Do international standards for hygienic handrubs reflect realistic usage?

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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 1500[1] have been developed to assess the efficacy of hand rubs claiming antimicrobial action. This standard compares a reference product (2 x 3ml applications of 60% v/v isopropanol (IPA) over 60 seconds) with a test product(s). However, as WHO guidelines[2] recommend that drying times of alcohol-based hand rubs (ABHRs) be limited to 30 seconds, one has to ask whether the standard represents realistic usage?

OBJECTIVE.

This study compared the volumes of ABHR applied, drying time, antimicrobial efficacy and user acceptability. The ABHR's studied were 60% v/v IPA and the two WHO-recommended ABHR formulations i.e. WHOF1 – 80% v/v ethanol and WHOF2 – 75% v/v IPA, both of which contain 1.45% v/v glycerol.

METHODS.

Drying time and acceptability as a function of volume: Fifteen volunteers were recruited to test six volumes of the three ABHR's, ranging from 0.5ml to 3ml. 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 subsequently applied the same six volumes of the three ABHR's 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 = 4.70×10^8) 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 10ml tryptone soya broth (TSB) for 1 minute. The requisite volume of one of the three ABHR's 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. At the end of the rubbing procedure, the hands were sampled for post-counts by massaging the fingertips in sterile Petri dishes containing 10ml TSB for 1 minute. All samples were plated onto tryptone soya agar (TSA) with added deoxycholate 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 spread of drying times per product, along with LOESS regression curves and 95% confidence intervals. The drying time for all three products increased as a function of volume. When calculated across all volumes, the mean drying time was 24.22 seconds for WHOF1, 25.57 seconds for WHOF2 and 28.32 seconds for 60% IPA. The only significant difference was between WHOF1 and 60% IPA (p=0.030; Wilcoxon signed rank test).

•Figure 2 displays the user comments regarding drying time for the three products. The black dotted line represents the mean acceptable drying time, which was calculated across all three products as being equal to 25.33 seconds. There was a significant relationship between user acceptability and volume of application across all three products (p<0.001; Kruskal-Wallis rank sum test), with user acceptability being greatest around the 1.5ml and 2ml applications.

•Figure 3 shows the $\log_{10}$ reduction factors produced by the different volumes of each product in the EN 1500-style test, along with linear regression lines and 95% confidence intervals. More than 12 years' worth of EN 1500 tests at HIRL have demonstrated that the reference product produces a mean $\log_{10}$ RF of 5.16. This value is represented by the thick dotted line on Figure 3. The thin dotted line represents the agreed inferiority margin of 0.6 $\log_{10}$ that is specified in EN 1500. The $\log_{10}$ RF's for all three products increased in a linear fashion as a function of volume. There was no significant difference between the mean $\log_{10}$ RF's produced by each product, when calculated across all volumes (p=0.247; Friedman rank sum test).

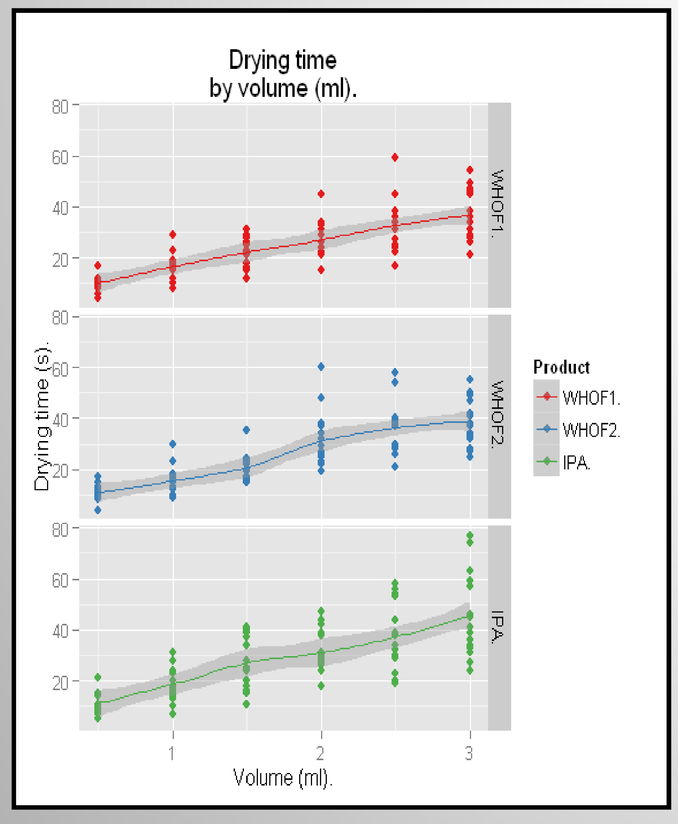

Figure 1.

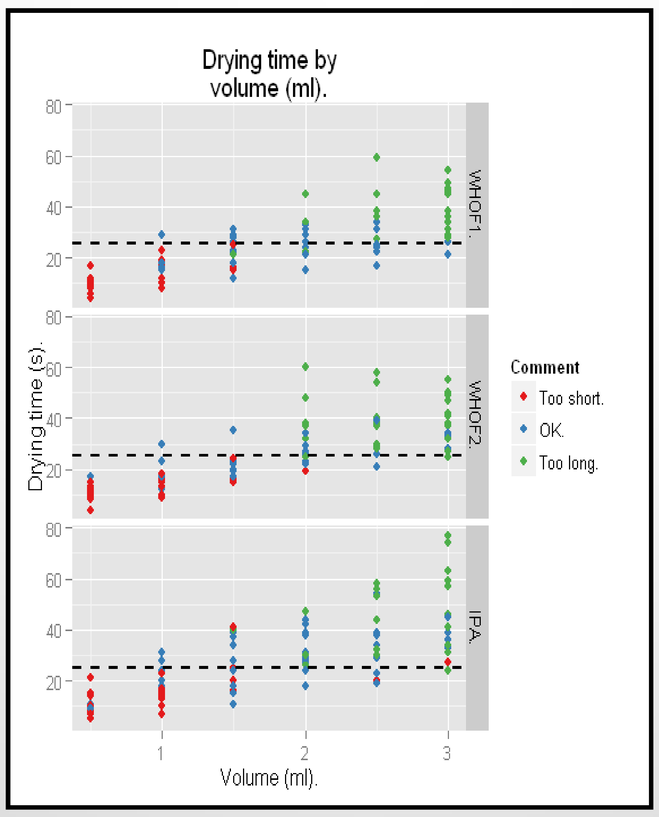

Figure 2.

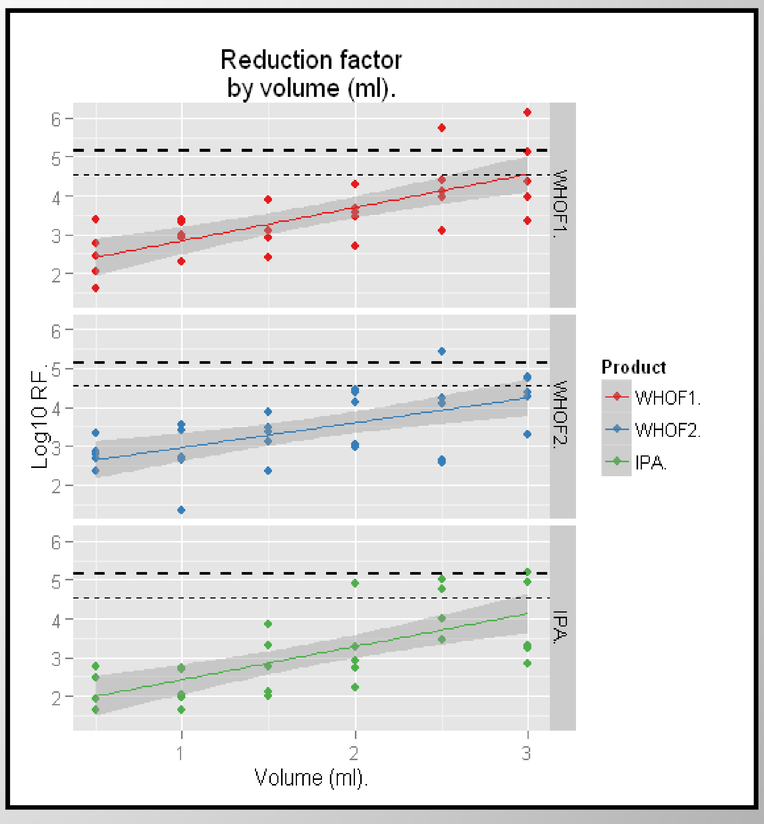

Figure 3.

CONCLUSION.

EN1500 was not originally designed as a means to define product dosage; however this is increasingly becoming normal practice. The BPR requires manufacturers to support their label claims with data which is principally compliance with EN 1500. However, the data presented here reinforce the need for standards to reflect more accurately the volumes of hand rubs that are used in practice. The perception of the volunteers of an acceptable volume and drying time is in line with the WHO recommendations but would not comply with the requirements of EN 1500 even with the agreed inferiority margin of 0.6$\log_{10}$. Similar results in relation to volume and drying time were recently published by Macinga *et al*[3]. Concerns have been expressed[4] that ABHRs 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.

One possible solution involves implementation of a phase 2 standard i.e. EN 1500 and a phase 3 test low volume/short drying times, thus allowing formulations to be tested against a reference product under both ideal and realistic conditions.

REFERENCES.

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