Introduction

- The Centers for Disease Control and Prevention Advisory Committee on Immunization Practices recommends vaccination against influenza for pregnant women.1
- Live attenuated influenza vaccine (LAIV) is not recommended to be administered during pregnancy; inadvertent administration of LAIV to pregnant women does occur.2
- There are limited data regarding fetal or maternal outcomes after LAIV administration during pregnancy.3
- Fetal outcomes among 6 individuals <18 years of age who were exposed to LAIV during pregnancy have been described. Among these pregnancies, there were 5 full-term healthy infants and 1 preterm delivery.4
- A Vaccine Adverse Events Reporting System (VAERS) analysis described 2 women exposed to LAIV while pregnant; neither experienced any known adverse consequences.5

Objective

- To analyze clinical trial and case report data regarding maternal and fetal outcomes for women exposed to LAIV during pregnancy

Methods

- All reports of women exposed to LAIV during pregnancy were collected and reviewed using data collected from clinical trials (September 1997 through April 2008) and spontaneous postlicensure reports (August 2003 through April 2008).
- All available information on maternal and fetal outcomes was analyzed.
- Adverse event data were obtained from pregnancy narratives.

Results

- LAIV vaccination during pregnancy was reported for 76 women across 10 clinical trials and 24 women in postlicensure reports (Figure 1).
- 29 pregnancies could be definitively classified as high risk based on maternal age <18 y (n=17) or >35 y (n=12).
- A total of 58 subjects had available data for their last menstrual period; 49 had their last menstrual period before or at the time of vaccination.
- Among these pregnancies, there were 5 full-term healthy infants and 1 preterm delivery.
- A Vaccine Adverse Events Reporting System (VAERS) analysis described 2 women exposed to LAIV while pregnant; neither experienced any known adverse consequences.

Information regarding pregnancy outcomes was available for 67 LAIV recipients (mean age, 27 y; range, 14–40); 40 live births, 8 spontaneous abortions, 8 elective abortions, 2 ectopic pregnancies, and 1 therapeutic abortion were reported.
- Among the live births with additional information available (n=38), 36 infants were described as “healthy”; 1 infant was premature (52 weeks gestational age), and 1 infant was diagnosed with clinical cholesty.
- Available data regarding maternal adverse events (AEs) were summarized for the period of 21 days after receipt of LAIV and from vaccination to delivery for those without information regarding the timing of events in relationship to vaccination.
- 4 women reported adverse events within 21 days of receiving LAIV: The most common AEs were headache (n=2) and sore throat (n=2; Table 1).
- 21 women reported AEs from the date of vaccination to the date of delivery. The most common AEs were arthralgia (n=6); upper respiratory tract infection (n=4), and abdominal pain (n=3; Table 2).
- 20 women reported common complications of pregnancy including vaginal bleeding (n=8), cramping (n=3), and irregular contractions (n=2; Table 3).

Conclusions

- The majority of inadvertent vaccinations with LAIV during the first trimester, a period which may pregnancy not have been detected.
- The observed rates of spontaneous abortions, ectopic pregnancies, preterm deliveries, and congenital anomalies are similar to rates described for US pregnant women overall.4-7
- In this limited cohort, inadvertent exposure to LAIV during pregnancy did not appear to be associated with any significant maternal or fetal adverse events.

References

6. Seth L. Toback, MD

For additional information, please contact Seth L. Toback, MD
(Toback@Medimmune.com)

This study was sponsored by Medimmune.