**Supplementary Table.** Reports following hepatitis B vaccination during pregnancy by trimester of vaccination when vaccine administered in the Vaccine Adverse Event Reporting System (VAERS), United States, 1990 – 2016 (N=115)

|  |  |  |  |
| --- | --- | --- | --- |
| **Trimester at time of hepatitis B vaccination** | **First trimester****(0-13 weeks)** | **Second trimester****(14-27 weeks)** | **Third trimester****(≥28 weeks)** |
| **Adverse Events** † |  |  |  |
| **Number of VAERS reports** | **86** | **18** | **11** |
| **Pregnancy-specific AEs** | 34 | **7** | **2** |
|  Spontaneous abortion (<20 weeks gestation) | 16 | 0 | 0 |
|  Elective termination | 3 | 1 | 0 |
|  Failure to progress | 3 | 0 | 0 |
|  Preterm delivery (<37 weeks) | 2 | 3 | 1 |
|  Hypertension | 2 | 0 | 1 |
|  Vaginal bleeding | 1 | 1 | 0 |
|  Chorioamnionitis | 1 | 0 | 0 |
|  Premature labor | 1 | 0 | 0 |
|  Cesarean section due to breech presentation | 1 | 0 | 0 |
|  Fluid retention | 1 | 0 | 0 |
|  Oligohydramnios | 1 | 0 | 0 |
|  Polyhydramnios | 1 | 0 | 0 |
|  Swelling | 1 | 0 | 0 |
|  Stillbirth | 0 | 1 | 0 |
|  Preeclampsia | 0 | 1 | 0 |
| **Non-pregnancy specific AEs** | **11** | **2** | **4** |
|  Systemic and local reactions | 7  | 1 | 4 |
|  Immune system disorders  | 2 | 0 | 0 |
|  Acute lymphocytic leukemia | 1 | 0 | 0 |
|  Atrial fibrillation | 1 | 0 | 0 |
|  Gastrointestinal disorders | 0 | 0 | 0 |
|  Urinary tract infection | 0 | 1 | 0 |
| **Infant outcomes** | **13** | **1** | **2** |
|  Birth defects†† | 4 | 0 | 0 |
|  Encephalocoele and orbital roof defect | 1 | 0 | 0 |
|  Tetralogy of Fallot | 1 | 0 | 0 |
|  Undescended testicle | 1 | 0 | 0 |
|  Absence of heart | 1 | 0 | 0 |
|  Death a  | 1 | 0 | 0 |
|  Jaundice | 2 | 0 | 1 |
|  Intrauterine brain damage | 0 | 1 | 0 |
|  Laryngomalacia | 0 | 0 | 1 |
|  Broken clavicle | 1 | 0 | 0 |
|  Baby large for vaginal delivery | 1 | 0 | 0 |
|  Deafness | 1 | 0 | 0 |
|  Autism | 1 | 0 | 0 |
|  Blisters in feet | 1 | 0 | 0 |
|  Meningitis | 1 | 0 | 0 |
| **No adverse event reported** | 32 | 8 | 4 |

†Adverse events are based on primary reported diagnoses identified during clinical review. One report may have more than one diagnosis if separate AEs are reported for the pregnant woman and her infant.

a Premature infant (27 weeks); presented small bowel with small perforations and mild hyaline disease and died at 54 days of age

†† For birth defect reports, Hepatitis B vaccine was administered to mother in the first trimester (at 3-4 weeks gestation). One report on Down’s syndrome did not contain information on gestational age at the time of vaccination and was not included in this analysis.