

A Pilot Study of the Effectiveness of a School-Based Influenza Vaccination Program

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ABSTRACT. *Objective.* The objective of this study was to evaluate the feasibility of a school-based influenza immunization program.

Methods. Pupils and their families from 3 demographically similar elementary schools participated in this pilot, unblinded, controlled intervention study. Live attenuated influenza vaccine (FluMist) was made available to all eligible pupils in 1 target school during regular school hours. Two schools where vaccine was not offered served as control schools. All families from the 3 study schools were sent an anonymous questionnaire requesting 7-day recall data on fever or respiratory illness (FRI)-related medical visits, medications purchased, and days of school or paid work lost during the peak influenza week. Changes in weekly pupil absenteeism were also examined.

Results. One hundred eighty-five (40%) of the target school pupils received vaccine, of whom >50% were vaccinated ≤ 3 weeks before the influenza outbreak period. Questionnaires were returned by 43% to 51% of households. Significant (45–70%) relative reductions in FRI-related outcomes, including doctor visits by adults or children, prescription or other medicines purchased, and family schooldays or workdays missed, were observed for target school households, compared with control school households. The increases in absenteeism rates during the influenza outbreak period, compared with baseline rates earlier in the fall, were not significantly different between target and control schools. Within the target school, however, the increase in absenteeism rates was significantly smaller for the FluMist-vaccinated pupils, compared with the non-FluMist-vaccinated pupils.

Conclusions. This school-based influenza immunization program was associated with significant reductions in FRI-related outcomes in households of pupils attending an intervention school. These results might have underestimated the potential impact of FluMist, because the majority of children received intraepidemic vaccination. *Pediatrics* 2005;116:e868–e873. URL: www.pediatrics.org/cgi/doi/10.1542/peds.2005-1301

[pediatrics.org/cgi/doi/10.1542/peds.2005-1301](http://www.pediatrics.org/cgi/doi/10.1542/peds.2005-1301); *influenza, vaccination, live attenuated, school-based.*

ABBREVIATIONS. FRI, fever or respiratory illness; TIV, trivalent inactivated vaccine.

Approximately 5% to 20% of US residents contract influenza each year. Of these, ~200 000 are hospitalized because of influenza-related complications, and 36 000 die as a result of complications of influenza. Rates of serious illness and death are highest among persons ≥ 65 years of age and persons of any age who have medical conditions that place them at increased risk for complications of influenza.^{1,2} Influenza-related costs are estimated to be between 11 and 18 billion dollars annually, including medical care utilization, medications, school-days lost, and workdays lost.^{3,4}

Children experience higher rates of influenza infection⁵ and they shed greater quantities of influenza viruses for longer periods of time, compared with adults.^{6–8} School-aged children are important vectors for the spread of influenza within their households.⁹ Influenza-related illnesses and school absenteeism have been observed to peak among schoolchildren before the occurrence of influenza-related illnesses and industrial absenteeism among adults in the same community.¹⁰

Vaccinating school-aged children might be an effective method of interrupting the chain of transmission and thereby reducing influenza-related morbidity in households and the entire community. In Japan, the cessation of a policy regarding influenza vaccination of schoolchildren was associated with increases in influenza-related and overall mortality rates among the elderly.¹¹ Vaccinating school-aged children with inactivated influenza vaccine in Michigan was associated with a reduction of influenza-like illness in the community.¹²

Influenza vaccination in physician practices involves a substantial amount of waiting room, medical staff, and examination room time.¹³ Administration of vaccines in school settings is a more efficient method of vaccinating large numbers of children, compared with individually appointed office visits.¹⁴ School-based immunization programs have been used in the past to administer influenza vaccines in Japan and Russia.^{15,16} Also, school-based settings have been used to administer live attenuated vac-

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Conflict of interest: Dr Stoddard is an employee of MedImmune, Inc, manufacturer of FluMist. Dr Tsai is an employee of Wyeth Vaccines. Wyeth Vaccines had a co-marketing agreement with Aviron, now part of MedImmune.

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cines, including poliomyelitis, varicella, measles, and rubella, and inactivated vaccines, such as hepatitis B, diphtheria, tetanus, and pertussis.^{17–20}

This small pilot study was designed to assess the feasibility of a school-based influenza immunization program and to examine its impact on influenza-related morbidity in the households of target school pupils. FluMist (influenza virus vaccine, live, intranasal; MedImmune, Gaithersburg, MD) was offered, at no cost, to healthy pupils in 1 elementary school (the target school). Influenza-related outcomes were compared between target school households and households of pupils in 2 control schools where FluMist was not offered. Outcomes measured included fever or respiratory illness (FRI)-related medical care utilization by household members, medication/humidifier purchases for household members, days of school lost by children, and days of paid work lost by adults. Overall pupil absenteeism was compared between the target and control schools during an influenza outbreak in the community and during the peak influenza week. Pupil absenteeism also was compared within the target school between FluMist and non-FluMist recipients during the influenza outbreak and during the peak influenza week.

METHODS

Study Design

This was an open-label, unblinded, controlled, community intervention study in which FluMist was offered to all healthy children ≥ 5 years of age in 1 target public elementary school during the fall of 2003. The selection of the target school was based on an established close working relationship with the school's staff in a previous influenza-related study.²¹ Two Carroll County elementary schools were selected as control schools on the basis of comparability to the target school with respect to geographic proximity, ethnic and socioeconomic distributions, and total numbers of enrolled pupils.

Recruitment

Parents were informed about the study through videotapes, informational flyers, posters, and various school-based functions. Interested parents contacted the school-based study nurses, who answered questions, confirmed the medical eligibility of the child, and obtained written informed consent.

Vaccine Eligibility

Children were eligible to receive vaccine if they attended the target school and their personal health care provider confirmed eligibility in accordance with the prescribing information and provided authorization for immunization. All vaccinated children were ≥ 5 years of age. Exclusion criteria included a history of severe hypersensitivity to eggs, a history of Guillain-Barré syndrome, concurrent aspirin therapy, chronic underlying medical conditions, immunosuppression, and a severely immunocompromised household member. The school nurse estimated that $\sim 20\%$ of the students would not be medically eligible.

Study Procedures

After written informed consent was obtained from the parents/guardians, study registered nurses administered the 2003–2004 formulation of FluMist (each dose formulated to contain $10^{6.5-7.5}$ times the 50% tissue culture infective dose of live attenuated influenza virus reassortants of the strains recommended by the US Public Health Service for the 2003–2004 season, ie, A/New Caledonia/20/99 [H1N1], A/Panama/2007/99 [H3N2] [A/Moscow/10/99-like], and B/Hong Kong/330/2001) to students during regular schooldays between November 4, 2003, and January 12, 2004. Children < 9 years of age were offered a second dose of FluMist 6 to 10 weeks after the first dose, in accordance with prescribing

information. Vaccine was transported to the target school on dry ice, where it was stored in a regular freezer in insulated storage containers provided by MedImmune, to maintain a constant temperature of -15°C or below. Vaccine was thawed just before use; if it was not used, it was discarded.

Influenza Surveillance

Community influenza surveillance was performed by using culture or antigen test results from the University of Maryland Medical Center Hospital Virology Laboratory, which is ~ 40 miles from the study schools. This laboratory receives and tests ~ 20 to 80 respiratory viral samples per week from 2 hospitals in the greater Baltimore metropolitan area. Two pediatric practices and 1 family medicine practice in Carroll County were given rapid influenza A and B antigen diagnostic test kits, at no charge, in return for providing weekly information on anonymous influenza test results to the study coordinators. These community practices were within 5 to 15 miles of the study schools.

According to the Center for Disease Control and Prevention, the 2003–2004 influenza season in the United States was characterized by the early onset of influenza activity; reports of severe illness, particularly among children; and predominant circulation of an influenza A (H3N2) virus strain that was antigenically distinct from the influenza A (H3N2) vaccine strain.²² Nationally, of the influenza A (H3N2) isolates that were characterized, 89% were similar to the drift variant A/Fujian/411/2002 (H3N2), whereas only 11% were antigenically similar to the vaccine strain A/Panama/2007/99 (H3N2).

Outcome Measures

On December 19, 2003, a self-administered, anonymous questionnaire was distributed to households of all pupils in both the target and control schools. The investigators selected this date as an estimate of peak influenza activity in the community, based on the Centers for Disease Control and Prevention and local influenza surveillance data and the prediction that the 2-week holiday vacation period from December 20, 2003, to January 4, 2004, would dampen the influenza outbreak. The household survey form elicited no personal identifying information and included questions about household composition and the receipt of either FluMist or parenteral trivalent inactivated vaccine (TIV) by household members that season. Using a 7-day (December 13–19, 2003) recall period, the survey elicited information regarding the occurrence of FRI, which was defined as a temperature of $> 100.4^{\circ}\text{F}$ or cough, wheezing, pharyngitis, runny nose, nasal congestion, sinus problem, earache, ear infection, headache, or muscle aches. FRI-related medical visits (medical offices or emergency departments) by adults and children were recorded. The survey also included questions regarding the number of FRI-related purchases, such as over-the-counter medications, herbal or natural remedies, prescription medicines, and humidifiers. Finally, the numbers of FRI-related days of school lost by children and days of paid work lost by adults were recorded by the respondents for the 7-day period. Parents were asked to mail back the completed questionnaires within 3 weeks after distribution. Returned surveys could be distinguished between target and control schools but contained no personal identifiers.

The Carroll County Public School System provided aggregate data from the 3 study schools on weekly absenteeism, regardless of cause, throughout the entire school year. For the target school, study coordinators collected individual weekly absentee data for children who received FluMist with the consent of their parents/guardians. Comparative weekly absenteeism rates among non-enrolled children in the target school were then calculated by subtracting the absences for vaccinated children from the total numbers of absences in the target school.

Data Analysis

Mean weekly absenteeism rates were calculated for each school. The peak influenza week was defined as the week when the largest number of positive tests for influenza was detected through community surveillance. The influenza outbreak period was defined as the cluster of consecutive weeks (including the peak influenza week) that encompassed 85% of the total positive tests for the season. The baseline period was defined as the school weeks of September and October.

To analyze the household questionnaire data, family-specific rates were calculated for each outcome and treated as the data points in the comparisons between schools. The effect of the intervention was then estimated by comparing the target school with the control schools with respect to the mean value for each outcome. *P* values were calculated with a mixed-effects regression model to account for correlation in the outcomes within schools.

To assess the impact of the intervention on absenteeism rates, we compared the target school with the control schools with respect to changes in absenteeism rates between baseline and influenza outbreak weeks. *P* values for this comparison were calculated with a 2-sample *t* test. We also compared absenteeism among children in the target school who received FluMist with that among children in the target school who did not receive FluMist. *P* values for this comparison were calculated by treating the difference in absenteeism between those who received FluMist and those who did not receive FluMist during each week as independent data points. A 2-sample *t* test was used to determine whether the mean difference in absenteeism rates between these groups during the baseline period differed significantly from the mean difference observed during the outbreak weeks.

RESULTS

The 3 study schools were similar with respect to geographic location, ethnic distribution, number of students, and percentage eligible for free lunches (a proxy measure for family income) (Table 1). A total of 202 signed consent forms were obtained for children in the target school; 14 children were later deemed medically ineligible by their physicians, and 3 were withdrawn from participation by their parents. Therefore, a total of 185 (40%) of the 460 target school pupils received a first dose of FluMist intranasally in this school-based program between November 4, 2003, and January 12, 2004. Ninety percent of the first doses were given by December 9, 2003. A second FluMist dose was given to 112 pupils between December 12, 2003, and February 10, 2004.

Surveillance data revealed that influenza occurred in the community beginning in the second week of November (Fig 1). Figure 1 also demonstrates the cumulative FluMist immunization efforts in the target school. It should be noted that much of the immunization intervention was conducted concurrently with the influenza outbreak period, which occurred early in the season, between December 1, 2003, and January 5, 2004. The peak influenza week was December 8 to 14, 2003.

The household questionnaire was distributed on December 19, 2003, temporally close to the peak influenza week. Questionnaires were returned by 157 families (43%) from the target school, 222 (51%) from control school 1, and 230 (47%) from control school 2. In the families that returned the questionnaires, the mean number of adults per household was 1.8 for the target school and 1.8 and 1.9 for control schools 1 and 2, respectively. The mean number of children per

household was 2.2 for all 3 study schools. Data from the household questionnaire revealed that similar proportions of elementary school pupils had received TIV in each of the study schools (17% in the target school and 12% in the control schools) but 49% of the target school pupils and none of the control school pupils had received FluMist. Respondents to the questionnaire indicated that TIV was used by 21% of the target school and 20% of the control school adults and by 14% and 12% of all of the children in the target and control school households, respectively. Also, FluMist was used by 1% of the target school and 0.2% of the control school adult household members and by 2% of the target school and none of the control school household children who were not in elementary school.

Significantly fewer FRI-related ambulatory physician visits during the 7-day recall period were reported for both adults and children in the target school households, compared with those in the control school households (Table 2). There were significantly fewer purchases of over-the-counter and prescription medications for FRI by the target school households, compared with the control school households. There was a trend toward fewer herbal/natural remedies purchased by target school households for FRI, compared with control school households. Finally, for the 7-day recall week, there were significant reductions in FRI-related days of work lost by adults and days of school lost by all children in the households of pupils attending target schools, compared with those attending control schools.

The increase in absenteeism rates during the influenza outbreak period or peak influenza week over baseline rates in September and October did not differ significantly between the target and control schools (Table 3). However, in the target school, during the influenza outbreak period, there was a significantly smaller increase in absenteeism rates, compared with baseline, for FluMist recipients versus non-FluMist recipients ($P < .05$) (Table 3). Similarly, there was a trend toward a smaller increase in absenteeism during the peak influenza week, compared with baseline, for FluMist recipients versus non-FluMist recipients ($P = .10$). However, unvaccinated children had a higher absenteeism rate during the baseline period, which suggests that these populations might be different.

DISCUSSION

During the peak week of influenza activity, there were significant reductions in FRI-related outcomes in the households of pupils attending the target

TABLE 1. Descriptive Characteristics of the Study Elementary Schools

Demographic Characteristics	Target School	Control Schools	
		School 1	School 2
Distance from target school, miles		13	10
Pupils who are white, %	93	94	97
Pupils who receive free lunch, %	18	14	13
Total no. of pupils	481	565	620
Mean daily absenteeism rate for entire previous school year, 2002–2003, %	4.96	4.45	4.22

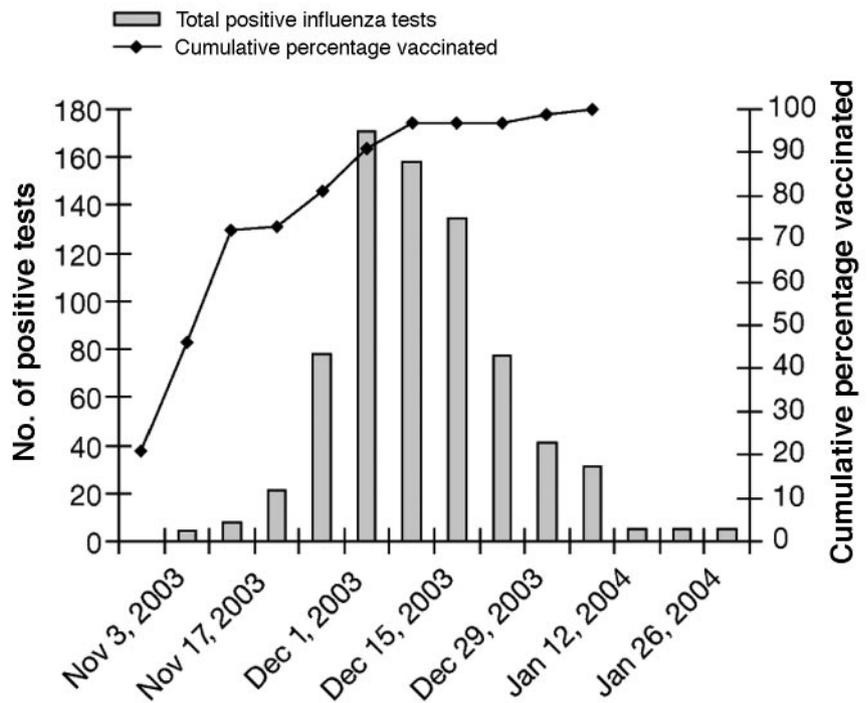


Fig 1. Community surveillance data for influenza for 2003–2004 and cumulative percentage of the 185 pupils who received their first dose of FluMist, according to date.

TABLE 2. FRI-Related Outcomes for Target and Control Schools

Outcome	Target School (n = 157)	Control Schools		P Value*
		School 1 (n = 222)	School 2 (n = 230)	
Mean rate of adult medical visits, no. per 100 adults	3.3	8.9	8.9	.015
Mean rate of child medical visits, no. per 100 children	5.6	15.3	18.3	.0008
Mean rate of adult emergency department visits, no. per 100 adults	0.6	0.3	0.5	.66
Mean rate of child emergency department visits, no. per 100 children	0.0	1.7	1.0	.29
Over-the-counter medications purchased, no. per 100 households	25.9	51.2	44.5	.0016
Herbal/natural medications purchased, no. per 100 households	4.0	15.0	10.0	.072
Prescription medications purchased, no. per 100 households	10.6	27.8	26.8	.002
Humidifiers purchased, no. per 100 households	3.4	4.7	9.6	.41
Mean rate of paid workdays lost, d per 100 adults	1.3	7.0	5.7	.0004
Mean rate of schooldays lost, d per 100 children	4.1	7.2	8.2	.023

* P values compare the target school with the control schools with a model that controls for between-school variation by including a random effect for school.

school with a school-based influenza vaccination program, compared with households of pupils who attended demographically similar control schools without this program. Target school household members had fewer medical visits, medications purchased, paid workdays lost by adults, and schooldays lost by children, compared with households of control school pupils.

These findings emphasize the important role that young schoolchildren play in the transmission of wild-type influenza to their households and presumably the community. Neuzil et al⁹ found marked excesses in secondary illnesses among household members (adults and siblings) after a child's absence because of illness during an influenza outbreak, com-

pared with absences during the noninfluenza period. They also found significant increases in analgesic use and parental industrial absenteeism during the influenza outbreak period. The importance of children in the spread of influenza to the rest of the community is also illustrated by the observation that, during influenza outbreaks, school absenteeism, pediatric emergency department visits, and pediatric hospitalizations for treatment of pneumonia all predate industrial absenteeism, adult emergency department visits, and adult pneumonia hospitalizations.¹⁰ Finally, it has been observed that there is a reduction in respiratory disease morbidity rates in the entire community when schools are closed during high levels of influenza activity.²³

TABLE 3. Absenteeism Rates in Target and Control Schools

Time Period	Absenteeism Rate, %						
	Target School	Control Schools		<i>P</i> Value*	Target School		<i>P</i> Value‡
		School 1	School 2		Pupils Who Received FluMist	Pupils Who Did Not Receive FluMist†	
Baseline (September and October 2003)	5.9	5.9	4.5	.69	3.4	7.8	.0001
Influenza outbreak period (December 1, 2003, to January 5, 2004)	7.9	7.6	7.4	.27	4.1	10.2	.0011
Peak influenza week (week of December 8–14, 2003)	9.2	10.2	8.9	.81	4.9	11.9	NA
Change between baseline and outbreak period	2.0	1.6	2.9	.86	0.7	2.4	.045
Change between baseline and peak influenza week	3.3	4.2	4.4	.11	1.5	4.1	.099

NA indicates not available (insufficient degrees of freedom to calculate).

* Based on a 2-sample *t* test.

† Includes target school children who received no vaccine and those who received inactivated influenza vaccine (estimate: 17%).

‡ Calculated with a *t* test by using the differences between the groups in each week as independent data points.

Evidence that immunization of young children can reduce the impact of influenza in households was reported previously. Vaccination of children attending out-of-home care with inactivated influenza vaccine was associated with significant reductions in febrile respiratory illnesses, missed schooldays, adult missed workdays, physician visits, antibiotics prescribed, and over-the-counter medications used in their households, compared with households of non-immunized children.²⁴ Finally, immunization of large numbers of children with inactivated vaccine has reduced the impact of influenza on the community as a whole.¹²

In the present study, changes in pupil absenteeism from baseline (September to October 2003) to the influenza outbreak period were similar in the target school and the control schools. Within the target school, there was a smaller increase in absenteeism during the peak influenza week, compared with baseline, for FluMist-vaccinated children versus unvaccinated pupils. However, the baseline rates of absenteeism in September and October were lower for FluMist recipients, compared with non-FluMist recipients, which suggests that comparing study outcomes for these 2 groups could be problematic.

Several factors might have contributed to the lack of observed differences in overall absenteeism between the study schools. First, only 40% of the target school pupils received FluMist. Second, all absenteeism, without respect to cause, was recorded. It is likely that there were many non-influenza-related causes for missing school. Third and perhaps most important, the influenza outbreak started very early in 2003, close to the time when FluMist was offered in the target school; therefore, the majority of children received intraepidemic vaccination. Fourth, many pupils in the intervention school received only a single vaccine dose before the arrival of the peak influenza activity week. Although a 1-dose schedule for children showed significant efficacy among children (89%), pooled data from several studies favored (73% vs 93%) a 2-dose regimen.^{25,26} Last, there was a

mismatch between the vaccine strain (A/Panama/2007/99-like) and the most common circulating A/H3N2 strain (A/Fujian/411/2002-like) in the United States.²⁷ Therefore, the pupils who received FluMist might not have been able to develop maximally protective immune responses. However, despite the lack of an observed effect on the vaccinated children themselves in terms of absenteeism, an apparent protective impact on their households was seen. These observations parallel those of Hurwitz et al,²⁴ who found similar indirect effects on household members of vaccinated day care attendees, although no efficacy against influenza was demonstrated among the inactivated vaccine recipients themselves.

There are several limitations of the present study. First, the selection of the target school was not random but rather was based on prior experience with the school by the study staff. Second, the study was neither blinded nor placebo controlled. These factors could contribute to bias in the responses to the household questionnaire, the primary tool used to assess influenza-related outcomes between target and control schools. Also, the study was small, in terms of both numbers of children and numbers of schools. The relatively low uptake of FluMist among target school pupils (40%) might have been attributable to parental caution, because this was a new type of vaccine in its first year of licensure. Also, vaccination was delayed until November 4 and the influenza outbreak started early (December 1), which likely reduced uptake because parents might have thought that it was too late for vaccination. Last, although the schools were clustered within a relatively small geographic area, there was no certainty that influenza affected the households of the 3 schools equally.

Despite these limitations, the observed results suggest that clinically meaningful outcomes can be obtained with a school-based influenza prevention program. This study also demonstrates acceptance of a school-based influenza immunization program by a substantial number of parents, despite the novelty of the vaccine and the setting for vaccination. On the

basis of this pilot project, a randomized study of select target and control schools in 4 areas throughout the country has been launched to address the problems of bias, unequal penetration of influenza infections, and small sample size. Live, attenuated, cold-adapted, influenza vaccine is ideal for use in a school-based immunization program. The needle-free intranasal delivery method may be perceived to be less noxious for children than parenteral vaccine. Furthermore, the convenience of a school-based vaccination program should increase the proportion of children immunized, because parents can avoid missing work or other activities to take their child to a primary care office for influenza vaccination.

CONCLUSIONS

An elementary school-based influenza immunization program was associated with significant reductions in FRI-related outcomes in the households of pupils attending an intervention school. These findings were especially impressive because the majority of children received intraepidemic vaccination. Additional studies are warranted to examine the feasibility, public health, and economic issues related to school-based influenza immunization efforts.

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