Research Article

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Reducing Illness Absenteeism and Outbreaks among Students with Persistent, Water-Based Antiseptic Products in a Controlled, Crossover Clinical Study

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ABSTRACT

Rationale: *With so many children in close proximity, schools can be breeding grounds for illness. Hand hygiene is the most effective way to prevent the transmission of germs, but children often don't wash their hands or fail to wash completely. Alcohol sanitizers have no persistent efficacy and concerns about flammability and ingestion limit their ability to be used in schools. A hand sanitizer capable of reducing illness absenteeism without these limitations is needed. This clinical trial evaluated the efficacy of a non-flammable, water-based hand sanitizer with both immediate and persistent antimicrobial efficacy in reducing illness absenteeism and illness outbreaks in a classroom setting.*

Methods: *A controlled, crossover study comparing different hand hygiene products was conducted at two sister schools specializing in teaching students with autism. One facility used traditional soap and water while the other added a persistent, water-based hand sanitizer (Zylast® Antiseptic Lotion, 0.2% BZT) and an antibacterial foaming soap (Zylast®, 0.2% BZT). After approximately eight weeks, the campuses switched products after a one-week washout phase. Administrators gathered illness absenteeism data for both students and staff over the course of the school year.*

Results: *At the campus where the novel hand hygiene products were used, the rate of illness absenteeism fell from 4.6% to 2.8% among students, a significant reduction of 38.9% ($p = 0.03$). Among the staff, illness absenteeism was reduced by 24.3% ($p = 0.1$) from 4.2% to 3.2%. Illness outbreaks, where more than 10% of students or staff were ill at the same time, was reduced by 87.5%.*

Conclusion: *The addition of a non-flammable, water-based antiseptic with both immediate and persistent efficacy was effective in reducing illness absenteeism among both students and staff in a school setting. This confirms previous results in school settings demonstrating the ability of persistent, water-based products to safely reduce illness absenteeism. This also confirms prior results with this test product demonstrating reductions in nosocomial infections in hospital and long-term care facility settings over traditional hand hygiene products.*

Keywords

Illness absenteeism, Hand hygiene, Persistent antimicrobial activity, Hand sanitizer, School nurse, Antimicrobial, Autism.

Introduction

Illness Absenteeism in Schools

Illness absenteeism is a major issue for students, teachers, and parents in the school system. The Center for Disease Control estimates that the average student misses five school days each year due to illness [1]. Studies have shown that short, frequent absences, like the ones due to illness, are more damaging to the learning process than a single, longer break from schoolwork [2].

The negative consequences of illness absenteeism extend beyond

academic concerns. Financially, federal funding is based on student days, so absences reduce school funding in public schools. Costs are associated with the use of substitute teachers when staff becomes ill. There is also a significant financial burden that is born by parents, who may need to leave their workplace to care for the child.

Hand hygiene is one of the most important, and controllable, factors in reducing the spread of pathogens and infection. The World Health Organization (WHO) calls hand washing the "most important hygiene measure in prevent the spread of infection" [3]. However, significant limitations in current hand hygiene products that reduce their efficacy in halting the transmission of infection.

Soaps and alcohol sanitizers do not have persistent effect [4]; they reduce the microorganisms on the skin immediately, but allow the hands to immediately become recontaminated by the next surface contacted. This is important because children are not particularly disciplined at washing their hands. Observational studies have shown that only 8% of boys and 28% of girls washed their hands with soap and water after using the bathroom [5]. Other studies have noted that the average time of handwashing, even when soap and water is used, is significantly below the two minutes recommended by the CDC. In an observational study of college students, more than 95% did not wash for more than 15 seconds [6]. Medical students have been observed to touch their faces an average of every 1.3 minutes [7]. Without persistent or residual efficacy, hand hygiene products are unable to be used often enough to prevent the transmission of germs.

Alcohol sanitizers are also relatively ineffective against many common viruses, which are a significant source of disease among students. The flu, common cold, many GI infections, and the norovirus ("stomach flu") are all caused by viruses. Researchers at Emory University demonstrated that alcohol sanitizers were actually less effective against norovirus than rinsing the hands with water alone [8]. Nursing homes – another setting with large populations in close quarters – that used alcohol sanitizers were 6 times more likely to have a norovirus outbreak than facilities that relied on hand washing alone [9]. As the CDC-sponsored study reported, "studies have demonstrated that ABHS [Alcohol-Based Hand Sanitizers] often exhibits inadequate effectiveness against non-enveloped viruses, including norovirus".

Another series of concerns with alcohol-based sanitizers in schools is the flammability of the products and the potential for student abuse. The high alcohol content means these products must be carefully stored, and have the potential to be set on fire by students. Furthermore, the trend of children drinking the ethanol-based sanitizers to become intoxicated continues to rapidly grow. The American Association of Poison Control Centers showed that 17,995 children ingested alcohol-based sanitizers in 2011 alone [10], with nearly 3,500 of those likely intentional.

Previous Clinical Studies

Results from studies using alcohol-based sanitizers in schools do not seem to provide solid evidence that the benefits of these products outweigh the risks and costs. The two largest studies with alcohol-based sanitizers showed a 19.8% reduction in illness absenteeism in one study [11], and no benefit in the second [2]. In addition, the study which showed a reduction had the teachers and staff enforce hand hygiene on the students each time they entered or left the classroom, which is not practical in real world situations and may be responsible for part or all of the noted improvement.

The smallest study showed a much higher 51% reduction in illness absenteeism [12]. In this study, the intervention arm with alcohol sanitizers was also given significant education that the control group did not receive. In fact, the children with the alcohol sanitizers also washed their hands significantly more than the control group, leading the authors to acknowledge that the lack of education for the control group may have biased the outcome. A critical review of these studies determined that they were of low quality and should be interpreted with caution [13]. In the only truly controlled study of alcohol-based hand sanitizers, where the same educational information was given to both the control and experimental groups and no additional teacher oversight was given to the experimental group, no difference was reported in absentee rates between hand washing and use of an alcohol-based sanitizer [2].

Non-alcohol based products have generally been seen to be more effective, potentially because of their persistent activity, though significant methodological differences prevent a direct comparison. Two studies using a quaternary ammonium compound (BZK) sanitizer demonstrated reductions of 41.9% and 33% in illness absenteeism [14,15]. Unlike studies with alcohol-based sanitizers, in these studies children were each given an individual bottle of the sanitizer. Teachers enforced use upon entering the classroom, leaving the bathroom, before eating snacks or lunch, and even whenever a child coughed or sneezed. The larger, placebo-controlled study demonstrated a 33% reduction, but still required teachers to enforce compliance 6 times daily, a significant imposition on their daily routine [15].

Test Products

The purpose of this clinical study was to determine the ability of persistent hand hygiene products to reduce illness absenteeism in schools among both students and staff. The test products include a water-based antiseptic (Zylast® Antiseptic Lotion, 0.2% Benzethonium Chloride) and an antimicrobial soap (Zylast® Foaming Soap, 0.2% Benzethonium Chloride).

The persistent, leave-on test product has previously been demonstrated to significantly reduce nosocomial infections in both hospital [16] and long-term care settings [17] over traditional alcohol sanitizers. In time-kill testing, the water-based antiseptic was shown to kill 99.99% of germs on contact, as fast as alcohol alone [18]. It was also among the first water-based antiseptic products to exceed the European standards for a hand sanitizer as compared to a reference alcohol product [19].

The test products have been shown to be persistent for six hours,

where alcohol sanitizers become ineffective immediately after they evaporate. In a test for persistence on human skin, the antiseptic test product used in this trial was shown to kill more than 99.9% of transient *E. coli* that contacted the skin even 6 hours after the product had been applied and allowed to dry [20].

Benzethonium Chloride (BZT), the active ingredient in the test products, has been demonstrated to destroy more than 99% of Rhinovirus (common cold), Rotavirus (causes diarrhea in children), Influenzae (flu), and other common viruses [21].

BZT has an extensive safety profile as an active ingredient, and is considered safe and effective by the Food and Drug Administration in open wounds and wound-care uses [22]. Extensive safety studies have shown BZT had no adverse events when ingested at levels 50,000 times higher than an application of the test product [23]. BZT increases moisture in the skin and had no irritation for users, even after 100 uses daily for five consecutive days [21]. The test product was proven to improve the skin condition of healthcare workers in a hospital setting over an alcohol sanitizer [16]. The test products used in this study are non-flammable and non-combustible, reducing safety concerns about flammability and the deliberate ingestion of alcohol-based products.

School Clinical Trial

It was anticipated that the installation of the persistent test products might reduce in illness absenteeism among both students and staff, without necessitating excessive teacher supervision or educational tools that take time away from the standard curriculum.

The study used a crossover design, with two primary outcome measures. The primary outcome measure was the overall reduction of illness absenteeism, as reported by the parents of the students and staff and recorded by the school administration.

While overall reduction in absentee days is certainly the primary purpose of adding a new antimicrobial product to a school, it is a measurement that is influenced by significant outside factors. A student may contract a disease from family, friends, extra-curricular activities, or a myriad of other vectors outside of the school. Another measurement is being taken in this trial to try and accurately measure effect of the new products: the number of illness outbreaks at the school. When a single child is ill, they could have been exposed to the disease either inside or outside of school. However, when a significant percentage of the class (>10%) is ill on the same day, it is highly likely that the illness is being spread at the school. This trial measured these illness outbreaks among both the students and staff.

Methods

Design

This 5-month crossover study was conducted at two sister schools with similar enrollment, socioeconomic status (SES), and student populations. The test products were used at one campus for the first 8 weeks of the trial, while the control campus continued with their current hand hygiene products. After a one-week washout period, where the students were not in school, the experimental and control campuses were switched.

Site

The Academy for Advancement of Children with Autism (Chatsworth, CA) was selected for this study. The two campuses had very similar demographic and numerical compositions of both students and staff, institutional support for the trial was strong, the K-12 student body provided a wide cross-section of student ages, and the close-knit community of parents allowed for accurate measurement of absenteeism due to illness.

Subjects

The study sample consisted of the entire student body and teaching staff at both campuses. Students were aged 5-18. A total of 32 students and 43 staff members participated in the study from both campuses. Parents and students were informed of the trial and given the opportunity to opt out of the trial. With the sample size and the length of the trial, it was estimated that more than 6,000 student and staff data points would be collected over the course of the trial, enough to generate statistically significant data.

Intervention

On the intervention campus, wall-mounted product dispensers were installed near the entrance to the classrooms and the administrative office, dispensing the water-based antiseptic. The previous non-antibacterial soap product was removed from the restrooms and replaced with an 8.25 oz bottle of the test soap at each sink. Teachers and staff were instructed by the administrators to attempt to use the dispensers when entering or leaving the classroom and encourage their students to do likewise. The designated control campus maintained their previous hand hygiene products, consisting of soap in the restrooms.

The principal, school administrators, and Chairman of the Board were consulted and determined there was no additional risk to students from changing hand hygiene products, no changes in daily routine were made for the students, and no identifying information would be used.

Measurements and Data Collection

A primary outcome measurement of this crossover clinical study was the incidence of illness-related absenteeism. School administrators and secretaries collected the absenteeism data as per their standard procedure, writing each absence in a notebook, but contacted each parent to determine whether the absence was due to illness or an excused absence. If the reason was illness, the parent was then asked whether the illness was due to a respiratory (R), gastro-intestinal (GI), or other (O) illness. Staff was also requested to report when their absence was due to an illness or personal reason. This information was collected for both the control and experimental campuses.

The second primary outcome measurement was the occurrence of

illness outbreaks among students and staff, and used the same data collection method as above. These outbreaks were defined as any day when more than 10% of the students or staff were ill on the same day. Functionally, with the size of the schools, this occurred when three or more students or staff were ill.

The results were tabulated by the school and reported to the sponsor at the crossover and upon completion of the study. The data was completely anonymous and no identifying data on the students or staff was reported. The results were compared using a two-sample t-test, with a confidence interval of 95% ($p < 0.05$) for statistical significance.

Results

Table 1: Raw Data.

	Student Illnesses (GI)	Student Illnesses (R)	Total Student Days	Staff Illnesses (GI)	Staff Illnesses (R)	Total Staff Days
Campus 1						
Experimental	2	4	405	6	15 (1NA)	745
Control	1	5	455	4	10	845
Campus 2						
Experimental	10	18	796	11	17	811
Control	19	30	734	25	32	830

Table 2: Summary Data.

	Students Illness (Illness/Total Days)	Total Student Days	Staff (Illness/ Total Days)	Staff Total Days
Experimental	34	1,201	50	1,556
Control	55	1,189	71	1,675

Table 3: Reduction in Illness Absenteeism.

	Student Chance of Illness	Staff Chance of Illness
Control	4.63%	4.24%
Experimental	2.83%	3.21%
Reduction in Illness	38.9% Reduction	24.3% Reduction

Table 4: Reduction in Illness Outbreaks*.

	Student Outbreaks	Staff Outbreaks
Control	8	8
Experimental	1	4
Reduction in Illness Outbreak	87.5%	50%

*Outbreak defined as 3+ students or staff (>10%) out with illness on the same day.

No students or staff elected to opt out of the study, and 43 staff members and 32 students completed the study.

Discussion

The addition of the persistent products significantly reduced illness absenteeism by 38.9% among students ($p = 0.03$) and trended towards a reduction of 24.3% among teachers and staff ($p = 0.1$) in this clinical study. Extrapolated over the course of a 180-day school year, this corresponds to 3-4 additional school days for children and nearly 2 less absences per year for teachers and staff.

These results show the test products to be significantly more effective than alcohol-based sanitzers used in other clinical studies. In the studies with comparable protocols, illness reduction was 0% in one trial and 19.8% in the second. The reduction in illness with these test products was shown to be nearly double that of alcohol-based hand sanitizers without persistent antimicrobial effect.

This study also shows that the intervention in the restrooms and in wall-mounted dispensers compared favorably to more labor-intensive hand hygiene protocols. In the placebo-controlled trial with an alcohol-free sanitizer where students were given individual bottles and teachers supervised use five times daily, illness was reduced by 33% among students, less effective than the unsupervised use of the test products in this study.

The frequency of illness outbreaks among students was reduced by 87.5% with the addition of the new products. These results strongly indicate that the test products significantly disrupted and reduced the transmission of germs at the school. Outbreaks of illness at a school, where more than 10% of the student population is ill, are almost certainly due to student-to-student transmission, where an individual absence may have many causes. Illness outbreaks were reduced by 50% among teachers and staff.

Respiratory and GI-related illnesses were reduced in equal proportion in this study. This is a departure from results in past studies, where the addition of a hand sanitizer reduced GI illnesses were reduced at only half the rate of respiratory illnesses, reductions suggesting additional efficacy of the test product against pathogens causing GI illness [14].

The products were well tolerated by both students and staff, with no complaints reported over the course of the trial. While the study was controlled and involved enough participants, time, and data points for statistically significant results, some limitations were inherent in the research. The study population is relatively homogenous, consisting of special-needs children from local communities. Because of the obvious differences between the control and test products, blinding of the study was not possible. The reduction in illness absenteeism can be due both to increased use of the products because of the moisturizing effects as well as the persistent efficacy of the products; the study design could not allow for separating the cause of the beneficial effects. Both aspects will always be present when the products are used and are therefore difficult, if not impossible, to separate. Further research among different age groups, particularly in college dormitories where students are living in on-campus housing, would be valuable to confirm the results of this study.

This data gives school nurses a valuable tool in reducing illness absenteeism and outbreaks among the student population while alleviating concerns about flammability, combustibility and ingestion with standard alcohol-based sanitizers.

Conclusion

The tested persistent products were shown to significantly reduce overall illness absenteeism and illness outbreaks in schools, without any additional education or disruption of classroom time. This reduction has the potiential result in wide-ranging benefits for students, including increasing academic performance, raising funding for schools compensated only for attended days, reducing the cost and disruption of substitute teachers, and improving quality of life for students, parents, and staff.

Sponsorship

The Zylast antimicrobial products were provided free of charge by Innovative BioDefense, Inc. No other financial support, direct or indirect, was provided. All data collection was performed by the site and independently of the sponsor.

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References

1. US Centers for Disease Control and Prevention. Current Estimates from the National Health Interview Survey. 1995.
2. Vessey J, Sherwood J, Warner D, et al. Comparing Hand Washing to Hand Sanitizers in Reducing Elementary School Students Absenteeism. 2007; 33: 368-372.
3. World Health Organisation (WHO) www.who.int/csr/surveillance/infectioncontrol/en/print.html
4. Centers for Disease Control and Prevention. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002; 51
5. Guinan M, McGuckin M, Sevareid A. Who washes hands after using the bathroom? Am J Infect Control. 1997; 25: 424-425.
6. Borchgrevink C, Cha J, Kim S. Hand washing practices in a college town environment. Journal of Environmental Health. 2013; 75: 18-23.
7. Kwok A, McLaws ML. Face-touching: A frequent habit for self-inoculation of transmitted infections? Antimicrobial Resistance and Infection Control. 2013; 2: P157.
8. Liu P, Yvonne Yuen, Hui-Mien Hsiao, et al. Effectiveness of Liquid Soap and Hand Sanitizer against Norwalk Virus on Contaminated Hands. Appl Environ Microbiol. 2010; 76: 394-399.
9. Blaney D, Daly ER, Kirkland KB, et al. Use of alcohol-based hand sanitizers as a risk factor for norovirus outbreaks in long-term care facilities in northern New England: December 2006 to March 2007. American Journal of Infection Control. 2011; 39: 296-301.
10. Bronstein, Daniel A. spyker, Louis R. cantilena, et al. Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 29th Annual Report, Clinical Toxicology. 2011; 50: 911-1164.
11. Hammond B, Ali Y, Fendler E, et al. Effect of hand sanitizer use on elementary school absenteeism. Am J Infect Control. 2000; 28: 340-346.
12. Guinan M, McGuckin M, Ali Y. The effect of a comprehensive handwashing program on absenteeism in elementary schools. American Journal of Infection Control. 2002; 30: 217-220.
13. Meadows E, Le Saux N. A systematic review of the effectiveness of antimicrobial rinse-free hand sanitizers for prevention of illness-related absenteeism in elementary school children. BMC Public Health. 2004.
14. Dyer D, Shinder A, Shinder F. Alcohol-free instant hand sanitizer reduces elementary school illness absenteeism, Fam Med. 2000; 32: 633-638.
15. White C, Shinder F, Shinder A, et al. Reduction of illness absenteeism in elementary schools using an alcohol-free instant hand sanitizer. The Journal of School Nursing. 2001; 17: 258-265.
16. Cozean J, Czerwinski S, Cozean C. Reduction of hospital-acquired infections with the use of a hand sanitizer with both immediate and persistent antimicrobial effect. Open Journal of Infectious Diseases and Epidemiology. 1: 22-25.
17. Czerwinski S, Cozean J. Use of a persistent, water-based sanitizer with anti-viral properties reduces nosocomial infection in long term care facility. Infection Control and Prevention Conference, Chicago, IL. 2017.
18. Czerwinski SE, Cozean J, Cozean C. Novel water-based Antiseptic Lotion compared with Alcohol Sanitizer Demonstrates Rapid, Broad-Spectrum Kill, Journal of Infection and Public Health. 2014; 7: 199-204.
19. Canew Testing and Certification. Evaluation of the Zylast products using the EN1500 protocol, Report Numbers CNT131008102 (2-3). 2013.
20. Czerwinski S, Cozean J, Taylor T, et al. Novel Persistent Products Significant Reduce In-Vivo Transmission of Transient Pathogens, BIT Annual Global Health Conference. 2016.
21. Paulson D. Handbook of Topical Antimicrobials: Industrial Applications in Consumer Products and Pharmaceuticals, CRC Press. 2002.
22. Food and Drug Administration, Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Final Monograph for OTC First Aid Antibiotic Drug Products. 21CFR Parts 333 and 369. 1987; 52.
23. Til HP. Sub-acute (28 day) oral toxicity study with benzethonium chloride in rats. TNO Report. 1986; 86.537/260702.