**Supplemental file for the manuscript, “Inactivated Influenza Vaccine and Spontaneous Abortion in the Vaccine Safety Datalink in 2012-13, 2013-14, and 2014-15” Donahue JG, et al.**

**Caption for supplemental information:**

“Supplementary information for this article (eight tables and one figure) is available online.”

Supplemental Table 1. ICD diagnosis codes for spontaneous abortion cases and controls

Supplemental Table 2. Selected demographic and medical characteristics of study subjects by influenza season of enrollmentand all seasons combined

Supplemental Table 3. Odds ratios for the association of SAB with influenza vaccination relative to conception, by influenza season and vaccination status in the previous season

Supplemental Table 4. Odds ratios for the association of SAB with influenza vaccination before the reference date, by influenza season and vaccination status in the previous season. Cases include those with gestational age of 5-<20 weeks

Supplemental Table 5. Odds ratios for the association of influenza vaccination with SAB relative to conception, by influenza season and by vaccination status in the previous season. Cases include those with gestational age of 5-<20 weeks

Supplemental Table 6. Odds ratios for the association of SAB with influenza vaccination before the reference date, by influenza season and vaccination status in the previous season. Matched pairs where either woman had a history of ≥2 SAB were excluded

Supplemental Table 7. Odds ratios for the association of SAB with influenza vaccination relative to conception, by influenza season and vaccination status in the previous season. Matched pairs where either woman had a history of ≥2 SAB were excluded

Supplemental Table 8. Odds ratios for the association of SAB with influenza vaccination before the reference date, by influenza season and vaccination status in the previous season. Analysis excludes 334 women (315 matched pairs) with no specified race.

Supplemental Table 9. Odds ratios for the association of SAB with influenza vaccination before the reference date for all women, by influenza season and all seasons combined. Analysis excludes 334 women (315 matched pairs) with no specified race.

Supplemental Table 10. Odds ratios for the association of SAB with influenza vaccination relative to conception, by influenza season and vaccination status in the previous season. Analysis excludes 334 women (315 matched pairs) with no specified race.

Supplemental Table 11. Comparison of selected characteristics of the current IIV-SAB study with the previous two IIV-SAB studies

Supplemental Figure 1. Gestational Age at the Time of SAB: IIV-SAB-3 Compared with IIV-SAB-2

|  |  |  |  |
| --- | --- | --- | --- |
| **SUPPLEMENTAL TABLE 1** |  |  |  |
| **ICD-9 Description** | **ICD-9** | **ICD-10** | **ICD-10 Description** |
| **CASE CODES** |  |  |  |
| Spontaneous abortion (5th digit 0=unspecified, 1=incomplete, 2=complete) |  |  |  |
| Complicated by genital tract and pelvic infection | 634.00 | O03.5 | Genital tract and pelvic infection following complete or unspecified spontaneous abortion |
|  |  | O03.87 | Sepsis following complete or unspecified spontaneous abortion |
|  | 634.01 | O03.0 | Genital tract and pelvic infection following incomplete spontaneous abortion |
|  |  | O03.37 | Sepsis following incomplete spontaneous abortion |
|  | 634.02 | O03.5 | Genital tract and pelvic infection following complete or unspecified spontaneous abortion |
|  |  | O03.87 | Sepsis following complete or unspecified spontaneous abortion |
| Complicated by delayed or excessive hemorrhage | 634.10 | O03.6 | Delayed or excessive hemorrhage following complete or unspecified spontaneous abortion |
|  | 634.11 | O03.1 | Delayed or excessive hemorrhage following incomplete spontaneous abortion |
|  | 634.12 | O03.6 | Delayed or excessive hemorrhage following complete or unspecified spontaneous abortion |
| Complicated by damage to pelvic organs or tissues | 634.20 | O03.84 | Damage to pelvic organs following complete or unspecified spontaneous abortion |
|  | 634.21 | O03.34 | Damage to pelvic organs following incomplete spontaneous abortion |
|  | 634.22 | O03.84 | Damage to pelvic organs following complete or unspecified spontaneous abortion |
| Complicated by renal failure | 634.30 | O03.82 | Renal failure following complete or unspecified spontaneous abortion |
|  | 634.31 | O03.32 | Renal failure following incomplete spontaneous abortion |
|  | 634.32 | O03.82 | Renal failure following complete or unspecified spontaneous abortion |
| Complicated by metabolic disorder | 634.40 | O03.83 | Metabolic disorder following complete or unspecified spontaneous abortion |
|  | 634.41 | O03.33 | Metabolic disorder following incomplete spontaneous abortion |
|  | 634.42 | O03.83 | Metabolic disorder following complete or unspecified spontaneous abortion |
| Complicated by shock | 634.50 | O03.81 | Shock following complete or unspecified spontaneous abortion |
|  | 634.51 | O03.31 | Shock following incomplete spontaneous abortion |
|  | 634.52 | O03.81 | Shock following complete or unspecified spontaneous abortion |
| Complicated by embolism | 634.60 | O03.7 | Embolism following complete or unspecified spontaneous abortion |
|  | 634.61 | O03.2 | Embolism following incomplete spontaneous abortion |
|  | 634.62 | O03.7 | Embolism following complete or unspecified spontaneous abortion |
| With other specified complications | 634.70 | O03.85 | Other venous complications following complete or unspecified spontaneous abortion |
|  |  | O03.86 | Cardiac arrest following complete or unspecified spontaneous abortion |
|  |  | O03.88 | Urinary tract infection following complete or unspecified spontaneous abortion |
|  |  | O03.89 | Complete or unspecified spontaneous abortion with other complications |
|  | 634.71 | O03.39 | Incomplete spontaneous abortion with other complications |
|  | 634.72 | O03.85 | Other venous complications following complete or unspecified spontaneous abortion |
|  |  | O03.86 | Cardiac arrest following complete or unspecified spontaneous abortion |
|  |  | O03.88 | Urinary tract infection following complete or unspecified spontaneous abortion |
|  |  | O03.89 | Complete or unspecified spontaneous abortion with other complications |
| With unspecified complication | 634.80 | O03.80 | Unspecified complication following complete or unspecified spontaneous abortion |
|  | 634.81 | O03.30 | Unspecified complication following incomplete spontaneous abortion |
|  | 634.82 | O03.80 | Unspecified complication following complete or unspecified spontaneous abortion |
| Without mention of complication | 634.90 | O03.9 | Complete or unspecified spontaneous abortion without complication |
|  | 634.91 | O03.4 | Incomplete spontaneous abortion without complication |
|  | 634.92 | O03.9 | Complete or unspecified spontaneous abortion without complication |
| Unspecified abortion | 637.\* |  | 637 maps to O04.xx "Complications following (induced) termination of pregnancy". |
| **CONTROL CODES** |  |  |  |
| Early onset of delivery | 644.20 | O60.10X0 | Preterm labor with preterm delivery, unspecified trimester, not applicable or unspecified |
|  | 644.21 | O60.12X0 | Preterm labor second trimester with preterm delivery second trimester, not applicable or unspecified |
|  |  | O60.13X0 | Preterm labor second trimester with preterm delivery third trimester, not applicable or unspecified |
|  |  | O60.14X0 | Preterm labor third trimester with preterm delivery third trimester, not applicable or unspecified |
| 645.1 Post term pregnancy | 645.11 | O48.0 | Post-term pregnancy |
| 645.2 Prolonged pregnancy | 645.21 | O48.1 | Prolonged pregnancy |
| Normal delivery | 650 | O80 | Encounter for full-term uncomplicated delivery |
| Twin pregnancy | 651.0\* | O30.0\* | Twin pregnancy |
| Triplet pregnancy | 651.1\* | O30.1\* | Triplet pregnancy |
| Quadruplet pregnancy | 651.2\* | O30.2\* | Quadruplet pregnancy |
| Twin pregnancy with fetal loss and retention of one fetus | 651.3\* | O31.1\* | Continuing pregnancy after spontaneous abortion of one fetus or more |
| Triplet pregnancy with fetal loss and retention of one or more fetus(es) | 651.4\* | O31.1\* | Continuing pregnancy after spontaneous abortion of one fetus or more |
| Quadruplet pregnancy with fetal loss and retention of one or more fetus(es) | 651.5\* | O31.1\* | Continuing pregnancy after spontaneous abortion of one fetus or more |
| Other multiple pregnancy with fetal loss and retention of one or more fetus(es) | 651.6\* | O31.1\* | Continuing pregnancy after spontaneous abortion of one fetus or more |
| Multiple gestation following (elective) fetal reduction | 651.7\* | O31.3\* | Continuing pregnancy after elective fetal reduction of one fetus or more |
| Other specified multiple gestation | 651.8\* | O31.8\* | Other complications specific to multiple gestation |
| Unspecified multiple gestation | 651.9\* | O30.9\* | Multiple gestation, unspecified |
| Unstable lie | 652.0\* | O32.0\* | Maternal care for unstable lie |
| Breech or other malpresentation successfully converted to cephalic presentation | 652.1\* | O32.1\* | Maternal care for breech presentation |
| Breech presentation without mention of version | 652.2\* | O32.1\* | Maternal care for breech presentation |
| Transverse or oblique presentation | 652.3\* | O32.2\* | Maternal care for transverse and oblique lie |
| Face or brow presentation | 652.4\* | O32.3\* | Maternal care for face, brow and chin presentation |
| High head at term | 652.5\* | O32.4\* | Maternal care for high head at term |
| Multiple gestation with malpresentation of one fetus or more | 652.6\* | O32.9\* | Maternal care for malpresentation of fetus, unspecified |
| Prolapsed arm | 652.7\* | O32.8\* | Maternal care for other malpresentation of fetus |
| Other specified malposition or malpresentation | 652.8\* | O32.8\* | Maternal care for other malpresentation of fetus |
|  |  | O32.6\* | Maternal care for compound presentation |
| Unspecified malposition or malpresentation | 652.9\* | O32.9\* | Maternal care for malpresentation of fetus, unspecified |
| Central nervous system malformation in fetus | 655.0\* | O35.0\* | Maternal care for (suspected) central nervous system malformation in fetus |
| Chromosomal abnormality in fetus | 655.1\* | O35.1\* | Maternal care for (suspected) chromosomal abnormality in fetus |
| Hereditary disease in family possibly affecting fetus | 655.2\* | O35.2\* | Maternal care for (suspected) hereditary disease in fetus |
| Suspected damage to fetus from viral disease in the mother | 655.3\* | O35.3\* | Maternal care for (suspected) damage to fetus from viral disease in mother |
| Suspected damage to fetus from other disease in the mother | 655.4\* | O35.4\* | Maternal care for (suspected) damage to fetus from alcohol |
| Suspected damage to fetus from drugs | 655.5\* | O35.5\* | Maternal care for (suspected) damage to fetus by drugs |
| Suspected damage to fetus from radiation | 655.6\* | O35.6\* | Maternal care for (suspected) damage to fetus by radiation |
| Decreased fetal movements | 655.7\* | O36.81\* | Decreased fetal movements, unspecified trimester |
| Other known or suspected fetal abnormality, not elsewhere classified | 655.8\* | O35.8\* | Maternal care for other (suspected) fetal abnormality and damage |
| Unspecified | 655.9\* | O35.9\* | Maternal care for (suspected) fetal abnormality and damage, unspecified |
| Fetal-maternal hemorrhage | 656.0\* | O43.0\* | Placental transfusion syndromes |
| Rhesus isoimmunization | 656.1\* | O36.0\* | Maternal care for rhesus isoimmunization |
| Isoimmunization from other and unspecified blood-group incompatibility | 656.2\* | O36.1\* | Maternal care for other isoimmunization |
| Fetal distress | 656.3\* | O68 | Labor and delivery complicated by abnormality of fetal acid-base balance |
| Intrauterine death | 656.4\* | O36.4\* | Maternal care for intrauterine death |
| Poor fetal growth | 656.5\* | O36.5\* | Maternal care for known or suspected poor fetal growth |
| Excessive fetal growth | 656.6\* | O36.6\* | Maternal care for excessive fetal growth |
| Other placental conditions | 656.7\* | O43.19\* | Other malformation of placenta |
|  |  | O43.81\* | Placental infarction |
|  |  | O43.10\* | Malformation of placenta, unspecified |
|  |  | O43.9\* | Unspecified placental disorder |
| Other specified fetal and placental problems | 656.8\* | O68 | Labor and delivery complicated by abnormality of fetal acid-base balance |
|  |  | O36.89\* | Maternal care for other specified fetal problems |
|  |  | O77.0 | Labor and delivery complicated by meconium in amniotic fluid |
| Unspecified fetal and placental problem | 656.9\* | O36.9\* | Maternal care for fetal problem, unspecified |
| Failed mechanical induction | 659.0\* | O61.1 | Failed instrumental induction of labor |
| Failed medical or unspecified induction | 659.1\* | O61.0 | Failed medical induction of labor |
|  |  | O61.9 | Failed induction of labor, unspecified |
| Maternal pyrexia during labor, unspecified | 659.2\* | O75.2 | Pyrexia during labor, not elsewhere classified |
| Generalized infection during labor | 659.3\* | O75.3 | Other infection during labor |
| Grand multiparity | 659.4\* | O09.4\* | O09.4 Supervision of pregnancy with grand multiparity |
| Elderly primigravida | 659.5\* | O09.51\* | Supervision of elderly primigravida |
| Elderly multigravida | 659.6\* | O09.52\* | Supervision of elderly multigravida |
| Abnormality in fetal heart rate or rhythm | 659.7\* | O76 | Abnormality in fetal heart rate and rhythm complicating labor and delivery |
| Other specified indications for care or intervention related to labor and delivery | 659.8\* | O75.89 | Other specified complications of labor and delivery |
| Unspecified indication for care or intervention related to labor and delivery | 659.9\* | O75.9 | Complication of labor and delivery, unspecified |
| Obstruction caused by malposition of fetus at onset of labor | 660.0\* | O64.9XX0 | Obstructed labor due to malposition and malpresentation, unspecified, not applicable or unspecified |
| Obstruction by bony pelvis | 660.1\* | O65.4 | Obstructed labor due to fetopelvic disproportion, unspecified |
| Obstruction by abnormal pelvic soft tissues | 660.2\* | O65.9 | Obstructed labor due to maternal pelvic abnormality, unspecified |
|  |  | O65.5 | Obstructed labor due to abnormality of maternal pelvic organs |
| Deep transverse arrest and persistent occipitoposterior position | 660.3\* | O64.0XX0 | Obstructed labor due to incomplete rotation of fetal head, not applicable or unspecified |
| Shoulder (girdle) dystocia | 660.4\* | O66.0 | Obstructed labor due to shoulder dystocia |
| Locked twins | 660.5\* | O66.1 | Obstructed labor due to locked twins |
| Failed trial of labor, unspecified | 660.6\* | O66.40 | Failed trial of labor, unspecified |
| Failed forceps or vacuum extractor, unspecified | 660.7\* | O66.5 | Attempted application of vacuum extractor and forceps |
| Other causes of obstructed labor | 660.8\* | O66.8 | Other specified obstructed labor |
| Unspecified obstructed labor | 660.9\* | O66.9 | Obstructed labor, unspecified |
| Primary uterine inertia | 661.0\* | O62.0 | Primary inadequate contractions |
| Secondary uterine inertia | 661.1\* | O62.1 | Secondary uterine inertia |
| Other and unspecified uterine inertia | 661.2\* | O62.2 | Other uterine inertia |
| Precipitate labor | 661.3\* | O62.3 | Precipitate labor |
| Hypertonic, incoordinate, or prolonged uterine contractions | 661.4\* | O62.4 | Hypertonic, incoordinate, and prolonged uterine contractions |
| Unspecified abnormality of labor | 661.9\* | O62.9 | Abnormality of forces of labor, unspecified |
| Prolonged first stage | 662.0\* | O63.0 | Prolonged first stage (of labor) |
| Prolonged labor, unspecified | 662.1\* | O63.9 | Long labor, unspecified |
| Prolonged second stage | 662.2\* | O63.1 | Prolonged second stage (of labor) |
| Delayed delivery of second twin, triplet, etc. | 662.3\* | O63.2 | Delayed delivery of second twin, triplet, etc. |
| Prolapse of cord | 663.0\* | O69.0XX0 | Labor and delivery complicated by prolapse of cord, not applicable or unspecified |
| Cord around neck, with compression | 663.1\* | O69.1XX0 | Labor and delivery complicated by cord around neck, with compression, not applicable or unspecified |
| Other and unspecified cord entanglement, with compression | 663.2\* | O69.2XX0 | Labor and delivery complicated by other cord entanglement, with compression, not applicable or unspecified |
| Other and unspecified cord entanglement, without mention of compression | 663.3\* | O69.81\* | Labor and delivery complicated by cord around neck, without compression |
|  |  | O69.82\* | Labor and delivery complicated by other cord entanglement, without compression |
|  |  | O69.89\* | Labor and delivery complicated by other cord complications |
| Short cord | 663.4\* | O69.3XX0 | Labor and delivery complicated by short cord, not applicable or unspecified |
| Vasa previa | 663.5\* | O69.4XX0 | Labor and delivery complicated by vasa previa, not applicable or unspecified |
| Vascular lesions of cord | 663.6\* | O69.5XX0 | Labor and delivery complicated by vascular lesion of cord, not applicable or unspecified |
| Other umbilical cord complications | 663.8\* | O69.89X0 | Labor and delivery complicated by other cord complications, not applicable or unspecified |
| Unspecified umbilical cord complication | 663.9\* | O69.9XX0 | Labor and delivery complicated by cord complication, unspecified, not applicable or unspecified |
| First-degree perineal laceration | 664.0\* | O70.0 | First degree perineal laceration during delivery |
| Second-degree perineal laceration | 664.1\* | O70.1 | Second degree perineal laceration during delivery |
| Third-degree perineal laceration | 664.2\* | O70.2 | Third degree perineal laceration during delivery |
| Fourth-degree perineal laceration | 664.3\* | O70.3 | Fourth degree perineal laceration during delivery |
| Unspecified perineal laceration | 664.4\* | O70.9 | Perineal laceration during delivery, unspecified |
| Vulval and perineal hematoma | 664.5\* | O71.7 | Obstetric hematoma of pelvis |
| Anal sphincter tear complicating delivery, not associated with third-degree perineal laceration | 664.6\* | O70.4 | Anal sphincter tear complicating delivery, not associated with third degree laceration |
| Other specified trauma to perineum and vulva | 664.8\* | O71.82 | Other specified trauma to perineum and vulva |
| Unspecified trauma to perineum and vulva | 664.9\* | O71.9 | Obstetric trauma, unspecified |
| Rupture of uterus before onset of labor | 665.0\* | O71.0\* | Rupture of uterus (spontaneous) before onset of labor |
| Rupture of uterus during labor | 665.1\* | O71.1 | Rupture of uterus during labor |
| Inversion of uterus | 665.2\* | O71.2 | Postpartum inversion of uterus |
| Laceration of cervix | 665.3\* | O71.3 | Obstetric laceration of cervix |
| High vaginal laceration | 665.4\* | O71.4 | Obstetric high vaginal laceration alone |
| Other injury to pelvic organs | 665.5\* | O71.5 | Other obstetric injury to pelvic organs |
| Damage to pelvic joints and ligaments | 665.6\* | O71.6 | Obstetric damage to pelvic joints and ligaments |
| Pelvic hematoma | 665.7\* | O71.7 | Obstetric hematoma of pelvis |
| Other specified obstetrical trauma | 665.8\* | O71.89 | Other specified obstetric trauma |
| Unspecified obstetrical trauma | 665.9\* | O71.9 | Obstetric trauma, unspecified |
| Third-stage hemorrhage | 666.0\* | O72.0 | Third-stage hemorrhage |
| Other immediate postpartum hemorrhage | 666.1\* | O72.1 | Other immediate postpartum hemorrhage |
| Delayed and secondary postpartum hemorrhage | 666.2\* | O72.2 | Delayed and secondary postpartum hemorrhage |
| Postpartum coagulation defects | 666.3\* | O72.3 | Postpartum coagulation defects |
| Retained placenta without hemorrhage | 667.0\* | O43.239 | Placenta percreta, unspecified trimester |
|  |  | O73.0 | Retained placenta without hemorrhage |
|  |  | O43.231 | Placenta percreta, first trimester |
| Retained portions of placenta or membranes, without hemorrhage | 667.1\* | O73.1 | Retained portions of placenta and membranes, without hemorrhage |
| Maternal distress | 669.0\* | O75.0 | Maternal distress during labor and delivery |
| Shock during or following labor and delivery | 669.1\* | O75.1 | Shock during or following labor and delivery |
| Maternal hypotension syndrome | 669.2\* | O26.5\* | Maternal hypotension syndrome |
| Acute renal failure following labor and delivery | 669.3\* | O90.4 | Postpartum acute kidney failure |
| Other complications of obstetrical surgery and procedures | 669.4\* | O75.4 | Other complications of obstetric surgery and procedures |
| Forceps or vacuum extractor delivery without mention of indication | 669.5\* | O66.5 | Attempted application of vacuum extractor and forceps |
| Breech extraction, without mention of indication | 669.6\* | O64.1XX0 | Obstructed labor due to breech presentation, not applicable or unspecified |
| Cesarean delivery, without mention of indication | 669.7\* | O82 | Encounter for cesarean delivery without indication |
| Other complications of labor and delivery | 669.8\* | O75.81 | Maternal exhaustion complicating labor and delivery |
|  |  | O75.89 | Other specified complications of labor and delivery |
| Unspecified complication of labor and delivery | 669.9\* | O75.9 | Complication of labor and delivery, unspecified |
| Z37 codes match up to V codes in ICD-9, but they were not used in previous studies. |  | Z37.\* | Outcome of delivery |
|  |  |  |  |
| **EXCLUSION CODES** |  |  |  |
| Legally induced abortion | 635.\* | O04.\* | Complications following (induced) termination of pregnancy |
| Illegally induced abortion | 636.\* | O04.\* | Complications following (induced) termination of pregnancy |
| Ectopic pregnancy | 633.\* | O00.\* | Ectopic pregnancy |
| Hydatidiform mole | 630 | O01.9 | Hydatidiform mole, unspecified |
| Other abnormal product of conception | 631.0 | O02.81 | Inappropriate change in quantitative human chorionic gonadotropin (hCG) in early pregnancy |
|  | 631.8 | O02.0 | Blighted ovum and nonhydatidiform mole |
|  |  | O02.89 | Other abnormal products of conception |

**Supplemental Table 2. Selected demographic and medical characteristics of study subjects by influenza season of enrollmentand all seasons combineda**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **2012-13** | **2013-14** | **2014-15** | **All seasons** |
| Women enrolled in the study | 850 | 802 | 820 | 2472 |
| Median age at LMP (IQR) | 34.3 (29, 38) | 34.6 (29, 37) | 34.8 (30, 38) | 34.6 (29, 38) |
| Median BMI (IQR) | 25.2 (22, 30) | 25.4 (22, 31) | 25.6 (22, 30) | 25.4 (22, 30) |
| At least 1 ultrasoundb | 407 (96) | 374 (93) | 388 (95) | 1169 (95) |
| Median number of ultrasounds (IQR)b | 3 (2, 4) | 3 (2, 4) | 3 (2, 4) | 3 (2, 4) |
| Concomitant Tdap vaccination | 5 (1) | 1 (0) | 2 (0) | 8 (0) |
| Vaccinated with IIV in the flu season in which the SAB for the matched pair occurred | 457 (54) | 479 (60) | 456 (56) | 1392 (56) |
| Parity (≥1 birth) | 552 (65) | 509 (63) | 515 (63) | 1576 (64) |
| Gravidity (≥1) | 653 (77) | 614 (77) | 630 (77) | 1897 (77) |
| History of prior SAB (≥1) | 264 (31) | 251 (31) | 259 (32) | 860 (31) |
| Mean (median) number of days between the LMP date of cases and matched controls | 0 (0) | 0 (0) | 0 (0) | 0 (0) |

aData are N (%) unless otherwise noted. Table includes data for cases (and matched controls) that are between 6 and less than 20 weeks gestation. IQR=interquartile range. BMI=body mass index. SAB=spontaneous abortion

bCases only

**Supplemental Table 3. Odds ratios for the association of SAB with influenza vaccination relative to conception,a by influenza season and vaccination status in the previous seasonb**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | |  | | | | | Influenza season | | | |  | | | |  |  |  |
|  | | 2012-13 | | | | | 2013-14 | | | | 2014-15 | | | | | All seasons combined | | |
| Days between vaccination and conception | Disc.  Pairsc | | | Crude ORd | aORe | Disc.  Pairsc | | | Crude ORd | aORe | | | Disc.  Pairsc | Crude ORd | aORe | Disc.  Pairsc | Crude ORd | aORe |
| >42 days before | 26/36 | | | 0.7 | 0.7 (0.4, 1.1) | 27/24 | | | 0.9 | 0.9 (0.5, 1.5) | | | 21/32 | 0.6 | 0.6 (0.3, 0.9) | 74/92 | 0.7 | 0.7 (0.5, 0.9) |
| 0-42 day before | 11/17 | | | 0.7 | 0.8 (0.4, 1.5) | 13/17 | | | 0.9 | 1.1 (0.6, 2.1) | | | 14/21 | 0.9 | 0.7 (0.4, 1.3) | 38/55 | 0.8 | 0.8 (0.6, 1.2) |
| 1-28 days after | 10/17 | | | 0.5 | 0.6 (0.3, 1.1) | 12/11 | | | 0.7 | 1.1 (0.5, 2.2) | | | 13/10 | 1.2 | 1.2 (0.6, 2.3) | 35/38 | 0.8 | 0.9 (0.6, 1.3) |
| >28 days after | 8/22 | | | 0.4 | 0.5 (0.2, 0.9) | 11/30 | | | 0.5 | 0.6 (0.3, 1.1) | | | 12/11 | 1.0 | 1.0 (0.5, 2.2) | 31/63 | 0.6 | 0.6 (0.4, 0.9) |

aConception is defined as the date of the last menstrual period plus 14 days.

bThe referent exposure group in all odds ratio calculations was comprised of women unvaccinated as of the reference date. Numbers in parentheses represent 95% confidence intervals. Gestational age of cases: 6 to <20 weeks. Based on the set of covariates included in models that pooled data across prior season vaccination status strata, there were 4 discordant pairs with missing values for ≥1 covariate (for either the case or control in the pair) among women in 2012-13, 2 in 2013-14, and 1 in 2014-15.

cDiscordant pairs: the first number is the number of matched pairs where the case was vaccinated in the relevant exposure window and the control was unvaccinated as of the reference date, the second number is the number of matched pairs where the control was vaccinated in the window and the case was unvaccinated as of the reference date.

dCrude odds ratios are controlled for matching variables: VSD site, LMP, vaccination in previous season, and age group (18-24, 25-34, and 35-44).

eIn addition to the matching variables, adjusted odds ratios (aOR) are adjusted in all models for maternal age, BMI, selected race variables, Hispanic ethnicity, and healthcare utilization. Models for the stratum, vaccinated in prior season=Yes, also adjusted for diabetes, asthma, and febrile illness in the 14 days before the reference date. Models for the stratum, vaccinated in prior season=No, also adjusted parity.

**Supplemental Table 4. Odds ratios for the association of SAB with influenza vaccination before the reference date, by influenza season and vaccination status in the previous season.a Cases include those with gestational age of 5-<20 weeks.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | | |  | | Influenza season | | | | |  | | | | | |
|  |  | 2012-13 | | | | | 2013-14 | | | 2014-15 | | | | All seasons combined | | | |
|  | Days from vaccination to reference date | | Crude ORb | | aORc | | | Crude ORb | aORc | | | Crude ORb | aORc | | Crude ORb | aORc |
| Vaccinated in previous season | 1-28 | | 0.6 | | 0.6 (0.3, 1.2) | | | 1.1 | 1.1 (0.5, 2.2) | | | 1.6 | 1.8 (0.8, 4.3) | | 1.0 | 1.0 (0.6, 1.5) |
| 29-56 | | 0.6 | | 0.6 (0.3, 1.3) | | | 0.5 | 0.7 (0.3, 1.6) | | | 1.0 | 1.1 (0.5, 2.6) | | 0.7 | 0.8 (0.5, 1.2) |
| >56 | | 0.7 | | 0.7 (0.4, 1.0) | | | 1.1 | 1.1 (0.6, 1.9) | | | 0.7 | 0.6 (0.4, 1.1) | | 0.8 | 0.8 (0.6, 1.0) |
| Not vaccinated in previous season | 1-28 | | 0.6 | | 0.8 (0.3, 1.8) | | | 0.4 | 0.6 (0.2, 1.3) | | | 0.7 | 0.6 (0.3, 1.5) | | 0.6 | 0.6 (0.4, 1.1) |
| 29-56 | | 0.4 | | 1.1 (0.2, 7.0) | | | 0.1 | 0.1 (0.0, 0.9) | | | 0.7 | 0.6 (0.1, 2.7) | | 0.3 | 0.4 (0.1, 1.0) |
| >56 | | 0.8 | | 0.9 (0.4, 1.8) | | | 1.0 | 1.3 (0.6, 2.7) | | | 0.8 | 0.7 (0.4, 1.4) | | 0.8 | 0.9 (0.6, 1.4) |

aThe referent exposure group in all odds ratio calculations was comprised of women unvaccinated as of the reference date. Based on the sets of covariates included in stratum-specific models, there were 2 discordant pairs with missing values for ≥1 covariate (for either the case or control in the pair) among women vaccinated in the previous season; there were 5 among women not vaccinated in the previous season.

bCrude odds ratios are controlled for matching variables: VSD site, LMP, vaccination in previous season, and age group (18-24, 25-34, and 35-44).

cIn addition to the matching variables, adjusted odds ratios (aOR) are adjusted in all models for maternal age, BMI, selected race variables, Hispanic ethnicity, and healthcare utilization. Models for the stratum, vaccinated in prior season=Yes, also adjusted for diabetes, asthma, and febrile illness in the 14 days before the reference date. Models for the stratum, vaccinated in prior season=No, also adjusted parity. Numbers in parentheses represent 95% confidence intervals.

**Supplemental Table 5. Odds ratios for the association of influenza vaccination with SAB relative to conception,a by influenza season and by vaccination status in the previous season.b Cases include those with gestational age of 5-<20 weeks.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | | |  | | | | Influenza season | | | |  | | | | |  |  | |
|  |  | 2012-13 | | | | 2013-14 | | | | 2014-15 | | | | All seasons combined | | | | | | |
|  | Days between vaccination and conception | | Crude ORc | | aORd | | Crude ORc | | aORd | | Crude ORc | | aORd | | Crude ORc | aORd | | |
| Vaccinated in previous season | >42 days before | | 0.8 | | 0.7 (0.4, 1.3) | | 1.1 | | 1.1 (0.6, 2.0) | | 0.7 | | 0.6 (0.3, 1.1) | | 0.8 | 0.8 (0.6, 1.1) | | |
| 0-42 day before | | 0.8 | | 0.9 (0.4, 1.7) | | 1.0 | | 1.1 (0.5, 2.2) | | 0.8 | | 0.6 (0.3, 1.3) | | 0.8 | 0.8 (0.6, 1.2) | | |
| 1-28 days after | | 0.4 | | 0.3 (0.1, 0.8) | | 1.0 | | 1.2 (0.6, 2.8) | | 1.8 | | 2.3 (0.9, 5.5) | | 0.8 | 0.9 (0.6, 1.5) | | |
|  | >28 days after | | 0.5 | | 0.6 (0.2, 1.4) | | 0.7 | | 0.8 (0.3, 1.8) | | 1.3 | | 1.6 (0.5, 4.6) | | 0.8 | 0.8 (0.5, 1.4) | | |
| Not vaccinated in previous season | >42 days before | | 1.0 | | 1.1 (0.5, 2.7) | | 0.9 | | 1.1 (0.5, 2.5) | | 0.6 | | 0.6 (0.3, 1.3) | | 0.8 | 0.8 (0.5, 1.3) | | |
| 0-42 day before | | 0.4 | | 0.5 (0.1, 1.8) | | 0.7 | | 1.1 (0.4, 3.3) | | 1.4 | | 1.3 (0.4, 3.8) | | 0.7 | 0.9 (0.5, 1.8) | | |
| 1-28 days after | | 1.9 | | 3.2 (0.9, 11.6) | | 0.4 | | 1.0 (0.2, 4.3) | | 0.7 | | 0.4 (0.1, 1.2) | | 0.8 | 1.0 (0.5, 2.0) | | |
|  | >28 days after | | 0.3 | | 0.4 (0.1, 1.2) | | 0.4 | | 0.4 (0.2, 1.0) | | 0.8 | | 0.9 (0.3, 2.9) | | 0.4 | 0.5 (0.3, 0.9) | | |

aConception is defined as the date of the last menstrual period plus 14 days.

bThe referent exposure group in all odds ratio calculations was comprised of women unvaccinated as of the reference date. Numbers in parentheses represent 95% confidence intervals. Based on the sets of covariates included in stratum-specific models, there were 2 discordant pairs with missing values for ≥1 covariate (for either the case or control in the pair) among women vaccinated in the previous season; there were 5 among women not vaccinated in the previous season.

cCrude odds ratios are controlled for matching variables: VSD site, LMP, vaccination in previous season, and age group (18-24, 25-34, and 35-44).

dIn addition to the matching variables, adjusted odds ratios (aOR) are adjusted in all models for maternal age, BMI, selected race variables, Hispanic ethnicity, and healthcare utilization. Models for the stratum, vaccinated in prior season=Yes, also adjusted for diabetes, asthma, and febrile illness in the 14 days before the reference date. Models for the stratum, vaccinated in prior season=No, also adjusted parity.

**Supplemental Table 6. Odds ratios for the association of SAB with influenza vaccination before the reference date, by influenza season and vaccination status in the previous season.a Matched pairs where either woman had a history of ≥2 SAB were excluded.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | | |  | | | | Influenza season | | | |  | | | |
|  |  | 2012-13 | | | | 2013-14 | | | | 2014-15 | | | All seasons combined | | |
|  | Days from vaccination to reference date | | Crude ORb | | aORc | | Crude ORb | | aORc | Crude ORb | aORc | | | Crude ORb | aORc |
| Vaccinated in previous season | 1-28 | | 0.5 | | 0.5 (0.2, 1.2) | | 1.7 | | 1.8 (0.8, 4.2) | 1.9 | 2.2 (0.8, 6.2) | | | 1.2 | 1.2 (0.7, 2.0) |
| 29-56 | | 0.8 | | 0.7 (0.3, 1.7) | | 0.9 | | 1.2 (0.5, 3.1) | 1.2 | 1.3 (0.5, 3.2) | | | 0.9 | 1.0 (0.6, 1.6) |
| >56 | | 0.6 | | 0.6 (0.3, 1.0) | | 1.2 | | 1.2 (0.6, 2.3) | 0.6 | 0.5 (0.3, 0.9) | | | 0.7 | 0.7 (0.5, 1.0) |
| Not vaccinated in previous season | 1-28 | | 0.7 | | 0.7 (0.3, 1.8) | | 0.6 | | 0.7 (0.3, 1.7) | 1.2 | 1.1 (0.4, 2.9) | | | 0.8 | 0.8 (0.5, 1.4) |
| 29-56 | | 0.3 | | 0.6 (0.1, 8.0) | | 0.2 | | 0.2 (0.0, 1.7) | 0.6 | 0.5 (0.1, 3.3) | | | 0.3 | 0.4 (0.1, 1.2) |
| >56 | | 0.7 | | 0.8 (0.3, 1.9) | | 0.8 | | 1.1 (0.5, 2.8) | 0.9 | 0.9 (0.4, 2.0) | | | 0.8 | 0.9 (0.6, 1.5) |

aThe referent exposure group in all odds ratio calculations was comprised of women unvaccinated as of the reference date. Gestational age of cases: 6 to <20 weeks. Based on the sets of covariates included in stratum-specific models, there were 2 discordant pairs with missing values for ≥1 covariate (for either the case or control in the pair) among women vaccinated in the previous season; there were 3 among women not vaccinated in the previous season.

bCrude odds ratios are controlled for matching variables: VSD site, LMP, vaccination in previous season, and age group (18-24, 25-34, and 35-44).

cIn addition to the matching variables, adjusted odds ratios (aOR) are adjusted in all models for maternal age, BMI, selected race variables, Hispanic ethnicity, and healthcare utilization. Models for the stratum, vaccinated in prior season=Yes, also adjusted for diabetes, asthma, and febrile illness in the 14 days before the reference date. Models for the stratum, vaccinated in prior season=No, also adjusted parity. Numbers in parentheses represent 95% confidence intervals.

**Supplemental Table 7. Odds ratios for the association of SAB with influenza vaccination relative to conception,a by influenza season and vaccination status in the previous season.b Matched pairs where either woman had a history of ≥2 SAB were excluded.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | | |  | | | | Influenza season | | | |  | | | | |
|  |  | 2012-13 | | | | 2013-14 | | | | 2014-15 | | | | All seasons combined | | | |
|  | Days between vaccination and conception | | Crude ORc | | aORd | | Crude ORc | | aORd | | Crude ORc | | aORd | | Crude ORc | aORd | |
| Vaccinated in previous season | >42 days before | | 0.7 | | 0.6 (0.3, 1.1) | | 1.1 | | 1.1 (0.5, 2.4) | | 0.6 | | 0.4 (0.2, 0.9) | | 0.7 | 0.7 (0.4, 1.0) | |
| 0-42 day before | | 0.8 | | 0.9 (0.4, 1.9) | | 1.4 | | 1.7 (0.7, 4.1) | | 0.7 | | 0.6 (0.3, 1.4) | | 0.9 | 1.0 (0.6, 1.5) | |
| 1-28 days after | | 0.4 | | 0.4 (0.1, 1.0) | | 1.6 | | 2.0 (0.7, 5.3) | | 2.0 | | 2.6 (0.9, 7.1) | | 1.1 | 1.2 (0.7, 2.0) | |
|  | >28 days after | | 0.4 | | 0.4 (0.1, 1.1) | | 1.0 | | 1.0 (0.4, 2.8) | | 1.6 | | 1.8 (0.5, 6.1) | | 0.8 | 0.9 (0.5, 1.6) | |
| Not vaccinated in previous season | >42 days before | | 0.7 | | 0.7 (0.2, 2.4) | | 0.6 | | 0.8 (0.3, 2.2) | | 0.7 | | 0.6 (0.2, 1.6) | | 0.7 | 0.7 (0.4, 1.3) | |
| 0-42 day before | | 0.4 | | 0.6 (0.1, 2.9) | | 0.9 | | 1.5 (0.4, 5.6) | | 2.5 | | 2.7 (0.7, 10.6) | | 1.0 | 1.5 (0.7, 3.2) | |
| 1-28 days after | | 2.1 | | 3.0 (0.7, 12.7) | | 0.5 | | 1.4 (0.3, 6.7) | | 1.0 | | 0.6 (0.2, 2.1) | | 1.1 | 1.3 (0.6, 2.8) | |
|  | >28 days after | | 0.4 | | 0.4 (0.1, 1.2) | | 0.5 | | 0.5 (0.2, 1.3) | | 1.0 | | 1.2 (0.3, 4.3) | | 0.5 | 0.6 (0.3, 1.0) | |

aConception is defined as the date of the last menstrual period plus 14 days.

bThe referent exposure group in all odds ratio calculations was comprised of women unvaccinated as of the reference date. Numbers in parentheses represent 95% confidence intervals. Gestational age of cases: 6 to <20 weeks. Based on the sets of covariates included in stratum-specific models, there were 2 discordant pairs with missing values for ≥1 covariate (for either the case or control in the pair) among women vaccinated in the previous season; there were 3 among women not vaccinated in the previous season.

cCrude odds ratios are controlled for matching variables: VSD site, LMP, vaccination in previous season, and age group (18-24, 25-34, and 35-44).

dIn addition to the matching variables, adjusted odds ratios (aOR) are adjusted in all models for maternal age, BMI, selected race variables, Hispanic ethnicity, and healthcare utilization. Models for the stratum, vaccinated in prior season=Yes, also adjusted for diabetes, asthma, and febrile illness in the 14 days before the reference date. Models for the stratum, vaccinated in prior season=No, also adjusted parity.

**Supplemental Table 8. Odds ratios for the association of SAB with influenza vaccination before the reference date, by influenza season and vaccination status in the previous season.a. Analysis excludes 334 women (315 matched pairs) with no specified race.**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Influenza season | | | | | |  | |
|  |  | 2012-13 | | 2013-14 | | 2014-15 | | All seasons combined | |
|  | Vaccination to reference date (days) | Crude ORb | aORc | Crude ORb | aORc | Crude ORb | aORc | Crude ORb | aORc |
| Vaccinated in previous season | 1-28 | 0.5 | 0.6 (0.2, 1.4) | 1.0 | 1.0 (0.4, 2.2) | 1.4 | 1.8 (0.5, 5.9) | 0.9 | 0.9 (0.5, 1.5) |
| 29-56 | 0.6 | 0.7 (0.3, 1.5) | 0.5 | 0.7 (0.2, 2.0) | 0.9 | 0.8 (0.3, 2.2) | 0.6 | 0.7 (0.4, 1.2) |
| >56 | 0.5 | 0.5 (0.3, 1.0) | 1.0 | 1.1 (0.6, 2.2) | 0.6 | 0.5 (0.3, 0.9) | 0.7 | 0.6 (0.4, 0.9) |
| Not vaccinated in previous season | 1-28 | 0.5 | 0.5 (0.2, 1.5) | 0.4 | 0.3 (0.1, 1.0) | 0.8 | 0.7 (0.3, 2.0) | 0.6 | 0.5 (0.3, 0.9) |
| 29-56 | 0.7 | 0.8 (0.1, 10.3) | 0.1 | 0.2 (0.0, 2.1) | 0.6 | 0.2 (0.0, 2.5) | 0.4 | 0.3 (0.1, 1.2) |
| >56 | 0.7 | 1.0 (0.5, 2.4) | 0.9 | 1.7 (0.7, 4.0) | 0.9 | 0.8 (0.3, 1.8) | 0.8 | 1.1 (0.7, 1.8) |

aThe referent exposure group in all odds ratio calculations was comprised of women unvaccinated as of the reference date. Gestational age of cases ranges from 6 to <20 weeks. Based on the sets of covariates included in stratum-specific models, there were 2 discordant pairs with missing values for ≥1 covariate (for either the case or control in the pair) among women vaccinated in the previous season; there were 4 among women not vaccinated in the previous season.

bCrude odds ratios are controlled for matching variables: VSD site, LMP, vaccination in the previous season, and age group (18-24, 25-34, and 35-44).

cIn addition to the matching variables, controlled odds ratios (aOR) are adjusted in all models for maternal age, BMI, selected race variables, Hispanic ethnicity, and healthcare utilization. Models for the stratum, vaccinated in prior season=Yes, also adjusted for diabetes, asthma, and febrile illness in the 14 days before the reference date. Models for the stratum, vaccinated in prior season=No, also adjusted for parity. Numbers in parentheses represent 95% confidence intervals.

**Supplemental Table 9. Odds ratios for the association of SAB with influenza vaccination before the reference date for all women, by influenza season and all seasons combined.a Analysis excludes 334 women (315 matched pairs) with no specified race.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | Influenza season | | | | | | | | | | |
|  | | | 2012-13 | | | | | 2013-14 | | | | 2014-15 | | | All seasons combined | | |
| Time from vaccination to reference date |  | Crude ORb | | aORc |  | Crude ORb | | | aORc |  | Crude ORb | | aORc |  | | Crude ORb | aORc | |
| 1-28 days |  | 0.5 | | 0.6 (0.3, 1.1) |  | 0.7 | | | 0.6 (0.3, 1.2) |  | 1.1 | | 1.0 (0.5, 2.1) |  | | 0.7 | 0.7 (0.5, 1.0) | |
| 29-56 days |  | 0.6 | | 0.7 (0.3, 1.5) |  | 0.3 | | | 0.4 (0.2, 1.0) |  | 0.8 | | 0.5 (0.2, 1.3) |  | | 0.6 | 0.6 (0.4, 0.9) | |
| >56 days |  | 0.6 | | 0.7 (0.4, 1.1) |  | 0.9 | | | 1.2 (0.7, 2.1) |  | 0.7 | | 0.6 (0.3, 0.9) |  | | 0.7 | 0.8 (0.6, 1.0) | |

aThe referent exposure group in all odds ratio calculations was comprised of women unvaccinated as of the reference date. Gestational age of cases: 6 to <20 weeks. Based on the set of covariates included in models that pooled data across prior season vaccination status strata, there were 4 discordant pairs with missing values for ≥1 covariate (for either the case or control in the pair) among women in 2012-13, 2 in 2013-14, and 1 in 2014-15.

bCrude odds ratios are controlled for matching variables: VSD site, LMP, vaccination in previous season, and age group (18-24, 25-34, and 35-44).

cIn addition to the matching variables, adjusted odds ratios are adjusted for maternal age, BMI, selected race variables, Hispanic ethnicity, healthcare utilization, diabetes, asthma, febrile illness in the 14 days before the reference date, parity, and pre-existing hypertension. Numbers in parentheses represent 95% confidence intervals.

**Supplemental Table 10. Odds ratios for the association of SAB with influenza vaccination relative to conception,a by influenza season and vaccination status in the previous season.b Analysis excludes 334 women (315 matched pairs) with no specified race.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | | | |  | | | | Influenza season | | | |  | | | | |  |  |  |
|  |  | | 2012-13 | | | | | 2013-14 | | | | 2014-15 | | | | | | All seasons combined | | |
|  | Vaccination to reference date (days) |  | | Crude ORc | | aORd |  | | | Crude ORc | aORd | | |  | Crude ORc | aORd |  | | Crude ORc | aORd |
| Vaccinated in previous season | >42 days before |  | | 0.6 | | 0.5 (0.3, 1.1) |  | | | 1.0 | 1.1 (0.5, 2.5) | | |  | 0.6 | 0.5 (0.2, 1.1) |  | | 0.7 | 0.6 (0.4, 1.0) |
| 0-42 day before |  | | 0.7 | | 1.0 (0.4, 2.2) |  | | | 1.0 | 1.1 (0.5, 2.8) | | |  | 0.7 | 0.4 (0.2, 0.9) |  | | 0.8 | 0.7 (0.5, 1.2) |
| 1-28 days after |  | | 0.3 | | 0.3 (0.1, 0.7) |  | | | 0.9 | 1.2 (0.4, 3.7) | | |  | 1.6 | 2.4 (0.8, 7.4) |  | | 0.7 | 0.8 (0.5, 1.4) |
|  | >28 days after |  | | 0.5 | | 0.6 (0.2, 1.8) |  | | | 0.7 | 0.7 (0.3, 1.8) | | |  | 1.2 | 1.3 (0.2, 6.9) |  | | 0.7 | 0.7 (0.4, 1.3) |
| Not vaccinated in previous season | >42 days before |  | | 0.9 | | 1.5 (0.5, 4.2) |  | | | 0.8 | 1.3 (0.5, 3.7) | | |  | 0.7 | 0.6 (0.2, 1.7) |  | | 0.8 | 1.0 (0.6, 1.8) |
| 0-42 day before |  | | 0.3 | | 0.5 (0.1, 2.0) |  | | | 1.0 | 1.8 (0.5, 5.8) | | |  | 1.7 | 1.7 (0.5, 6.0) |  | | 0.9 | 1.2 (0.6, 2.5) |
| 1-28 days after |  | | 1.8 | | 2.4 (0.6, 9.4) |  | | | 0.4 | 0.3 (0.0, 2.6) | | |  | 0.8 | 0.4 (0.1, 1.5) |  | | 0.9 | 0.8 (0.4, 1.7) |
|  | >28 days after |  | | 0.3 | | 0.3 (0.1, 1.0) |  | | | 0.4 | 0.3 (0.1, 1.0) | | |  | 0.8 | 0.7 (0.2, 3.2) |  | | 0.4 | 0.4 (0.2, 0.8) |

aConception was defined as the date of the last menstrual period plus 14 days.

bThe referent exposure group in all odds ratio calculations was comprised of women unvaccinated as of the reference date. Numbers in parentheses represent 95% confidence intervals. Gestational age of cases ranges from 6 to <20 weeks. Based on the sets of covariates included in stratum-specific models, there were 2 discordant pairs with missing values for ≥1 covariate (for either the case or control in the pair) among women vaccinated in the previous season; there were 4 among women not vaccinated in the previous season.

cCrude odds ratios are controlled for matching variables: VSD site, LMP, vaccination in previous season, and age group (18-24, 25-34, and 35-44).

dIn addition to the matching variables, adjusted odds ratios (aOR) are adjusted in all models for maternal age, BMI, selected race variables, Hispanic ethnicity, and health care utilization. Models for the stratum, vaccinated in prior season=Yes, also adjusted for diabetes, asthma, and febrile illness in the 14 days before the reference date. Models for the stratum, vaccinated in prior season=No, also adjusted parity.

**Supplemental Table 11. Comparison of selected characteristics of the current IIV-SAB study with the previous two IIV-SAB studiesa**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **VSD study and**  **influenza seasons covered** | IIV-SAB-1b  2005-06, 2006-07 | | IIV-SAB-2c  2010-11, 2011-12 | | IIV-SAB-3  2012-13, 2013-14, 2014-15 | |
|  | **Cases** | **Controls** | **Cases** | **Controls** | **Cases** | **Controls** |
| Mean age (years) | 31.7 | 29.3 | 31.8 | 31.2 | 33.8 | 33.1 |
| Parity (1+) | 64 | 64 | 57 | 56 | 63 | 65 |
| Previous SAB | 33 | 27 | 29 | 26 | 31 | 31 |
| Febrile illness in 1st trimester | 2 | 2 | 1 | 0 | 2 | 1 |
| Smoker | 10 | 10 | 11 | 7 | 5 | 5 |
| Diabetes | 4 | 0 | 1 | 2 | 2 | 1 |
| Asthma | 10 | 11 | 11 | 12 | 12 | 10 |
| Hypertension | 4 | 4 | 2 | 3 | 4 | 3 |
| 1 or more ultrasoundsd | 82 | NA | 89 | NA | 93 | NA |
| Median gestational age (weeks) at time of SABd | 7.1 | NA | 7.0 | NA | 7.0 | NA |
| Mean (median) number of days between the LMP date of cases and matched controls | -0.41 (0) | | -0.55 (0) | | 0 (0) | |

aNumbers are percentages unless otherwise indicated. NA=Not applicable

bIrving SA, et al. Obstet Gynecol, 2013

cDonahue JG, et al. Vaccine, 2017

dCases only

**Supplemental Figure 1. Gestational Age at the Time of SAB: IIV-SAB-3 Compared with IIV-SAB-2\***

\*IIV-SAB-3 is the current VSD study of women pregnant in 2012-15 (median gestational age=7 weeks); IIV-SAB-2 studied women pregnant in 2010-12 (median gestational age=7 weeks) (Donahue JG, et al. Vaccine 2017;35:5314-22)