Surveillance of Vaccine Adverse Events in Pregnant Women Reported to the Vaccine Adverse Events Reporting System (2010-2019)

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BACKGROUND

- The Vaccine Adverse Events Reporting System (VAERS) is a national public health surveillance system that monitors adverse events associated with US license vaccines

Objective: To assess the safety of vaccines administered to pregnant women by analyzing VAERS reports in the US from 2010-2019

METHODS

- Included pregnancy reports for women 12-44 years old from 2010-2019
- Used Medical Dictionary for Regulatory Activities (MedDRA) terms for AEs
- Proportional reporting ratios (PRR) were calculated for reported preferred terms to assess for disproportionately higher reporting of AEs after vaccine administration to pregnant women
- AEs of vaccines with the most frequent reports were compared to overall AEs to assess any unexpected safety concern
- Signal criteria for disproportionality were set at PRR≥2, number of reports≥3

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Review of reported vaccine adverse events found no new or unexpected vaccine safety concerns among women who received a **vaccine during pregnancy**

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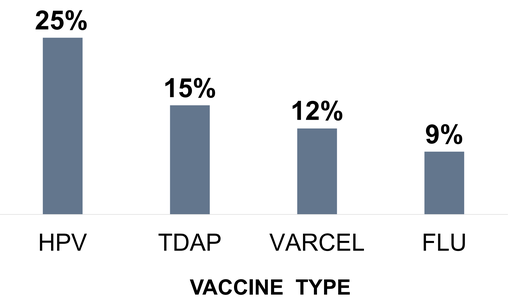
RESULTS

- VAERS received a total of **3,846 reports** for AEs in pregnant women in the period of analysis
- Of those reports, 1,042 (27%) mentioned a serious AE and 1,012 (26%) mentioned a pregnancy-related serious AE. The maternal mean age for women was 26 years (SD±7.3)

Serious AEs	N	%
Death	5	0.1
Life threatening	36	0.9
Emergency room visit	892	23.2
Hospitalization	223	5.8
Disability	42	1.1

Pregnancy-related serious AEs	N	%
Spontaneous abortion (<20 weeks)	862	22.4
Stillbirth (>20 weeks)	63	1.6
Preterm Delivery (<37 weeks)	51	1.3
Preterm Labor	11	0.3
Birth Defect	8	0.2
Miscarriage	292	7.6

Proportion of Adverse Event Reports Submitted to VAERS by Vaccine Type



- PRR screening criteria were only met for the Tdap vaccine and AE preterm delivery (PRR 3.1; 95%CI 1.7-5.8)
- Further studies are needed to confirm association in controlled study design