Product Dose Considerations For Real-World Hand Sanitiser Efficacy

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INTRODUCTION

Alcohol based hand rubs (ABHRs) are extremely effective at reducing microbial contamination and today play a central role within established best practices for infection control. Modern dispensing systems have also brought many advantages such as hygienically sealed cartridges with integral pumps for dosing liquids, gels or foams. However a remaining issue concerns the measured efficacy of such products and their use in practice as directed by the pump volume.

ABHRs used in professional healthcare settings are evaluated using standard methods at volumes not necessarily consistent with real use by healthcare workers, who are "time-starved" and want hand hygiene to be as rapid and "efficient" as possible.

We define the critical relationships for optimal dose of an ABHR product in Figure 1. In this study we aim to establish this optimal dose based on observation of in-facility behavior and laboratory evaluation, aligning real-world requirements to measured efficacy. We discuss the challenges this brings and potential trade-offs required.

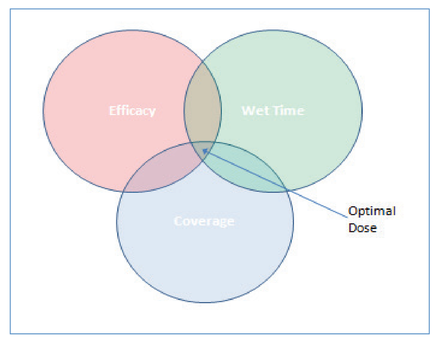

Figure 1: Critical relationships determining optimal ABHR dose

METHODS

1. Monitoring Dispenser Usage

The DebMed GMS® Hand Hygiene Monitoring System tracks ABHR and handwashing soap usage in enabled healthcare facilities. Dispenser use is tracked and used to calculate the Hand Hygiene Compliance Index (HHCI) as a percentage compliance to best practice defined by WHO 5 Moments as measured by validated benchmark data[1],[2]. In this study we used anonymised system-wide data from November 2011 – June 2013. In all facilities, Deb wall-mounted dispensers were used with a dose volume of 0.75ml per shot of ABHR in the form of alcohol foam.

2. Establishing ABHR drying time as function of dose

a) Laboratory Evaluation

Nine volunteer healthcare workers were trained to the WHO hand hygiene method[2]. Measured volumes of the same formulation (Deb InstantFoam, 65% Ethanol, 10% n-propanol alcohol composition) in liquid, gel and foam format was placed in the palm of the hand. The volunteers were observed and timed while applying the products. Volunteers self-reported when hands were dry and the time to dry was recorded.

b) Real-world Evaluation

Three evaluations of drying time and user perceptions were carried out at healthcare facilities in the US, Canada and UK. Healthcare workers used ABHR products in foam format dispensed in two pump sizes; 0.75ml and 1.5ml. Participants were first asked their expectation of drying time for ABHR, then asked to estimate the drying time of the product they were using. Actual drying time was recorded in parallel. At the end of the test, participants were asked for their perceptions of the volume used; too little, about right or too much.

3. Establishing Hand Coverage for ABHRs

Volunteers were trained to the WHO hand hygiene method[3], then asked to apply measured doses of ABHR in gel and foam format at different volumes. The ABHR products were doped with a small amount of UV marker substance such that coverage could be assessed via image analysis (ImageJ).

4. Standard Measures of Product Efficacy

ASTM 1174 (HCPHW) and EN1500 were performed by independent laboratories (EN 1174 by BSL, Boseman, Montana and EN 1500 by Blu Test, Glasgow, UK).

RESULTS

1. Monitoring Dispenser Usage

Table 1 shows consolidated system-wide GMS data, totalling approximately 27 million hand hygiene events taking place in a number of hospital settings in North America.

Approximately 90% of events used a single dose (0.75ml) of ABHR. This intuitive behaviour presents a clear challenge to ABHR manufacturers to ensure that the optimal dose for a hand hygiene event is as dispensed by one "action" of the accompanying dispenser or pump.

Doses per event	Number of events	% of Total
1	24,184,501.00	89.577969%
2	2,359,594.00	8.739797%
3	333,590.00	1.235598%
4	81,748.00	0.302790%
5	27,150.00	0.100562%
6	9,502.00	0.035195%
7	2,065.00	0.007649%
8	115.00	0.000426%
9	4.00	0.000015%
Total	**26,998,269.00**	

Table 1: The number of doses per hand hygiene event

2. Establishing ABHR drying time as function of dose

WHO guidelines[3] recommend that ABHR is wet on the hands for 20-30s to ensure effective contact time. We aimed to determine optimal product dose as a function of wet time, taking into account also product format (liquid, foam, gel) but not varying ormulation. We also aimed to determine any differences between actual and perceived drying times and user expectation/preference.

a) Laboratory Evaluation

Results of this study are shown in Figure 2 in which we combine the results of 2 tests on 9 volunteers t o give a total of 18 data-points per stated chart value. WHO recommended drying times are achieved using liquid and foam doses of between 0.75 and 1.5ml and for gel between 1.5ml and 2.25ml.

ABHR as gel dries faster than the other two formats. This could be user perception due to the feel of the gel product which is sometimes reported as "tacky".

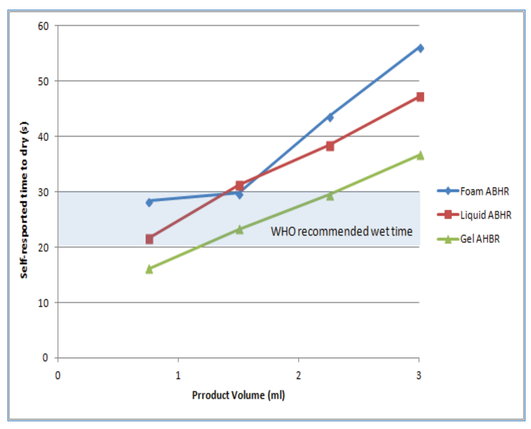

Figure 2: Laboratory evaluation of ABHR drying time as a function of volume and format

At higher volumes, foam dries slower than liquid which could be perception caused by the silicone foaming agent or due to liquid dripping from the hands leading to lower actual volumes. These hypotheses are to be investigated in future work.

b) Real-world Evaluation

Figure 3 shows the expected, actual and perceived drying times for both product doses based on UK data. Figure 4 shows similar data (1.5ml dose only) from the US evaluation.

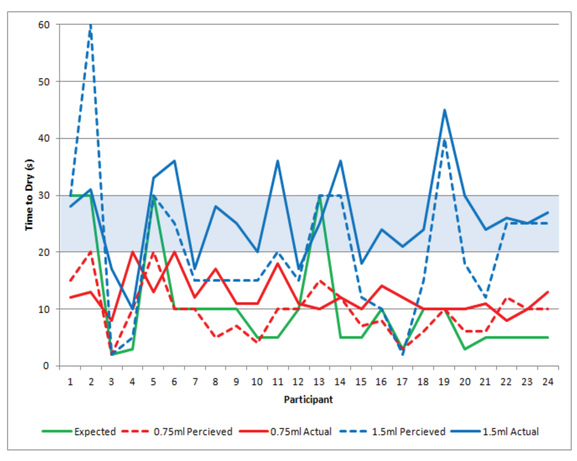

Figure 3: User evaluation of ABHR drying time, UK subjects

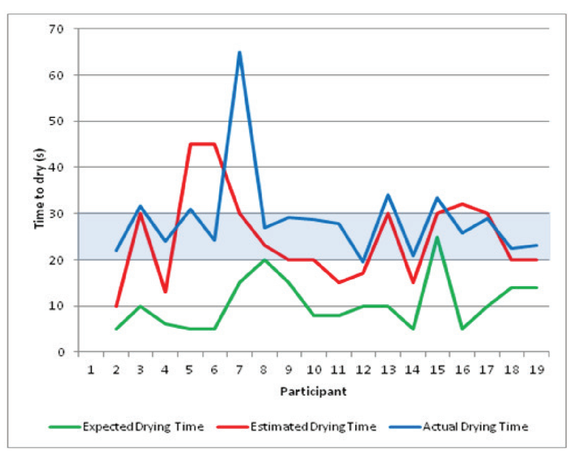

Figure 4: User evaluation of ABHR drying time, US subjects

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Figures 3 and 4 are well correlated. Both confirm that 1.5ml ABHR dose achieves the desired wet time according to WHO guidelines, but is consistently perceived to longer to dry than expected.

Figure 3 shows that 0.75ml dose achieves less than the recommended wet time, but more closely matches expectations. In both studies perceived and actual drying time are reasonably well correlated (R2 = 0.51, consolidated).

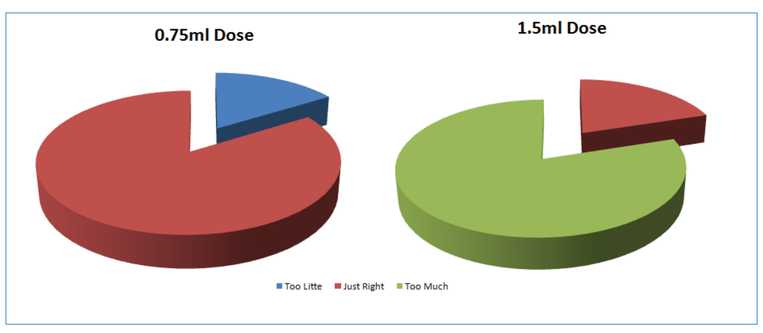

Figure 5: UK User judgement of ABHR volume (foam)

Figure 5 shows UK data rating product volume. Users were more likely to rate the 0.75ml dose as "just right" (84%) while rating the 1.5ml dose as "too much" (80%). It is notable that in Canada where users were familiar with local campaigns on the importance of wet time, acceptance of the 1.5ml dose was much higher.

3. Establishing Hand Coverage for ABHRs

Standard laboratory efficacy tests control contamination on the finger-tips, however real-world conditions should require full hand coverage for complete confidence. Consolidated data from NL and UK is presented in Figure 6.

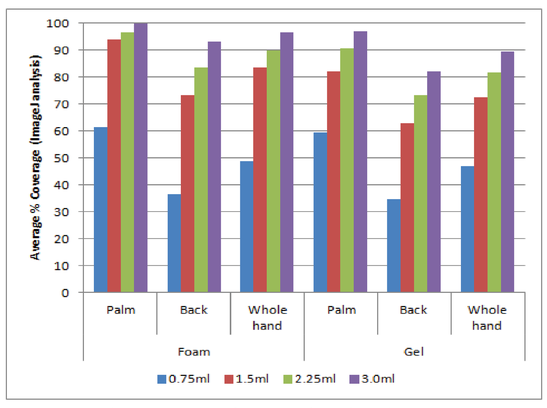

Figure 6: Hand coverage as a function of product dose

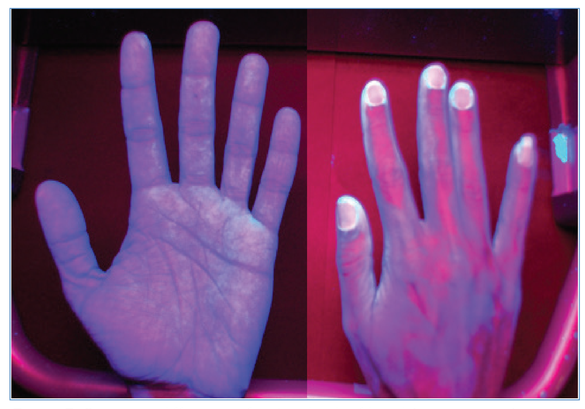

Figure 7: Coverage differences front vs back of hand (same person)

Coverage of the palms of the hands and fingers is achieved much more readily and with smaller volumes of product than the backs of the hands; an example of this result is shown in Figure 7.

Results indicate that of at least 2.25ml ABHR is required for optimised coverage of both the front and back of the hand. Small differences are observed between formats; foam covering slightly more than gel. This data represents a further challenge in that such a volume is likely to produce a wet time of > 30 seconds; fine for efficacy but unlikely to be tolerated in practice by time-starved healthcare workers.

4. Standard Measures of Product Efficacy

Table 2 compares performance in standard tests with hand coverage and wet time evaluations using the same test formulation.

Table 2 confirms that product efficacy to established standards can be achieved at a dosed volume of 1.5ml or greater, which (given that the applied contamination is on the fingertips) is consistent with our evaluations that establish such a volume can produce the required wet time and (front of hand) coverage required.

ABHR Product Volume (Deb InstantFoam AFS6510)	Wet Time	Hand Coverage		In-vivo Efficacy	
		Fronts	Backs	ASTM 1174	EN 1500
0.75ml	approx 20s	PARTIAL	NO	FAIL	FAIL
1.5ml	20-30s	YES	PARTIAL	PASS	Preliminary Pass (testing in progress)
2.25ml	>30s	YES	YES	PASS	PASS
3.0ml	>30s	YES	YES	PASS	PASS

Table 2: Summary of evaluations including standard efficacy testing

DISCUSSION AND FUTURE WORK

We aimed to address key questions about use of ABHRs in real-world settings and design of products including dose control, wetting and coverage characteristics in addition to standard efficacy measures. Figure 1 shows our objective at the outset; to identify an "optimal" dose meeting all requirements. While this remains our aim we are faced with some challenges and potentially the recognition that in reality, the vision of Figure 1 may be better represented by Figure 8; there is no readily acceptable optimum!

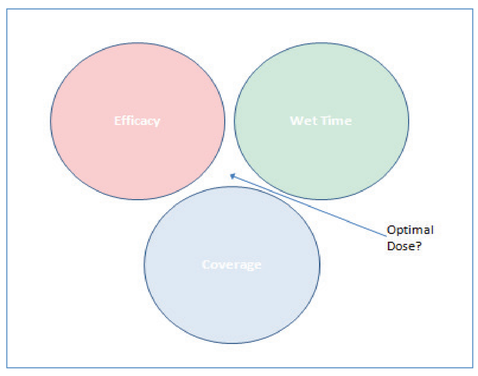

Figure 8: Is there an optimum ABHR dose in the real-world?

In healthcare facilities today, the effectiveness of many hand hygiene events is lower than understood because users self titrate the dose to "acceptable" wet times of <15s.

Through education and training aligned to properly metered products, we must re-establish that proper hand hygiene takes 20-30 seconds to complete. The authors will continue research in all these areas.

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