Assessment of the efficacy of a patient hand wipe: development of a test method

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Assessment of the efficacy of a patient hand wipe; development of a test method

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Summary

Background

Much attention has focused on hand decontamination for healthcare workers; little has been paid to patient hand hygiene. Patients confined to bed are often unable to access hand washing facilities. They could use an alcohol hand rub but these are not advised for soiled hands or social hand hygiene. One alternative is the use of a hand wipe. However, are they effective at removing transient micro-organisms from the hands?

Aim

To develop a method assessing the antimicrobial efficacy of hand wipes compared with hand washing, and so determine if a hand wipe can be acceptable for patient hand hygiene.

Methods

The methodology was based on the European standards EN 1499 (2013) and EN 1500 (2013) as there is no standard for hand wipes. The hands of 20 healthy volunteers were artificially contaminated by immersion in *Escherichia coli* and then sampled before and after using a reference soft soap or hand wipes for 60 seconds. The counts obtained were expressed as $\log_{10}$ and the $\log_{10}$ reductions calculated.

Findings

The patient hand wipe with no antimicrobial agent was inferior to the soft soap. However, the antimicrobial wipe was statistically non-inferior to the soft soap. A $\log_{10}$

reduction of 3.54 was obtained for the reference, 2.46 for the control patient wipe, and 3.67 for the antimicrobial patient wipe.

Conclusion

The evidence suggests that the antimicrobial patient wipe, when applied for 60 seconds, is at least as good as soap and water, representing an acceptable alternative to handwashing from a bactericidal perspective.

Introduction

It is well recognised that hand hygiene has a role to play in prevention of the transmission of healthcare-associated infection. The focus tends to be on hand hygiene for healthcare workers but it is acknowledged that patients' hands may also have a role to play although the evidence is somewhat limited [1, 2]. One study looked at a bundle which included patient hand hygiene and showed a reduction in hospital-acquired infection with *Clostridium difficile* [3]. Another study identified that 39% of patients' hands were contaminated with at least one pathogenic microorganism [4].

Some patients may be confined to bed and not able to access a hand wash basin independently; studies have suggested that staff rarely support patient hand hygiene [5, 6]. Therefore, if patient hand hygiene is to be implemented and encouraged, an easy way of carrying out this task is required. Alcohol hand rubs could be offered to the patient but this is not recommended if the hands are visibly soiled, which in many instances may be the case. Although alcohol sanitisers for patient use have been proposed, there are safety concerns in relation to the consumption of alcohol from dispensers. The use of a suitably-applied hand wipe would be a feasible strategy to support patient hand hygiene.

There are no European standards for testing wipes designed for hand hygiene. The European standard for the evaluation of hygienic handwash formulations is EN 1499. EN 1499 (2013) is a test for the evaluation of the bactericidal activity of skin disinfectants, simulating practical conditions for establishing whether a product is

suitable for hygienic handwash where disinfection is medically indicated, or in food, industrial, domestic and institutional areas [7].

The standard comprises an assessment of the number of test organisms (*E. coli*) released from the fingertips of artificially-contaminated hands of 12 – 15 volunteers, before and after hygienic handwash with test and reference products. The ratio of the two resulting values is called the reduction factor (RF). It represents a measure of the antimicrobial efficacy of the handwash product tested. To pass the test, the RF of the test product(s) should be significantly superior to the reference product i.e. European standard soft soap.

The aims of this study were to a) evaluate a modification of EN hand tests specifically for assessing the efficacy of a hand wipe and b) to determine if a hand wipe can meet the EN requirements and be acceptable for patient use.

It was decided to increase the number of volunteers from the 15 described in EN 1499 to 20; this was to allow the statistical analyses in EN 1500 to be performed, in addition to those of EN 1499. EN 1500 (2013) is a test for the evaluation of bactericidal activity of skin disinfectants, simulating practical conditions for establishing whether a product is suitable for hygienic handrub where disinfection is medically indicated, or in food, industrial, domestic and institutional areas [8].

To pass this standard, the RF of the test product(s) shall be at least non-inferior to that achieved by the reference product i.e. 60% v/v propan-2-ol, when used on 18 – 22 volunteers. Therefore, using both criteria allows the demonstration of non-inferiority as well as superiority and increases the level of statistical power.

Methods.

All testing was performed in a containment level 2 laboratory on healthy adult volunteers. The volunteers comprised general laboratory staff, nurses and hospital cleaners. All volunteers had healthy, intact skin and provided informed consent. Ethics approval was sought but as the method used was based upon published EN standards, we were informed that this was not required.

Products assessed

Test product 1 (P1) Control Hand Wipe with no biocides or chelating agent

Test product 2 (P2) Clinell Antibacterial Hand Wipe containing benzalkonium chloride, didecyldimonium chloride, PHMB, phenoxyethanol plus an emollient, surfactant and chelating agent.

Reference product - European standard soft soap as described in EN 1499 and EN 1500

Test method and validation

Artificial contamination of the hands

Prior to contamination, the hands were washed for one minute using European standard soft soap. After thoroughly drying, the fingers were then contaminated by immersion of the hands up to the mid metacarpals into a bowl containing 2 litres of contamination fluid, i.e. an overnight culture of *E coli* K12 NCTC 10538 in Tryptone Soya Broth (TSB). After 5 seconds, the hands were withdrawn from the contamination fluid, excess fluid was allowed to drip from the fingers, and then the hands were held horizontally with the fingers spread apart and allowed to dry for 3 minutes. The fingertips were then sampled to obtain 'Pre-values' of surviving test organisms before applying the 'Test' or 'Reference' procedure.

Reference handwash procedure

Five ml of soft soap was poured into the pre-wetted cupped hands, and rubbed vigorously into the skin for 60 seconds up to the wrists in accordance with the standard handwash procedure shown in Appendix A of EN 1500 to ensure total coverage of the hands. This comprises five strokes backwards and forwards, palm to palm, right palm over left dorsum and left palm over right dorsum, palm to palm with fingers interlaced, back of fingers to opposing palms with fingers interlocked, rotational rubbing of right thumb clasped in left palm and left thumb clasped in right palm, rotational rubbing with clasped fingers of right hand in palm of left hand and clasped fingers of left hand in palm of right hand.

The reference procedure was completed by a 10 second water rinse of the fingers from distal to proximal with fingertips upright, under running tap water. The hands were held with the fingers pointing upwards until excess water was dried off by the experimenter, using two dry paper towels to dab any excess water from the base of the hands and the wrists. The hands were then sampled immediately by rubbing the fingertips and thumb for one minute on the base of a Petri dish containing 10ml of TSB containing a validated neutralizer for 1 minute. All samples were plated onto tryptone soya agar supplemented with 0.5g/l sodium deoxycholate and incubated at 37°C for 18-24 hours followed by a further 24 hours. Reduction factors were calculated by subtracting mean $\log_{10}$ post-values from mean $\log_{10}$ pre-values. The neutralizer comprised the following ingredients, per litre of distilled water: tryptone soy broth, 30g; polysorbate 80, 30ml; lecithin, 3g; saponin, 30g; sodium thiosulphate, 5g; L-histidine, 1g. This was shown to be non-toxic to the test organism and effective in neutralizing the reference and test products (data not shown).

Test handwipe procedures

For both products, the wipe was carefully removed from its sachet, and unfolded into the palm of one hand. The procedure then comprised of (Figure 1) five strokes backwards and forwards, palm to palm, right palm over left dorsum and left palm over right dorsum, endeavouring to maintain the wipe unfurled in the palm of the hand performing the wiping action. Each digit of the left hand was then individually inserted into the wipe for five strokes of rotational rubbing, a procedure which was then repeated for the right hand. The wipe was then placed between the clasped fingers and thumb of each hand for five strokes of rotational rubbing. This whole procedure was repeated for a total of 60 seconds. At the end of the procedure, the hands were sampled in 10ml of neutralizer broth, in the same manner as for the reference procedure.

Suspension test

In addition to the test described above the bactericidal and yeasticidal efficacy of the fluid within the test and control wipe was established using the modified 97% suspension test as described in EN 13727 (2012) and EN 13624 (2013) [9, 10].

Fluid was extracted from both of the wipes (P1 and P2), and tested for antimicrobial efficacy against bacteria (*S. aureus*, *E. coli*, *E. hirae* and *P. aeruginosa*) and a yeast *(C. albicans*). The acceptability criteria applied were the same as for a hygienic handwash product, i.e. a ≥3 $\log_{10}$ reduction against bacteria, and a ≥2 $\log_{10}$ reduction against yeast within 60 seconds under dirty conditions (0.3% w/v bovine serum albumin + 0.3% v/v packed sheep erythrocytes). Tests were performed in triplicate at 30 second and 60 second contact times.

The neutralizer used in these tests comprised the following ingredients, per litre of distilled water: polysorbate 80, 30ml; lecithin, 3g; sodium lauryl sulphate, 4g; tryptone, 1g; sodium chloride, 8.5g. This was shown to be non-toxic to the test organisms and effective in neutralizing the test products at a dilution of 1:100 (data not shown).

Statistical analyses

A Shapiro – Wilk test was performed to analyse the $\log_{10}$ reduction factors for normality, using the R statistical programming language [11]. Wilcoxon – Wilcox and Hodges – Lehmann tests were performed on the $\log_{10}$ reduction factors to assess for superiority and non-inferiority, respectively, using Excel [12].

Results

The method of application is depicted in figure 1. This method of application produced standard deviations that compared favourably with the reference procedure. The standard deviation of the $\log_{10}$ reduction factors for the reference procedure was 0.683, that for P1 was 0.380, whilst that for P2 was 0.605.

Statistical comparison of products.

The reference soap produced a mean $\log_{10}$ RF of 3.54, whilst for P2 (antimicrobial hand wipe) it was 3.67, and 2.46 for P1 (control hand wipe). Figure 2 displays the $\log_{10}$ RF's for the reference and two products. A Shapiro – Wilk test confirmed that the data were not normally distributed ($p = 0.021$), and so nonparametric tests would be required for statistical comparison.

The data were initially subjected to a superiority test. As two test wipes were compared to the reference, a one-sided Wilcoxon – Wilcox test was used (in a similar manner to

EN 1499 or EN 12791 (2016) [13]), with a level of significance set at α = 0.01. The equivalent test for one product would be a Wilcoxon signed rank test. The Wilcoxon – Wilcox test (case II B) is described in Wilcoxon and Wilcox [14]. There was insufficient evidence to suggest that either P1 or P2 was superior to the reference procedure ($p > 0.01$).

For a product that is not found to be superior to the reference, a test for non–inferiority can be performed, as in EN 1500. The inferiority margin is set at 0.6.
The test is one-sided, with a level of significance set at $\alpha = 0.025$. Because the data are non-normal, the Hodges – Lehmann test is used as described in EN 1500.
The 97.5% confidence limit for the difference between the $\log_{10}$ RF's produced by the reference procedure and the control wipe (P1) was 1.33, whilst that for the difference between the reference procedure and the antimicrobial wipe (P2) was 0.25. Accordingly, there was sufficient evidence to reject the null hypothesis of inferiority for P2, but not P1, at the 2.5% level.

Suspension tests.

The test wipe (P2) passed all of the requirements within 30 seconds. The control wipe (P1) was also effective, passing the bactericidal requirements within 30 seconds, but failed to fulfil the yeasticidal requirement within 60 seconds. Table 1 and figure 3 display the results of these suspension tests.

Discussion

This study used an amalgam of EN 1499 and EN 1500 to assess the efficacy of a patient hand wipe. The modification was necessary to gain the required level of precision with the number of volunteers used and also the use of an acceptable statistical method for the analysis of the results. These tests demonstrated that when applied for 60 seconds both control and antimicrobial handwipes achieved $\log_{10}$ RF's of more than 2. The antimicrobial handwipe achieved a greater $\log_{10}$ RF that the soft soap reference method but the difference was not significant. Since the aim for the study was to determine if the handwipes could provide an effective alternative to hand hygiene using soap and water, the important finding was that the antimicrobial handwipe was statistically non-inferior to the reference standard soft soap method, although the control handwipe was inferior. The test methodology described mimics that described in EN 1499 and EN 1500, and would appear to be an acceptable method for evaluating this type of product. The results presented are based on one study using 20 volunteers. Further work may be necessary to establish the reproducibility and repeatability of the methodology.

The evidence presented in this test suggests that an antimicrobial handwipe, when applied for 60 seconds, is at least as good as soap and water and represents an acceptable alternative to handwashing from a bactericidal perspective. This study is important because it has evaluated these products using a standard methodology for assessing efficacy of hand decontamination products against test bacteria. Other studies on the efficacy of hand wipes have primarily focused on removal of viruses. Larsen et al reported significant log reductions in influenza A on hands associated with alcohol-impregnated handwipes with comparable reductions to those associated with alcohol applied in foam and gel [15]. Similarly, Tamimi et al 2015 demonstrated significant reductions in viral transmission and risk of illness in a home setting using a bacteriophage as a surrogate for human pathogenic viruses [16].

Contamination of the healthcare environment with a range of pathogens is recognised to contribute to the risk that patients will acquire healthcare-associated infections [17]. *Clostridium difficile* is a particular problem since transmission occurs via a faecal-oral route and patients may acquire the infection though touching contaminated surfaces [1]. Since it is neither practical nor feasible to remove

contamination from all surfaces at all times, patients should be encouraged to minimise the risk that they acquire pathogens during their hospitalisation by frequent performance of hand hygiene. In addition, patients need to be encouraged to decontaminate their hands before eating or after using a bedpan/commode.

This study was performed on healthy volunteers with normal skin, using a highly standardised technique. Further work is required to ascertain how well these types of wipe perform on patients who would likely have sub-optimal hand wiping techniques, and may have compromised skin. Another limitation is that the control wipe used in this study displayed an unexpectedly high bactericidal efficacy; thus we were unable to isolate completely the effect of removal of bacteria/soil from that of bactericidal activity. Future work addressing these aspects would be welcome.

Conclusion

This study suggests that an antimicrobial handwipe may provide a suitable alternative to soap and water as an effective approach to supporting patient hand hygiene.

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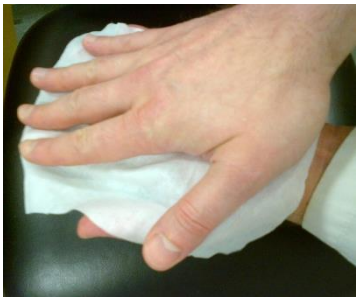
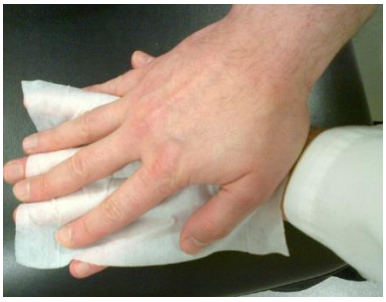
Figure 1

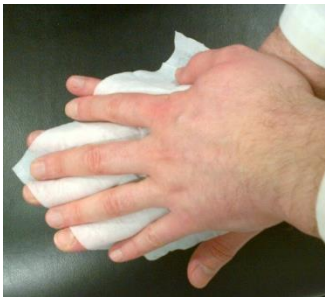
HAND WIPE APPLICATION PROCEDURE



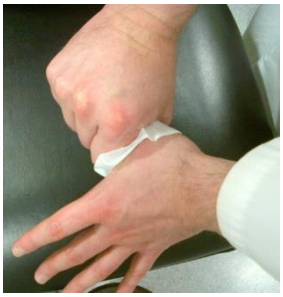
Palm to palm



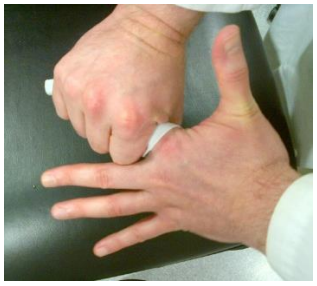
Right palm over back of left hand



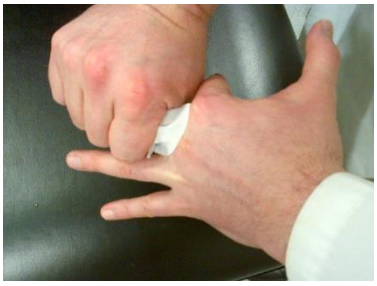
Left palm over back of right hand



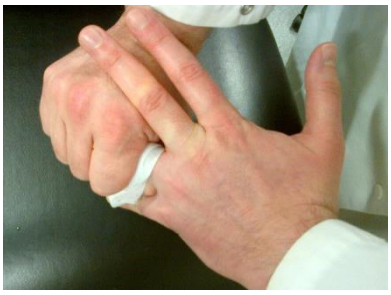
Rotational rubbing of thumb*



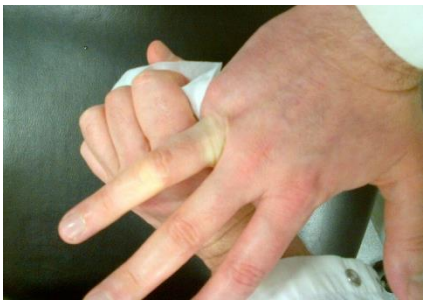
Rotational rubbing of index finger*



Rotational rubbing of middle finger*



Rotational rubbing of ring finger*



Rotational rubbing of little finger*

Rotational rubbing while scrunched between fingertips

*carry out for both hands

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Figure 2

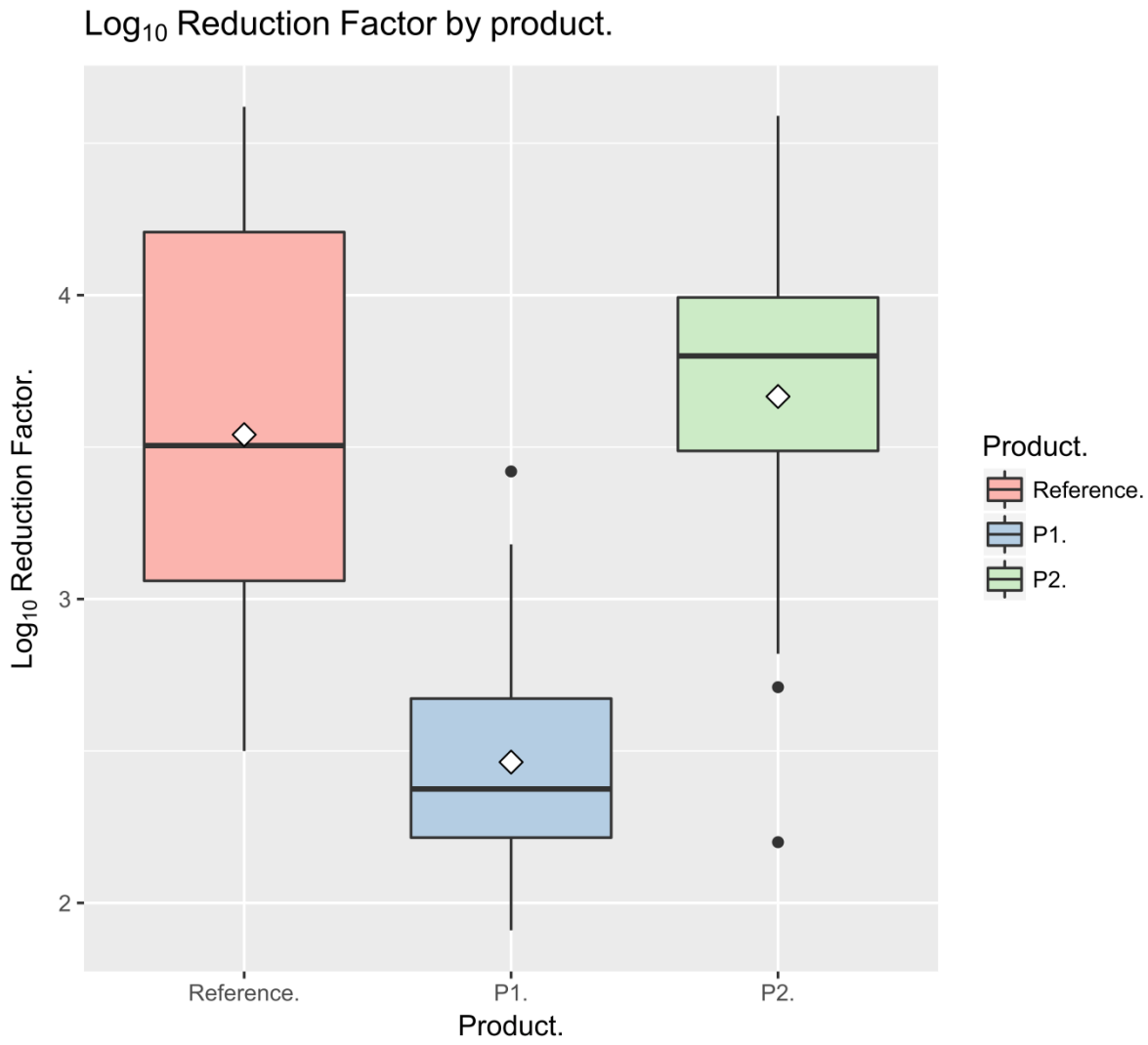

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Figure 3

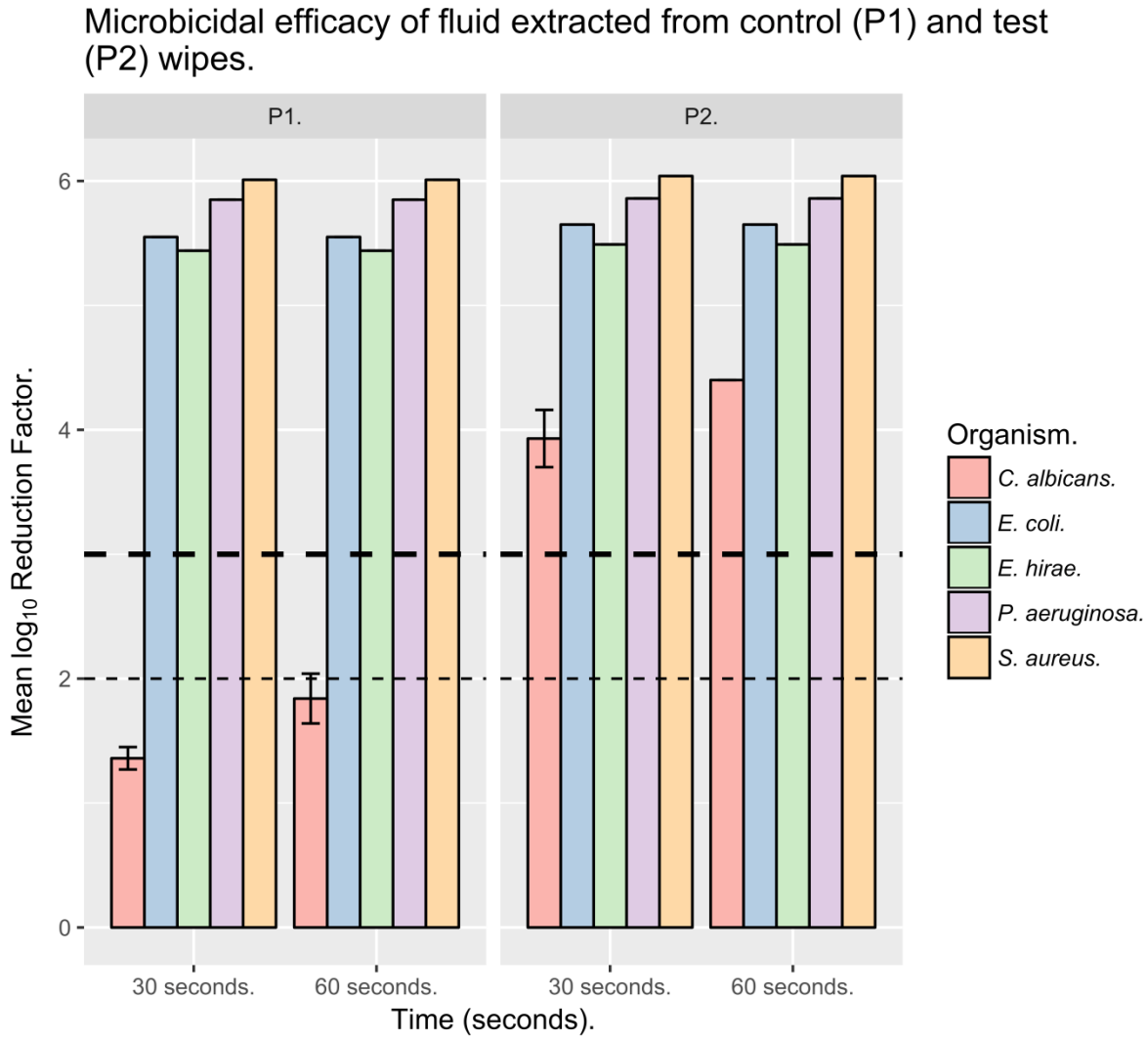

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Table 1

Results from EN 13727 and EN 13624; Dirty conditions only.

Test organism	Contact time	Log_{10} initial count	Mean log_{10} reduction	
			P1	P2
Staphylococcus aureus **(NCTC 10788)**	30 sec	8.01	**>6.01**	**>6.04**
	60 sec		**>6.01**	**>6.04**
Pseudomonas aeruginosa **(NCTC 13359)**	30 sec	7.85	**>5.85**	**>5.86**
	60 sec		**>5.85**	**>5.86**
Escherichia coli **(NCTC 10538)**	30 sec	7.55	**>5.55**	**>5.65**
	60 sec		**>5.55**	**>5.65**
Enterococcus hirae **(NCTC 13383)**	30 sec	7.44	**>5.44**	**>5.49**
	60 sec		**>5.44**	**>5.49**
Candida albicans **(NCPF 3179)**	30 sec	6.60	**1.36**	**3.93**
	60 sec		**1.84**	**>4.40**