

Association of spontaneous abortion with receipt of inactivated influenza vaccine containing H1N1pdm09 in 2010–11 and 2011–12

James G Donahue¹, Burney A Kieke², Jennifer P King³, Frank DeStefano⁴, Maria A Mascola⁵, Stephanie A Irving⁶, T Craig Cheetham⁷, Jason M Glanz⁸, Lisa A Jackson⁹, Nicola P Klein¹⁰, Allison L Naleway¹¹, Eric Weintraub¹², Edward A Belongia¹³

Affiliations

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Abstract

Introduction: Inactivated influenza vaccine is recommended in any stage of pregnancy, but evidence of safety in early pregnancy is limited, including for vaccines containing A/H1N1pdm2009 (pH1N1) antigen. We sought to determine if receipt of vaccine containing pH1N1 was associated with spontaneous abortion (SAB).

Methods: We conducted a case-control study over two influenza seasons (2010–11, 2011–12) in the Vaccine Safety Datalink. Cases had SAB and controls had live births or stillbirths and were matched on site, date of last menstrual period, and age. Of 919 potential cases identified using diagnosis codes, 485 were eligible and confirmed by medical record review. Exposure was defined as vaccination with inactivated influenza vaccine before the SAB date; the primary exposure window was the 1–28days before the SAB.

Results: The overall adjusted odds ratio (aOR) was 2.0 (95% CI, 1.1–3.6) for vaccine receipt in the 28-day exposure window; there was no association in other exposure windows. In season-specific analyses, the aOR in the 1–28days was 3.7 (95% CI 1.4–9.4) in 2010–11 and 1.4 (95% CI 0.6–3.3) in 2011–12. The association was modified by influenza vaccination in the prior season (post hoc analysis). Among women who received pH1N1-containing vaccine in the previous influenza season, the aOR in the 1–28days was 7.7 (95% CI 2.2–27.3); the aOR was 1.3 (95% CI 0.7–2.7) among women not vaccinated in the previous season. This effect modification was observed in each season.

Conclusion: SAB was associated with influenza vaccination in the preceding 28days. The association was significant only among women vaccinated in the previous influenza season with pH1N1-containing vaccine. This study does not and cannot establish a causal relationship between repeated influenza vaccination and SAB, but further research is warranted.

Keywords: Influenza; Influenza vaccine; Pregnancy; Spontaneous abortion.