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David L. Dyer, PhD; Arnold Shinder, DO; Fay Shinder, RN

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Alcohol-free Instant Hand Sanitizer Reduces Elementary School Illness Absenteeism

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Background and Hypotheses: A substantial percentage of school absenteeism among children is related to transmissible infection. Rates of transmission can be reduced by hand washing with soap and water, but such washing occurs infrequently. This study tested whether an alcohol-free instant hand sanitizer (CleanHands®) could reduce illness absenteeism in school-age children. **Methods:** A 10-week, open-label, crossover study was performed on 420 elementary school-age children (ages 5–12). Students were given a brief orientation immediately prior to the start of the study on the relationship of germs, illness, and hand washing. Each student in the treatment group then received the test product in individual bottles, with instructions to apply one to two sprays to the hands after coming into the classroom, before eating, and after using the restroom, in addition to their normal hand washing with soap and water. The control group was instructed to continue hand washing as normal with non-medicated soap. After 4 weeks of treatment and a 2-week wash-out period, the control and experimental groups were reversed. Data gathered on absenteeism were classified as gastrointestinal or respiratory related and normalized for non-illness-related absenteeism and school holidays. **Results:** Compared to the hand washing-only control group, students using CleanHands® were found to have 41.9% fewer illness-related absence days, representing a 28.9% and a 49.7% drop in gastrointestinal- and respiratory-related illnesses, respectively. Likewise, absence incidence decreased by 31.7%, consisting of a 44.2% and 50.2% decrease in incidence of gastrointestinal- and respiratory-related illnesses, respectively. No adverse events were reported during the study. **Conclusions:** Daily use of the instant hand sanitizer was associated with significantly lower rates of illness-related absenteeism.

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A leading predictive factor of academic success for elementary school-age children is attendance.¹ However, attendance optimization is impeded by illness absenteeism; the average school-age child contracts four or more colds per year, with each such cold potentially lasting from 5 to 14 days.² In public schools, illness absenteeism can result in the loss of public monetary compensation for the student. Absences also burden schools with remedial work for absentees and with the additional cost of substitute teachers to replace teachers who have fallen ill due to classroom exposure to sick children. Finally, student absences can require parents to stay home, which adversely affects businesses. Therefore, in addition to academic impact, illness ab-

senteism slows the educational machinery and strains the human and financial resources of our schools.

Although many factors lead to illness absenteeism, close contact and insufficient hand washing contribute greatly to the communicable nature of colds and gastrointestinal (GI) infections.³⁻⁴ Microbial (viral and bacterial) infections of the respiratory and GI tract cause a significant percentage of school illnesses. A specific example of this is rhinovirus, which is more effectively transmitted by hand contact than by droplet dispersion.^{3,4} Studies that examined the relationship between illness absenteeism and hand washing concluded that scheduled hand washing reduces acute communicable illnesses in school-age children.⁴ Also, the US Centers for Disease Control states that hand washing is the best way to prevent the spread of infections.⁵⁻⁸

In spite of positive results with regimented hand washing routines,⁹⁻¹² other studies indicate that maintaining an effective hand-washing program in US

schools is difficult because many classrooms lack basic facilities for proper hand washing. Further, even with proper facilities, the time required for 20 to 30 students to perform minimal hand washing (30–60 seconds each) would significantly interfere with classroom instruction time.

In response to the need for hand sanitization in situations where soap and water are not readily available, and time is limited, antimicrobial rinse-free hand-sanitizing formulas have been developed. Antimicrobial product effectiveness claims reveal several limitations of the active ingredients in this category, the majority of which are alcohol based, with a few containing triclosan.^{13,14} Triclosan has limited antiviral activity and is generally bacteriostatic at most concentrations available to the consumer.^{13,14} Recent work further indicates that triclosan may promote antibiotic-resistant variants of *Escherichia coli*, *Salmonella typhimurium* and *Mycobacterium tuberculosis*, through mutation of gene products involved in fatty acid synthesis.¹⁵ Alcohol-based hand sanitizers are effective as short-term antimicrobial preparations, but long-term, frequent use of certain alcohol products can cause skin irritation.¹³ It has been observed that frequent use of the alcohol-based sanitizers hinders the product's effectiveness and can leave the hands more susceptible to microbial contamination.¹⁶ Further, after an alcohol sanitizer dries, no antimicrobial agent remains on the skin, which is readily recolonized by pathogens. In addition, alcohol-based sanitizers are flammable and can irritate eyes and open wounds. Products with these active ingredients are, therefore, undesirable in school settings and can present a safety hazard to children.

Because of these issues, a safe, effective, nonflammable, nonirritating antimicrobial instant hand sanitizer could be useful for hand sanitization in the absence of soap and water. Such a sanitizer containing surfactants, allantoin, and benzalkonium chloride (SAB formulation¹⁹) has been recently developed. This product meets federal standards for antiseptic hand washes^{16,17} for health care personnel, is fast acting with a broad antimicrobial spectrum, and demonstrates a significant persistence of activity.¹⁶ The SAB hand sanitizer is nonflammable and does not dry or damage the skin.¹⁶

The formulation's effectiveness at reducing illness absenteeism in a school setting was tested in a 10-week, open-label, crossover study of programmed use of the hand sanitizer in conjunction with at-will soap-and-water hand washing.

Methods

The study was conducted at Grace Christian School, a private elementary school in Cypress, Calif. Children (n=420) ranging from ages 5–12 (all grades from kindergarten through sixth grade) were included in the study; each classroom group contained 30 students, and

there were two classrooms per grade level. Although the study protocol required exclusion of children with known allergies to any of the ingredients in the SAB sanitizer, no exclusions from the population were necessary during the course of the study. While the study was not approved by a formal university institutional review board, it was reviewed and approved by the principal and school board of education. Prior to study initiation, the school board and principal (institutional oversight board) informed the school parents about the purpose and nature of the study. Although parents had the option of not letting their child participate in the study, no objections or withdrawals were received for the study's duration.

Subjects were grouped by classroom without formal randomization. Seven classes received the instant sanitizer, while the remaining seven classes were assigned to the control group. Male-to-female ratios and age distributions of the two groups did not differ significantly. Two weeks prior to study initiation, all students received a 30-minute presentation on germs, the relationship of germs to colds, and the importance of washing hands with soap and water to prevent illnesses. The students also viewed an educational videotape presentation that described the hand-to-hand spreading of germs between people.

SAB Sanitizer

The SAB formulation is effective against a wide variety of pathogens, including gram-positive and gram-negative bacteria, mold, and fungi and a variety of viruses, including *Haemophilus influenzae*, lipid-encapsulated viruses, and Hepatitis B virus. The SAB hand sanitizer surpasses the Food and Drug Administration (FDA) performance standards for health care personnel hand washes and meets the criteria for inclusion into the Health Care Continuum Model (HCCM), a performance-based standard developed by industry to assist the FDA in classification of topical antimicrobial drug products, in that it 1) is fast acting, 2) has a broad antimicrobial spectrum, 3) displays persistence of activity, and 4) is effective under a heavy bacterial soil load.¹⁶⁻¹⁸

Sanitizer Group

Children in the hand sanitizing group received a 1-oz bottle of the SAB hand sanitizer fitted with a pump-spray top, which facilitated reproducible product dispensing and dispersion. Students were instructed to use the spray under teacher supervision to supplement normal, at-will hand washing with non-medicated (non-antibacterial) soap and water. The situations determined for sanitizer use were 1) immediately after entering the classroom, 2) before eating (snacks and lunch), 3) after sneezing or coughing in the classroom, and 4) after using the restroom facility. Students were instructed to

use the sanitizer by pushing the pump once and spraying (approximately .25 ml) into the palm of the hand. Students were told to then rub their hands together, in a normal washing motion, concentrating on the fingertips and under the nails, until the hands were dry.

Control Group

The control group was instructed to wash hands before eating, after visiting the restroom, and as otherwise necessary during the day. Students were instructed to wash hands with warm water and non-medicated soap, as usually performed, concentrating on the fingertips and under the fingernails. Handwashing in this group was not supervised.

Data Collection

Data were collected for 10 weeks (March to May, 1998). In the first 4 weeks of the study, SAB sanitizer was distributed to half of the student population, while the other half washed at will (described above). This first test period was followed by a 2-week wash-out period, during which neither group of students used the SAB sanitizer, and they were asked to wash their hands when necessary with water and non-medicated soap and refrain from using any other type of instant hand sanitizer. Students then received the review orientation on germs and illness, and SAB sanitizer was distributed to the student group that had previously served as the control. The study proceeded for another 4 weeks.

Scoring of Absences

Teachers were responsible for recording absences during the study. Absence classification categories included: total absence number, total absence incidences (discrete illness periods per student), and total days of absence (absence caused by communicable illness).

Parents provided information on the nature of the student's absence to the health secretary's office during the study. Absences were counted as GI (symptoms included vomiting, abdominal pain, and diarrhea), respiratory related (symptoms included cough, sneezing, sinus trouble, bronchitis, fever alone, pink eye, headache, mononucleosis, and acute exacerbation of asthma), or non-transmissible illness related (vacations, non-transmissible urinary tract infections, sprained or broken limbs, etc).

Total possible student days of attendance was defined as the number of students in the study group multiplied by the number of study days, minus the number of days of "other" non-transmissible

illness-related absences. Relative risk of absence (RRA) was calculated as follows: $RRA = A_s/T$ divided by A_c/T , where A_s =absences (sanitizer group), A_c =absences (control group), and T =total possible days of attendance.

Statistical Analysis

Statistical significance was measured using chi-square analysis.

Results

Of the total absences in the first 4 weeks of the study for the sanitizer-using group, 38.5% were due to GI illness, and 61.5% were caused by respiratory illness. This distribution was comparable to the control group, where 40.9% were caused by GI illness and 59% by respiratory illness. However, as shown in Table 1, the total number of absences due to communicable acute illness was 33.6% lower in the sanitizer group ($P<.001$) than in the control group.

Absence incidence in the sanitizer group was approximately 48% ($P<.001$) lower than in the control group. Total GI and respiratory-related absences were decreased by 37.5% ($P<.001$) and 30.9% ($P<.02$), respectively, compared with the control group. Likewise, GI and respiratory absence incidences were suppressed in the sanitizer group by 57.7% and 39.1%, respectively, compared with the control group.

Following the 2-week nonuse period, no significant difference was noted in GI or respiratory absences between the two groups. Test groups were then reversed as described above, and the test proceeded for another 4 weeks. A significant decrease in total illness-related absences was again observed in the sanitizer group, compared with the control group (55.7%, $P<.001$; Table 2). Although fewer GI-related absences occurred in the sanitizer group, the number was not significantly different than the control group ($P=.66$). In contrast, respiratory absences were 76% lower than the control group ($P<.001$). Absence incidence was 43% less in

Table 1

Part I—Student Absence Data

| ABSENCES: | TOTAL | | R RELATED | | GI RELATED | |
|-----------------------------|---------|-------|-----------|-------|------------|-------|
| | Control | SAB | Control | SAB | Control | SAB |
| Number of classes | 7 | 7 | 7 | 7 | 7 | 7 |
| Participating students | 210 | 210 | 210 | 210 | 210 | 210 |
| Possible days of attendance | 4,120 | 4,136 | 4,120 | 4,136 | 4,120 | 4,136 |
| Absence incidence | 69 | 36 | 36 | 22 | 33 | 14 |
| Days of illness | 105 | 70 | 62 | 43 | 43 | 27 |
| Different students absent | 57 | 31 | 26 | 19 | 31 | 12 |
| Days absent per student | 1.84 | 2.26 | 2.38 | 2.26 | 1.39 | 2.25 |

R—respiratory
GI—gastrointestinal
SAB—hand sanitizer

Table 2

Part II—Student Absence Data

| ABSENCES: | TOTAL | | R RELATED | | GI RELATED | |
|-----------------------------|---------|-------|-----------|-------|------------|-------|
| | Control | SAB | Control | SAB | Control | SAB |
| Number of classes | 7 | 7 | 7 | 7 | 7 | 7 |
| Participating students | 210 | 210 | 210 | 210 | 210 | 210 |
| Possible days of attendance | 4,140 | 4,156 | 4,140 | 4,156 | 4,140 | 4,156 |
| Absence incidence | 43 | 23 | 26 | 9 | 17 | 14 |
| Days of illness | 63 | 28 | 43 | 10 | 20 | 18 |
| Different students absent | 37 | 17 | 20 | 8 | 17 | 9 |
| Days absent per student | 1.70 | 1.65 | 1.00 | 2.25 | 2.53 | 1.11 |

R—respiratory
GI—gastrointestinal
SAB—hand sanitizer

the sanitizer group than in the control group for total absences ($P<.05$) and 65% lower for respiratory absences ($P<.001$). The absence incidence for GI was not significantly different than the control group. The distribution of GI and respiratory illness as a percentage of the total illnesses differed between the two groups in the second half of the test: in the sanitizer group, 64.3% of the illness absenteeism recorded was assessed to be GI and 35.7% respiratory in origin, while

observed or reported during or following the study in either use group.

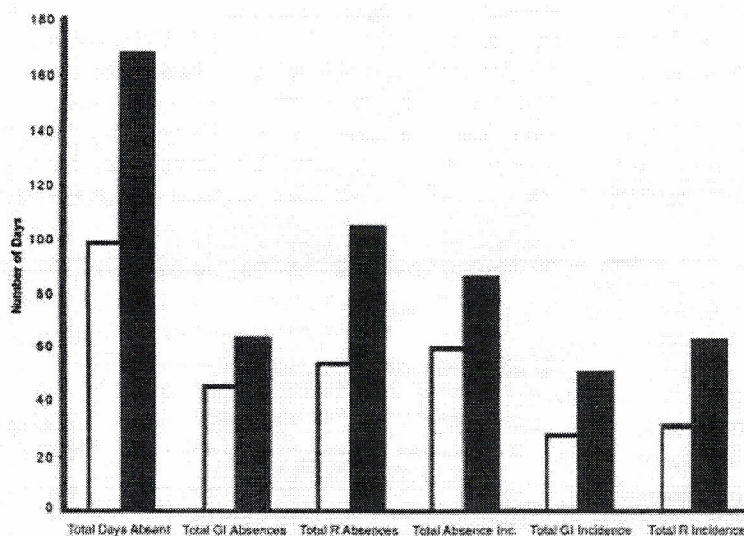
Discussion

The results from this study indicated that, overall, the SAB sanitizer use, in conjunction with at-will hand washing with non-medicated soap, significantly decreased illness absenteeism in terms of total absence days and absence incidence. Further, the relative risk of absence for students in the sanitizer group was 41% lower than that of students in the control group. The SAB sanitizer was apparently mainly effective at suppressing respiratory absences, even though significant suppression of GI-related absences was also observed.

Master et al² emphasize the concept that basic soap-and-water hand washing prevents the spread of infection and should be encouraged as a standard infection control measure. In that study, programmed hand washing significantly decreased overall illness absenteeism (25% reduction). In spite of these and others' similar findings,^{2,9-12} hand washing is not consistently practiced or promoted in public school systems. It appears that the main reasons include a lack of proper washing facilities and less-than-optimal teacher participation in continuously educating students about the health benefits of hand washing,^{2,9,11} as well as the excessive time requirement. While teacher motivation can be

Figure 1

Combined Absences and Absence Incidences



R—respiratory
GI—gastrointestinal

Black bars: control group. White bars: SAB hand-sanitizer use group. All SAB sanitizer use group measures were statistically significant ($P\leq.05$, see text).

Table 3

Combined Student Absence Data

| ABSENCES: | TOTAL | | R RELATED | | GI RELATED | |
|-----------------------------|---------|-------|-----------|-------|------------|-------|
| | Control | SAB | Control | SAB | Control | SAB |
| Number of classes | 7 | 7 | 7 | 7 | 7 | 7 |
| Participating students | 210 | 210 | 210 | 210 | 210 | 210 |
| Possible days of attendance | 8,260 | 8,292 | 8,260 | 8,292 | 8,260 | 8,292 |
| Absence incidence | 112 | 59 | 62 | 31 | 50 | 28 |
| Days of illness | 168 | 98 | 105 | 53 | 63 | 45 |
| Different students absent | 94 | 48 | 46 | 27 | 48 | 21 |
| Days absent per student | 1.79 | 2.04 | 1.78 | 2.26 | 1.79 | 1.76 |

R—respiratory

GI—gastrointestinal

SAB—hand sanitizer

addressed at an educational and/or institutional policy level, a lack of proper and sufficient washing facilities (ie, clean water source/sink and soap) is a more difficult issue to address from a logistics perspective. Recent legislation from the California State Government that encourages class downsizing, together with the steady increase in overall student enrollment, have forced schools to use classrooms that lack washing facilities. Therefore, structural limitations are a substantial barrier to implementing an effective scheduled hand-washing program.

Another consequence to scheduled hand washing in schools is the loss of instruction time. A 30-second hand wash with soap and water for each of 20 students in an average size classroom, with proper hand-washing facilities, requires 10 minutes for hand washing alone, with a net loss in instruction time of 30–40 minutes per day (for three to four hand wash runs). It has been observed, however, that the educational benefits of a student's daily presence in school outweigh any potential detriment of entire days of absence, even if each day's instruction period was shortened by several minutes.² Prior to the start of the present study, teachers were given the choice of directly dispensing the sanitizer themselves onto students' hands or letting the students apply it themselves. All teachers chose to let students apply the SAB hand sanitizer themselves at the appropriate times during the day. In this situation, the teachers verbally instructed students when to use the SAB formula and visually monitored the application process. There were no reports of inappropriate product use. Given the sanitizer's quick drying time (30–45 seconds), time lost from instruction is minimized; moreover, the entire sanitization procedure required at most 1 minute per application period, for a total of 5 minutes per day.

The majority of instant hand sanitizers available commercially contain alcohol at a concentration of 62%–70% by weight. Due to their flammability and potential for drying and irritating the skin, alcohol sanitizers

are not compatible with school hand-sanitization programs. The SAB formulation used in this study differs from alcohol-containing instant hand sanitizers because it is not flammable, does not contain organic solvents, and contains allantoin, a well-accepted skin conditioner (Chodosh D. US Patents 5,661,107 and 5,827,870, 1998). The lack of adverse events reported during the course of the study supports its safety as a daily-use sanitizer.

Limitations

Although the present study was prospective, controlled, and involved a sufficient number of participants, it had some limitations in design. These included limited socioeconomic diversity in the study population, limitation to a single study site, and lack of blinding. Further, soap-and-water washing was not monitored. It is, therefore, possible that the effect yielded in this study was in part due to lack of soap-and-water washing in the control group. In both study groups, however, at-will hand washing with soap and water was recommended equally and simultaneously and reinforced by providing educational material on the importance of hand washing. Also, soap and water hand washing compliance in school populations has been shown to range from 8%–28%.¹⁹ Further, control group baseline absences in the present study were similar to those reported previously.² Therefore, it is likely that unmonitored soap-and-water hand washing was similar and minimal for both groups in this study.

Implications

In response to the antimicrobial consumer and health care product proliferation, the FDA has questioned whether such products provide any "real-life" benefits. In fact, such demonstrations are scarce in the literature. However, a recent open-label, non-placebo controlled, non-crossover study of an alcohol-based hand sanitizer at suppression of illness absenteeism demonstrated approximately a 25% overall reduction.²⁰ In contrast, the present study demonstrated approximately a 41% reduction in absenteeism, with the added stringency of population crossover.

The family physician, as the medical liaison to the community, has the opportunity to educate and inform key individuals such as teachers, school nurses, school board members, and others responsible for students' health and well-being. Even if one doesn't have school-age children, it is necessary to understand the importance and benefits of good hand hygiene, not only in clinical practice but also in the greater community. Vital tax dollars will be saved on expenses for remedial

student services and lost employee work time by this simple and effective way to decrease illness-related absenteeism.

Conclusions

In summary, this study determined that daily use of the SAB instant hand sanitizer with at-will hand washing using soap and water significantly decreased absences due to acute communicable illness. While a larger, placebo-controlled study should be performed to further support these findings, these initial results suggest that the alcohol-free SAB instant hand sanitizer allows optimization of student attendance with minimal financial and instruction time impact.

Corresponding Author: Address correspondence to Dr Dyer, Woodward Laboratories, 11132 Winners Circle, Suite 100, Los Alamitos, CA 90720. 562-598-0800. Fax: 562-598-0010. E-mail: dldyer@woodwardlabs.com.

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