

Comparison of VAERS fetal-loss reports during three consecutive influenza seasons: Was there a synergistic fetal toxicity associated with the two-vaccine 2009/2010 season?

GS Goldman

Abstract

The aim of this study was to compare the number of inactivated-influenza vaccine-related spontaneous abortion and stillbirth (SB) reports in the Vaccine Adverse Event Reporting System (VAERS) database during three consecutive flu seasons beginning 2008/2009 and assess the relative fetal death reports associated with the two-vaccine 2009/2010 season. The VAERS database was searched for reports of fetal demise following administration of the influenza vaccine/vaccines to pregnant women. Utilization of an independent surveillance survey and VAERS, two-source capture–recapture analysis estimated the reporting completeness in the 2009/2010 flu season. Capture–recapture demonstrated that the VAERS database captured about 13.2% of the total 1321 (95% confidence interval (CI): 815–2795) estimated reports, yielding an ascertainment-corrected rate of 590 fetal-loss reports per million pregnant women vaccinated (or 1 per 1695). The unadjusted fetal-loss report rates for the three consecutive influenza seasons beginning 2008/2009 were 6.8 (95% CI: 0.1–13.1), 77.8 (95% CI: 66.3–89.4), and 12.6 (95% CI: 7.2–18.0) cases per million pregnant women vaccinated, respectively. The observed reporting bias was too low to explain the magnitude increase in fetal-demise reporting rates in the VAERS database relative to the reported annual trends. Thus, a synergistic fetal toxicity likely resulted from the administration of both the pandemic (A-H1N1) and seasonal influenza vaccines during the 2009/2010 season.

Keywords

Human toxicology, immunization, influenza vaccine, spontaneous abortion, stillbirth, Thimerosal

Introduction

Since 1997, the Advisory Committee on Immunization Practices (ACIP) has recommended the routine vaccination of pregnant women with trivalent inactivated influenza vaccine (TIV) after the first trimester of pregnancy. This recommendation was expanded in 2004 to include all trimesters of pregnancy.¹

All previously published studies of pregnant women who were administered with TIV have reported this vaccine as safe during all stages of pregnancy.^{2–4} Christian et al. explained the reason for this record of safety: ‘The inflammatory response elicited by TIV is substantially milder and more transient than seen in infectious illness.’⁵

Two frequently cited peer-reviewed reports on the safety of influenza vaccination during pregnancy did not reveal any adverse outcomes among 56 women⁶ and 180 women.⁷ Both these studies, which used ‘no Thimerosal’ influenza vaccines, had insufficient statistical power to adequately detect and assess complications due to the small sample size. A third follow-up safety study (conducted among 2291

Independent Computer Scientist, Pearblossom, CA, USA

Corresponding author:

Gary S Goldman, Independent Computer Scientist, P.O. Box 847, Pearblossom, CA 93553, USA.
Email: gsgoldman@roadrunner.com