Evaluation of a Novel Hypochlorous Acid Based Hand Hygiene Product With Sporicidal Activity in an Inpatient Ward Setting

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Article

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Abstract: Introduction: We under took an in-use evaluation of a novel hypochlorous acid-based hand hygiene product with *in vitro* sporicidal efficacy in a NHS Older Persons inpatient ward setting. Methods: The novel hand hygiene product was implemented for a trial period of seven weeks commending in September 2023. Healthcare worker (HCW) hands were sampled before and after direct patient care, and after the application of either an alcohol-based handrub (ABHR) (n=50) or the novel product (n=50). Samples were cultured to quantify the total aerobic count (TAC) and presence or absence of MRSA, ESBLs, CREs, and *C. difficile.* Trends in weekly observational hand hygiene audit results were reviewed, and a survey of HCW views about the new product undertaken. Results: HCW hands had a significantly greater TAC after ABHR (p=0.01) but not after the novel product (p=0.11) compared with their respective baseline counts. 3% of 100 samples grew MRSA or ESBLs after application of the alcohol-based or novel hand hygiene products. No *C. difficile* was cultured from healthcare worker hands. There was no significant difference in observed hand hygiene compliance. The majority of HCW surveyed preferred the novel product to the alcohol-based hand hygiene product.Discussion: The novel hand hygiene product was more effective than ABHR at reducing the TAC on HCW hands. Poor hand hygiene technique may explain the identification of antibiotic-resistant bacteria on staff hands after ABHR or the novel product. We were not able to evaluate sporicidal efficacy since no *C. difficile* was cultured from hands.

Keywords: hand hygiene; microbiology; hypochlorous acid; antibiotic resistance

Introduction

Adherence to good hand hygiene practice reduces the risk of healthcare-associated infection and transmission of key hospital pathogens, including antibiotic-resistant bacteria.[1,2] In a ward setting, hand hygiene is usually undertaken using alcohol-based handrubs (ABHR), with soap and water recommended either when hands are visibly contaminated, when caring for patients with vomiting or diarrhoea, or after exposure of the hands to certain pathogens for which alcohol-containing products are less effective – especially *Clostridioides difficile* and norovirus.[1,2] In a theatre setting, hand hygiene ("scrubbing") is conducted at the beginning of each shift using an antiseptic surgical solution, with either the same process or hand hygiene using alcohol-based products between cases (unless hands are visibly soiled).[3]

A number of different biocides have been evaluated as potential hand hygiene products to use in healthcare settings including alcohol, chlorhexidine, chlorine-based products, quaternary ammonium compounds, iodine and iodophors, and others.[1,4–6] Current guidelines in England and other countries, including the most recent recommendations from the World Health Organisation, specifically recommend the use of ABHR to undertake hand hygiene in most scenarios.[1,2] ABHR

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are widely available and can be produced locally in resource-limited settings, are affordable, have rapid activity against a wide range of microbes, and are generally well-tolerated by staff.[1,7] However, ABHR have several limitations. For example, they are not effective against bacterial endospores, including *C. difficile*, and have limited effectiveness against non-enveloped viruses, such as norovirus.[1,8,9] This limits the ability of ABHR to be used in some scenarios, for example, when patients have confirmed *C. difficile*, new diarrhoea and vomiting symptoms, or during outbreaks of norovirus. ABHR has been linked with contact dermatitis in staff, [1,10] and a risk of both poisoning via ingestion and fire.[11,12] Some healthcare workers see ABHR as a barrier to high levels of compliance with hand hygiene.[13]

We evaluated a novel hand hygiene product containing 0.032% hypochlorous acid, Spectricept Care+ Hands ("Spectricept", Spextrum X, Knutsford, UK). According to manufacturer claims, the product has passed a range of laboratory tests including BS EN 17126:2018, a quantitative suspension test to establish sporicidal activity with a >4-$\log_{10}$ reduction against *C. difficile* (<15 seconds contact time), *B. subtilis and B. cereus* (<1 minute contact time), BS EN 1500:2013 establishing non-inferiority compared with a reference alcohol-based hand hygiene product, and quantitative suspension tests to establish bactericidal, virucidal, fungicidal, and mycobactericidal activity. According to manufacturer claims, a patch test involving 25 healthy volunteers concluded that the product is well-tolerated on the skin, with no irritations or allergic reactions recorded. The product is available on the NHS Supply Chain (since December 2022).

We undertook an in-use service evaluation of the implementation of the novel hand hygiene product in an Older Persons ward including sampling of healthcare worker (HCW) hands to establish efficacy in practice, determining whether the new product resulted in any changes to observational hand hygiene audit findings, and gathering feedback from healthcare workers on the use and acceptability of the product.

Methods

Following a baseline period where an AHBR product (SC Johnson, Cutan InstantFOAM) was used, the novel hand hygiene product was implemented in one 28 bed Older Persons ward for a trial period of seven weeks commending in September 2023. All wall mounted and bed-end dispensers were replaced with the novel product. No personal ABHR dispensers were used.

Hand sampling

Hand sampling was undertaken for 50 HCW during the weeks prior to implementation of the new product and a further 50 HCW once the new product was implemented. HCWs could be included more than once but on separate days. HCW hands were sampled during episodes of care that would usually involve only ABHR hygiene. Hands were sampled at three timepoints for each HCW: immediately before hand hygiene prior to direct patient contact (to assess the baseline level of contamination); immediately after direct patient contact but before hand hygiene; and immediately after hand hygiene. The intention was to allow the ABHR and novel product to fully dry before performing hand sampling immediately after application, but this was not always possible due to the need for HCW to continue with their duties. The left hand was sampled immediately before hand hygiene prior to direct patient contact, the right hand after direct patient contact but before hand hygiene, and the left hand after hand hygiene. The hand that was sampled was alternated because the sampling process was likely to lower the bacterial counts on hands.

A separate set of hand samples were collected to evaluate in-use sporicidal activity. Patients with a new diagnosis of *C. difficile* infection were identified. These patients are cared for using contact transmission-based precautions, requiring the use of gloves for direct patient contact in this organisation. Hand samples were collected from HCW hands following direct contact with a patient with *C. difficile* infection immediately after glove removal (one hand), and again immediately after hand hygiene (the other hand) with either soap and water (pre-evaluation) or the novel hand hygiene product (during the evaluation). HCW with visibly soiled hands undertook hand hygiene using soap and water both before and during the evaluation. We planned to take hand samples from 50 HCW

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for soap and water, and a further 50 HCW following the new hand hygiene product after direct patient care for a patient with *C. difficile* infection.

Microbiology methods

Hand sampling was undertaken using a modified "glove juice" method,[14] placing a hand in a sample collection bag, adding 20 mL sterile 0.9% saline, and massaging the hand in the bag for 30s. The saline was then decanted into a sterile universal container and 25 µL plated onto Columbia blood agar (Thermo Scientific™, incubated for 24 hours in aerobic conditions at 37°C) to determine the total aerobic count, and the presence or absence of the following: meticillin-resistant *Staphylococcus aureus* (MRSA) (Thermo Scientific™ Brilliance™ MRSA 2 Agar media, incubated for 24 hours in aerobic conditions at 37°C), antibiotic-resistant Gram-negative bacteria (Thermo Scientific™ Brilliance™ ESBL Agar/ Brilliance™ CRE Agar, incubated for 24-48 hours at aerobic condition at 37°C), and *C. difficile* (Thermo Scientific™ *Clostridium difficile* Selective Agar, incubated for 48 hours in anaerobic conditions at 37°C). As a negative control, 10 empty sample bags were filled with 20 mL saline and 25 µL plated onto Columbia blood agar as above to provide evidence that the sample bags were not contaminated.

Paired t-tests were used to compare mean total aerobic counts.

Audits of compliance with hand hygiene

The organisation has a standardised approach to auditing compliance with the WHO's '5 Moments for Hand Hygiene'. These audits were undertaken weekly by IPC in the ward during the evaluation. Audit results for the seven week period before the evaluation and during the seven week evaluation were compared to determine whether any changes in hand hygiene compliance occurred. Fisher's Exact Test was used to compare observed hand hygiene compliance.

Survey of HCW views around hand hygiene products

A simple six question survey was issued to HCW working during the evaluation period to assess their views about the novel product. The questions that were asked are included in the Appendix A.

This was undertaken as an NHS Service Evaluation, exempt from Research Ethics approval.

Results

Mean total aerobic counts are summarised in Table 1. The mean total aerobic count was significantly greater after patient care compared with before patient care during ABHR and novel product phases of the evaluation ($p<0.05$ for both). The total aerobic count on HCW hands was not significantly different following ABHR or the novel product compared with the after patient care samples. However, HCW hands had a significantly greater total aerobic count after alcohol compared with their respective baseline counts ($p=0.01$), whereas HCW hands did not have a significantly greater total aerobic count after the novel product compared with their respective baseline counts ($p=0.11$). No bacteria were cultured from the empty sample bags.

Table 1. Mean total aerobic counts from hand samples. Hand samples were collected from 50 healthcare workers at the three timepoints both for alcohol and the novel hand hygiene product (Spectricept).

	Spectricept	Alcohol
	Log_{10} mean cfu (standard deviation)	
Before patient care	2.22 (1.16)	1.88 (0.99)
After patient care	2.59 (1.12)	2.07 (1.02)
After alcohol / Spectricept	2.46 (0.95)	2.05 (1.11)

For ABHR, 2/50 samples were contaminated with MRSA before patient care, 2/50 after patient care, and 1/50 after ABHR. For the novel product, 2/50 samples were contaminated with MRSA before

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patient care, 4/50 after patient care, and 2/50 after the novel product. One of these samples collected after patient care and one of these samples after the novel product also grew ESBL *Klebsiella*. No *C. difficile* was cultured from staff hands during the evaluation. Therefore, only 10 of the planned 50 samples were collected following direct patient care for patients with a new diagnosis of *C. difficile.*

Weekly hand hygiene audits showed no significant difference in observed hand hygiene compliance during the alcohol based hand hygiene product phase or the evaluation phase (observed hand hygiene compliance was 77.5% from 80 observations during the alcohol phase vs. 80.0% of 100 observations during the novel hand hygiene product phase, p=0.72).

12 HCW completed the evaluation form. 83% felt that the novel product was either easy or very easy to use, 82% either preferred the novel product (54%) or didn't have a preference over alcohol (27%), 58% felt that the novel improved patient safety around hand hygiene, 33% were neutral, and one member of staff disagreed with this statement. Two local skin reactions related to the novel product were noted during the evaluation, one of which was reported to Occupational Health.

Discussion

This in-use evaluation in an Older Persons NHS setting found that the novel hand hygiene product was more effective than ABHR at reducing the total aerobic count of bacteria on the hands of HCW. HCW generally found the product to be acceptable, and the majority of HCW surveyed preferred the novel product to ABHR. Observational hand hygiene audits suggest that the switch to the novel product did not adversely affect hand hygiene compliance.

We used the mean total aerobic count of bacteria recovered from the hands of HCW to evaluate the in-use effectiveness of the incumbent ABHR and the novel product. We found that the total aerobic count following direct patient care was significantly greater than before patient care, most likely representing the acquisition of transient hand contamination from patient care activities. Surprisingly, the application of either ABHR or the novel hand hygiene product did not significantly reduce the total aerobic counts on HCW hands when hands were sampled after application of the products. Studies have shown that hand hygiene technique is often incomplete.[15,16] This, combined with the fact that the resident microflora of the hand is stable over time and not amenable to removal via hand hygiene practices [1] suggests that the lack of reduction in total aerobic count immediately after application reflects poor hand hygiene technique, either in terms of volume applied, incomplete hand coverage, or insufficient contact time. Related to this, there was not enough time for the ABHR or novel product to dry prior to sampling the hands immediately after patient care on every occasion. Also, HCW undertook observed hand hygiene immediately before patient care, which although recommended only happens on 21% of occasions on average.[7] The hand hygiene undertaken immediately before patient care could have influenced bacterial counts after patient care. Most but not all studies have shown a significant reduction in total aerobic bacterial count following the application of ABHR.[1,17,18] Our finding that the total aerobic count on HCW hands was significantly greater after the ABHR compared with respective baseline counts but was not significantly different to baseline after the novel product suggests that the novel product was more effective at dealing with transient flora acquired during patient care, which is consistent with the higher levels of efficacy achieved by hypochlorous acid than by alcohol in laboratory studies.[19]

We sampled the hands of HCW immediately before they undertook hand hygiene and before direct patient care to evaluate contamination levels at baseline. We found that 4% of the 100 baseline samples grew MRSA, and none grew antibiotic-resistant Gram-negative bacteria or *C. difficile*. The prevalence of antibiotic-resistant bacteria and *C. difficile* in these baseline samples are lower than expected: a review and meta-analysis of staff hand contamination found that 4% were contaminated with MRSA (as in our study) but that 6% were contaminated with *Acinetobacter baumannii*, 5% with *Pseudomonas aeruginosa*, and up to 10% with *C. difficile.*[20] After direct patient care, the overall prevalence of antibiotic-resistant bacteria increased to 6% of 100 samples. 3% of 100 samples grew MRSA or ESBL-producing Gram-negative bacteria after application of the ABHR and novel hand hygiene products. Both ABHR and the novel hand hygiene product have convincing *in vitro* efficacy against these pathogens, so this is most likely explained by poor hand hygiene technique.

We chose an Older Persons ward for this evaluation given the higher prevalence of *C. difficile* infection in this patient cohort. However, we did not culture *C. difficile* from the hands of HCW following the direct care of patients with a new diagnosis of *C. difficile.* In our study, gloves were worn by HCW during direct patient care, which may explain why no *C. difficile* were cultured from hands following glove removal.

A small number of HCW were asked for their views on the novel hand hygiene product. The majority of staff were positive about the novel product, with 82% either preferring the novel product or having no preference over the alcohol based hand hygiene product. Two local skin reactions were noted during the novel hand hygiene product evaluation. We did not actively monitor for skin reactions to ABHR prior to implementing the novel product. Whilst skin reactions to ABHR are rare, they have been reported and alcohol-based hand hygiene products have been linked to hand dermatitis.[1,10]

Our evaluation has a number of important strengths. The evaluation was undertaken in an NHS setting, allowing for 'real-world' evaluation of the product. The evaluation was comparative, allowing us to compare the impact of ABHR with the novel product. We took microbiological cultures to evaluate changes in the total aerobic bacterial count and detect key hospital pathogens. We also included a survey of staff and any impact on observational hand hygiene compliance trends as part of the evaluation.

Limitations of our evaluation include relatively small samples sizes for the microbiological assessment of hands and for the HCW survey. We did not evaluate the impact of hand hygiene using soap and water, which was used throughout the study when hands were visibly soiled. Also, we did not link the findings of antibiotic-resistant bacteria on the hands of staff to individual staff members or to patients, since this was a pragmatic service evaluation. Since we did not culture *C. difficile* from staff hands, we were not able to evaluate the in-use sporicidal capability of the novel hand hygiene product.

Future work should consider longitudinal cultures of staff hands to establish efficacy in practice, laboratory evaluations of sporicidal activity of hand disinfectants given our challenges in identifying contamination with *C. difficile* on healthcare worker hands, and whether switching to hand hygiene product with sporicidal activity results in reduced risk of *C. difficile* infection.

Our comparative in-use evaluation has shown that a novel hypochlorous-acid based hand hygiene product appeared to be more effective than ABHR at addressing transient hand contamination, was generally well-tolerated by staff, and did not negatively impact observed hand hygiene practice in a general NHS inpatient ward setting.

Potential conflict of interest

JAO is a consultant to Biointeractions Ltd, Gama Healthcare Ltd, Ondine Inc, and Spectrum X Ltd; he has given paid talks for 3M, ASP, Bode, Ecolab, and Knowlex.

All other authors have no potential conflicts of interest to declare.

Spectrum X contributed financially to the costs of this evaluation but did not influence the protocol.

Appendix A. Staff survey questions

1. How was the product to use? Very difficult / difficult / neutral / easy / very easy
2. I would prefer this product to the usual alcohol gel. Strongly disagree / disagree / neutral / agree / strongly agree
3. I feel this product improves patient safety around hand hygiene. Strongly disagree / disagree / neutral / agree / strongly agree
4. This product can be a barrier to hand hygiene for me. Never / sometimes / always
5. Did the product cause any adverse effects to your skin? Yes / No
6. If Yes: were these reported to Occupational Health? Yes / no / not applicable

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