



**Release Date:** September 2005  
**Valid Until:** February 2007

This educational activity is conducted as a part of the *Pediatric Respiratory Care Initiative™* (PRCI™), sponsored by Thomson Professional Postgraduate Services® (PPS), Secaucus, NJ.

Issue No. 2, October 2005, is part of a 12-part CME activity (September 2005 – August 2006).

Physicians who wish to receive CME credit for this educational activity should do the following: (1) read each of the 12 monthly issues in the series and retain them for future reference; (2) review the original articles discussed in their entirety; and (3) complete the post-test that accompanies the last issue in the series (August 2006). The post-test may also be obtained by calling 1 (800) 223-8978. You will receive the post-test and CME Activity Evaluation/Registration Form by fax. To receive CME credit, the participant must complete the 12-part series, post-test, and CME Activity Evaluation/Registration Form and return the completed forms to: Thomson Professional Postgraduate Services, Attn: CME Dept. T304, PO Box 1505, Secaucus, NJ 07096-1505 (Fax: 1 [201] 430-1441).

Applicants will receive a certificate of participation from PPS by return mail within 6 to 8 weeks of the date of receipt of the completed evaluation/registration form.

#### Learning Objectives

After studying the literature presented in this Pediatric Respiratory Care series, participants will be able to:

- Identify respiratory disorders in pediatric patients
- Summarize risk factors for respiratory disorders in pediatric patients
- Select an appropriate therapeutic regimen for patients with pediatric respiratory disorders

#### Target Audience

This educational activity is designed for pediatricians, neonatologists, infectious disease specialists, allergists, pulmonologists, immunologists, primary care physicians, and other healthcare professionals involved in the care and management of pediatric respiratory patients.

Thomson Professional Postgraduate Services® is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Thomson Professional Postgraduate Services® designates this educational activity for a maximum of 2.25 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

This CME activity is supported by an unrestricted educational grant from MedImmune, Inc.

*Pediatric Respiratory Care Initiative*, PRCI, *Clinical Insights in Pediatric Respiratory Care* are trademarks used herein under license.

Copyright © 2005 Thomson Professional Postgraduate Services®.

All rights reserved.

*Clinical Insights in*

# PEDIATRIC RESPIRATORY CARE™

VOLUME 1, NUMBER 2 • OCTOBER 2005

PEDRO A. PIEDRA, MD,\* EDITOR-IN-CHIEF; GRACE L. MCBRIDE,† SENIOR MANAGING EDITOR; LUCIANO PASSADOR, PHD,‡ MEDICAL WRITER

## Limited Vaccine Supplies Lead to Proposal for New Flu Vaccination Strategy

For decades, the prevailing influenza immunization policy in the United States was that of targeting high-risk groups, including the very young, the elderly, the institutionalized, individuals with chronic medical conditions, pregnant women, healthcare workers with direct patient contact, and other caregivers. Once the needs of these high-risk individuals were met, influenza vaccination would be made available to the general population. A recent article by Longini and Haloran suggests, however, that the current approach fails to address a key component of influenza epidemiology: transmissibility of the illness. The authors propose that vaccination of schoolchildren is an effective method to reduce transmissibility of influenza and that such an approach can dramatically impact morbidity and mortality among the high-risk groups. They propose that vaccination of schoolchildren be carried out concomitantly with the vaccination of high-risk individuals to achieve a more beneficial effect.

To support the case that the current approach is ineffective, the investigators refer to data from numerous studies that indicate a modest effect on morbidity and mortality when those apparently most at risk are immunized. In addition, they discuss published data indicating many high-risk individuals are never vaccinated and

that although reports of the five most recent flu seasons suggest that an average of 30% of the US population is vaccinated, there is little effect on transmission of the illness or on overall influenza morbidity and mortality in the United States. In contrast, to support their proposal, the authors discuss epidemiologic data from both US and Japanese studies in which significant decreases in excess influenza-related deaths

*“According to the mathematical models, more lives would be saved and more illness prevented if schoolchildren were vaccinated.”*

in the elderly and decreased influenza-like illness in communities were observed when schoolchildren were vaccinated. Mathematical models suggest that vaccination of 70% of schoolchildren would be considered a threshold limit, a level at which vaccination would maintain transmission of influenza to below-epidemic levels. The models also demonstrated that vaccination of as few as 50% of schoolchildren would still result in considerably reduced transmission of the influenza. Hence, according to the mathematical models, more lives would be saved and more illness prevented if

*Continued*

#### Disclosures:

\* Dr Piedra is an associate professor of Molecular Virology and Microbiology, and Pediatrics at Baylor College of Medicine. He has indicated relevant financial relationships as noted: he receives grants/research support from MedImmune, Inc.; speaker for MedImmune, Inc.; is an expert witness for Sanofi-Pasteur; and is an ad hoc consultant for GlaxoSmithKline, MedImmune, Inc., and Sanofi-Pasteur.

† Ms McBride is a senior managing editor for Thomson Professional Postgraduate Services®. She has indicated no relevant financial relationships.

‡ Dr Passador is a medical writer for Thomson Professional Postgraduate Services®. He has indicated no relevant financial relationships.



## Limited Vaccine Supplies Lead to Proposal for New Flu Vaccination Strategy

*Continued*

schoolchildren were vaccinated. An indirect benefit of the proposed approach is that fewer doses of vaccine would be required. The authors present the example of vaccinating 70% of the current 60 million US schoolchildren. This would require 42 million doses of vaccine, a number of doses that is still far less than the 57 million doses available even during the severe shortages seen in the 2004 to 2005 flu season. The authors also suggest options for testing the benefit of vaccinating schoolchildren. One option might consist of carrying out the vaccinations in some states and comparing the findings with those states in which schoolchildren had not been vaccinated, a methodology that could readily measure the efficacy of such an approach. This would, in effect, amount to having the

entire country participate in a single, large community trial.

The investigators point out that the idea of vaccinating schoolchildren to reduce transmission of influenza and indirectly reducing morbidity and mortality is not novel. However, it is surprising that a strategy has never been recommended in the United States. Perhaps recent trends, in which US officials are beginning to more seriously consider the indirect benefits of vaccinations, and questions regarding the availability of sufficient vaccine doses may result in adoption of such a strategy.

Longini IM Jr, Halloran ME. Strategy for distribution of influenza vaccine to high-risk groups and children. *Am J Epidemiol.* 2005;161:303-306.

## Live Attenuated Influenza Vaccine: Is It Safe for Children?

**I**nfluenza is responsible for significant hospitalization of children for lower respiratory tract illness. In comparison to adults, children are more susceptible to influenza because they either have not been infected or have been infected less often with any of the major influenza virus types. The results of an earlier trial involving children 1 to 17 years of age indicated that administration of live attenuated influenza vaccine, trivalent (LAIV-T), demonstrated a statistically significant increase in asthma encounters for those participants younger than 59 months. These findings were in contrast to a phase III efficacy trial that indicated that LAIV-T was both safe and efficacious in children younger than 5 years. Nonetheless, based on concern for the development of asthma, LAIV-T is approved for use only in persons aged 5 to 49 years. Furthermore, the use of LAIV-T is not recommended in children with a history of asthma. These recommendations result in the exclusion of many children

from access to complementary influenza vaccination programs. The need for a safe, effective influenza vaccine for children was clearly emphasized by the influenza-associated deaths of healthy children reported during the 2003 to 2004 influenza season. Now, a recently published paper by Piedra and colleagues reports the findings of the largest safety study in children to date of the recently licensed LAIV-T.

The study was an open-label, nonrandomized, community-based trial in children aged 18 months through 18 years, carried out in Texas from 1997 to 2002. In each vaccine year, all children, regardless of age, received a single intranasal dose of LAIV-T. Over the 4-year study, 18,780 doses of vaccine were given to 11,096 children. A total of 4,529, 7,036, and 7,215 doses of LAIV-T were given to children aged 18 months to 4 years, 5 to 9 years, and 10 to 18 years, respectively. Over the 4 years, a total of 42 serious adverse events were identified,

*Continued*



*“Children aged 18 months to 4 years tolerated LAIV-T as well as did children aged 5 to 18 years.”*

## PRCI™ MISSION STATEMENT

The PRCI™ is a multicomponent educational program on pediatric respiratory disorders designed for pediatricians, neonatologists, infectious disease specialists, allergists, pulmonologists, immunologists, primary care physicians, and other healthcare professionals involved in the care and management of pediatric respiratory patients. PRCI programs address issues concerning asthma, respiratory syncytial virus, viral respiratory tract infections, and other respiratory disorders and evaluate methods to prevent, control, and treat respiratory illnesses.

## Live Attenuated Influenza Vaccine: Is It Safe for Children?

*Continued*

including appendicitis, lower respiratory tract illness, skeletal pain, and psychiatric disorders. None of the adverse events were judged as being related to LAIV-T. Children aged 18 months to 4 years tolerated LAIV-T as well as did children aged 5 to 18 years. Healthcare utilization was also evaluated by determining the relative risk of medically attended acute respiratory illness and asthma rates at 0 to 14 days and 15 to 42 days after vaccination compared with rates prior to vaccination. Use of LAIV-T in children was not associated with increased risk in healthcare utilization attributable to acute respiratory illness or asthma. Six pregnancies were also identified among teenagers over the course of the study. With the exception of one case, in which a healthy preterm baby was delivered, all pregnancies resulted in the birth of healthy full-term babies.

The results of this study do not suggest a link between LAIV-T and asthma exacerbation. Furthermore, this current report indicates that use of LAIV-T in children is well tolerated. Based on the lack of serious adverse events and the agreement between their findings and those of a previous phase III clinical trial, the investigators urge consideration of lowering the age limits for LAIV-T use to 15 or 18 months and to expand the current recommendations to include children with mild intermittent asthma.

**NOTE:** the FDA has not approved the discussed use of the drug in this study.

Piedra PA et al. Live attenuated influenza vaccine, trivalent, is safe in healthy children 18 months to 4 years, 5 to 9 years, and 10 to 18 years of age in a community-based, nonrandomized, open-label trial. *Pediatrics*. 2005;116:e397-e407.

### Receive CME credit for *Clinical Insights in Pediatric Respiratory Care*™

Physicians who wish to receive CME credit for this educational activity should

- 1) Read each of the 12 monthly issues in the series and retain for future reference
- 2) Review the original articles discussed in their entirety
- 3) Complete the post-test that accompanies the last issue in the series (August 2006)
- 4) Fill out the accompanying CME Activity Evaluation/Registration Form
- 5) Return the post-test and CME Activity Evaluation/Registration Form to Thomson Professional Postgraduate Services, Attn: CME Dept.-T304, PO Box 1505, Secaucus, NJ 07096-1505, or fax the forms to 201-430-1441. Applicants will receive a certificate of participation from PPS by return mail within 6 to 8 weeks from the date of receipt of the completed evaluation and registration forms.

For more information about upcoming PRCI™ CME activities, visit us at [www.ppscme.org](http://www.ppscme.org).

*Clinical Insights in Pediatric Respiratory Care*™ is edited by PRCI™ faculty member Pedro A. Piedra, MD.

**You have received this email because we believe it may be of interest to you. If you would like your name to be removed from our mailing list, please reply to [prci@pps.thomson.com](mailto:prci@pps.thomson.com) and place REMOVE in the subject line.**

Copyright © 2005 Thomson Professional Postgraduate Services®. All rights reserved.

EM-T304-PHYCME-1005-9.7k