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Maternal Influenza Vaccination and Risk for Congenital Malformations: A Systematic Review and Meta-analysis

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Abstract

OBJECTIVE: To systematically summarize the literature on maternal influenza vaccination and the risk for congenital malformations using the methodology of meta-analysis.

DATA SOURCES: PubMed, Scopus, and Embase databases (up to December 2014) as well as [ClinicalTrials.gov](#) (May 2015) and references of relevant articles were searched. The search strategy included combinations of the terms “influenza,” “vaccin*,” “pregnan*,” “safe*,” “adverse,” “congenital,” “malformation,” “defect,” and “anomal*.”

METHODS OF STUDY SELECTION: Eligible studies examined the association between antepartum or preconceptional maternal immunization with inactivated influenza vaccines (seasonal trivalent or monovalent H1N1) and the risk for congenital malformations. Studies with no or inappropriate control group (comparison with population background rates or other vaccine types) were excluded.

TABULATION, INTEGRATION, AND RESULTS: The risk for congenital anomalies after influenza vaccination was examined in 15 studies: 14 cohorts (events per vaccinated compared with unvaccinated: 859/32,774 [2.6%] compared with 7,644/245,314 [3.1%]) and one case-control study (vaccinated per cases compared with controls: 1,351/3,618 [37.3%] compared with 511/1,225 [41.7%]). Eight studies reported on first-trimester immunization (events per vaccinated compared with unvaccinated: 258/4,733 [5.4%] compared with 6,470/196,054 [3.3%]). No association was found between congenital defects and influenza vaccination at any trimester of pregnancy (odds ratio [OR] 0.96, 95% confidence interval 0.86–1.07; 15 studies; $I^2=36$) or at the first trimester (OR 1.03, 0.91–1.18; eight studies;

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$I^2=0$). When assessing only major malformations, no increased risk was detected after immunization at any trimester (OR 0.99, 0.88–1.11; 12 studies; $I^2=31.5$) or at the first trimester (OR 0.98, 0.83–1.16; seven studies; $I^2=0$). Neither adjuvanted (OR 1.06, 0.95–1.20; five studies; $I^2=18.8$) nor unadjuvanted vaccines (OR 0.89, 0.75–1.04; seven studies; $I^2=22.6$) were associated with an increased risk for congenital defects.

CONCLUSION: This systematic review did not indicate an increased risk for congenital anomalies after maternal influenza immunization adding to the evidence base on the safety of influenza vaccination in pregnancy.

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