

CLINICAL CAPSULES

Intranasal Flu Vaccine Looks Safe

No unexpected serious adverse events were reported with appropriate use of live, attenuated intranasal influenza vaccine in the first two seasons after its U.S. approval.

About 2.5 million people have received the vaccine since June 2003. As of July 2005, 460 adverse events—mostly in the first season, and with no fatalities—were reported to the vaccine adverse event reporting system, said Dr. Hector S. Izurieta of the Food and Drug Administration and his colleagues (JAMA 2005;294:2720-5).

Of the reported events, 217 were respiratory (including 8 cases of asthma exacerbations), 67 were constitutional, 54 were allergic, 33 involved abdominal symptoms, 18 involved ear-nose-throat symptoms, 7 were ocular, 10 were neurologic, 10 were cardiovascular, and 44 were classified as "other." Fewer than 10% were considered serious, and 16% of events occurred in persons for whom the vaccine was not indicated. Secondary transmission of vaccine virus was reported in 22 cases.

The findings suggest that continued monitoring for neurologic events—such as Guillain-Barré syndrome, reported in two cases—is warranted, as is closer attention to the package insert, given the number of vaccine administration errors and use of the vaccine in persons for whom it is not indicated, the investigators concluded.

West Nile Virus Assay Approved

An assay used to screen blood, organ, cell, and tissue donations for West Nile virus recently has been approved by the Food and Drug Administration.

The Procleix West Nile Virus Assay has been used on an investigational basis to screen more than 29 million units of blood since June 2003. The assay has intercepted more than 1,500 WNV-positive donations that might otherwise have been given to as many as 4,500 people, according to Gen-Probe Inc., which developed the test, and Chiron Corp., which will market the test.

The test detects viral RNA and is approved for use on the Procleix enhanced semiautomated instrument system. Since 2002, when it was first discovered that West Nile Virus could be transmitted via blood, 30 cases of West Nile Virus that were most likely acquired through blood transfusions have been documented, and 9 of the affected patients have died, according to the FDA.

Pneumonia Hospitalization Up for Aged

The burden of pneumonia among U.S. patients aged 65 and older is large and increasing, according to Dr. Alicia M. Fry and her colleagues at the Centers for Disease Control and Prevention, Atlanta.

Among the 173 million people aged over 64 years hospitalized from 1988 through 2002, about 9% had pneumonia as a discharge code, and 6% had pneumonia as a first-listed discharge code. From 2000 to 2002, compared with 1988-1990, pneumonia hospitalizations rose 20%-25% among those aged 65-74 years and 75-84 years. The hospitalization rate for those aged over 84 years held steady (JAMA 2005;294:2712-9).

Of 9 million deaths among hospitalized patients, 22% were among those with a pneumonia-related hospitalization; the risk of death in these patients was 1.5 times

greater than the risk in patients with any of the 10 other most common causes of hospitalization. Additionally, the proportion of comorbid conditions, including chronic cardiac or pulmonary disease and diabetes, increased from 66% during 1988-1990 to 80% during 2000-2002.

An increase in chronic underlying conditions appears to be a contributing factor in pneumonia hospitalizations in older adults; efforts to prevent pneumonia in this population should focus on reducing comorbidity and improving vaccine programs and effectiveness, the researchers said.

Infection Tied to Macular Degeneration

A common infection may trigger the development of neovascular age-related macular degeneration in genetically susceptible individuals.

Dr. Murat Kalayoglu and his colleagues at the Massachusetts Eye and Ear Infirmary at Harvard Medical School, Boston, detected *Chlamydia pneumoniae* in the ocular tissue of five of nine patients with neovascular age-related macular degeneration (AMD) but in none of 20 people who did not have macular degeneration (Graefes. Arch. Clin. Exp. Ophthalmol. [Epub ahead of print] May 21, 2005. Article DOI: 10.1007/s00417-005-1169-y).

In addition, in vitro studies on human monocyte-derived macrophages and retinal pigment epithelial (RPE) cells showed that infection with *C. pneumoniae* induced production of vascular endothelial growth factor (VEGF), interleukin-8 (IL-8), and monocyte chemoattractant protein 1 (MCP-1). This suggests that *C. pneumoniae* can alter cell function in ways that may cause neovascular AMD, the authors reported.

"It may be possible to stop or reverse progression of AMD by identifying susceptible patients by diagnostic testing and then treating these susceptible patients," Dr. Kalayoglu said in a statement.

—From staff reports

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Important Safety and Other Information

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- The most frequently reported adverse events with PREVACID in adults were diarrhea (3.8%), abdominal pain (2.1%), and nausea (1.3%).
- Symptomatic response to therapy does not preclude the presence of gastric malignancy. PREVACID formulations are contraindicated in patients with known hypersensitivity to any component of the formulation.

See adjacent page for brief summary of prescribing information.

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