

Flu Vaccine Safe in Second Half of Pregnancy

BY ROBERT FINN
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RENO, NEV. — The inactivated influenza vaccine is 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 19-fold, with no evidence of worsening in several obstetric and neonatal outcomes, including premature rupture of membranes, stillbirths, 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 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), yielding an efficacy of 94%.

The relative risk of developing influenza decreased almost 19-fold when the vaccine was given 2 weeks before exposure.

There were some statistically significant differences between the groups, study co-investigator Scott W. Roberts, M.D., said in an interview with this newspaper.

Women in the vaccination group were seen more frequently than the controls. Those in the vaccination group also had

more repeat cesarean deliveries and cases of dystocia, and larger body-mass indexes, the researchers said.

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 go 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 it is possible that most or all of these differences reflect the fact that the women who were seen in the clinic were more likely to choose getting the vaccination. ■



Women who were vaccinated had infants that were much less likely to be admitted to the intensive care nursery.

New ACIP Flu Vaccine Guidelines Focus On Prioritization, Health Care Workers

BY MIRIAM E. TUCKER
Senior Writer

ATLANTA — Influenza vaccine recommendations for the 2005-2006 season will seek to minimize disruption in the event of another shortage and will strongly urge annual vaccination of health care workers against influenza.

A risk-based prioritization scheme for the inactivated (injectable) influenza vaccine and a stronger recommendation for immunization of health care workers with the live attenuated influenza vaccine (LAIV, or FluMist) are among the proposed changes to the yearly influenza vaccine statement discussed at a meeting of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

There is no concrete information to suggest that there will be flu vaccine

supply problems again next fall, but disruptions have occurred in four of the five previous seasons. Contributing factors have included production issues and regulatory actions. In addition, two manufacturers have left the market.

Thus "there is uncertainty about the 2005-2006 vaccine supply," Keiji Fukuda, M.D., of the CDC's influenza branch, told the committee.

Although the final language was still being worked out at press time, ACIP voted in principle to support a three-tiered prioritization system in which high-risk groups are ranked based on rates of influenza-associated mortality and hospitalization in the United States. (See box.)

The tiering scheme applies only to the inactivated influenza vaccine, and the document is expected to contain a strong recommendation for the preferential use of LAIV for healthy persons

aged 5-49 years—particularly health care workers—in the event of a shortage.

During periods of vaccine shortfall, persons listed in tier 1 should be vaccinated preferentially, followed by tiers 2 and 3. The subdivisions within tier 1 would be used only in the unlikely event that the local vaccine supply is extremely limited. Should that occur, state and local health officials should vaccinate the two populations in tier 1A—those aged 65 and older with comorbid conditions and long-term care facility residents—before all others.

In all other vaccine shortfall situations, populations falling into tiers 1A, 1B, and 1C should be considered equivalent and should be vaccinated simultaneously. Eligible individuals in tiers 1C, 2, and 3 should be encouraged to receive LAIV (those in tier 1C—health care personnel and close contacts of children less than 6 months of age—could receive either the injectable vaccine or LAIV, depending upon supply circumstances).

The committee also voted to include much stronger language about immunization of health care workers overall, regardless of vaccine supply status. Among the likely recommendations are that campaigns be organized to encourage workplace efforts to improve immunization rates among health care workers, and that such rates be regularly measured and reported.

"Giving the influenza vaccine to health care workers keeps them at work. It becomes a quality issue," said ACIP member Jon S. Abramson, M.D. "When you increase the number of patients a nurse has to take care of [due to absenteeism], it affects patient outcome." ■

Amnioinfusion Trial Fails to Prevent Meconium Aspiration

RENO, NEV. — Saline amnioinfusion for labors with thickly meconium-stained amniotic fluid does not prevent meconium aspiration syndrome, William D. Fraser, M.D., said at the annual meeting of the Society for Maternal-Fetal Medicine.

In an international, randomized, prospective trial of laboring women with thickly stained fluid, there was a 4% rate of moderate or severe meconium aspiration syndrome or death in 985 neonates born after amnioinfusion, compared with a 3% rate in 988 neonates born to women who did not undergo the procedure, said Dr. Fraser of the University of Montreal.

"Our evidence does not support amnioinfusion," Dr. Fraser said.

The findings of the current study run counter to those of some previous studies, including a recent metaanalysis of 12 trials, which concluded that the practice reduces by two-thirds the rate of meconium aspiration syndrome.

The metaanalysis, however, was dominated by a single study conducted in Zimbabwe, where modern labor and delivery practices usually aren't implemented, Dr. Fraser said, adding that the other studies that showed a positive benefit from amnioinfusion were much smaller than his.

His study was conducted in 56 different centers in 13 countries, including South Africa, Canada, and the United States, with the majority of patients enrolled in South Africa. There was no significant difference in results obtained from the various countries, Dr. Fraser said.

The study participants were at greater than 36 weeks' gestation and were stratified for randomization to one of two groups: one group with fetal heart-rate decelerations and one without decelerations. There was no significant difference in results between these two groups.

The investigators also saw a slight trend toward cesarean delivery in the group that received amnioinfusion (32% versus 29%), Dr. Fraser noted.

—Timothy F. Kirm

Proposed Tiering in the Event of an Influenza Vaccine Shortage

Group 1A

- ▶ Aged 65 years and older with comorbid conditions.
- ▶ Long-term care facility residents.

Group 1B

- ▶ Pregnant women.
- ▶ Aged 2-64 years with comorbid conditions.
- ▶ Aged 65 years and older without comorbid conditions.
- ▶ Aged 6-23 months.

Group 1C

- ▶ Health care personnel.
- ▶ Close contacts of children less than 6 months of age.

Group 2

- ▶ Contacts of high-risk children and adults.
- ▶ Healthy persons aged 50-64 years.

Group 3

- ▶ Aged 2-49 years without high-risk conditions.

Source: Dr. Fukuda