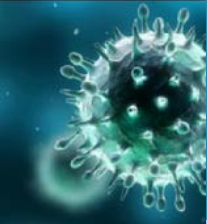




Protein Sciences
CORPORATION

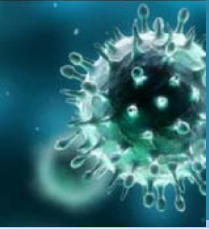
Flublok Pregnancy Data

ACIP 21 June 2017
Wayne E. Hachey DO, MPH



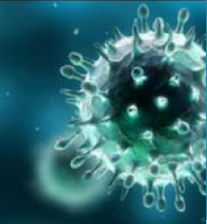
Pregnancy Data

- Pregnancy registry includes all pregnancies reported during clinical trials and during seasonal use
- Package insert includes request for notification of all Flublok vaccine exposures during pregnancy
- Limited data from a vaccine coverage program conducted in Mongolia by Center for Vaccine Equity



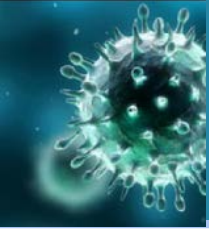
Pregnancies Reported During Clinical Trials

- PSC 01: 3 pregnancies/181 doses to women of childbearing age
 - One Subject received vaccine at 5 weeks gestation – uneventful term pregnancy
 - One subject became pregnant 3 months after receiving Flublok. Elective termination at 12 weeks
 - One subject became pregnant 20 weeks following immunization. Elective termination at 12 weeks



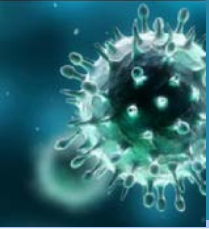
Pregnancies Reported During Clinical Trials

- PSC 04: 20 pregnancies/1371 doses to women of childbearing age
 - 12 live births
 - 1 spontaneous abortion. Received vaccine 2 months before pregnancy. SAB at 5 weeks
 - 2 elective terminations
 - 3 lost to follow-up
 - 2 withdrew from study and would not provide pregnancy outcome data



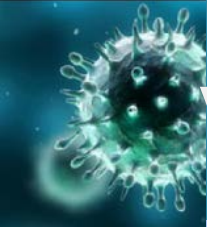
Pregnancies Reported During Clinical Trials

- PSC 16: 7 pregnancies/675 women of childbearing age
 - 1 subject reported pregnancy 3 weeks following immunization – SAB 6 weeks later.
 - 6 uncomplicated live births



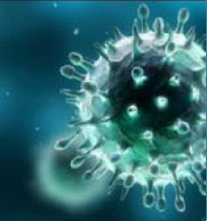
Pregnancies After Routine Seasonal Influenza Immunization

- 5 pregnancies reported
- 4 uneventful pregnancies
- 1 SAB 2 days after immunization
- Approximately 1,000,000 total doses



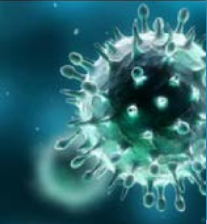
Vaccine Coverage Project-Mongolia

- Program conducted by Center for Vaccine Equity at the Task Force for Global Health
- Goal to increase influenza vaccine coverage in Mongolia
- 40,000 doses donated
- 330 pregnant women received Flublok



Pregnancy Outcome Data - Mongolia

- No serious AE reported - passive surveillance network
- Limitations:
 - No active follow-up of pregnancies
 - Surveillance network capability to capture pregnancy related AE are uncertain.
- With continued participation in this project we hope to include active follow up of individuals who received Flublok during pregnancy



Summary

- 35 Pregnancies
 - 23 Pregnancies with normal outcome
 - 3 Spontaneous Abortions
 - 4 Elective Terminations
 - 3 Lost to follow up
 - 2 Withdrew from study

Flublok[®]

Influenza vaccine

Product Features

Questions

