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Birth outcomes following immunization of pregnant women with pandemic H1N1 influenza vaccine 2009–2010

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ABSTRACT

Background: Following the H1N1 influenza pandemic in 2009, pregnant women were recommended to receive both seasonal (TIV) and H1N1 influenza vaccines. This study presents incidence of adverse birth and pregnancy outcomes among a population of pregnant women immunized with TIV and H1N1 vaccines at Kaiser Permanente Northern California during 2009–2010.
Methods: We telephone surveyed pregnant Kaiser Permanente Northern California members to assess non-medically-attended reactions following H1N1, TIV or both vaccines during 2009–2010 (n = 5365) in a separate study. Here we assessed preterm birth (<37 weeks), very preterm birth (<32 weeks), low birth weight (<2500 g, LBW), very low birth weight (<1500 g), small for gestational age, spontaneous abortions, stillbirths and congenital anomalies among this cohort by comparing incidence and 95% confidence intervals between the following immunization groups: TIV only, H1N1 only, H1N1 prior to TIV immunization, TIV prior to H1N1 and both immunizations given at the same time.
Results: Results did not vary significantly between groups. Comparing H1N1 with TIV, incidence were similar for preterm births (6.37 vs 6.28/100 births), very preterm births (5.30 vs 8.29/1000 births), LBW (4.19 vs 2.90/100 births), very LBW (4.54 vs 5.52/1000 births), small for gestational age (9.99 vs 9.24/1000 births), spontaneous abortion (7.10 vs 6.83/1000 pregnancies), stillbirths (7.10 vs 4.57/1000 pregnancies), and congenital anomalies (2.67 vs 2.43/100 births).
Conclusions: Although constrained by small sample size, complex vaccine groups, and differential vaccine availability during 2009–2010, this study found no difference in adverse birth outcomes between H1N1 vaccine and TIV.

1. Introduction

During the 2009–2010 influenza season, the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practice (ACIP) recommended that pregnant women receive the novel pandemic monovalent H1N1 influenza vaccine, along with the seasonal trivalent influenza vaccine (TIV, which included an A/Brisbane/59/2007(H1N1)-like virus, an A/Brisbane/10/2007(H3N2) like virus, and a B/Brisbane/60/2008-like virus), due to reports of increased adverse outcomes among pregnant women infected with H1N1 influenza. At the time, little was known about H1N1 vaccine safety in this population, including potential adverse birth outcomes.

Since then, several studies have compared pregnant women vaccinated with H1N1 with unvaccinated pregnant women and generally found no increase in adverse pregnancy outcomes between the groups [1–5]. Most of these studies, however, focused mainly on women immunized in the latter half of their pregnancy.

The aim of this study was to assess the safety of H1N1 vaccine compared with TIV vaccine administered during all three trimesters by evaluating birth outcomes following immunization of pregnant women during 2009–2010 within Kaiser Permanente Northern California (KPNC).

Abbreviations: ACIP, Advisory Committee on Immunization Practices; CDC, Centers for Disease Control and Prevention; CI, Confidence Interval; ICD-9, The International Classification of Diseases, 9th Revision; KPNC, Kaiser Permanente of Northern California; LBW, Low birth weight; SGA, Small for gestational age; TIV, Trivalent influenza vaccine.

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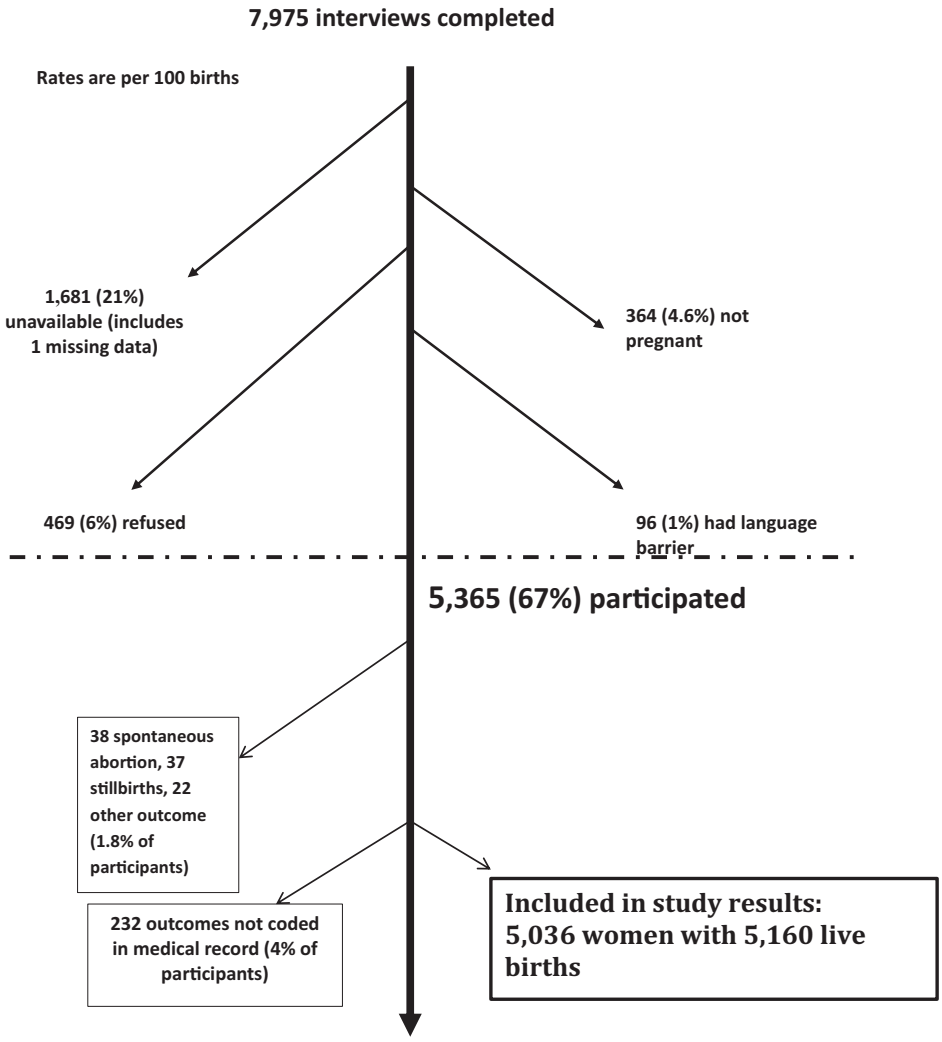

Fig. 1. Original study population.

Table 1
Trimester of vaccination and advanced maternal age by vaccine group among the study population of vaccinated pregnant women, October 2009–March 2010.

Vaccine group	First trimester	Second trimester	Third trimester	Mother over 35 years old	Total
TIV only[a]	*44.0%* (194)	*32.6%* (144)	*23.4%* (103)	*16.6%* (73)	441
H1N1 only[b]	*59.1%* (819)	*25.6%* (355)	*15.3%* (212)	*19.6%* (271)	1386
H before T[c]	*26.7%* (39)	*39.7%* (58)	*33.6%* (49)	*16.4%* (24)	146
T before H[d]	*29.8%* (578)	*36.6%* (712)	*33.6%* (653)	*20.7%* (403)	1943
Simultaneous[e]	*38.2%* (553)	*35.1%* (509)	*26.7%* (387)	*16.6%* (240)	1449
Total	*40.7%* (2183)	*33.1%* (1778)	*26.2%* (1404)	*18.8%* (1011)	5365

[a] Received only TIV.
[b] Received only H1N1 vaccine.
[c] Received H1N1 vaccine prior to TIV.
[d] Received TIV vaccine prior to H1N1 vaccine.
[e] Received both TIV and H1N1 vaccines given on the same day.

2. Methods

2.1. Setting

KPNC is an integrated healthcare delivery system which provides comprehensive health care for its 3.7 million members in more than 15 counties. KPNC employs over 7000 physicians, and operates 51 outpatient clinics and 22 hospitals distributed throughout the greater San Francisco Bay and Sacramento metropolitan areas. KPNC members receive nearly all their care at KPNC facilities. KPNC utilizes a unique medical record number for each member throughout all administrative and clinical databases, linking information for the same individual over time and across all services, including hospitalizations, emergency department, and outpatient visits. KPNC clinical databases include, but are not limited to, pharmacy, laboratory, procedures, radiology, authorized outside medical services, health plan membership and demographic information. KPNC maintains an immunization database which routinely captures all vaccines administered. KPNC has an annual birth cohort of approximately 34,000 (and an Infant

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