New Info on the Safety of A/H1N1 Flu Vaccine in Pregnancy

Evidence mounts that flu vaccine in pregnancy is safe, but congenital anomalies need to be better defined and slight increases in maternal outcomes explained.

The pandemic flu vaccine given to pregnant women in 2009 did not increase the risk of either fetal or birth outcomes, researchers studying singleton births in Italy report in *BMJ*.

**Pertinent Points**
- Giving the MF59 adjuvanted A/H1N1 vaccine to pregnant women was not associated with an increased risk of either fetal or birth outcomes, found researchers in Italy.
- A slight increase in gestational diabetes and eclampsia was observed in women who received the vaccination.
- There was a slight but statistically insignificant increased risk in congenital malformations in babies born to women who received the vaccine.

Gestational diabetes and eclampsia were slightly more prevalent among vaccinated women (adjusted ORs, 1.26 and 1.19, respectively). However, the researchers noted that residual confounding may partly explain the finding.

To assess the maternal, fetal, and neonatal outcomes of the MF59 adjuvanted A/H1N1 vaccine during pregnancy, the researchers looked at all deliveries between October 2009 and September 2010. Both vaccinated and nonvaccinated women were included among the 86,171 eligible pregnancies. Among the 6246 women who were vaccinated, 3615 (57.9%) received the shot in their third trimester.

The findings also showed a slight but statistically insignificant increase in congenital malformations among babies born to mothers who received the vaccine (OR, 1.14; CI, 0.99 to 1.31). Still, rates of fetal and neonatal outcomes (spontaneous deliveries and admission to NICU) were similar in both vaccinated and nonvaccinated women.

In calling for a meta-analysis of published studies to better define the risk of vaccines, the authors suggested the risk of less frequent outcomes, such as congenital malformations, must be better defined.

“In comparison with the past, future vaccination campaigns targeted at pregnant women will rely on more sound evidence on the safety of vaccine,” the authors wrote. “Clearly, two other factors—maternal and fetal risks associated with the influenza infection during pregnancy, together with the evidence on the effectiveness of the vaccination—should also be taken into account in decision making.”

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