

# Cold-Adapted Nasal Flu Vaccine Shows Promise

BY MIRIAM E. TUCKER  
Senior Writer

ATLANTA — Medimmune's investigational cold-adapted trivalent influenza vaccine appears to have a highly favorable risk-benefit profile in children aged 12-59 months without a history of wheezing, Dr. Robert Walker said at the fall meeting of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.

The cold-adapted influenza vaccine, trivalent (CAIV-T) is Medimmune's next-generation intranasal influenza vaccine. Unlike its currently licensed live-virus intranasal influenza vaccine, Flumist, CAIV-T does not need to be kept frozen and may be stored at 2°-8° Celsius in a refrigerator, said Dr. Walker, vice president of clinical development at Medimmune.

The company has submitted a biologics licensing application to switch formulations from Flumist, currently approved for

healthy individuals aged 5-49 years, to CAIV-T for the same population. It also is seeking an expanded label for CAIV-T in children aged between 12 and 59 months without a history of wheezing. A Food and Drug Administration response is expected in the second quarter of 2007. Pending a positive outcome, Medimmune plans to commercially provide CAIV-T for the 2007-2008 influenza season, according to a company statement.

At the ACIP meeting, Dr. Walker pre-

sented pivotal data from a double-blind, multinational study in which 8,475 children aged 6-59 months were randomized to receive two doses of either CAIV-T or the injected trivalent influenza vaccine (TIV). All first doses were given by Oct. 29, 2004.

From Nov. 1, 2004, through June 1, 2005, the overall attack rate of all influenza strains was 3.9% among the CAIV-T recipients, compared with 8.6% among the children who received TIV, a significant 54.7% improvement in efficacy. Attack rates also were significantly lower with CAIV-T for the H1N1 strain (0.1% vs. 0.7%) and for H3N2 (0.9% vs. 4.5%), while the difference in attack rates of influenza B was not significant (2.9% vs. 3.5%).

Runny and/or stuffy noses were reported more often with CAIV-T, while injection site reactions were more common with TIV. Among children younger than 2 years, medically significant wheezing was significantly more common within 42 days after

**Using CAIV-T instead of TIV in a nonwheezing population would result in about 1.5 million fewer cases of symptomatic influenza annually.**

the first dose among the CAIV-T group, occurring in 3.2%, compared with 2.0% of the TIV recipients at weeks 2, 3, and 4 after immunization. Those rates were not different after 42 days or after the second dose, he said.

Hospitalization associated with medically significant wheezing occurred in 0.3% with CAIV-T and 0.2% with TIV, with mean durations of 4.5 days and 4.0 days, respectively. There were no deaths, and no patient required intensive care or a ventilator. Recurrences of medically significant wheezing occurred in 32% of CAIV-T recipients and in 28% with TIV.

All-cause hospitalization was significantly greater with CAIV-T only in children aged 6-11 months (6.1% of 684 patients, compared with 2.8% of 683 who received TIV). The most common reasons for hospitalization were lower respiratory tract infections and gastrointestinal problems (frequently rotavirus), Dr. Walker noted.

In children with a history of wheezing, those aged 12-47 months in the CAIV-T group had significantly higher hospitalization rates than did those in the TIV group. In the 12- to 23-month age group with a history of wheezing, for example, 5.1% of the CAIV-T recipients compared with 2.6% of TIV patients were hospitalized.

However, among the children aged 12-59 months who did not have a history of wheezing, there were no differences in hospitalization rates between the CAIV-T and the TIV recipients. Similar reductions in influenza rates were seen with CAIV-T compared to TIV in the groups with and without wheezing, Dr. Walker reported. About 80% of children aged 12-59 months have no history of wheezing. Using CAIV-T in that population instead of TIV would result in about 1.5 million fewer cases of symptomatic influenza annually, he said. ■

**Skin & Allergy News**<sup>®</sup>


## Common Viral Skin Diseases in Clinical Practice

Register now for this archived webcast at [www.viralskindiseases.com](http://www.viralskindiseases.com)

### Introduction

**Stephen K. Tyring, MD, PhD, MBA**

*Professor of Dermatology*

Department of Dermatology

University of Texas Health Science Center  
Houston, Tex.



**Human Papillomaviruses:  
Basic Virology to Clinical Management**

**Stephen K. Tyring, MD, PhD, MBA**



**Molluscum Contagiosum  
and Treatment Options**

**Douglas W. Kress, MD**

*Chief of Pediatric Dermatology*  
Children's Hospital of Pittsburgh  
Pittsburgh, Penn.



**Treatment of Cutaneous Warts:  
An Updated Inventory  
of Therapeutic Options**

**Robert B. Skinner, MD**

*Professor of Medicine*

Department of Dermatology

University of Tennessee

Health Science Center

Memphis, Tenn.

### PROGRAM DESCRIPTION

Viral skin diseases represent a major component in the busy practices of dermatologists. In this activity, the focus is on the most common cutaneous viral diseases, genital/anal warts (condylomata acuminatum) and common warts, caused by human papillomaviruses (HPV), and molluscum contagiosum, caused by Poxviruses.

The manifestations of cutaneous viral infections range from simple erythematous, macular presentations to papules, vesicles, pustules, ulcers, and crusting that may represent any of a long list of possible etiologies. Clinicians must be able to accurately assess and differentiate among these manifestations and presentations, particularly now because of the emerging possibility that the causative organisms may be the etiologic agents responsible for smallpox infections or disseminated vaccinia. The poxviruses, especially, may mimic or be mimicked by vaccinia, and clinicians should know the differences in the morphology of the lesions as well as in the presentation, timing, and progression of these lesions.

Advances in the understanding of the natural history and treatment of common viral skin diseases highlight the need for a continuing educational process that guides the clinician in patient management, including the latest treatment options, such as topical immune response modifier therapy.

This activity will provide dermatologists with current information regarding the nature of viral skin diseases caused by HPV and poxviruses and will help clinicians remain up-to-date on patient applied and physician applied therapies in the treatment of genital warts, common warts, and molluscum contagiosum.

### INTENDED AUDIENCE

This activity has been developed for dermatologists, primary care physicians, and other clinicians who are involved in the diagnosis and treatment of viral skin diseases.

### EDUCATIONAL OBJECTIVES

After reading this supplement and taking the test, participants should be able to:

- Summarize the current understanding of the pathogenesis of human papillomavirus (HPV) infections of the skin—as manifested by genital/anal and common warts—and the role of local immune responses in the clearing of infection.
- Discuss the HPV types that are associated with external genital/anal warts and with cervical malignancies, and explain the role of diagnostic testing in the management of patients with external genital/anal warts.
- Recognize the most common presentations of human papillomavirus (HPV) and poxvirus infections, as well as the atypical morphologic characteristics that must be considered in diagnosing various types of warts and molluscum contagiosum.
- Describe the methods that may be used to confirm a clinical diagnosis of molluscum contagiosum, and explain when such methods should be used.
- List and explain the destructive/ablative methodologies and the pharmacologic treatments that are currently available for treating genital/anal and common warts and molluscum contagiosum.
- Name and describe the factors that should be considered in choosing a specific therapeutic regimen for individual patients.

### ACCREDITATION STATEMENT

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the Elsevier Office of Continuing Medical Education (EOCME) and *Skin & Allergy News*. The EOCME is accredited by the ACCME to provide continuing medical education (CME) for physicians.

### CME CREDIT STATEMENT

The EOCME designates this educational activity for a maximum of 1 *AMA PRA Category 1 Credit*<sup>®</sup>. Physicians should only claim credit commensurate with the extent of their participation in the activity.

**Financial Support:** This CME activity is supported by an educational grant from

**3M Pharmaceuticals**