



eLITERATURE REVIEW

eInfluenza Review

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May 2007: VOLUME 1, NUMBER 7

Pediatric Influenza Prevention

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[EDITOR'S NOTE: Clinicians treating neonates and infants are invited to link to our sister e-publication, [eNeonatal Review](#), to access monthly accredited programs focused on those patient populations.]

The recognition that influenza is associated with increased rates of hospitalization and other medically attended visits in otherwise healthy infants and young children has led to the recommendation that all children 6 months to 5 years old receive influenza immunization each Fall. Since children under 8 years old must receive two doses of influenza vaccine if they have never received influenza vaccine in the past, pediatric providers are faced with a potentially daunting expansion in the number of patients they should immunize each Fall.

In this issue, we review information about the persistently low rates of influenza immunization among children who would benefit from it; explore the use of alternative immunization schedules to ease visit burden and provide protection earlier in the Fall season; review investigations into the safety and potential advantages of live, intranasal influenza vaccine for the population of children under 5; and examine the feasibility of a school-based influenza immunization strategy as a means to reduce influenza in households and communities.

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Commentary & Reviews:
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Commentary & Reviews:

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LEARNING OBJECTIVES

The Johns Hopkins University School of Medicine and The Institute for Johns Hopkins Nursing take responsibility for the content, quality, and the scientific integrity of this CE activity.

At the conclusion of this activity, participants should be able to:

- Explain the reasons for the low immunization rates among children for whom influenza immunization is indicated
- Describe new strategies for influenza immunization in children
- Discuss the advantages and disadvantages of the live attenuated intranasal influenza vaccine in young children

COMMENTARY

Influenza-related morbidity has been increasingly recognized in children, particularly among young children and children with chronic underlying medical conditions. Estimates of annual excess hospitalization rates due to influenza range from 2 to 10 per 1000 for children under the age of 24 months^[1,2], and 2 to 19 per 1000 children with asthma and other chronic medical conditions^[3]. The best defense we have to protect this high-risk population is influenza vaccine.

How well are we are doing in complying with national recommendations regarding influenza vaccination in children? Asthma represents one of the most common illnesses of childhood, affecting up to 14% of all U.S. children^[4], yet the report from the Centers for Disease Control and Prevention describing the first national estimates that measure influenza vaccination among children with asthma show that vaccine coverage in this group is disappointingly low, highlighting the difficulties we have in reaching this highly vulnerable population.

Can strategies such as an alternative schedule and/or an alternative vaccine improve coverage among children? Englund and colleagues examined a Spring-Fall vaccine dosing schedule as an alternative to the logistical challenge of administering two vaccine doses in the Fall for all young children who have not previously received influenza vaccine. In their study, young children who received one dose of vaccine in the previous season were enrolled to receive a single dose the following year using the new season's heterotypic vaccine, compared to vaccine-naïve children who received two Fall doses of the new vaccine. While the two schedules were comparable in inducing seroprotection against the unchanged vaccine antigen, unfortunately the protective immune response of the Spring-Fall dosing against the antigens that were discordant between the Spring and Fall vaccines was inferior to the protection provided by two doses of the same



formulation in the Fall. The use of a Spring priming dose remains appealing in situations when the following year's vaccine antigens will not change — if providers know about next year's vaccine decision in time.

Has live influenza vaccine administered by intranasal spray proven to be a major advance in improving the efficacy and acceptability of influenza vaccination for children? While the live attenuated influenza vaccine (LAIV) has been shown to be more effective than the inactivated intramuscular form in selected populations^[5,6], studies on the safety and efficacy of this vaccine in young children have been lacking. The report by Belshe and colleagues demonstrated that live attenuated vaccine is indeed safe and more efficacious than inactivated vaccine for healthy young children down to the age of 12 months. However, the possible increased risk in hospitalization among children who have asthma and in infants <12 months will limit its use in these patients, at least until further data are available.

The concept that vaccination can produce benefits beyond the individual recipient is not new. A well-documented phenomenon in the fight against polio and measles, the evidence for herd immunity in the epidemiology of influenza has been demonstrated and debated since the 1970's^[7]. While a herd immunity benefit had been previously suggested in the use of the new live attenuated influenza vaccine (LAIV)^[8], the work by King et al extended these findings, demonstrating that school-based immunization of healthy children with LAIV can indeed reduce the spread of influenza in their households. Future efforts will likely focus on broad-based immunization programs in schools and other settings of high influenza transmission to interrupt community epidemics and protect the most vulnerable people throughout the community.

The future of influenza prevention in children is bright: innovations in vaccine development, vaccine schedules, and vaccine delivery strategies hold the promise of reducing the considerable influenza morbidity in young children as well as in the community at large.

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FAILURE TO IMMUNIZE ASTHMATIC CHILDREN AGAINST INFLUENZA



Brim SN, Rudd RA, Funk RH, Callahan DB, Euler GL. **Influenza Vaccination Coverage Among Children with Asthma --- United States, 2004-05 Influenza Season.** MMWR March 9, 2007 / 56(09);193-196.

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The National Health Interview Survey (NHIS) is an ongoing, cross-sectional, household survey of the civilian population of the United States. From each household, one child is randomly selected for a comprehensive medical history. This survey has assessed asthma status for the past several years; however, beginning in 2005, the NHIS added new questions regarding influenza vaccination. In this report, the Centers for Disease Control and Prevention analyzed data from the 2005 NHIS to estimate national influenza vaccination coverage rates among children aged 2-17 years with asthma.

In order for a child to be classified as having "current asthma", respondents must have reported that a health professional had diagnosed the child with asthma, and that he or she still has asthma. An additional question families were asked was if the child had experienced an asthma episode or attack in the past 12 months. Influenza vaccination during the 2004-05 season was defined as an immunization administered September 2004 - February 2005. In this study, univariate analyses were used for comparisons, and samples were weighted to produce national estimates.

Over 5,000 children aged 2-17 years during the 2004-05 influenza season were analyzed in this report. Overall, influenza vaccination coverage for children with current asthma was 29.0%, as compared to a rate of 10.3% among children without current asthma. Interestingly, while coverage rates among children with current asthma did not differ significantly by age (32.9% among 2-4 year olds and 28.0% among 5-12 year olds), age had a much stronger effect on rates among children without current asthma (20.7% among 2-4 year olds vs. 6.4% among 5-12 year olds ($p<0.001$)). Having an asthma episode during the previous 12 months also made vaccination more likely (35.9% vs. 20.0%). Among children who visited their provider frequently, those with asthma had higher coverage rates than those without asthma. Similarly, among children with asthma, influenza vaccination coverage increased along with the reported number of visits. In particular, those children with asthma who had visited their provider only once had a coverage rate of 10.8%, while those with 10 or more visits had a 42.0% coverage rate.

This survey found that in 2005, 6.5 million children aged less than 18 years in the United States currently have asthma, and the report provides the first estimate of how well children with asthma have been vaccinated against influenza on a national level (a recommendation made by the Advisory Committee on Immunization Practices (ACIP) since 1964). Prior studies had either examined vaccination coverage among children with asthma only at a local level^[1,2], or had examined coverage at a national level among children with an expanded list of chronic medical conditions^[3]. The authors of these studies correctly acknowledge their most important limitations of recall and information bias.

Taken together, the findings of all these studies indicate that despite the increased attention given to influenza in recent years and evidence that children with asthma are at higher risk for influenza-related complications, vaccination coverage remains quite low. It has been noted that even among adults, risk-

based recommendations for vaccination such as those based on underlying medical conditions are often harder to disseminate than recommendations based strictly on age groups. Indeed, the ACIP has recently advanced its age-based strategy for influenza vaccination in children, expanding recommendations to include all children aged 6 – 59 months, regardless of underlying health status^[4]. Certainly, the hope is that as vaccine producers and health care providers adjust to the increased demands this new recommendation will create, the necessary infrastructure will be put in place to additionally expand vaccine uptake among older children at risk due to asthma.

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INVESTIGATING A 2-DOSE INFLUENZA IMMUNIZATION SERIES FOR INFANTS

Englund JA, Walter EB, Gbadebo A, Monto AS, Zhu Y, Neuzil KM. **Immunization with trivalent inactivated influenza vaccine in partially immunized toddlers**. Pediatrics. 2006 Sep;118(3):e579-85.

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Walter EB, Neuzil KM, Zhu Y, Fairchok MP, Gagliano ME, Monto AS, Englund JA: **Influenza vaccine immunogenicity in 6- to 23-month-old children: are identical antigens necessary for priming?** Pediatrics 2006;118:e570-578.

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In this recent study, Englund and colleagues examined the immunogenicity of two alternative trivalent inactivated influenza vaccination regimens in infants and young children. Antibody responses to the three components of the 2004-05 influenza vaccine were compared between children who received one dose of the 2003-04 influenza vaccine in the Fall of 2003 and a second dose of the 2004-05 vaccine the next Fall (Group 1), versus children who received two doses of the 2004-05 vaccine in the Fall of 2004 (Group 2). The study was conducted at three primary care clinics near Seattle, Washington and Durham, North Carolina between September 1 and October 15, 2004. Between 2003-04 and 2004-05, the H1N1 vaccine component remained unchanged, the H3N2 component was replaced with a minor antigenic drift variant, and the influenza B strain was replaced by a B virus from another lineage.

To assess responses to the three vaccine antigens, hemagglutination-inhibition antibody titers were measured 4 weeks after the second dose. The proportion of subjects with antibody titers over 1:32 and the geometric mean titer (GMT) were compared between groups. The primary objective of the study was to

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demonstrate that the immunogenicity of the alternate vaccination regimen in Group 1 was noninferior to the standard regimen in Group 2.

A total of 122 children were enrolled during the study period, 58 in Group 1 and 64 in Group 2. Children in Group 1 were significantly older (median age 18.5 vs. 8.5 months). Hemagglutination-inhibition demonstrated that the proportion with titers greater than 1:32 to the H1N1 component were similar (82.1% vs. 85.7%). For the H3N2 component, the GMT was higher in Group 1, but the proportions with titers greater than 1:32 were not statistically different (91% vs 84%). In contrast, the antibody responses to the influenza B component were substantially lower in Group 1 as compared to Group 2 (27% vs. 86%). The rates of reactogenicity were low and similar for the two groups. Within Group 2, fever was more common after the first dose than after the second dose. Finally, fever was more common when the influenza vaccine was administered along with other vaccines.

This study is one among a set of trials published in the past two years that have examined alternative influenza vaccine regimens in young children. The earliest of these, also lead by Englund^[1], compared immunogenicity in children aged 6-23 months who received one dose in the Spring of 2003 and one in the Fall to a group who received both doses in the Fall. Immunogenicity in the two groups was equivalent for all three antigens, but in this study the vaccine antigens were the same for the two seasons.

During the same two influenza seasons as the more recent Englund study, in the Spring of 2004, Walter et al enrolled and randomized 6-23 month old children to receive either a Spring and Fall immunization dose, or two Fall doses. Similar to Englund, immunogenicity to the unchanged H1N1 component was not different, and immunogenicity to the B component was much lower in the Spring-Fall group compared to the Fall-Fall group. In contrast to Englund, however, protection for Spring vaccinees against the H3N2 component was inferior to those who received two Fall doses. This may be because of the age differences between groups in the Englund study, i.e., all children in Group 1 were alive during the 2003-04 season, and potentially infected by the circulating wild-type strain incorporated into the 2004-05 vaccine, while only 56% of children in Group 2 were alive during the prior season. (In the Walter study, age and exposure history were more similar between the two intervention arms.)

These trials support the concept of "priming" vaccine-naïve children during the Spring. Such a practice would make use of vaccine that would otherwise be discarded. If the antigenic composition of the two seasons' vaccines did not change, Spring immunization would permit completion of the series with the first Fall dose. Even if the vaccine composition changes, springtime immunization may augment protection to some extent after the first Fall dose, which might make a difference during seasons when vaccine distribution is delayed or influenza arrives early. Vaccine strain selection for a particular influenza season is usually determined by the FDA the preceding February^[2]. More effective dissemination of this information may potentially allow time for providers and parents to assess the relative benefits of springtime immunization. Strategies such as this may help meet the challenge of providing for an ever-expanding population for whom influenza vaccination is recommended.

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SAFETY AND EFFICACY OF LIVE ATTENUATED VS INACTIVATED INFLUENZA VACCINE IN YOUNG CHILDREN

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Belshe RB, Edwards KM, Vesikari T, Black SV, Walker RE, Hultquist M, Kemble G, Connor EM; CAIV-T Comparative Efficacy Study Group. **Live attenuated versus inactivated influenza vaccine in infants and young children.** N Engl J Med. 2007 Feb 15;356(7):685-96.

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In this 2007 publication, Belshe and colleagues report on a double-blind, placebo-controlled trial comparing live attenuated intranasal influenza vaccine (LAIV) to intramuscular inactivated influenza vaccine (IIV) in children between 6 months and 5 years old. More than 8000 children recruited from 249 sites in 16 countries were enrolled in October 2004. The influenza A seed strains (H1N1 and H3N2) used in the intranasal and intramuscular vaccines were identical; the influenza B seed strains used in the two vaccine formulations, while antigenically equivalent, were not identical. Children with a wheezing episode in the preceding 42 days and children with a history of severe asthma were excluded, but children with a history of less recent and less severe wheezing episodes were included. Subjects were stratified by presence of a history of ≥ 3 medically attended wheezing episodes, age, presence of previous influenza vaccination, and country of residence. Children who had never received influenza vaccination before (87-88% in both study arms) received a second dose of the same assigned study vaccine 28-42 days after the first dose. The study was powered to detect a 40% superior efficacy of the intranasal vaccine compared to the intramuscular vaccine in this population. The primary outcome measures were incidence of culture-confirmed influenza-like illness caused by well-matched influenza strains (efficacy) and incidence of adverse events (safety).

Overall, there were 55% fewer cases of culture-confirmed influenza in the children who received live attenuated vaccine than in the group who received inactivated vaccine. The most substantial superior relative efficacy was observed for reduction in cases of influenza A/H1N1 (89% reduction) and A/H3N2 (79% reduction) infections, while the efficacy for preventing additional cases of influenza B was only 16% and not statistically significant. During the study year, the circulating strains compared to the vaccine strains were well-matched for H1N1, not well-matched for H3N2, and variable for B because of more than one circulating strain. Interestingly, the live attenuated vaccine conferred superior protection against infecting strains, whether those strains were well-matched or not well-matched to the vaccine strain. This study also demonstrated a 50% reduction in influenza-associated lower respiratory illness and 46% reduction in clinically diagnosed acute otitis media in the live attenuated vaccine group relative to the inactivated vaccine group.

Injection site complaints were more common in those who received inactivated vaccine, while nasal symptoms in the 10 days after vaccination were more common among those who received the live attenuated vaccine. Fever (≥ 37.8 C) was significantly more common after the first dose of live attenuated vaccine (5.4%) than after the first dose of inactivated vaccine (2%); however, higher fever (≥ 38.9 C) after the first dose and any fever after the second dose were equal in the two groups.

While there was no difference overall in medically significant wheezing in the 6 weeks following vaccination between the two groups, there were significantly more such wheezing episodes in previously unvaccinated children after dose one of LAIV (2.3%) than after one dose of IIV (1.5%). This increased risk of wheezing

was not observed in the children ≥ 24 months old, and the increased risk among children < 24 months old occurred predominantly in those less than 12 months old. Hospitalization for respiratory illness and for any cause was higher among 6-11 month olds who received LAIV compared to those who received IIV, but these findings were not different for the older age groups. There was a trend for the LAIV-immunized children who had a history of wheezing to be hospitalized at a higher rate and a trend for LAIV-immunized children who had no history of wheezing to be hospitalized at a lower rate than IIV-immunized children, though these findings did not reach statistical significance.

The live attenuated intranasal influenza vaccine used in this study is not currently licensed for children under 5 years old, but there has been great interest in expanding its use to this population for whom annual influenza immunization is recommended^[1]. Reasons for this interest include greater acceptability by young children and their parents of a nasal spray over an injection, and facilitating broader, school- and community-based influenza immunization programs (discussed further in the review of the report by King et al, following). Since this is a live attenuated vaccine that elicits an immune response through vaccine virus replication in the nose, it is expected to produce a more protective immune response than inactivated vaccine, as reported in prior studies^[2]. This study by Belshe and colleagues offers additional, strong evidence that the LAIV offers significantly better protection against influenza in these young children. Further, the superior efficacy of LAIV even against infection by influenza strains poorly matched to the vaccine virus suggests that LAIV may offer substantial advantages over IIV to young children.

The use of an intranasal live viral vaccine, however, raises safety concerns for those who are most susceptible to complications due to influenza, such as infants and asthmatics. In fact, the increased rate of hospitalization among children under 12 months old raises substantial concern about the use of LAIV in infants. Asthmatic children who received LAIV had higher hospitalization rates than those who received IIV, while the opposite was true for children without a history of recurrent wheezing. While these trends did not quite reach statistical significance, the pattern of the findings suggests that further study of LAIV is warranted before use in asthmatic children can be recommended. The other observed adverse events, such as injection site reactions, fever, and nasal symptoms, while important for counseling vaccine recipients, did not reach a level of frequency or severity that would likely affect wider use of LAIV in children.

The authors make the reasonable conclusion that LAIV should be safe and effective for children 12-59 months old without a history of asthma or wheezing. As we increasingly use LAIV to improve recommended annual Fall immunization of healthy young children, we need to look to other strategies to do the same for children with asthma and for infants.

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**SCHOOL-BASED INFLUENZA VACCINATION TO
REDUCE THE SPREAD OF INFLUENZA IN
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King and colleagues studied the efficacy of a school-based influenza immunization strategy in reducing the burden of influenza in households and communities in the 2004-2005 influenza season. 28 elementary schools in 4 states were grouped into 11 clusters of 2-3 schools each; within each cluster, one school was assigned to intervention and the other one (or two) as control. In the intervention schools, all healthy children ≥ 5 years old were offered live attenuated intranasal influenza vaccine (LAIV); those children under 9 years old without previous influenza vaccination were offered a second dose of LAIV 6-10 weeks later. 2717 (47%) children in intervention schools received LAIV; 95% of those offered a second dose received it. A survey was distributed to all households with control or intervention school children immediately after the predicted peak week of influenza activity for that community (based on local surveillance data). The survey assessed demographics, influenza-like illness and other symptoms, medical visits, hospitalizations, medications used, and absences from school or work for anyone in the household. About 80% of households in both groups completed the survey. The main outcome measured was a comparison of household rates of influenza-like illness (ILI) in households with intervention school children to rates in households with control school children. For safety assessment, surveys about symptoms and medication use were also completed at baseline and one week following immunization for LAIV recipients.

Compared to households with control school children, households with children from schools in which LAIV was universally offered experienced significant, even if only modest, reductions in most of the measured outcomes. These reductions included lower rates of children with fever or ILI (-10.9%), adults with fever or ILI (-10.8%), pediatric outpatient visits (-3.4%), prescription (-3.71%) and non-prescription (-7.71%) medication use, school absenteeism (-2.35%) and work absenteeism due to ILI in parent or child (-0.07 days). However, there was also a small but significant increase in the proportion of intervention households in which a child (+0.13%) or adult (+0.13%) required hospitalization for any reason. There was no significant difference in overall school absenteeism rates related to the vaccine intervention. Surveys at baseline and after vaccine disclosed a small increase in some ILI symptoms and non-prescription medication use, but no increase in wheezing episodes or prescription medication use.

These findings demonstrate the potential for school-based influenza immunization programs to reduce the burden of influenza, not only on vaccine recipients but also on those with whom they come in contact. This beneficial effect was achieved despite only 47% uptake of LAIV in the intervention group.

The finding of small but significant rates of increased hospitalization in intervention households is concerning and somewhat puzzling. The authors performed a post hoc analysis demonstrating that actual receipt of study immunization by a child in the household (as opposed to having a child in an intervention school, whether or not that child received the vaccine) was not a predictor of increased hospitalization rates for members of the household. While this finding suggests that the increased hospitalization is not due to vaccination within the household, it remains unexplained and must be factored in to future studies.

It is well known that schools are often the amplifiers and propagators of influenza epidemics in the community, and limiting the spread of influenza among mostly healthy schoolchildren may be the best strategy to prevent influenza from reaching the very old, the very young, and other vulnerable people with whom

schoolchildren come in contact in their homes and communities^[1]. The Japanese experience has been instructive: universal school-based influenza immunization through 1987 was associated with dramatic reductions in all-cause and influenza/pneumonia mortality rates in the whole population; abandonment of school-based programs in 1994 was followed by a return of mortality rates to pre-intervention levels^[2]. The study by King et al establishes a precedent for successful use of school-based LAIV for reduction of household ILI. The greater ease of administration and the greater efficacy of this vaccine (as shown by Belshe et al in the previous review) compared to inactivated vaccine suggest that broad, school-based LAIV immunization programs may be the future path for reducing influenza morbidity and mortality for the entire community.

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To take the post-test for eInfluenza Review you will need to visit [The Johns Hopkins University School of Medicine's CME website](#) or [The Institute for Johns Hopkins Nursing](#). If you have already registered for another Hopkins CME program at these sites, simply enter the requested information when prompted. Otherwise, complete the registration form to begin the testing process. A passing grade of 70% or higher on the post test/evaluation is required to receive CME/CNE/CPE credit.

COMPLETE THE POST TEST

Step 1.
Click on the appropriate link below. This will take you to the post-test.

Step 2.
If you have participated in a Johns Hopkins on-line course, login. Otherwise, please register.

Step 3.
Complete the post-test and course evaluation.

Step 4.
Print out your certificate.

PHYSICIAN
POST-TEST

NURSE
POST-TEST

Pharmacy credit is only available via PDF mail-in form:

PHARMACY
POST-TEST

Statement of Responsibility · [back to top](#)

The Johns Hopkins University School of Medicine and The Institute for Johns Hopkins Nursing take responsibility for the content, quality, and scientific integrity of this CME/CNE/CPE activity.

Target Audience · [back to top](#)

This activity has been developed for the Primary Care Physicians, Internists, Infectious Disease Specialists, Pharmacists, and Nurses. There are no fees or prerequisites for this activity.

Learning Objectives · [back to top](#)

At the conclusion of this activity, participants should be able to:

- Explain the reasons for the low immunization rates among children for whom influenza immunization is indicated
- Describe new strategies for influenza immunization in children
- Discuss the advantages and disadvantages of the live attenuated intranasal influenza vaccine in young children

Internet CME/CNE Policy · [back to top](#)

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Faculty Disclosure · [back to top](#)

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The presenting faculty reported the following:

- **Niranjan Bhat, MD**, has disclosed no relationship with commercial supporters.
- **George K Siberry, MD, MPH**, has disclosed no relationship with commercial supporters.

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