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A Randomized, Controlled Trial of a Multifaceted Intervention Including Alcohol-Based Hand Sanitizer and Hand-Hygiene Education to Reduce Illness Transmission in the Home

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ABSTRACT. *Objective.* **Good hand hygiene may reduce the spread of infections in families with children who are in out-of-home child care. Alcohol-based hand sanitizers rapidly kill viruses that are commonly associated with respiratory and gastrointestinal (GI) infections. The objective of this study was to determine whether a multifactorial campaign centered on increasing alcohol-based hand sanitizer use and hand-hygiene education reduces illness transmission in the home.**

Methods. **A cluster randomized, controlled trial was conducted of homes of 292 families with children who were enrolled in out-of-home child care in 26 child care centers. Eligible families had ≥1 child who was 6 months to 5 years of age and in child care for ≥10 hours/week. Intervention families received a supply of hand sanitizer and biweekly hand-hygiene educational materials for 5 months; control families received only materials promoting good nutrition. Primary caregivers were phoned biweekly and reported respiratory and GI illnesses in family members. Respiratory and GI-illness–transmission rates (measured as secondary illnesses per susceptible person-month) were compared between groups, adjusting for demographic variables, hand-hygiene practices, and previous experience using hand sanitizers.**

Results. **Baseline demographics were similar in the 2 groups. A total of 1802 respiratory illnesses occurred during the study; 443 (25%) were secondary illnesses. A total of 252 GI illnesses occurred during the study; 28 (11%) were secondary illnesses. The secondary GI-illness rate was significantly lower in intervention families compared with control families (incidence rate ratio [IRR]: 0.41; 95% confidence interval [CI]: 0.19–0.90). The overall rate of secondary respiratory illness was not significantly different between groups (IRR: 0.97; 95% CI: 0.72-1.30). However, families with higher sanitizer usage had a marginally lower secondary respiratory illness rate than those with less usage (IRR: 0.81; 95% CI: 0.65-1.09).**

Conclusions. **A multifactorial intervention emphasizing alcohol-based hand sanitizer use in the home reduced transmission of GI illnesses within families with children in child care. Hand sanitizers and multifaceted educational messages may have a role in improving hand-hygiene practices within the home setting.** ***Pediatrics*** **2005;116:587–594;** ***hand hygiene, hand sanitizer, child care, illness transmission, randomized controlled trial.***

ABBREVIATIONS. GI, gastrointestinal; IRR, incidence rate ratio; CI, confidence interval.

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More than 7.5 million children who are younger than 5 years are enrolled in out-of-home child care in the United States,[1] where they are at high risk for acquiring contagious diseases, especially viral respiratory tract and gastrointestinal (GI) infections.[2–11] Transmission rates are high because children readily exchange secretions, children with potentially communicable infections are not always excluded from child care, and staff face daunting challenges in personal hand hygiene and environmental sanitation.[12,13] Infections that are acquired in child care are readily transmitted to family members in the home,[14–16] where organisms are spread primarily via contaminated hands.[17–25] Handwashing with soap and water generally is accepted as a simple, effective measure to reduce the spread of infections in diverse settings. For example, handwashing interventions decreased illness rates in child care centers and absenteeism in schools.[26,27] A recent randomized, controlled trial showed that a home handwashing intervention in Pakistan reduced the incidence of diarrhea in households, an impressive result considering the extremely challenging environment.[28]

Despite the acknowledged effectiveness of handwashing with soap and water, compliance requires convenient access to a sink and sufficient time to perform the procedure. Alcohol-based hand sanitizers, which do not require water, are a boon for harried parents and busy caregivers in hospitals and other institutions. They rapidly kill most bacteria and viruses, and products that contain emollients tend to be gentler on the hands than soap and water. An increasing body of literature suggests that regular use of alcohol-based hand sanitizers can reduce transmission of infections in hospitals and other health care settings.[29–34] Hand sanitizers also have been associated with reduced absenteeism in schools.[35–37] A recent observational study by Lee et al[38] found an association between reported hand sanitizer use and decreased illness transmission in families who have children enrolled in out-of-home child care. However, no randomized trials have demonstrated the efficacy of hand sanitizers in the home.

METHODS

Design

We performed a cluster randomized, controlled trial (Healthy Hands Healthy Families) to assess the effectiveness of a multifactorial hand-hygiene intervention in reducing respiratory and GI-illness transmission in the homes of families with children enrolled in out-of-home child care. The intervention centered on increasing use of alcohol-based hand sanitizer by supplying families with the product in the context of a vigorous hand-hygiene educational and behavior change campaign. We hypothesized that families who received this intervention would have lower rates of secondary respiratory and GI illness compared with control families. This study was reviewed and approved by the Children's Hospital Boston Institutional Review Board.

Participants

Recruitment of families began in November 2002, and the study was closed to new enrollment in April 2003. Families were recruited on the basis of the attendance of their children in specific child care centers. Twenty-six potential study centers in 3 Massachusetts neighborhoods (Boston, Brookline, and Cambridge) were identified from the Web site of the Massachusetts Office of Child Care Services.[39] The director of each center was contacted by telephone and gave permission to recruit families who were enrolled in the center. An initial recruitment letter was distributed through the child care centers to all families. Families chose either to provide contact information for eligibility screening or to decline participation by means of an opt-out postcard. All interested families then were screened by telephone for study eligibility.

A family was eligible for inclusion in the study when (1) the family had at least 1 child between 6 months and 5 years of age enrolled in out-of-home child care (the oldest child who met these criteria was defined as the index child), (2) the index child was enrolled in out-of-home child care with at least 5 other children for ≥10 hours per week, (3) the family planned to reside in the area and keep the index child enrolled in the center for the duration of the study, (4) the family had access to a telephone, and (5) the primary home caregiver could speak English or Spanish. A household member was defined as an individual who spent >3 nights per week in the home. We excluded families whose homes also functioned as family child care centers and families with a household member whose occupation included working with children under the age of 6 for >10 hours per week. We also excluded families who reported using alcohol-based hand sanitizer in the home at least once a day. Families who met eligibility criteria for enrollment provided written consent to participate in the study.

Intervention

Randomization was clustered (with the child care center as the unit of randomization) in recognition of possible correlations between families within the same center (eg, illness affecting multiple families in a center or families influencing one another regarding hand-hygiene practices). Random assignments were generated by computer using a permuted-blocks design with random block sizes. Assignments were concealed in opaque envelopes, and centers were assigned to control or intervention groups by a study investigator as they were enrolled. Families whose centers were assigned to the intervention group received a supply of alcohol-based hand sanitizer (Purell Instant Hand Sanitizer; GOJO Industries, Inc, Akron OH; active ingredient: 62% ethyl alcohol) to use in the home during a 5-month study period. In addition, intervention families received biweekly hand-hygiene educational materials at home for 5 months. These materials consisted of engaging fact sheets and tips to educate families about hand hygiene, as well as games and toys designed to serve as triggers for awareness of hand-hygiene practices. Families whose centers were assigned to the control group did not receive hand sanitizer or materials related to hand hygiene; instead, they received biweekly educational materials about a healthy diet including fruits and vegetables. Control families were asked not to use hand sanitizer during the study period. No placebo for the sanitizer was provided because we believed that it would be unethical if families used an inactive hand-hygiene product as a substitute for routine handwashing.

Data Collection and Illness Definitions

At the beginning of the study, caregivers were mailed a survey that asked about family demographics as well as knowledge and practices regarding hand hygiene and illness transmission. This survey was adapted from a standardized instrument used by our group in previous studies of knowledge, attitudes, beliefs, and practices regarding infections in the home setting.[40] Completed surveys were returned by mail at the beginning of the study. This survey was repeated at the conclusion of the 5-month study period. Families also received a symptom diary to record the timing and duration of illnesses among family members. Caregivers were contacted by telephone biweekly to elicit reports of symptoms of respiratory and GI illnesses in the family during the preceding 2 weeks. Primary caregivers also reported the amount of sanitizer used and adverse reactions to the product on a biweekly basis. Given that no placebo was provided and sanitizer use was recorded, neither families nor data collectors could be blinded as to the group assignment of the family. All written materials and telephone calls were in English or Spanish depending on the primary language spoken in the home.

We used definitions of respiratory and GI illness that had been used in our previous study[38] and had been adapted from the literature by an expert panel.[41–50] Respiratory illness was defined as 2 of the following symptoms for 1 day or 1 of these symptoms for 2 consecutive days: (1) runny nose; (2) stuffy or blocked nose or noisy breathing; (3) cough; (4) fever, feels hot, or has chills; (5) sore throat; and (6) sneezing. GI illness was defined as either or both of the following symptoms: (1) watery or loose bowel movements and (2) vomiting. In either category, an illness was considered new or separate when a period of at least 2 symptom-free days had elapsed since the previous illness. An illness was defined as a secondary case when it began 2 to 7 days after the onset of the same illness type (respiratory or GI) in another household member.

Outcomes

Our main outcome measures were the overall rates of secondary respiratory and GI illness (defined as the number of secondary illnesses per susceptible person-month). Additional outcomes included primary respiratory and GI-illness rates. We also recorded amount of hand sanitizer used (as reported by the primary caregiver) and any adverse events related to the hand sanitizer.

Primary illness incidence rates were calculated by dividing the number of primary illnesses by the number of person-months at risk for acquiring a primary illness. To measure secondary illness rates, we calculated the number of primary illnesses that occurred among all members of a family, determined the susceptibility period (the 2–7-day period after each new illness) for exposed family members, and counted the number of secondary illnesses that occurred during the susceptibility period. Secondary illness incidence rates then were calculated by dividing the number of secondary illnesses by the number of susceptible person-months at risk in each family.

Statistical Analysis

All 292 families who were randomly assigned were included in the analyses, which were conducted on an intention-to-treat basis. For families who withdrew or were lost to follow-up, data up to the last available contact were included in the analysis. Baseline demographic characteristics in the control and intervention groups were compared using Fisher's exact test for categorical variables and Wilcoxon rank sum test for continuous variables. The number of secondary illnesses in each family was modeled by a Poisson distribution. Generalized estimating equations[51] were used to compare transmission rates between the control and intervention groups, accounting for correlations between families within a child care center. We adjusted for demographic variables (including number of children age 0–5 in household, household income, race, and primary caregiver occupation and education level) and previous experience using hand sanitizers (measured by response to the survey item, "Have you ever used alcohol-based hand sanitizers in your home?"). Our model also included a term to adjust for reported hand-hygiene practices in the home at baseline; this term was a score derived from responses to respiratory- and GI-specific hand-hygiene items on the baseline survey (Cronbach α,[52] a measure of internal consistency, was .86 for the respiratory score and .86 for the GI score). The items that made up this score addressed issues such as length of time to perform routine handwashing, changes in handwashing practices during times of illness, and frequency of handwashing in relation to specific events associated with a high likelihood of illness transmission. In a preplanned secondary analysis, we also compared secondary illness rates stratified by amount of sanitizer use, adjusting for the same set of covariates described above for the primary analysis. This analysis was performed to examine the impact of amount of hand sanitizer use on rates of illness transmission in the intervention group. Statistical analyses were performed using SAS version 9.0 (SAS Institute, Cary, NC). Two-sided $P < .05$ indicated statistical significance.

Because we anticipated that the majority of observed illnesses would be respiratory illnesses, sample size was calculated on the basis of the outcome of secondary respiratory illness rate. Under the assumption of 2.14 secondary cases per family in the control group during the study period (based on data from our previous study), 348 families would be required to detect a 20% decrease in secondary infections with 80% power. This calculation assumes that the correlation of illness burden among families in the same child care center is 0.01.[53]

RESULTS

A total of 647 families received initial letters about the study, and 218 of them opted out of further contact (Fig 1). Of the remaining 429 families, 358 (83%) were eligible for enrollment. Of the 71 ineligible families, the most common reasons for ineligibility were current use of sanitizer in the home at least daily (n = 17), no children aged 6 months to 5 years enrolled in child care for at least 10 hours/week (n = 15), family member working with children under 6 (n = 15), and family moving before end of study (n = 8). Of the eligible families, 292 (82%) agreed to enroll and provided written consent; 155 families (14 child care centers) were assigned randomly to the intervention group, and 137 families (12 child care centers) were assigned randomly to the control group. In the intervention group, 12 families withdrew before completion of the 5-month study period, and 3 were lost to follow-up; in the control group, 11 families withdrew, and 8 were lost to follow-up. The proportion of families who completed the study did not differ between intervention and control groups (P = .28, Fisher's exact test).

Baseline demographic characteristics were similar in the control and intervention groups (Table 1). Overall, 79% of enrolled families were white; 91% of primary caregivers had at least a college degree, and

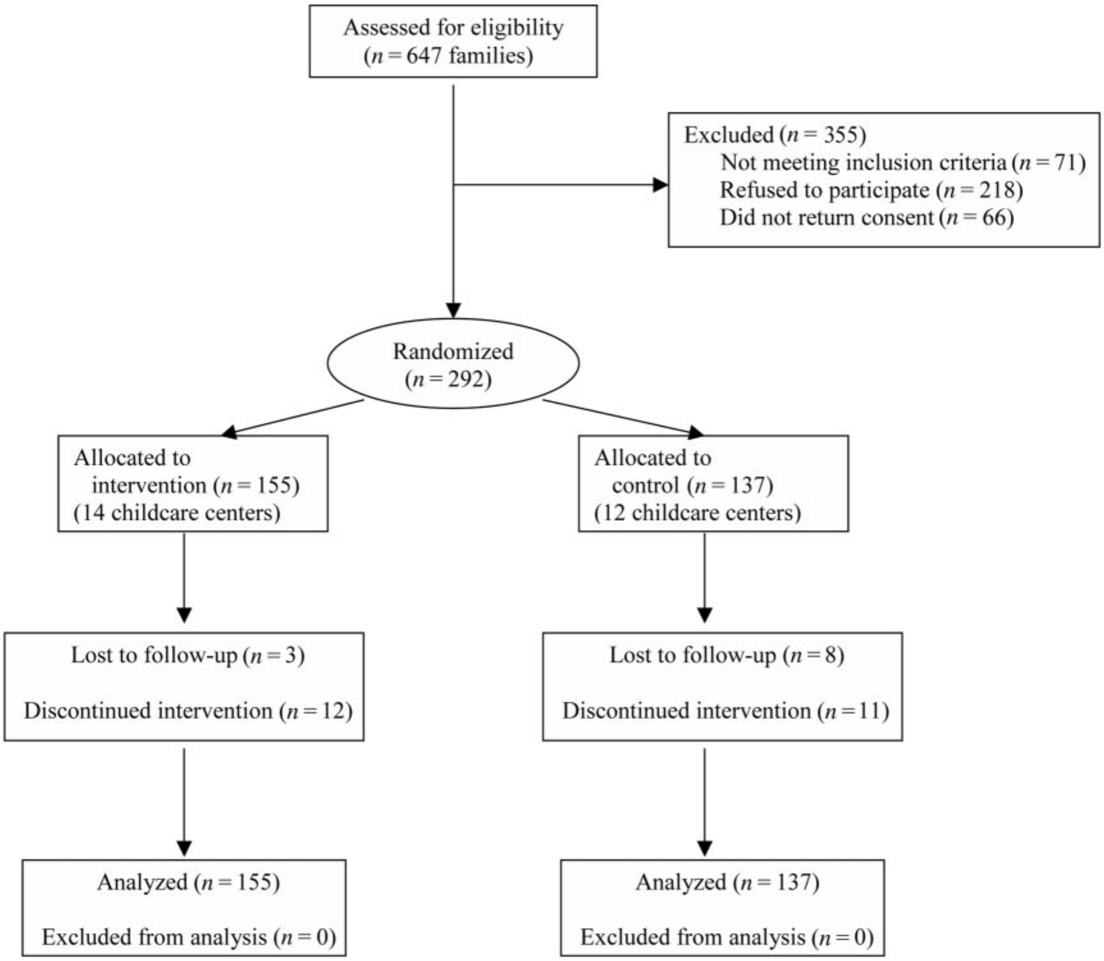

Fig 1. Participant flow diagram.

TABLE 1. Baseline Demographic Characteristics

Demographic Variable	Control (n = 137 Families)*	Intervention (n = 155 Families)*	P†
Age of index child, mean (SD)	3.0 (1.3)	2.7 (1.3)	.08
Age of primary caregiver, mean (SD)	37.1 (6.5)	36.3 (6.0)	.27
Race, n (%)			.48
White	104 (78)	123 (79)	
Black	18 (14)	15 (10)	
Other	11 (8)	17 (11)	
Ethnicity, n (%)			.76
Hispanic	9 (7)	9 (6)	
Non-Hispanic	124 (93)	144 (94)	
Education level of primary caregiver, n (%)			.18
≤High school	15 (11)	11 (7)	
College	40 (30)	60 (39)	
Advanced degree	80 (59)	83 (54)	
Household income, n (%)			.55
<$40 000 per y	18 (13)	14 (9)	
$40 000–79 999 per y	24 (18)	29 (19)	
≥$80 000 per y	92 (69)	107 (71)	
Occupation of primary caregiver, n (%)			.46
Medical‡	9 (7)	14 (9)	
Nonmedical	125 (93)	140 (91)	
No. of children age 0–5 in household, n (%)			.25
1	90 (66)	115 (74)	
2	47 (34)	37 (24)	
3	0 (0)	3 (2)	
No. of participants with ≥1 comorbidity§, n (%)‖	76 (15)	78 (14)	.73
Household member health status, n (%)‖			.12
Excellent	256 (52)	313 (58)	
Very good	172 (35)	174 (32)	
Good	52 (11)	49 (9)	
Fair	10 (2)	4 (1)	
Poor	0 (0)	0 (0)	
Previous hand sanitizer use in home, n (%)			.37
Yes	48 (36)	63 (41)	
No	87 (64)	92 (59)	
Hand-hygiene–practice score, mean (SD)			
Respiratory (range: 0–9)	5.3 (1.6)	5.1 (1.5)	.27
Gastrointestinal (range: 0–12)	8.3 (1.8)	8.1 (1.7)	.19

* Numbers may not sum to group totals for all variables because of missing responses.
† Fisher's exact test for categorical variables and Wilcoxon rank-sum test for continuous variables.
‡ Defined as physician, nurse, or dentist.
§ Comorbidities include asthma, allergies, heart disease, cancer, diabetes, kidney failure, immune system disorders, and chronic lung disease.
‖ The denominator for these variables is number of participants enrolled (control: n = 502; intervention: n = 551).

70% of families had an annual household income of at least $80 000. Participants were generally healthy; the most common underlying illness was asthma, occurring in 7% of participants.

A total of 1053 individuals in 292 families contributed a total of 129 531 person-days of observation during the study; 382 of the individuals were 0 to 5 years of age, 98 were 6 to 17 years of age, 559 were 18 years or older, and 14 did not have age recorded. Table 2 shows the overall incidence rates for respiratory and GI illness. A total of 1802 respiratory illnesses occurred in 258 families; 1359 (75%) of these were primary illnesses. The overall respiratory illness incidence rate was 0.42 illnesses per person-month. A total of 252 GI illnesses occurred in 138 families; 224 (89%) of these were primary illnesses. The overall GI-illness incidence rate was 0.06 illnesses per person-month.

A total of 443 secondary respiratory illnesses occurred over 18 173 susceptible person-days at risk, producing a transmission rate of 0.74 secondary illnesses per susceptible person-month. Twenty-eight secondary GI illnesses occurred during 3359 susceptible person-days at risk, producing a transmission rate of 0.25 secondary illnesses per susceptible person-month. The unadjusted incidence rate ratio (IRR) for secondary respiratory illness in intervention families compared with control families was 1.05 (95% confidence interval [CI]: 0.78–1.42; P = .75). The unadjusted IRR for secondary GI illness in intervention families compared with control families was 0.48 (95% CI: 0.21–1.10; P = .08).

Predictors of GI and respiratory illness transmission in the multivariable models are shown in Table 3. After adjustment for race, household income, education level, and occupation of the primary caregiver; number of children aged 0 to 5 in the household; previous experience using hand sanitizers; and baseline hand-hygiene practices in the home, the rate of secondary GI illness was significantly lower in intervention families compared with control families (IRR: 0.41; 95% CI: 0.19–0.90; P = .03). The overall rate of secondary respiratory illness was not significantly different between groups; the IRR in the in-

TABLE 2. Illness Rates

	GI Illnesses		Respiratory Illnesses	
	Control	Intervention	Control	Intervention
Total no. of illnesses	117	135	828	974
No. of families contributing illnesses	60	78	118	140
Total no. of person-days of observation	60 413	69 118	60 413	69 118
Total illness incidence rate*	0.06	0.06	0.42	0.43
No. of primary illnesses	99	125	626	733
No. of susceptible person-days at risk for primary illness	58 864	67 308	51 888	59 470
Primary illness incidence rate†	0.05	0.06	0.37	0.37
No. of secondary illnesses	18	10	202	241
No. of susceptible person-days at risk for secondary illness	1549	1810	8525	9648
Secondary illness incidence rate‡	0.35	0.17	0.72	0.72

* Measured as number of illnesses per person-month.
† Measured as number of primary illnesses per susceptible person-month
‡ Measured as number of secondary illnesses per susceptible person-month

TABLE 3. Predictors of Secondary Illness Transmission

Covariate*	GI-Illness Transmission		Respiratory Illness Transmission	
	IRR (95% CI)	*P*	IRR (95% CI)	*P*
Study arm				
Control	1.0†	–	1.0	–
Intervention	0.41 (0.19–0.90)	.03	0.97 (0.72–1.30)	.83
Race/ethnicity				
White non-Hispanic	1.0	–	1.0	–
Other	1.45 (0.58–3.63)	.42	0.66 (0.44–1.0)	.05
Household income				
<$80 000 per y	1.0	–	1.0	–
≥$80 000 per y	0.60 (0.27–1.32)	.21	0.84 (0.62–1.14)	.27
Education level				
≤College	1.0	–	1.0	–
Advanced degree	1.60 (0.57–4.50)	.37	1.17 (0.87–1.57)	.31
Occupation				
Nonmedical	‡	‡	1.0	–
Medical			1.17 (0.81–1.69)	.40
No. of children age 0–5 in household				
1	1.0	–	1.0	–
≥2	0.79 (0.31–2.00)	.62	0.81 (0.64–1.04)	.10
Previous sanitizer use in home				
No	1.0	–	1.0	–
Yes	1.31 (0.63–2.73)	.47	1.14 (0.92–1.41)	.23
Hand-hygiene–practice score	0.97 (0.84–1.13)	.72	0.96 (0.88–1.04)	.29

* Analyses adjusted for race/ethnicity (white non-Hispanic versus other), household income (<$80 000 vs ≥$80 000 per year), education level of primary caregiver (≤college versus advanced degree), occupation of primary caregiver (medical [physician, nurse, dentist] versus not medical), number of children age 0 to 5 in household (1 vs ≥2), reported previous sanitizer use ever in home (yes versus no), and baseline hand-hygiene–practice score (for GI or respiratory items).
† Reference groups for calculating IRRs are indicated by an IRR of 1.0.
‡ Occupation was not included in the GI-illness model because of nonconvergence (as a result of small number of transmissions).

tervention group was 0.97 compared with the control group (95% CI: 0.72–1.30; $P = .83$).

We also performed a preplanned stratified analysis to assess whether the rate of respiratory illness transmission in intervention families was associated with amount of sanitizer use. Primary caregivers reported using the hand sanitizer with a median frequency of 5.2 times per day. Fifty-five (38%) of the intervention families used >2 oz of hand sanitizer per 2-week period (which corresponds to ~60 pushes [1 mL each] from a pump bottle, or 4–5 uses per day). We compared secondary respiratory illness rates in these families with rates in families who used ≤2 oz per 2-week period. Adjusting for the same covariates as in the primary model, the IRR of secondary respiratory illness for those who used the larger amount of hand sanitizer was 0.81 compared with those who used the smaller amount (95% CI: 0.65–1.09; $P = .06$). In addition, comparing each stratum within the intervention group with control families, those who used the larger amount of hand sanitizer had an IRR of 0.83 (95% CI: 0.60–1.17) for secondary respiratory illness, whereas those who used the smaller amount had an IRR of 1.02 (95% CI: 0.74–1.41). This dose-response relationship was not observed for GI illness; the adjusted IRR for secondary GI illness was similar in those who used >2 oz of hand sanitizer per 2-week period compared with those who used ≤2 oz (IRR: 0.93; 95% CI: 0.21–4.16). However, the small numbers of secondary GI illnesses make investigation of such a trend difficult.

To ensure that seasonal differences did not influence our findings, we analyzed the impact of month of enrollment on illness transmission. There were no differences in either GI or respiratory illness transmission rates among families who entered the study in the first half of the enrollment period compared with those who began in the second half (data not shown).

Forty-five families reported 112 adverse events related to hand sanitizer use in 97 (7%) of the 1387 telephone calls; 21 of these families reported an adverse event only once, and 24 of them reported an adverse event on 2 or more occasions. Seventy-one (63%) of the 112 reported reactions were "dry skin," and 20 (18%) were "irritation." Other reported adverse events such as "stinging" ($n = 11$), "smells bad" ($n = 7$), "dislike it" ($n = 2$), "allergic reaction" ($n = 2$), and "too slippery" ($n = 1$).

DISCUSSION

We report the results of the first randomized, controlled trial to assess a multifactorial promotional campaign focusing on increasing alcohol-based hand sanitizer use in the home setting. This intervention significantly reduced the transmission of GI illnesses in the homes of families with children who were enrolled in out-of-home child care. In addition, although an overall effect on transmission of respiratory illness was not demonstrated, families who used >2 oz of hand sanitizer per 2-week period tended to have a lower rate of secondary respiratory illness than families who used a smaller volume of hand sanitizer.

In 2002, the Centers for Disease Control and Prevention emphasized the role of alcohol-based hand sanitizers as part of a comprehensive strategy to improve hand hygiene in health care settings.[54] Waterless hand-hygiene agents reduce the time required to perform hand hygiene and provide a good alternative to handwashing when access to a sink is not convenient.[55–57] These characteristics may be especially advantageous in the home, where busy family members have frequent exposure to infectious agents while caring for children with respiratory or GI disease (eg, diaper changing, wiping respiratory secretions from the face). Hand sanitizers are affordable and widely available; nearly 40% of primary caregivers in our study population reported ever having used them.

The observed effect of alcohol-based hand sanitizers on the transmission of GI illnesses in this study is consistent with known data. Previous studies have suggested that rotavirus (the most common cause of GI infection in the child care setting) is not removed effectively by routine handwashing with soap and water, whereas alcohol reliably kills the virus.[21,58,59] Noroviruses may be killed less efficiently by alcohol-based products,[44] although fewer data exist regarding this issue because noroviruses cannot be grown easily in culture systems. Although the CI for the IRR is wide, reflecting the relatively low number of secondary GI illnesses observed during our study, the upper limit is <1.0 and the reduction in illness transmission is statistically significant. Even if the true reduction in GI-illness transmission is lower than our point estimate of 59%, it remains clinically important because of the enormous number of intestinal infectious diseases in the United States, which may approach 100 million cases annually, and because of their cost, which has been estimated at $23 billion per year in health care expenditures and lost productivity.[60]

We were somewhat surprised by the failure of the intervention to reduce the overall rate of secondary respiratory illness. Alcohol is active against many common respiratory viruses,[61] although one study found it to be relatively less effective than several other antimicrobial preparations in inactivating rhinovirus on the hands.[62] A previous observational study suggested that use of alcohol-based products was associated with a reduced risk for transmission of respiratory illness in the home.[38] We found in this study (as demonstrated by our hand-hygiene–practice score) that hand-hygiene practices were less consistent around events that may lead to the transmission of respiratory illness than around events that lead to GI-illness transmission. For example, most caregivers at baseline reported that they wash their hands after using the bathroom and after changing a child's diaper; in contrast, fewer wash their hands after wiping a child's nose. This inconsistency in hand-hygiene practices could mask the ability to detect an impact of hand sanitizer use on respiratory illness transmission. Moreover, we found that families who used more hand sanitizer experienced fewer secondary respiratory illnesses than those who used smaller amounts. These data suggest that the impact of adherence may have influenced our ability to detect an effect in our overall outcome measure. In addition, although common respiratory viruses are transmitted primarily by contact via the hands,[17–20] it is possible that any contribution of droplet transmission may have reduced our ability to demonstrate an impact of hand hygiene. Our final enrollment was below our preplanned sample size of 348 families; however, our observed sample size of 292 families (137 control and 155 intervention) still provides 75% power to detect a 20% reduction in respiratory illness transmission. Given that the observed IRR was close to 1.0, lack of power is unlikely to be the explanation for our inability to detect the anticipated difference in respiratory illness transmission.

This study has several limitations. Documentation of illness was based on symptom reporting by caregivers rather than microbiologic confirmation of infection. However, previous work has suggested that symptom reporting for respiratory and GI illnesses is a valid proxy for physician assessment.[63–65] Neither the participants nor the investigators were blinded. However, we attempted to reduce ascertainment bias by the use of structured instruments to record data (symptom diaries for families to increase the accuracy of recall and structured telephone interview forms for data collectors). We did not directly observe hand sanitizer use in this study, and it is possible that families overreported the amount of sanitizer used to conform to social expectations. However, in our secondary analysis that examined the relationship of amount of hand sanitizer use to illness transmission rates, any overestimation of sanitizer use likely would result in an underestimation of its true impact on illness transmission. In addition, our study design does not allow us to separate the impact of hand sanitizer use from the effect of the educational intervention. However, handwashing practice scores were similar in both groups, providing confidence that the observed impact on illness transmission is not attributable solely to increased use of soap and water. Finally, the low initial rate of participation may limit generalizability to families who are willing to take part in such a study. In addition, because our families were largely white and many had high income and education levels, the results may be difficult to generalize to families of different cultural backgrounds or lower socioeconomic status.

CONCLUSIONS

We have shown that the use of a multifactorial hand-hygiene intervention that included educational outreach, reminders, and free supply of alcohol-based hand sanitizer can reduce the transmission of GI illness in the homes of families with children in out-of-home child care. Respiratory illness transmission may also be reduced among families who use these products in larger amounts. Hand sanitizers are widely available and could be included as one component of a larger public health strategy for disease prevention. Additional research may help to define the precise role of hand sanitizers in the home, but multifaceted efforts to reduce illness transmission should include discussions about hand sanitizers, especially during episodes of illness in the family. Health care and child care providers are particularly well positioned to deliver these health messages to parents within the larger context of hand-hygiene education.

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CHILDREN OF JEHOVAH'S WITNESSES AND ADOLESCENT JEHOVAH'S WITNESSES: WHAT ARE THEIR RIGHTS?

"The Jehovah's Witnesses Society (JW), a fundamentalist Christian sect, is best known to laypersons and healthcare professionals for its refusal of blood products, even when such a refusal may result in death. Since the introduction of the blood ban in 1945, JW parents have fought for their rights to refuse blood on behalf of their children, based on religious beliefs and their right to raise children as they see fit. Adolescent JWs have also sought to refuse blood products based on their beliefs, regardless of the views of their parents."

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