

SUPPORTING INFORMATION FOR

Outcomes in Pregnant Persons Immunized with Cell-Based Quadrivalent Inactivated Influenza Vaccine: A Prospective Observational Cohort Study

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Study Population Selection

The minimum eligibility criteria required for enrollment were as follows:

- Sufficient information to confirm that the exposure of interest occurred during pregnancy and at which date.
- Sufficient information to determine whether it concerned a prospectively enrolled person, since retrospective cases were ineligible for enrollment.
- Reporter (eg, HCP) contact information was required to allow for follow-up.

Recruitment Strategies

Study enrollment was open to all eligible pregnant persons; however, a number of activities were implemented to increase the enrollment rate. Both passive and active recruitment strategies were implemented. One recruitment strategy targeted HCPs who were known to immunize pregnant persons specifically with the cell-based quadrivalent inactivated influenza vaccine (IIV4c). Also, a targeted awareness campaign was undertaken. This included the distribution of a comprehensive informational kit designed to support HCPs in soliciting interest among pregnant persons in study participation. All messaging was in line with approved US product labeling of IIV4c.

The kit included:

- A brochure that briefly described the study purpose and procedures
- Enrollment form and sample informed consent form
- Important Safety Information
- Participant consent to contact card, which enabled the Coordinating Center to contact the potentially participating persons and provide additional information about the study

A variety of other approaches to provide information to pregnant persons and their HCPs for possible enrollment in the pregnancy registry was also used:

- Internet:
 - FDA listing of pregnancy registries on www.fda.gov
 - www.clinicaltrials.gov
 - Society for Maternal Fetal Medicine listing of registries
 - Immunizationforwomen.org “Monitoring the Safety of Influenza Vaccination during Pregnancy”
 - REPROTOX®
 - Seqirus US website
- Print:
 - IIV4c package insert
 - IIV4c medication guide
- Education:
 - Active outreach to obstetric HCPs using IIV4c routinely in their practice

Table S1. Demographic and baseline characteristics

| Characteristic | Primary analysis population (n=665) | Lost to follow-up population (n=27) |
|---|--|--|
| Mean age \pm SD, years | 28.0 \pm 5.3 | 28.9 \pm 5.3 |
| Age group, n (%) | | |
| <20 years | 18 (2.7) | 1 (3.7) |
| 20-24 years | 178 (26.8) | 5 (18.5) |
| 25-34 years | 389 (58.5) | 17 (63.0) |
| 35-39 years | 68 (10.2) | 3 (11.1) |
| \geq 40 years | 12 (1.8) | 1 (3.7) |
| Race and ethnicity, n (%) | | |
| White | 399 (60.0) | 13 (48.1) |
| Black or African American | 194 (29.2) | 7 (25.9) |
| Asian | 29 (4.4) | 5 (18.5) |
| American Indian or Alaskan Native | 1 (0.2) | 0 |
| Native Hawaiian or Other Pacific Islander | 2 (0.3) | 0 |
| Other | 28 (4.2) | 1 (3.7) |
| Unknown | 12 (1.8) | 1 (3.7) |
| Hispanic or Latino ethnicity | 44 (6.6) | 1 (3.7) |
| Mean body mass index \pm SD, kg/m ² | 29.6 \pm 8.2 | 27.6 \pm 6.8 |
| Number of previous pregnancies, n (%) | | |
| 0 | 195 (29.3) | 11 (40.7) |
| 1 | 186 (28.0) | 3 (11.1) |
| 2 | 135 (20.3) | 5 (18.5) |
| \geq 3 | 149 (22.4) | 8 (29.6) |
| Family history of congenital malformations, n (%) | | |
| Offspring | 8 (1.2) | 0 |
| Maternal history | 40 (6.0) | 2 (7.4) |
| Paternal history | 40 (6.0) | 2 (7.4) |
| Any family history | 78 (11.7) | 4 (14.8) |
| Any concurrent condition, n (%) | 527 (79.2%) | 16 (59.3) |
| Any concomitant medication, n (%) | 651 (97.9) | 25 (92.6) |
| Substance use, n (%) | | |
| Tobacco | 84 (12.6) | 4 (14.8) |
| Alcohol | 1 (0.2) | 1 (3.7) |
| Illicit drug | 0 | 0 |
| Gestational age at enrollment, n (%) | | |
| <20 weeks | 211 (31.7) | 19 (70.4) |
| \geq 20 weeks | 454 (68.3) | 8 (29.6) |

| Characteristic | Primary analysis population (n=665) | Lost to follow-up population (n=27) |
|--|--|--|
| Gestational age at IIV4c exposure (days) | | |
| Mean \pm SD | 152.7 \pm 64.0 | 85.3 \pm 34.0 |
| First trimester, n (%) | 178 (26.8) | 18 (66.6) |
| Second trimester, n (%) | 277 (41.7) | 9 (33.3) |
| Third trimester, n (%) | 210 (31.6) | 0 |

Abbreviations: SD, standard deviation.

Figure S1. IIV4c exposure per gestational week for all enrolled participants.

