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Considering User Preference and Acceptability to Optimise ABHR Design for Real-World Effectiveness

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ACPIC, Perth, November 2019

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Disclosures

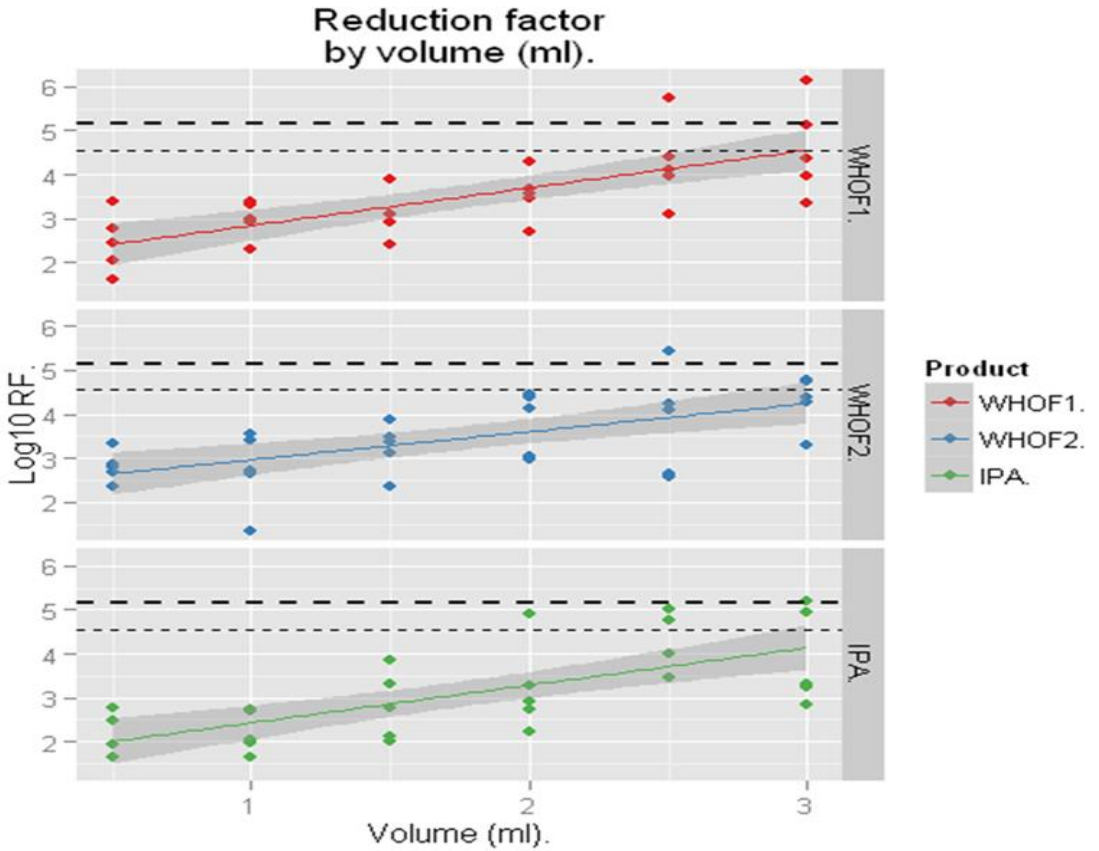
- John Hines and Kevin Ormandy are employees of SC Johnson Professional Ltd
- Consumables required for the studies performed at QEH Birmingham by Tina Bradley and Martyn Wilkinson were funded by SC Johnson Professional Ltd

Effective hand hygiene is as much about behaviour and choices as it is about microbiological efficacy

- …and yet, ABHRs are typically solely evaluated using laboratory standard methods (EN1500, ASTM E-1194, etc)
  - Not necessarily reflective of real-world application
  - Do not consider key factors such as aesthetics, tolerability, preference, etc that may influence use patterns
  - May impose unrealistic or impractical requirements if taken too strictly (e.g. on dosage)
- Nevertheless efficacy standards are important and products must meet them
  - And more importantly, must perform adequately in clinical practice
- So how should we determine the key design features for ABHR for optimum clinical effectiveness?
  - We have studied and aimed to characterise ABHR effectiveness in clinical conditions by considering drying time & hand coverage in addition to efficacy as f(volume, format)
  - We have studied ABHR aesthetic & handling characteristics and linked these to user preference when considered at clinically effective dose

Efficacy as f(volume) – Liquid ABHR

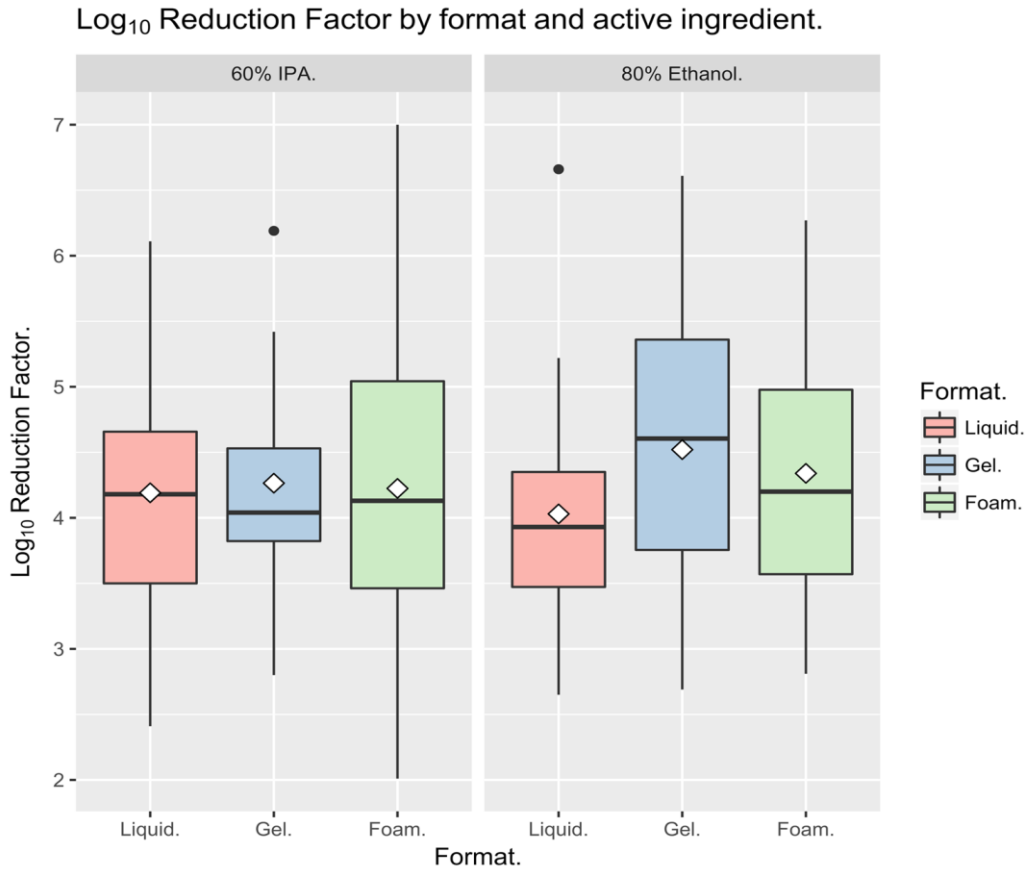
- Efficacy was assessed with 5 volunteers using EN1500 test method. The reference product was 2 x 3 mL of 60% IPA for 60s, as described in EN1500 (2013).
- Test Products were WHOF1 (80% v/v Ethanol) and WHOF2 (75% v/v IPA) formulations + 60% IPA (EN1500 reference)
- In all cases, efficacy improves linearly with volume – no plateau in this range
- Dashed line is EN1500 “pass” level based on historical averages. Dotted line is 0.6LR below (non-inferiority limit)
- Confirms at least 3ml required to pass EN1500 in all cases



Wilkinson MAC, Ormandy K, Bradley CR, Fraise AP, Hines J.
Dose Considerations for Alcohol-based Hand Rubs. J Hosp Infect 2017;95:175e82.

Efficacy as f(format)

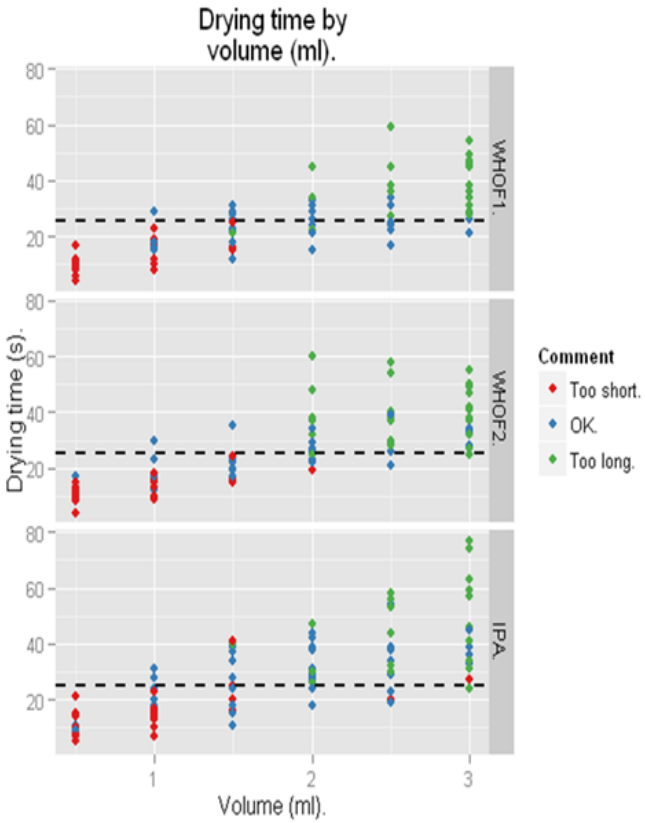
- For each test product, efficacy was assessed using EN1500 test method carried out with 20 volunteers. The reference product was 2 x 3ml of 60% isopropyl alcohol (IPA) for 60 seconds, as described in EN1500 (2013)
- Two formulations in liquid, gel and foam format were tested
  - 60% v/v IPA (EN1500 reference)
  - 80% v/v ethanol (WHOF1)
- All test products were assessed using 3ml for 30 seconds. Each volunteer tested all three formats, their order of application decided by a Latin square design.
- This study found no difference in antibacterial efficacy attributable to formulation or format for the two 'standard' ABHR formulations, as assessed by EN1500.

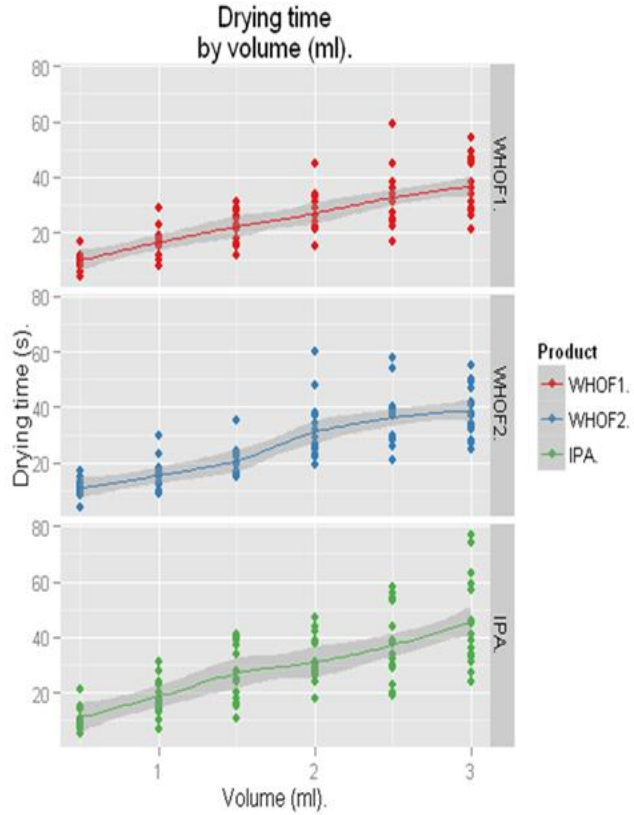


M.A.C.Wilkinson, K.Ormandy, C.R.Bradley, J.Hines
Comparison of the Efficacy and Drying Times of Liquid, Gel and Foam Formats of Alcohol-based Hand Rubs. J Hosp Infect 2018; 385-364

Drying time as f(volume) – Liquid ABHR

- 15 HCW tested each product at volumes 0.5 - 3ml. Product was applied to the hands with a calibrated pipette and rubbed in using the Ayliffe technique.
- Volunteers reported hands dry & time from application was recorded. Volunteers were asked to rate drying time on a three point scale : too short, ok, too long.
- At volumes required to pass EN1500, wet times are > 30s for all products
- Volume required to meet WHO recommended wet time (20-30s) ~ 1.5ml (Dotted line represents WHO recommended mid-point for wet time (25s))
- 20-30s rated “OK”. 3ml produces overwhelming “too long” response





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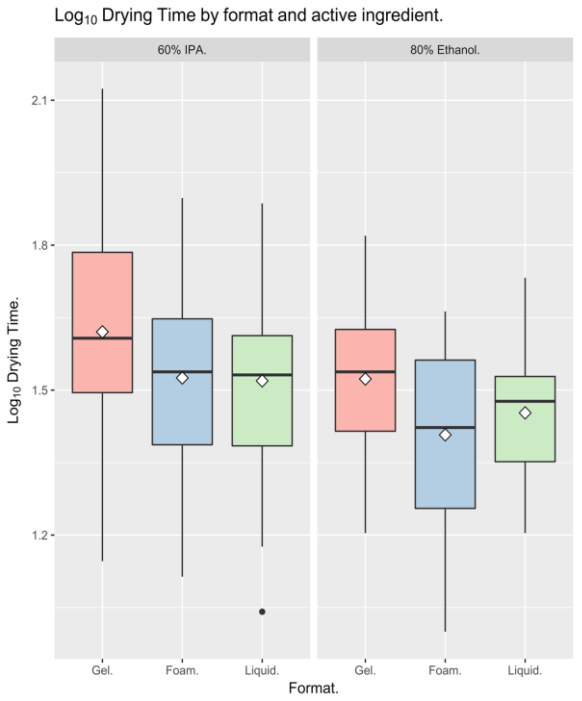
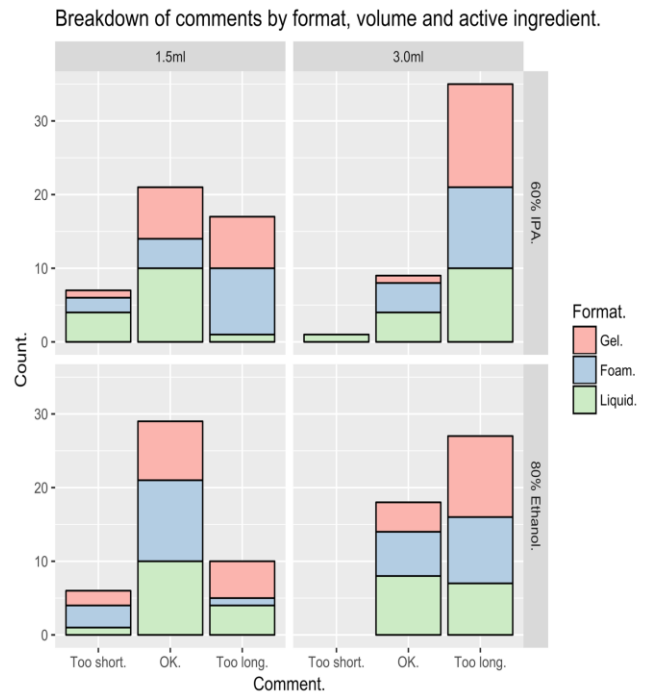
Drying time as f(dose, format)

- 1.5 and 3.0ml of test formulations in liquid, gel or foam format were applied to the hands of 15 HCW.
- Volunteers reported hands dry & time from application was recorded. Volunteers were asked to rate drying time on a three point scale : too short, ok, too long
- For both formulations, gels take longer *to be perceived as* dry than other formats.
- IPA is perceived to take longer to dry than EtOH.
- For both formulations, 1.5ml is more likely to be considered “ok” while 3ml is “too long”.
- For 80% EtOH at 1.5ml there is a greater tendency for foams to be perceived as “ok” compared to the other formats





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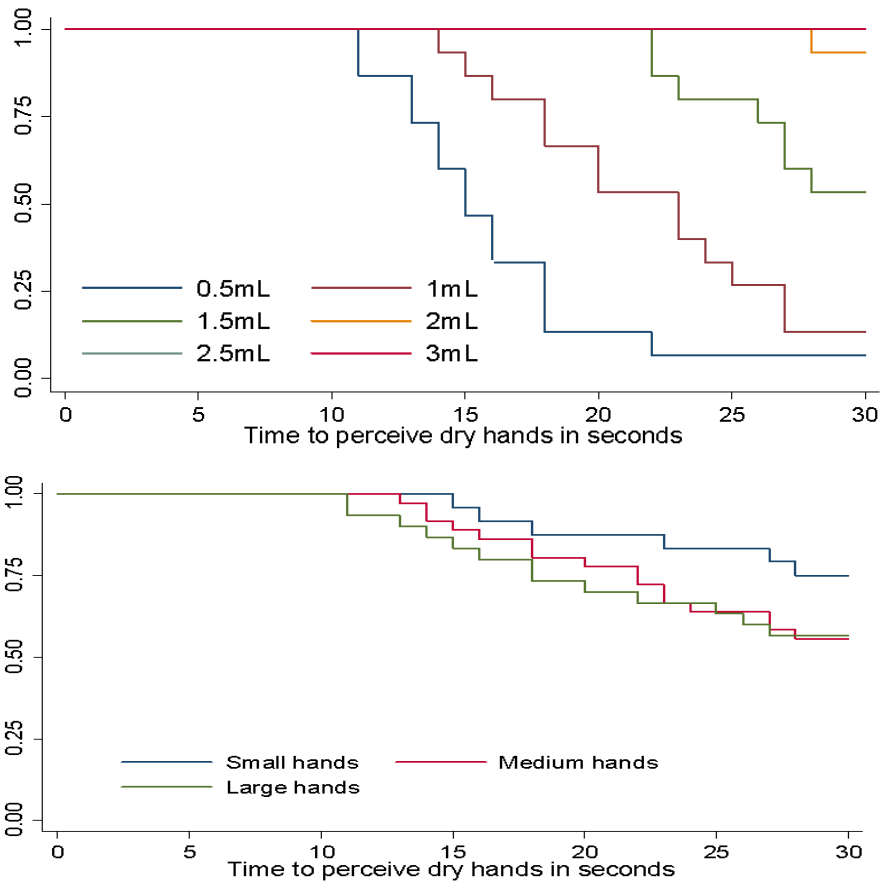
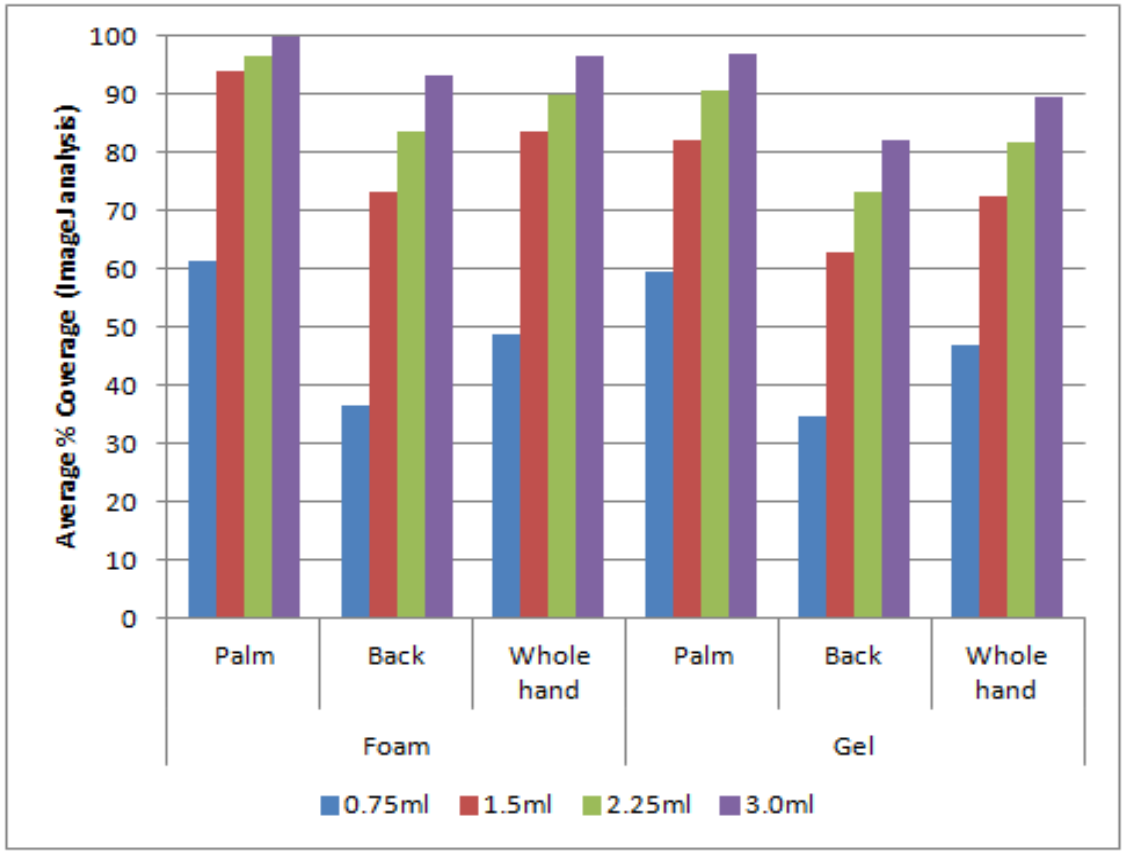
Drying time as f(volume, hand size)



- Experimental study among healthy healthcare workers trained to hand hygiene performance according to the WHO sequence
- Healthcare workers were asked about their perception to obtain dry hands during the hand rubbing sequence
- Primary outcome was the acquisition of dry hands related to time of observation in seconds (censored at 30 seconds)
- Study supports conclusion that 1.5ml fits WHO recommendations for drying time
- Drying times tendentially longer than UK study
- Hand size makes a significant difference (1ml tested)
- Plays into the need to consider gender differences w.r.t hand size when thinking about the right dosage

A. Gayet-Ageron, F. Bellissimo-Rodrigues et al., Relationship Between Hand Size, Volume of Alcohol-based Handrub and Time Needed to Dry Hands. An Experimental Laboratory-based Study. Antimicrobial Resistance & Infection Control 4(Suppl 1):P303 · June 2015

Hand Coverage as f(volume, format)



- Study used commercial ABHR foam & gel formulations (both 75% EtOH) with added fluorescent marker.
- 9 volunteer HCW asked to rub products (Ayliffe technique) until dry
- Image analysis software used to determine % coverage on front & back of hands
- At least 2.25ml required for good coverage on both front and back of hands
- 1.5ml gives good coverage on front, acceptable on back
  - Foam slightly more effective coverage than gel at same volume
- 0.75ml is insufficient for both products

Presented at ICPIC 2013, Voss, Eikelboom, McGeer, Hines, Alper

Sensory Descriptive Analysis

- Sensory Panel (n=13) assessed 10 leading brands of ABHR in Foam/Liquid/Gel format using Qualitative Descriptive Analysis (QDA) style methodology
- The panel generated descriptive vocabulary that covered appearance, texture, aroma, rub-in and after-feel of the samples (see Table 1)
- 3 replicates rated in individual sensory booths - assessments made on unstructured line scales with verbal anchors
- A two-factor ANOVA (with fixed model) was used to analyse the data. Data were further analysed using Tukey-Kramer HSD multiple comparison test to explore differences in more detail. A significance level of 5% was used (p=0.05).

Table I
List of attributes assessed by trained descriptive panellists at various stages of alcohol-based hand-rub application

Attribute	Assessment stage						
	Before application	Visual	Tactile	Post dispense/ pre-rub	During rub in	Immediately after application	2 min after application
Tightness	✓					✓	✓
Moisturized feel	✓					✓	✓
Aerated		✓					
Thickness		✓	✓				
Denseness			✓				
Intensity aroma				✓	✓		
Intensity alcohol aroma				✓	✓		
Change of state				✓			
Temperature				✓	✓		
Handleability				✓			
Drying time					✓		
Spreadability					✓		
Skin feel					✓		
Stickiness					✓	✓	✓
Soapiness					✓		
Ease of full-dose application					✓		
Clean feel						✓	✓
Smooth feel						✓	✓

Panellists followed a strict protocol developed in training sessions and defined by the lexicon (see Appendix A for full lexicon).

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Sensory Mapping Analysis

- Principle Component Analysis (PCA) was used to summarise how the samples compared to each other and identify the key characteristic sensory attributes
- Dimension 1 explains the majority of variation between the samples; Dimension 2 explains the next largest amount of sample variation. Two dimensions explains 78% of total variation, indicating a good overall representation of product differences.
- Focus groups conducted with healthcare workers in two UK NHS Trusts assigned attributes as positive (+) or negative (-)
- **Foams and gels became stickier, less clean-feeling and slower to dry at higher doses.**
- **Liquids gave a cleaner, smoother, more moisturized feel, but increased tight skin feel and aroma at higher doses**

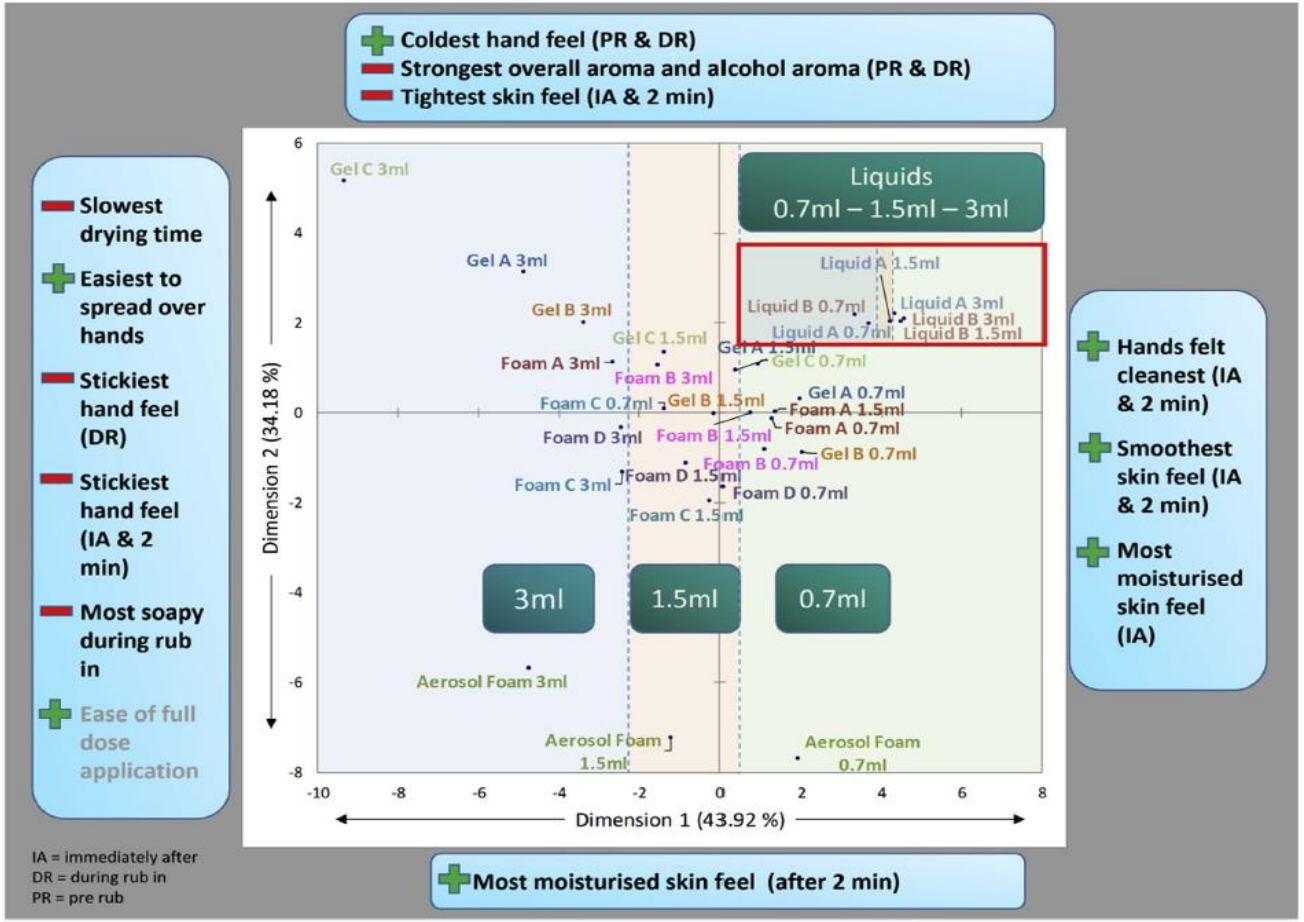

Figure 2. Principal component (PC) analysis biplot showing PC1 versus PC2 including results for all alcohol-based hand rubs tested at the three dose levels (0.7 mL, 1.5 mL, and 3 mL).

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Drivers of user preference – Combined PCA & Focus Groups

Findings and Conclusions

- Hygiene experience is less desirable at higher doses for all formats
- Foams and gels were the most preferred formats overall
- Foams and gels became stickier, less clean-feeling and slower to dry at higher doses.
- Liquids gave a cleaner, smoother, more moisturized feel but increased difficulty in handling and applying the product negated these benefits
- 1.5 mL dose yielded the most acceptable properties with no extreme negative consequences
- Foam format provided the major benefits of both the liquid and gel and combined them into a more widely acceptable format that *may* lead to greater hand hygiene compliance when used at effective volumes.

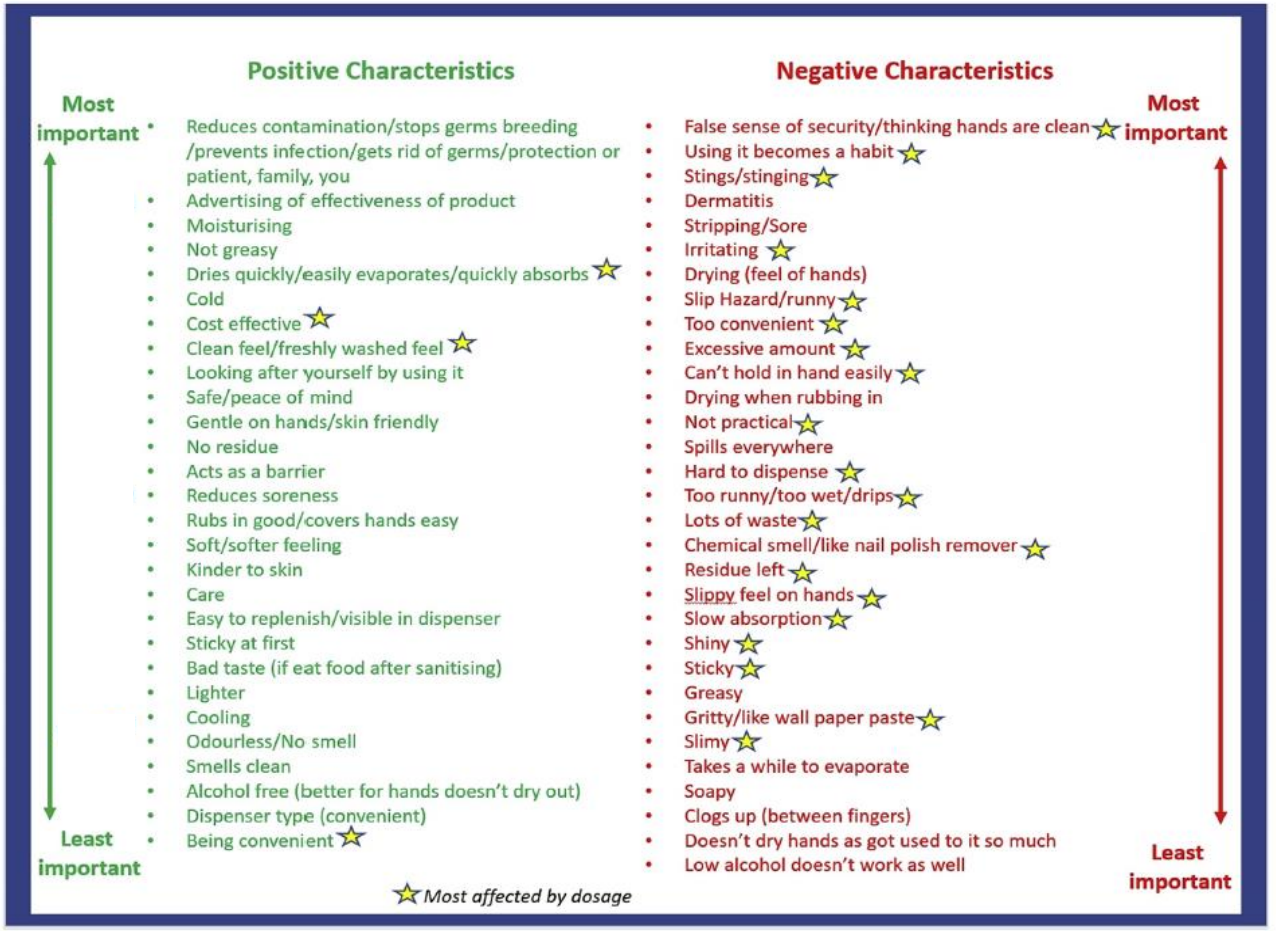

Figure 1. Combined results for positive and negative characteristics of alcohol-based hand rubs as perceived by focus groups 1 and 2. Stars represent product qualities affected by dose.

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Conclusions

- For effective hand hygiene as part of Infection Prevention we need the right products, used in the right way, at the right times
- Product design can play a key role in promoting this by considering aesthetics & handling characteristics, alongside efficacy, at appropriate volumes
  - Laboratory standard testing is important but is not wholly reflective of real-world settings or requirements
- Not surprisingly, acceptability decreases with ABHR volume while efficacy increases
  - Some “trade-off” between these elements is inevitable
- Careful design to optimise key drivers of preference can create meaningful differences in the position of the “trade-off” point leading to better holistic solutions
- In our studies, foam format (non-sticky, non-dripping, pleasant skin-feel) at 1.5ml dose provides the best balance of all elements, optimising efficacy + acceptability


Thank You