# Inactivated Flu Vaccine Safe, Effective in Pregnancy

#### BY ROBERT FINN San Francisco Bureau

RENO, NEV. — The influenza vaccine is both safe and effective for women in the second half of pregnancy, results of a large prospective study suggest.

When given at least 2 weeks before exposure, the vaccine reduced the rate of influenza 19fold, with no evidence of worsening in several obstetric and neonatal outcomes, including premature rupture of membranes, stillbirth, low birth weight, neonatal pneumonia, neonatal death, and major malformations.

The study, which was conducted at the University of Texas Southwestern Medical Center at Dallas, included 2,889 women who received the inactivated influenza vaccine during the 2003-2004 flu season, which began earlier than usual and was

moderately severe. They were compared with 1,988 gestational age-matched pregnant women who did not get vaccinated during the same time period, Jeanne S. Sheffield, M.D., and her associates wrote in a poster presented at the annual meeting of the Society for Maternal-Fetal Medicine.

Six women in the vaccinated group (2.4 per 1,000 women) and 13 women in the nonvaccinated group (6.5 per 1,000 women) developed laboratory-confirmed influenza, a statistically significant difference. The overall efficacy of the vaccine was 68%.

But when the analysis was restricted to women who developed influenza more than 2 weeks after vaccination (the time required to develop immunity), there was only one case of influenza (0.4 per 1,000 women) in the group, yielding an efficacy of 94%. The relative risk of devel-

oping influenza decreased almost 19-fold when the vaccine was given 2 weeks before exposure.

There were some statistically significant differences between



When given at least 2 weeks before exposure to influenza, the vaccine dramatically reduced the rate of infection.

the groups, study co-investigator Scott W. Roberts, M.D., told this newspaper.

Women in the vaccination group were seen more frequent-

ly than the controls, they had more repeat cesarean deliveries and cases of dystocia, and larger body-mass indexes.

The estimated gestational age (EGA) at delivery was slightly, but significantly, higher in the vaccination group (39.6 weeks), compared with the unvaccinated group (39.4 weeks).

The vaccinated group had significantly fewer births with EGAs of 36 weeks or less, compared with the unvaccinated group. Infants whose mothers were vaccinated were significantly less likely to be admitted to the intensive care nursery.

Women in the vaccinated group were significantly more likely to undergo a cesarean delivery (27% vs. 23%). Dr. Roberts said that most or all of these differences may reflect the fact that women who were seen in the clinic more often were more likely to choose vaccination.

## Safety, Not Logistics, Is Parents' **Biggest Flu Shot Concern**

#### BY MICHELE G. SULLIVAN Mid-Atlantic Bureau

Knowledge and attitudes about the flu vaccine—especially about its safety and side effects-are the biggest influences in parents' decisions about whether to vaccinate, Sharon G. Humiston, M.D., and her colleagues reported.

The finding may come as a surprise to physicians who view the logistics and cost are the biggest factors, said Dr. Humiston of the University of Rochester (N.Y.), and her associates (Arch. Pediatr. Adolesc. Med. 2005;159:108-12).

"Although health care providers surveyed previously emphasized practicality and convenience, our findings suggest that improving those factors for caregivers is not likely to substantially enhance immunization rates," they wrote. "Provider time and resources might be better directed at educational and safety concerns."

The researchers surveyed 153 caregivers of children aged 6-23 months, who presented for care at an ambulatory pediatric clinic or pediatric emergency department. The survey was conducted during the summer of 2003.

Clinic respondents were more likely to be Hispanic or another minority, have lower household incomes, and less education than ED respondents.

Of the entire group, 78% said they intended to have their children vaccinated for the flu that season. But fewer (61%) believed that influenza is serious enough to have all children aged 6-23 months vaccinated. Almost half (49%) believed that the vaccine could cause

the flu, 56% said vomiting was a main symptom of the flu, and 63% believed that many babies with the flu need to be hospitalized.

Safety of the vaccine was the most common primary concern (46%). If they had fewer safety concerns, 73% of caregivers said they probably would have their children vaccinated. Prevention of otitis media also was a big issue, with 85% saying they probably would get the vaccine if it prevented OM.

Far fewer caregivers expressed concerns about the number of vaccines a child must have (13.7%), the cost (6.5%), or the number of doctor visits required (4.6%).

Most (68%) said they would get the vaccine if it cost \$10-\$20, and 51% said they probably would get it even if the cost was more than \$20. Extra doctor visits weren't a big concern; 70% reported they probably would still get the vaccine even if it meant another trip. In fact, 94% said a doctor's office or clinic was their first choice of vaccination location. Only 3% said they preferred a public health clinic, 2% said they preferred a school, and 1% said they preferred a grocery store.

The only demographic variable associated with intent to vaccinate was education: Those with a high school education or less were more likely to vaccinate than were those with higher education. The low impact of demographics on intent to vaccinate "might also be attributable to the degree to which parents' concerns and motivations help them overcome barriers imposed by their social locations," the authors wrote.

### Add Neuromuscular Conditions To Influenza High-Risk List

#### BY MIRIAM E. TUCKER Senior Writer

ATLANTA — Children and adults with neurologic and neuromuscular conditions that place them at increased risk for influenza complications will be added to the list of individuals who should be targeted to receive the vaccine, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices decided at its winter meeting.

The final wording of the 2005-2006 influenza immunization statement is still being finalized, but in general, any neurologic and neuromuscular condition that increases the risk for respiratory compromise or aspiration would place patients at even greater risk if they were to contract influenza, said Carolyn Bridges, M.D., of the CDC's National Immunization Program

The list of individual conditions is long, but it broadly includes seizure disorders, mental retardation, cerebral palsy, Down syndrome, muscular dystrophy, and other developmental problems with limitation. Among adults, stroke, multiple sclerosis, Parkinson's disease, and senility/dementia / Alzheimer's disease with limitation also are likely to be included.

Depending on which conditions are included in the final statement, the number of children and adults who may be added to the target list for influenza vaccination would be approximately 524,000-907,000 children aged 2-17 years, 529,000-1.7 million adults aged 18-49, and 571,000-844,000 individuals aged 50-64, Dr. Bridges said.

Among the data supporting the recommendation are preliminary findings from two studies in which such conditions were prevalent among children with severe influenza

Of 153 fatal influenza cases reported during the 2003-2004 season in persons younger than 18 years (range 2 weeks to 17 years), 45% were previously healthy, 20% had conditions that ACIP had previously designated as high risk, while 20% had conditions such as congenital anomalies, gastrointestinal disorders, and neurologic/neuromuscular conditions. Another 20% had both neurologic/neuromuscular conditions and a previously designated high-risk condition. (No data were available for the other 3%.)

The neurologic conditions in those children were mental retardation/developmental delay, seizure disorder (excluding febrile), chronic encephalopathies, neurodegenerative disorders, and congenital neurologic disorders. The neuromuscular conditions were cerebral palsy and Duchenne's muscular dystrophy. Some children had more than one of the diagnoses.

A 4-year retrospective study of 757 children hospitalized with community-acquired, laboratory-confirmed influenza was conducted at Children's Hospital of Philadelphia, where diagnostic testing is routinely done for most children admitted with respiratory symptoms. Previously designated high-risk conditions were present in 44% of the children, the most common being asthma, in 24%, Dr. Bridges reported.

Among the 425 who did not have one of the previously listed conditions, neurologic/neuromuscular conditions were present in 22%. These included disease of the central or peripheral nervous system, seizure disorders, or myopathies. In a subanalysis of 33 children with respiratory failure, having a neurologic or neuromuscular condition increased the risk nearly sevenfold.