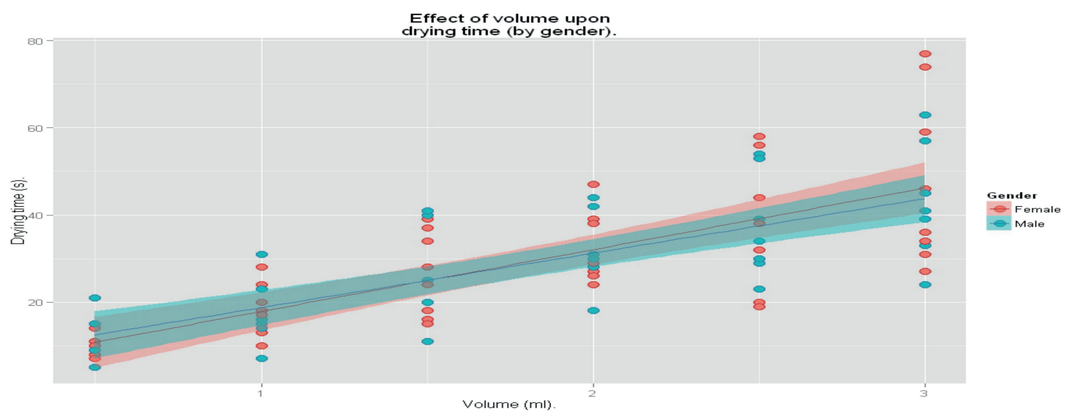


Figure 2

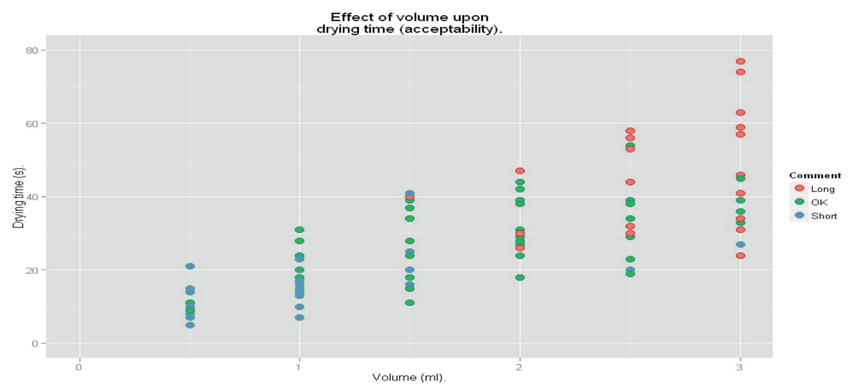


Figure 3

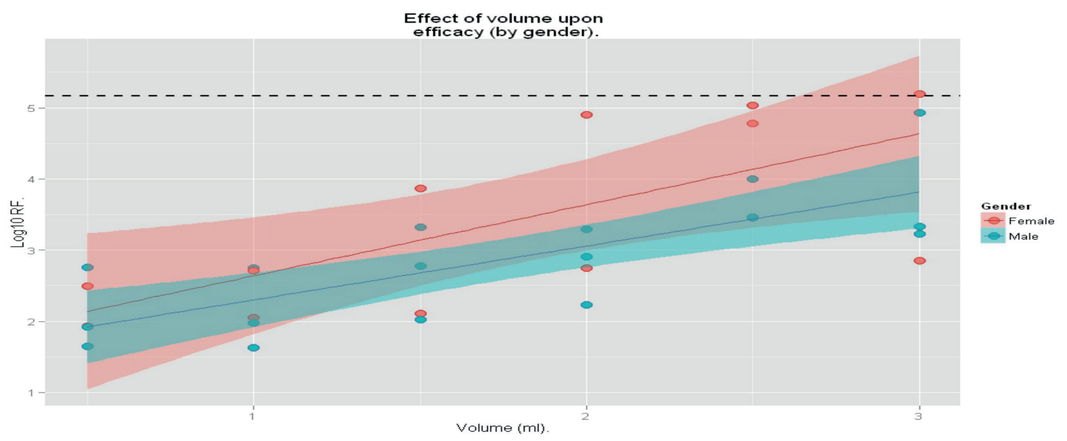
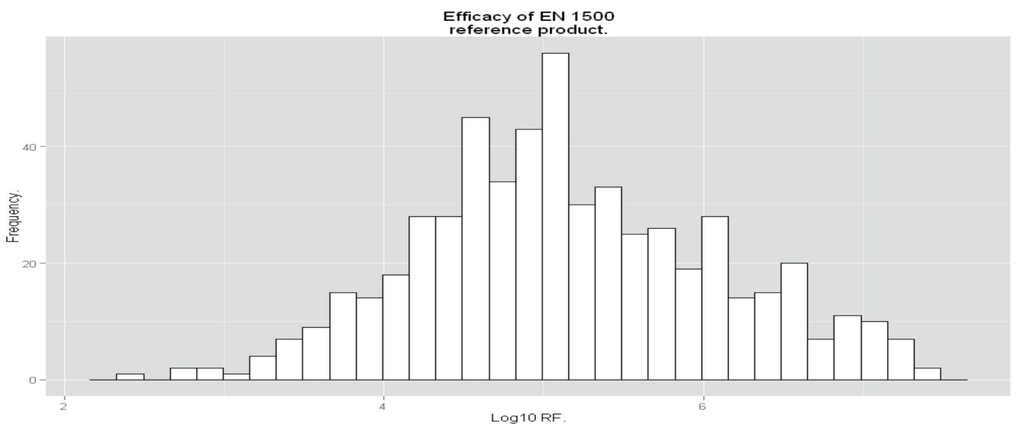


Figure 4



DISCUSSION

The data presented suggest that the volume of alcohol / drying time that is deemed most acceptable for a hand hygiene event by volunteers is 1.5 ml / 27.07 seconds. When this volume was applied during the EN 1500-style test, it gave a mean $\log_{10}$ RF of 2.82. To pass EN 1500, a product has to be statistically non-inferior to the reference product, with a margin of inferiority set at 0.6 $\log_{10}$ units. When compared to the average $\log_{10}$ RF of 5.16 produced by the reference product, the most user-acceptable volume of alcohol gave a margin of inferiority of 2.34 $\log_{10}$ units, even though this volume is at least equal to that involved in greater than 98 % of healthcare-based hand hygiene events. From Figure 3, we can see that even 3 ml of 60 % IPA for 30 seconds would be highly unlikely to pass EN 1500, though the drying time of such a volume is well in excess of the recommended WHO limit. Concerns have been expressed[4] that ABHRs that are applied as foams are unlikely to pass EN 1500, due to the low volumes often applied; the data presented here suggest that this is also true of liquid AHBRs when applied in realistic volumes. Manufacturers of ABHRs face the dilemma of passing standards such as EN 1500 whilst providing instructions for use that are practical for time-pressured healthcare workers. A more pragmatic standard would test at both high volume / long drying times and low volume / short drying times - requiring parity with a reference product under both settings, thus providing an incentive for manufacturers to develop products that pass under in-use conditions. Continually insisting on high volume / drying times alone is unlikely to remedy the notoriously poor compliance with correct hand hygiene in a clinical setting[5].

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