Mass Distribution of Free, Intranasally Administered Influenza Vaccine in a Public School System
L. Rand Carpenter, John Lott, Brian M. Lawson, Stephanie Hall, Allen S. Craig, William Schaffner and Timothy F. Jones

Pediatrics 2007;120;e172-e178; originally published online Jun 25, 2007;
DOI: 10.1542/peds.2006-2603

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://www.pediatrics.org/cgi/content/full/120/1/e172
ARTICLE

Mass Distribution of Free, Intranasally Administered Influenza Vaccine in a Public School System

L. Rand Carpenter, DVM\textsuperscript{a,b}, John Lott, MS\textsuperscript{c}, Brian M. Lawson, MA\textsuperscript{c}, Stephanie Hall, MD, MPH\textsuperscript{c}, Allen S. Craig, MD\textsuperscript{b}, William Schaffner, MD\textsuperscript{d}, Timothy F. Jones, MD\textsuperscript{b}

\textsuperscript{a}Epidemic Intelligence Service, Centers for Disease Control and Prevention, Atlanta, Georgia; \textsuperscript{b}Communicable and Environmental Disease Services, Tennessee Department of Health, Nashville, Tennessee; \textsuperscript{c}Knox County Health Department, Knoxville, Tennessee; \textsuperscript{d}Department of Preventive Medicine, Vanderbilt University School of Medicine, Nashville, Tennessee

Financial Disclosure: Mr Lott and Dr Jones were unpaid attendees at a meeting of the MedImmune 2006 FluMist for Schools Advisory Board meeting, where results of this mass vaccination campaign were presented. Dr Schaffner served as a session moderator at the same meeting and received an honorarium.

ABSTRACT

OBJECTIVE. School-based influenza vaccination programs are a potentially important method of protecting the community against influenza. We evaluated the feasibility and success of a large, school-based influenza vaccination campaign.

METHODS. On-site administration of intranasally administered, live attenuated influenza vaccine was offered to all students and staff members in a large, metropolitan public school system in October to December 2005. We evaluated vaccine coverage levels, resources expended, and physician and parent attitudes and knowledge.

RESULTS. Of 53,420 public school students, 24,198 were vaccinated with live attenuated influenza vaccine. Of 5,841 school staff members, 3,626 were vaccinated with live attenuated influenza vaccine or inactivated influenza vaccine. The proportions of students vaccinated were 56% among elementary schools, 45% among middle schools, and 30% among high schools. Schools with larger proportions of black or low-income families had lower vaccine coverage levels. The health department and school system expended 6,900 person-hours during the campaign, and various health department clinics were closed for a total of 84 half-days. Community physicians were supportive of the campaign and frequently advised participation for eligible patients. Some physicians had misunderstandings about live attenuated influenza vaccine contraindications. Concern about adverse effects, having asthma, negative physician advice, and nonparticipation in any vaccination program were common reasons for students not participating.

CONCLUSIONS. This influenza vaccination campaign in a large public school system achieved relatively high vaccine coverage levels but required a substantial resource commitment from the local health department. This evaluation has critical implications for the ongoing debate regarding immunization policies for school-aged children and preparedness plans for pandemic influenza.
Five percent to 20% of the US population may be infected with influenza each year, and influenza is associated with an average of ≥200,000 hospitalizations and 36,000 deaths annually.1-3 Among school-aged children, influenza attack rates can be as high as 25% to 30%, generally higher than for all other age groups.3-5 This high influenza morbidity rate among schoolchildren leads to excess school absenteeism and increased parental work absenteeism.5 Children have long been considered to be important sources of influenza in the community.3,4,6,7

Vaccination of schoolchildren in a small Michigan city reduced overall influenza morbidity in the community.8 A school vaccination program in Japan resulted in reduced numbers of influenza-related deaths among elderly individuals.9 Recent studies demonstrated reductions in the occurrence of acute respiratory illness in families and the community after vaccination of 25% to 47% of school-aged children with intranasally administered, live attenuated influenza vaccine (LAIV).10-12

LAIV is a temperature-sensitive, live attenuated virus vaccine that offers protection against influenza A and B viruses. This cold-adapted, heat-labile vaccine replicates readily in the upper respiratory tract and produces an immune response but does not replicate efficiently in the lower respiratory tract. The risk of LAIV virus transmission to others is thought to be very low.11,14 LAIV is licensed for use among healthy children and adults 5 to 49 years of age. LAIV has been reported to provide effective durable immunity, including protection against antigenically related influenza strains not included in the vaccine.15-17 It is administered annually as a single-dose nasal spray into each nostril and is well tolerated by children.14 These characteristics make LAIV an attractive choice for use in school-based mass vaccination campaigns. Strategies for mass vaccination have implications for planning for pandemic influenza. We evaluated a campaign to vaccinate students with LAIV in a large, metropolitan, public school system, to assess feasibility and success.

**Methods**

Knox County, Tennessee (population: 389,327), includes the city of Knoxville and has a single public school system. The county health department staff of 299 persons includes 84 doctors and nurses. In June to December 2005, a campaign was conducted to provide LAIV to students and staff members in the Knox County public school system. The campaign’s objective was to offer LAIV, free of charge, to all eligible students ≥5 years of age in kindergarten through 12th grade and to school staff members. The vaccine was donated by the manufacturer (MedImmune, Gaithersburg, MD), but most costs associated with education, administration of the campaign, and purchase of inactivated vaccine were borne by the Knox County Health Department.

Planning and community education began in June, and vaccinations occurred in October to December. Initial planning included managers from the health department and the school system. County health department staff members made numerous informational presentations to the regional children’s hospital staff, a local medical organization, school principals, and parent-teacher associations. News media were informed through press releases and interviews with health department staff members. Information about childhood influenza vaccination and LAIV was sent directly to local physicians’ offices and hospitals through the use of facsimile and mail. The health department established a telephone help-line for questions from parents, school staff members, students, and health care providers in the weeks before and during the campaign.

Health department staff members were responsible for LAIV inventory, including ordering, storing, and dispensing. Schools sent an introductory letter, a vaccine information sheet, the Centers for Disease Control and Prevention LAIV Information Statement, and a consent form home with each student. The completed forms, signed by a parent or guardian, were collected by school personnel; distribution and collection methods varied among schools. Vaccination teams, including health department and school nurses, health department physicians, and administrative personnel, were trained in campaign protocols. The first round of vaccination included 3 to 6 schools per day, with a target time limit at each location of 3 hours.

Recipients were required to be 5 to 49 years of age with no chronic medical conditions, immunosuppression, hypersensitivity to egg products, history of Guillain-Barré syndrome, or history of asthma, as reported on the consent form. School staff members who were not eligible for LAIV were offered trivalent inactivated influenza vaccine (TIV), but students were not offered TIV because of financial and time constraints during the campaign. Students <9 years of age who had not been administered influenza vaccine (either TIV or LAIV) previously were offered a second dose of LAIV. Second doses were provided in December, during a single follow-up visit to each school; at the same time, persons who desired vaccination but had not been vaccinated during the first round were offered LAIV.

Information regarding each school’s vaccine coverage levels and student and staff member demographic features was collected by health department staff members. Health department administrators tracked resources expended by health department and school nursing staff members throughout the campaign. Coverage levels were based only on vaccine administered on-site, and the number of persons vaccinated outside the campaign was not assessed. Eligibility for the National School Lunch Program, based on low household income, was used to approximate the mean socioeconomic status of

---

*PEDIATRICS Volume 120, Number 1, July 2007 e173*
each school’s students. School absenteeism after vaccination was monitored daily by health department personnel, using a previously described, automated, early aberration reporting system. An anonymous questionnaire was mailed to all primary care physicians in Knox County, to assess knowledge, attitudes, and perceptions regarding the campaign and influenza vaccination. A second survey asking about campaign participation of 1 student in the household was mailed to the parents or guardians of a random sample of students. The sample of 11% of students was selected by using the SPSS (SPSS Inc, Chicago, IL) “random sample of cases” function. Responses were returned anonymously. Data were analyzed by using Epi-Info (Centers for Disease Control and Prevention, Atlanta, GA) and SAS 9.0 (SAS Institute, Cary, NC) software. This evaluation was classified as a public health program evaluation by the institutional review board of the Tennessee Department of Health and the Centers for Disease Control and Prevention.

RESULTS

Vaccine Coverage

The school district consisted of 81 schools with total enrollment of 53,420 students, including 43,270 (81%) white, 8,013 (15%) black, and 2,137 (4%) other races/ethnicities, as classified by the school system. Fifty elementary schools (kindergarten to 5th grade), 14 middle schools (6th–8th grades), and 12 high schools (9th–12th grades) participated in the campaign. Five alternative schools for kindergarten to 12th-grade students with special needs, students with behavioral disorders, and adult-education students (total enrollment: 197 students) were not included in this analysis.

The campaign resulted in 24,198 (45%) students vaccinated with at least 1 dose of LAIV at school. Vaccination levels were highest among elementary students (56%) and lowest among high school students (30%) (Table 1). Vaccination levels in individual schools varied from 13% to 75%. Elementary school students represented 46% of all students in the school system and 57% of vaccinated students.

A second dose of LAIV was administered to 2,945 (58%) of 5,099 students <9 years of age who received LAIV during the primary vaccination day and who required a second dose. When vaccination levels were adjusted to reflect only students who were fully vaccinated, 47% of elementary students were fully vaccinated in this campaign.

The proportion of students at each school who were eligible for free or reduced-price lunches through the National School Lunch Program ranged from 6% to 99% (mean: 48%). Students in schools with relatively higher levels of enrollment in the National School Lunch Program were less likely to have been vaccinated than were students in schools with lower levels of enrollment in the lunch program (Fig 1). Similarly, students in schools with relatively higher levels of enrollment of black students were less likely to have been vaccinated than were students in schools with lower levels of enrollment of black students (Fig 2).

Approximately one half of the students did not return consent forms. In a convenience sample of 5 schools, a mean of 5.1% of each school’s returned forms indicated ineligibility for LAIV.

Of 5,841 school staff members, 3,626 (62%) were vaccinated; 1,464 (40%) received LAIV and 2,162 (60%) were given TIV. The staff vaccination level in elementary schools was 68%, that in middle schools was 64%, and that in high schools was 58%.

No severe adverse reactions to LAIV were reported to the health department or school nurses. No marked change in absenteeism among students in any school was detected during the 2 weeks after vaccine administration.

Surveys

Questionnaires were mailed to 622 primary-care physicians. A total of 331 questionnaires (53%) were returned, and 268 respondents (81%) were aware of the vaccination campaign. Of the respondents, 233 (70%) practiced family medicine, pediatrics, or internal medicine. All pediatricians who responded were aware of the campaign. Of the 196 physicians who had given patients advice regarding the campaign, 185 (94%) had advised ≥1 patient to participate and 103 (53%) had advised ≥1 patient against vaccination. Reasons for advising a student against receiving LAIV included asthma (cited by 74% of respondents), immunocompromised status of the patient (34%), immunocompromised status of a close contact (34%), presence of a chronic metabolic disease (32%), and egg allergy or history of Guillain-
Barreé syndrome (27%). Eight physicians reported advising a patient (student or staff member) to be absent from the school on vaccination day, to avoid exposure to the vaccine virus. By using a scale of 1 to 5 (“not important” to “very important”), physicians ranked the importance of student influenza vaccination to the students’ health and to their families’ and community’s health; 84% ranked importance to the individual as either 4 or 5, and 92% ranked importance to the community as 4 or 5. All except 4 respondents ranked importance to the family and community the same as or higher than importance to the individual student.

A parent questionnaire was mailed to the homes of 5749 students. Responses were received from 1432 (25%), representing 2.7% of the student population. The distribution of respondents matched the proportions of the school population enrolled in elementary, middle, and high schools. Black students’ parents represented 5% of survey respondents, whereas black students represented 14% of the school system enrollment. Of survey respondents, 62% reported that their child had been vaccinated, compared with 45% vaccine coverage overall in the campaign. Nonparticipation in the vaccination campaign was reported by 34 (53%) of 64 parents of black students and 494 (36%) of 1339 parents of nonblack students (risk ratio: 1.44; 95% confidence interval: 1.13–1.83). The most common reasons parents gave for students not being vaccinated in the campaign included...
concerns about adverse effects (29%), having asthma (23%), being vaccinated elsewhere (19%), being advised by a physician to not participate (11%), and being someone who does not participate in vaccinations at all (10%).

Resources
The Knox County health officer and nursing director expended ~840 hours during 7 months (30% of full-time employment) preparing for and supervising the campaign. Health department staff members expended 4200 person-hours, and school nursing staff members contributed 2700 person-hours during the 2 months of vaccine administration, representing 85 person-hours per school. Approximately 75% of these person-hours were expended by professional medical personnel. Administrative hours contributed by school staff members in handling consent forms were not recorded.

To provide staffing for school vaccination days, certain health department services were closed periodically. Four remote-location health clinics and certain other health department services (eg, adult preventive care and indigent primary-care clinics) were closed for a total of 84 half-days during the 5-week vaccination campaign. Approximately 9900 patient visits were missed or delayed because of these closures.

Expenditure of health department funds for the campaign was approximately $43,000, of which $28,000 was used for the purchase of TIV. Freezers and alarm equipment for vaccine storage, dry ice for vaccine transport, printed information packets and consent forms, and expendable materials for vaccine administration cost approximately $15,000, a portion of which was supported by the LAIV manufacturer.

DISCUSSION
This school-based influenza vaccination campaign using LAIV achieved 45% coverage of students in kindergarten through 12th grade in a large, diverse, metropolitan school system. This evaluation demonstrates that coverage levels comparable to those of smaller pilot campaigns are achievable in large school systems with the application of substantial time and resources. Despite intensive efforts at education and promotion, certain population groups had low participation rates.

The LAIV package insert states that individuals with a history of asthma or reactive airway disease should not receive LAIV. The Advisory Committee on Immunization Practices also recommends that persons with asthma or reactive airway disease should not be vaccinated with LAIV. It is estimated that 5% to 15% of US children have a history of asthma and that self-reported and proxy-reported asthma rates may exceed 20%. By using a conservative 20% ineligibility estimate, the overall vaccine coverage level achieved among eligible students approached 60%. Previous LAIV vaccination efforts, with coverage levels as low as 20% of eligible children, demonstrated a reduction in the community’s burden of influenza-related illness. Stochastic modeling predicts that vaccination of only 20% of US children could reduce the number of influenza cases in the general population by 46%. Influenza vaccination of children as a strategy for community control of influenza is a topic of substantial current interest. Several lines of evidence suggest that vaccinating younger and healthier groups, in addition to persons at high risk, may benefit the larger community as well as those being vaccinated. Japanese officials began a program of influenza vaccination in schools in 1962. In 1977, influenza vaccination of schoolchildren 7 to 15 years of age became mandatory; this was followed by remarkable nationwide declines in both total excess pneumonia and influenza mortality and all-cause mortality rates. After the vaccination requirements were repealed in 1994, excess pneumonia and influenza mortality rates increased again. Ecologic evaluation of the project suggests that the vaccination of schoolchildren had an effect on mortality rates in the older population.

In 1968 and 1969, during the Hong Kong influenza pandemic, a school-based influenza vaccination campaign (kindergarten through 12th grade) was conducted in the small community of Tecumseh, Michigan, and achieved an 86% vaccination level. During the peak influenza season, school absenteeism and the community occurrence of respiratory illness were substantially lower in Tecumseh than in a control community that did not vaccinate schoolchildren. Although these evaluations of school-based vaccinations in Japan and Michigan have substantial limitations, they have each advanced the idea that influenza vaccination of children may provide an important strategy for protecting the older population.

In a multisite study in 2004 and 2005, LAIV was administered to 2717 (47%) of 5840 students in 11 elementary or parochial schools. Additional schools at the same sites served as control schools. During peak influenza season, intervention school household members reported fewer episodes of influenza-like illness, purchased fewer medications, and missed fewer days of work and school than reported among control school household members. Absenteeism during the peak influenza period was reduced among vaccinated children, compared with nonvaccinated children, in the intervention schools. Similarly, a 3-year LAIV clinical trial in Texas demonstrated that vaccination of 20% to 25% of eligible children (age: 18 months to 18 years) in the community was associated with a modest reduction in the community burden of medically attended, acute respiratory illness. A simultaneous study of the same LAIV-vaccinated children demonstrated protection against both influenza A and influenza B among vaccinees. Assessment of the feasibility of large-scale,
school-based interventions using LAIV is an important addition to these studies and was the focus of our evaluation.

Within each grade category, participation levels varied substantially among schools in Knox County. Socioeconomic status and race were important factors in this variability, and schools with relatively large proportions of economically disadvantaged students or black students had lower participation rates. The parent survey indicated that concern regarding vaccine adverse effects was a major barrier to participation. This finding is consistent with a 2004 study among Tennessee residents that indicated that nonwhite persons were less likely to be vaccinated for influenza because of concern regarding adverse effects and the lack of perceived need for influenza vaccination. Although the low response rate in our parent survey might have limited its representativeness, the survey results clearly point to a need to focus educational efforts among lower-participating groups to address safety concerns even more prominently. Fewer than 60% of children <9 years of age for whom a second dose was indicated received that second dose at school. It is possible that the second dose was delivered in another setting or that the importance of this second vaccine dose was not communicated adequately.

School district officials were eager to reduce absenteeism among students and staff members to meet state standards and to avoid school closures. During the previous year’s influenza season (2004–2005), the entire Knox County school system was closed for 2 days because of high staff absenteeism rates. To encourage support for this campaign, the health department purchased and provided TIV for staff members who were not eligible to receive LAIV. Because of financial and logistic concerns, TIV was not offered to students at school during the school-based campaign. Although it was available free to students at the Knox County Health Department, not offering TIV to LAIV-ineligible students at school likely decreased vaccine coverage among certain groups of students, including children who reported a history of asthma.

Concern regarding vaccine virus transmission was a notable barrier to campaign participation. The safety of LAIV in different situations is well established, and multiple studies have detected minimal or no vaccine virus transmission. Knox County Health Department staff members made extensive efforts to educate physicians and parents regarding vaccine safety, benefits, and contraindications during the campaign, and the physician survey revealed an extremely positive response to the campaign among physicians. Nevertheless, some physicians demonstrated confusion regarding LAIV contraindications. Concerns about vaccine virus transmission prompted several physicians to advise some patients not to participate in the campaign. Reasons cited included having a household contact with asthma or a history of chronic disease, which are not valid contraindications for LAIV. At least 4 local obstetricians advised pregnant patients to be absent from school on the day of vaccination, to avoid exposure to vaccine virus.

This campaign required extraordinary resource commitment by both the health department and the school system. Motivated supervisors within the health department provided strong leadership. However, even with donated vaccine, the demands on health department and school system personnel and the effect on regular patient services made the vaccine campaign an expensive and disruptive endeavor.

Plans for future campaigns should include provisions to reduce the public health resource burden. Planners might consider using temporary staff members or limiting the campaign to younger students, to minimize the impact on regular health department and school health functions. In addition, it is important to improve targeted education for groups with low vaccination coverage and to focus on improved professional communication with local physicians, to correct misconceptions regarding LAIV.

CONCLUSIONS
We evaluated a widely accepted, resource-intensive intranasal influenza vaccine campaign in a large school system with 45% overall vaccine coverage among students. Certain groups, including high school students, black students, and students in schools with low family incomes, should be targeted for promotion and education during future campaigns, to improve acceptance of the vaccine. The substantial expenditure of resources necessary for this campaign might limit feasibility in other settings. However, vaccination of school-aged children could serve as an important strategy for reducing influenza morbidity in the wider community, and it will be important for future studies to estimate the effects of such campaigns on community influenza rates and influenza complications. This evaluation provides important information regarding the feasibility of school-based vaccination programs for children and has potential implications for pandemic preparedness plans for vaccine distribution.

ACKNOWLEDGMENTS
The Knox County Health Department received financial support and LAIV for this campaign from MedImmune.

We thank Mike Winstead, PhD, Director of Research and Evaluation, Knox County Schools, for assistance with the parent survey.

REFERENCES
2. Thompson WW, Shay DK, Weintraub E, et al. Influenza-
Mass Distribution of Free, Intranasally Administered Influenza Vaccine in a Public School System

L. Rand Carpenter, John Lott, Brian M. Lawson, Stephanie Hall, Allen S. Craig, William Schaffner and Timothy F. Jones

*Pediatrics* 2007;120;e172-e178; originally published online Jun 25, 2007; DOI: 10.1542/peds.2006-2603

| Updated Information & Services | including high-resolution figures, can be found at: http://www.pediatrics.org/cgi/content/full/120/1/e172 |
| References | This article cites 27 articles, 12 of which you can access for free at: http://www.pediatrics.org/cgi/content/full/120/1/e172#BIBL |
| Subspecialty Collections | This article, along with others on similar topics, appears in the following collection(s): **Office Practice** http://www.pediatrics.org/cgi/collection/office_practice |
| Permissions & Licensing | Information about reproducing this article in parts (figures, tables) or in its entirety can be found online at: http://www.pediatrics.org/misc/Permissions.shtml |
| Reprints | Information about ordering reprints can be found online: http://www.pediatrics.org/misc/reprints.shtml |