# Influenza vaccination during pregnancy: a systematic review of effectiveness and safety.

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### **Abstract**

#### **Background**

Pregnant women are the World Health Organisation's top priority group for influenza vaccination and it is the primary intervention to protect pregnant women, their foetus, and infant from influenza infection. However, it is considered to be an expensive public health measure and data on the effectiveness and safety of the vaccine has been lacking and inconsistent. Evidence of the vaccine's effectiveness and safety is critical to the decision making process of governments and policy-makers, as well as clinicians and pregnant women.

#### **Objectives**

To synthesise the best available evidence on the effectiveness and safety of influenza vaccination during pregnancy for pregnant women, their foetus, and infant up to six months of age.

Inclusion criteria.

Types of participants

Pregnant women with or without risk factors for complications from influenza infection, their foetus, and infants up to the age of 6 months.

Types of intervention

Inactivated influenza vaccination administered to pregnant women of any trimester.

Types of studies

Studies using quantitative research methods were considered for this systematic review.

Types of outcomes

This systematic review considered studies that reported on the effectiveness of maternal influenza vaccination at reducing the rate and severity of influenza and influenza-like illness for pregnant women and infants up to six months of age. The review also investigated the safety outcomes for pregnant women and foetus following influenza vaccination during pregnancy including adverse events, spontaneous abortion, foetal death, premature birth, low birth weight, small for gestational age, and congenital malformation.

#### Search strategy

An extensive search of the literature was undertaken to find both published and unpublished English language studies between the inception of each database to April 2013.

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#### Methodological quality

Papers selected for retrieval were assessed by two independent reviewers for methodological validity prior to inclusion in the review.

#### **Data collection**

Data were extracted from included papers using data extraction tools.

#### **Data synthesis**

Data were, where possible, pooled in statistical meta-analysis. Where statistical pooling was not possible the findings were presented in narrative and table form.

#### Results

A total of 39 relevant studies were included in the review following critical appraisal. Studies investigating birthing and foetal outcomes were reported in 28 studies. Adverse event outcomes for pregnant women were present in 24 studies. The effectiveness of maternal influenza vaccination in reducing illness in pregnant women and infants up to 6 months was reported in 13 studies.

#### **Conclusions**

Influenza vaccine administered during pregnancy is effective and provides a similar reduction in influenza-like illness as it does for a healthy adult population. Despite this, there is no evidence on the effectiveness of the influenza vaccine at reducing severe illness or hospitalisation in pregnant women. Infants of pregnant women vaccinated during their second or third trimester can expect to have reduced rates of influenza, and influenza related hospitalisation, for their first 6 months of life.

Influenza vaccination during pregnancy had no association with adverse outcomes for the foetus including premature birth, small for gestational age infants, congenital malformation, spontaneous abortion, and foetal death.

# **Declaration**

I, Mark McMillan, certify that this work contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. In addition, I certify that no part of this work will, in the future, be used in a submission for any other degree or diploma in any university or other tertiary institution without the prior approval of the University of Adelaide, and where applicable, any partner institution responsible for the joint-award of this degree.

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