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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, but little attention has been paid to patient hand hygiene. Patients confined to bed are often unable to access handwashing 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, it is important to ascertain the effectiveness of hand wipes for removal of transient micro-organisms from the hands.

Aim: To develop a method to assess the antimicrobial efficacy of hand wipes compared with handwashing, and thus determine if a hand wipe can be acceptable for patient hand hygiene.

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

Findings: The hand wipe with no antimicrobial agent (control wipe) was inferior to the soft soap. However, the antimicrobial hand wipe was statistically non-inferior to the soft soap. A $\log_{10}$ reduction of 3.54 was obtained for the soft soap, 2.46 for the control hand wipe, and 3.67 for the antimicrobial hand wipe.

Conclusion: The evidence suggests that the antimicrobial hand wipe, when applied for 60 s, is at least as good as soap and water, representing an acceptable alternative to hand-washing from a bactericidal perspective.

Introduction

It is well recognized 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 that 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 micro-organism [4].

Some patients may be confined to bed and not able to access a handwash basin independently; studies have suggested that staff rarely support patient hand hygiene [5,6]. Therefore, if

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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 may be the case in many instances. Although alcohol sanitizers 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 standard for the evaluation of hygienic handwash formulations is EN 1499. EN 1499 (2013) is a test for the evaluation of bactericidal activity of skin disinfectants, simulating practical conditions for establishing whether or not a product is suitable for hygienic handwashing where disinfection is medically indicated, or in food, industrial, domestic and institutional areas [7].

EN 1499 comprises an assessment of the number of test organisms (*Escherichia coli*) released from the fingertips of artificially contaminated hands of 12–15 volunteers, before and after hygienic handwashing with test and reference products. The ratio of the two resulting values is called the reduction factor (RF). This 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) 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 or not a product is suitable for hygienic hand rub where disinfection is medically indicated, or in food, industrial, domestic and institutional areas [8].

To pass EN 1500, 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. Ethical approval was sought, but this was not required as the method used was based upon published EN standards.

Products assessed

–Test product 1 (P1): control hand wipe with no biocides or chelating agent.
–Test product 2 (P2): Clinell antimicrobial hand wipe containing benzalkonium chloride, didecyldimonium chloride, PHMB and 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 1 min using European standard soft soap. After drying thoroughly, the fingers were contaminated by immersion of the hands up to the mid metacarpals into a bowl containing 2 L of contamination fluid [i.e. an overnight culture of *E. coli* K12 NCTC 10538 in tryptone soya broth (TSB)]. After 5 s, the hands were withdrawn from the contamination fluid, excess fluid was allowed to drip from the fingers, and the hands were held horizontally with the fingers spread apart and allowed to dry for 3 min. The fingertips were then sampled to obtain 'pre-values' of surviving test organisms before applying the 'test' or 'reference' procedure.

Reference handwash procedure

Five millilitres of soft soap was poured into the pre-wetted cupped hands, and rubbed vigorously into the skin for 60 s up to the wrists, in accordance with the standard handwashing 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, and 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-s 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 1 min on the base of a Petri dish containing 10 mL of TSB containing a validated neutralizer for 1 min. All samples were plated on to tryptone soya agar supplemented with 0.5 g/L sodium deoxycholate, and incubated at 37°C for 18–24 h followed by a further 24 h. RFs 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, 30 g; polysorbate 80, 30 mL; lecithin, 3 g; saponin, 30 g; sodium thiosulphate, 5 g; and L-histidine, 1 g. This was shown to be non-toxic to the test organism and effective in neutralizing the reference and test products (data not shown).

Test hand wipe procedures

For both products, the wipe was removed carefully from its sachet, and unfolded into the palm of one hand. The procedure (Figure 1) then comprised of 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