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Reduction of hospital-acquired infections with the use of a hand sanitizer with both immediate and persistent antimicrobial effect

Jesse Cozean*, MBA, Steve Czerwinski, PhD and **Colette Cozean, PhD**

Innovative BioDefense, Inc., USA

***Corresponding Author:**
Jesse Cozean
Email: jcozean@gmail.com

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Abstract

Introduction: Alcohol-based sanitizers offer rapid antimicrobial activity, but provide no persistent or residual effect. While more convenient for healthcare workers, leave-on sanitizers alone have not been shown to reduce hospital-acquired infections (HAIs) over hand washing in controlled clinical trials. This clinical trial in a hospital setting was designed to evaluate the Centers for Disease Control and Prevention's recommendation to determine whether a hand sanitizer with persistent efficacy can reduce the rate of nosocomial infection over a traditional alcohol sanitizer.

Methods: A controlled clinical trial was conducted in a 327-bed hospital for 39 months to determine the effect of replacing traditional alcohol-based sanitizer (Steris®, 62% ethyl alcohol) with a novel water-based hand sanitizer (Zylast® Antiseptic Lotion, 0.2% BZT) with both immediate and persistent antimicrobial activity. A questionnaire was given to the staff with both products to evaluate skin irritation, dryness, and overall hand feel.

Results: The hospital averaged 10.3 HAIs per month with the control arm and 8.1 in the experimental arm, which was a 20% reduction in HAI rate ($p = 0.03$). A statistically significant reduction of 28% was seen in C. difficile infection rates ($p = 0.03$) and Vancomyicin-Resistant Enterococcus infections were reduced by 40% ($p = 0.06$). A trend towards a reduction in MRSA infections was seen, with a 14% reduction over the course of the trial ($p = 0.22$). The staff reported statistically significant improvements in moisture level (24% improvement, $p = 0.03$), skin appearance (41% improvement, $p = 0.003$), skin integrity (33% improvement, $p – 0.01$), and overall hand feel (40% improvement, $p < 0.0005$).

Discussion: The addition of a water-based hand sanitizer with both immediate and persistent antimicrobial effectiveness significantly reduced HAIs in a hospital setting. The product was well-adopted by staff, who reported significant improvements in the condition of their skin.

Introduction

Prevention of Hospital-Acquired Infection

Medical errors are the third leading cause of death in the United States, trailing only heart disease and cancer.[1] Hospital-acquired infections (HAIs) are a major component of these preventable deaths. Nearly 5% of hospital patients will acquire a new infection after being admitted, causing approximately 90-100,000 deaths annually.[2]

Preventing the transmission of pathogens by hands has been identified as the most effective way to reduce these nosocomial infections. More than a decade ago, the Centers for Disease Control and Prevention (CDC) recommended switching from soap-and-water hand washing in medical facilities to the use of leave-on products.[3] Studies showed that alcohol sanitizers delivered a faster, more complete kill of pathogens than did hand washing, reducing the time burden for healthcare workers, but more than a decade later the hoped-for reduction in infection rates has not materialized.

Leave-On Products in Real World Settings

Real-world clinical trials haven't demonstrated a clear ability to reduce HAI rate with the use of traditional alcohol sanitizers.[4]When accompanied by extensive additional training, the addition of alcohol-based hand sanitizers resulted in significant improvements in HAI rates.[5,6]But when no additional emphasis or training is provided, there has either been no reduction in the risk of infection[7,8,9] or up to a 33% increase in infection rate.[10]

One limitation of alcohol-based sanitizers is the lack of any persistent effect. According to the US Food and Drug Administration, "Persistence, defined as prolonged activity, is a valuable attribute that assures antimicrobial activity during the interval between washings, and is important to a safe and effective healthcare personnel handwash."[11] Alcohol-based sanitizers deliver rapid antimicrobial activity, but have no residual effect,[3] so that hands can immediately become decontaminated with pathogens as soon as the alcohol evaporates.

This lack of persistent activity makes compliance with hand hygiene protocols crucial in preventing HAIs. Most studies show compliance rates in hospitals are only at 40-50%,[12] leaving patients at risk more than half the time. With the demands on the time of healthcare workers and the skin irritation associated with repeated use of hand hygiene products, increasing compliance rates can be challenging. The CDC estimated that up to 85% of healthcare workers experience significant skin irritation that can affect compliance.[3]

In addition, it is unclear that incremental improvements in hand hygiene compliance result in any meaningful benefit to patients. In one randomized, controlled trial in a hospital, compliance rates rose from 38% to 69%, but no difference in infection rates was detected.[7]When monitoring hand hygiene compliance and pathogen transmission in a hospital, researchers found "no correlation between the transmission rates of nosocomial pathogens and hand hygiene compliance."[13]

Prior studies have shown increased benefits of persistent products. In a hospital setting, the use of a persistent hand lotion three times each shift caused a reduction in HAIs of 41%. In an controlled, crossover clinical study, replacing traditional hand washing with a persistent hand sanitizer reduced HAIs by 23.1% over hand washing alone.[14]

Additionally, alcohol sanitizers are relatively ineffective against non-enveloped viruses. Researchers from Emory University demonstrated that rinsing the hands with plain water was more effective in eliminating the Norovirus than use of an alcohol sanitizer.[15]In a survey of more than 100 long-term care facilities, the CDC found facilities relying on alcohol sanitizers were more than 6 times more likely to have a Norovirus outbreak than those using hand washing alone.[16]

Comparing Leave-On Products

The purpose of this clinical trial was to compare a product with both immediate and persistent antimicrobial activity against a traditional alcohol sanitizer with no residual effect. This was the first controlled clinical trial have compared different leave-on hand hygiene products in a real world setting. All previous clinical studies have compared to hand washing alone.

The CDC acknowledged the potential impact of persistence on reducing HAI rates in their 2002 Guidelines for Hand Hygiene. Among the top items in the Hand Hygiene Research Agenda was a desire to "Determine if preparations with persistent antimicrobial activity reduce infection rates more effectively than do preparations whose activity is limited to an immediate effect."[3] This study was designed to provide data to evaluate the hypothesis that persistence can have an impact on hospital-acquired infection rates.

Because of the persistent nature of the hand hygiene product, the experimental and control groups must be separate in either space or time, because the persistent effect of the experimental product would continue into the control group if there is any crossover of either patients or healthcare workers. Healthcare workers often move between different units or floors on their rounds, so the trial was separated in time. Approximately two years of historical controls were used with the traditional alcohol sanitizer, and compared against the usage of the persistent product.

The objective was to directly compare the effect of the products, so no other changes were implemented in the study. No changes were made to hand hygiene protocols, and no additional training or emphasis was placed on hand hygiene. Dispensers for the control product were removed and dispensers for the experimental product were placed in the same locations.The hospital collected data on infections as part of their standard protocol, so data continued to be collected in the hospital's standard format.

A staff questionnaire was also completed before the switch to the experimental product and then after the staff had been using the experimental product for six months. It used the validated Visual-Analogue Scale[17]to evaluate the moisture level, skin appearance, skin integrity, skin feel, odor, number of times a moisturize had to be used daily, and overall hand feel of healthcare workers.

Methods

The facility is a 327 bed hospital located in California (Hemet Valley Hospital).HAIs were determined by the CDC criteria of an infection occurring at least 48 hours after admission. No changes were made to the data collection procedures of the facility for this trial. The patient's gender, admission date, event date, event type, location, the type of specimen taken, and the type of infection were recorded. No patient identifying information was provided by the hospital.

The previous alcohol-based sanitizer (Steris®, 62% ethyl alcohol) was replaced with a water-based Antiseptic Lotion (Zylast®, 0.2% BZT). The test product had been shown to kill gram-positive and gram-negative bacteria in 15 seconds.[18]In another study, the product was shown to continue to kill more than 99.9% of *E. coli* coming into contact with human skin at 20 minutes, 1 hour, and 6 hours after application.[19]A similar persistent product had been shown to reduce the Norovirus surrogate on human skin by 99.97% on contact.[20]It was hypothesized that this combination of immediate and persistent effect may result in improved clinical outcomes.

A questionnaire about their experience with the control hand hygiene product was given to the staff before the products

were changed and again six months after beginning use of the experimental water-based product. The questionnaire asked about the biggest concerns with their current hand sanitizer. It also asked staff to rate the moisture, appearance, and integrity of their skin, the feel of their hands, and the odor of their hand hygiene products. The staff was asked if they felt that skin dryness or irritation made compliance with hand hygiene protocols more difficult and how often they applied a moisturizer daily to try and recover moisture. Finally, the staff was asked how their hands typically feel overall at the end of a day or shift.

The primary endpoint of this study is the rate of hospital-acquired infection across the facility. Secondary endpoints include the impact of the change in hand hygiene products on the rate of infection caused by specific pathogens, including *C. difficile, Methicillin-Resistant S. aureus*(MRSA), and *Vancomycin-Resistant Enterococcus* (VRE). Other secondary endpoints are the impact of the water-based product on hand feel, skin irritation, and moisture level of the skin. A two-sample *t*-test was used to analyze the results of this study for significance. The confidence interval for significance in this study will be set at 95% ($p < 0.05$). Without patient identifying information this post-marketing survey does not require institutional review board approval.

Results

HAI Incidence

Over the 23 months where control data was gathered, the hospital identified 236 incidences of HAIs, averaging 10.3 per month (SD 3.7). In the 16 months of experimental data there were 131 reported HAIs for an average of 8.1 (SD 2.8). The experimental arm of the study saw a 20% reduction overall in HAIs ($p = 0.03$)

The most common HAIs were reported as *C. difficile* which averaged 4.6 per month for the control group (SD 2.5) and 3.3 per month in the experimental group (SD 1.7). In the experimental group, these infections were reduced by 28% ($p = 0.03$). Methicillin-resistant Staphylococcus aureus (MRSA) was also common, averaging 3.8 HAIs per month in the control setting (SD 2.5) and 3.3 in the experimental (SD 1.7) with a reduction of 14% ($p = 0.22$). Vancomycin-resistant Enterococcus (VRE) was found at a rate of 1.6 per month for the control (SD 0.9) and 0.9 per month in the experimental arm (SD 1.3) of the study, a reduction of 40% in the experimental arm ($p = 0.06$). Cephalosporin resistant Klebsiella(CEPHRK) and Acinetobacter were also reported. In the control arm six cases of CEPHRK and one case of Acinetobacter were reported, and in the experimental arm 10 cases of CEPHRK and no cases of Acinetobacter were observed.

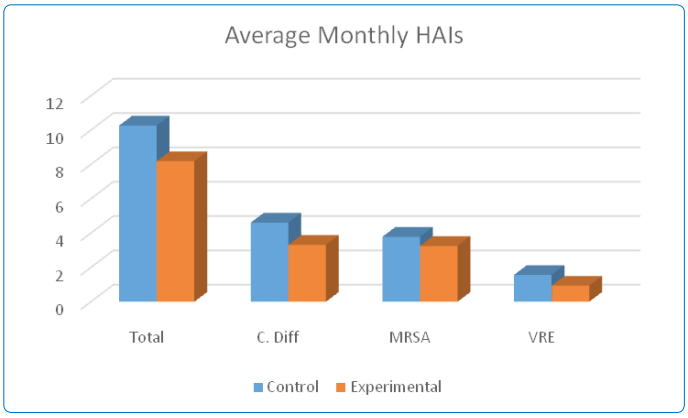

Figure 1

Survey Results

The survey given to the staff had 61 responses. With the alcohol sanitizer, respondents noted an average moisture level of 4.1, a skin appearance of 4.5, and skin integrity of 5.0 out of 10. The odor of the product was rated a 6.5 by the staff. The skin feel with the alcohol based sanitizer was 4.1, and overall hand feel at the end of the shift was reported at a 3.2.

In the pre-trial survery, 71% of the healthcare workers reported that skin irritation made compliance with hand hygiene protocols more difficult with the alcohol-based control product and 56.7% reported skin irritation interfering with compliance in the experimental group ($p = 0.12$).

With the water-based product, moisture level was 5.5, appearance was 6.8, and integrity was 6.6. The odor of the product was rated at 7.9, with skin feel at 5.7. Overall hand feel at the end of the shift was 5.9.

	Control	Experimental	Percent Improvement	Certainty Level
Moisture Level	4.1	5.5	24%	p = 0.03*
Skin Appearance	4.5	6.8	41%	p = 0.003*
Skin Integrity	5.0	6.6	33%	p = 0.01*
Skin Feel	4.1	5.7	27%	p = 0.005*
Felt Skin Irritation Affects Compliance	71.0%	56.7%	21.2%	p = 0.12
Odor	6.5	7.9	38%	p = 0.02*
Overall Hand Feel	3.2	5.9	40%	p < 0.0005*

*Statistically significant

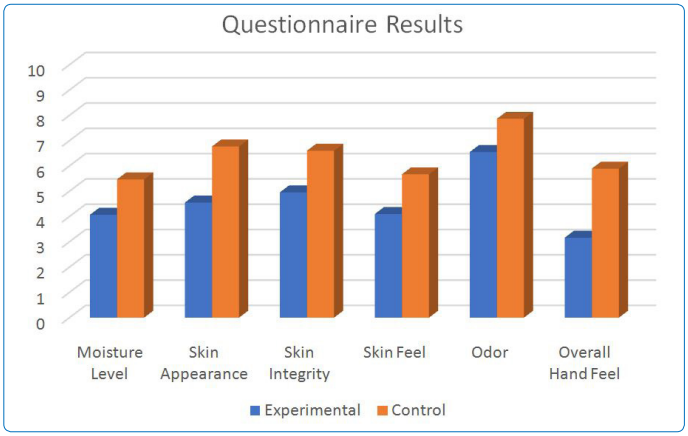

Figure 2

Discussion

A statistically significant reduction($p = 0.03$) was seen in the presence of nosocomial infection across the hospital. Nosocomial C. diff infections were also significantly reduced by 28% ($p = 0.03$). With a 96% confidence interval the reduction in VRE infections showed a strong trend towards significance, while the sample size was not high enough to show statistical significance for MRSA reductions.

The staff of the hospital also reported significant benefits in using the water-based product. Statistically significant improvements were seen in overall hand feel, moisture levels, skin appearance, skin integrity, skin feel, and odor. While compliance was not monitored by the facility in this study, it is possible that these improvements in the feel of the product may lead to less resistance to complying with hand hygiene guidelines.

Limitations of this study included a relatively small sample size and a single facility. Additional studies in other facilities or multi-site trials are recommended to confirm the results of this study. A larger sample size may allow researchers to identify whether a statistically significant effect can be observed on the presence of MRSA infection rates, which was beyond the ability of this study to confirm. Further studies could also observe the compliance rate of healthcare workers with hand hygiene protocols in an attempt to determine whether the improvements in HAI rates are due to the persistence of the hand hygiene product, increased compliance, or a combination of both factors.

Conclusion

The results demonstrate that a water-based, persistent hand sanitizer can reduce hospital-acquired infection rates without additional training or emphasis on hand hygiene compliance. It is the first controlled study to compare leave-on hand sanitizers within a hospital, suggesting that the choice of hand hygiene product plays a significant role in the health of patients and staff.

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