Maternal vaccinations

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Khai Lin Kong, Sushena Krishnaswamy, Michelle L Giles

Background
Maternal immunisation, which refers to vaccinations administered during pregnancy, is an integral part of preventive healthcare for pregnant women and infants. With new maternal vaccines in development, the scope of maternal immunisation is expanding.

Objective
This review focuses on the principles underpinning maternal immunisation, the existing recommendations and maternal vaccines in development, a review of vaccines that may be indicated for pregnant women who wish to travel, and safety data on inadvertent administration of live vaccines to pregnant women.

Discussion
Maternal immunisation has the potential to protect women from severe disease (as in the case of influenza) and infants from severe morbidity and mortality (as in the case of pertussis). With other maternal vaccines currently in development, such as vaccines against respiratory syncytial virus and Group B streptococcus, maternal immunisation is playing an increasingly important role in improving maternal and neonatal health.

MATERNAL IMMUNISATION has the potential to protect the mother and/or the infant from mortality and morbidity from certain infectious diseases. Two vaccines recommended during pregnancy in Australia are influenza and pertussis vaccines. Influenza vaccination has the potential to protect the mother from severe influenza disease and to protect the infant from influenza infection up to six months of age. In contrast, pertussis vaccination during pregnancy is mainly given to protect the newborn from pertussis disease. Maternal immunisation is playing an increasingly important part in improving maternal and neonatal health. This article provides a review and update on maternal immunisation.

Principles underpinning maternal immunisation

The main purpose of maternal immunisation is to directly protect mothers and – through the transfer of maternal antibodies – to passively protect infants who are too young to be vaccinated themselves.[1] Transfer of maternal antibodies across the placenta to the fetus begins from 13 weeks' gestation and increases exponentially throughout pregnancy, with the majority of antibody transfer occurring after 28 weeks' gestation.[1] Although these maternal antibodies slowly wane, the aim of maternal immunisation is for the antibodies to remain above a protective level and provide passive immunity to the infant until the infant develops their own immunity through routine childhood vaccinations.[2] Infants born to pregnant women who are vaccinated against influenza and pertussis have significantly higher levels of antibodies at birth,[3,4] with maternal antibodies from antenatal pertussis vaccination persisting in infants for up to two months postpartum.[4]

Efficacy and safety of vaccines currently recommended in pregnancy

Influenza

The Australian Technical Advisory Group on Immunisation recommends pregnant women receive seasonal influenza vaccination during each pregnancy.[5] In keeping with this, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists[6] and The Royal Australian College of General Practitioners[7] also both recommend influenza vaccination during pregnancy.

Influenza vaccination is recommended during pregnancy to protect pregnant women and their newborns from severe

influenza disease. A literature review of the impact of the 2009 influenza pandemic reported a higher risk of hospitalisation, mortality and intensive care unit (ICU) admission among pregnant women when compared with non-pregnant adults.[8] A recent meta-analysis of pregnant women with influenza infection, which included seasonal and pandemic infections, found that pregnant women were seven times more likely to be hospitalised when compared with the non-pregnant population.[9] Influenza infection during pregnancy has also been associated with adverse pregnancy outcomes including preterm birth and fetal death.[10–12] Influenza infection also poses a risk to newborns. Infection in newborns aged <6 months is associated with severe disease including an increased risk of ICU admission.[13] With no influenza vaccines currently licensed in Australia for use in infants aged <6 months of age, influenza vaccination during pregnancy is the only strategy currently available to prevent influenza in these very young infants.[14]

Pregnant women are frequently seen for antenatal care outside of the traditional 'influenza season'. However, a recent examination of Victorian data found that influenza vaccination coverage was higher for pregnancies ending in winter or spring (influenza season) when compared with other times throughout the year.[15] Regardless of when a pregnant woman presents for antenatal care, influenza vaccination should always be recommended. This also applies if the woman has been recently vaccinated for influenza in the pre-pregnancy period. The rationale for this is twofold: 1) cases of influenza occur outside of influenza season (85,286 influenza cases were reported in Australia from November 2018 to May 2019)[16] and pregnant women should be protected during this interseasonal period, and 2) maternal influenza vaccination is the only strategy for affording protection to infants born in the interseasonal period who will be in the first six months of life during the subsequent influenza season. A meta-analysis of four randomised controlled trials and three observational studies reported that maternal influenza vaccination reduced the risk of laboratory-confirmed influenza in infants aged <6 months by 48% (95% confidence interval [CI]: 33%, 59%).[17]

Pregnant women are not at higher risk for adverse events following influenza vaccination than non-pregnant adults.[18] In addition, influenza vaccination can be safely administered at any gestation including the first trimester, with multiple systematic reviews showing no association between influenza vaccination during pregnancy and adverse birth outcomes.[19–22]

Pertussis vaccine

Unlike influenza vaccination, maternal pertussis vaccination is recommended primarily for infant benefit. During the 2008–2011 pertussis epidemic in Australia, infants aged <3 months had the highest hospitalisation rate and accounted for more than 90% of deaths.[23] At least three doses of a pertussis-containing vaccine are required for infants to achieve a protective level of antibodies;[24] therefore, infants aged <6 months remain vulnerable.

Infants of mothers vaccinated during pregnancy have been shown to be 91% less likely to acquire a pertussis infection in the first three months of life, compared with infants whose mothers were not vaccinated.[25] This protection is higher than that previously reported for postnatal maternal vaccination, otherwise known as a 'cocooning' strategy.[26,27]

A single dose of a pertussis-containing vaccine (available in Australia as the combined diphtheria-tetanus-acellular pertussis vaccine) is recommended for all pregnant women between 20 and 32 weeks' gestation.[5] This is based on research showing that:[28–30]

- it takes at least two weeks post-vaccination for maternal pertussis antibodies to peak
- vaccine effectiveness in preventing pertussis infection drops to 38% if given 0–6 days before birth
- vaccination earlier in pregnancy maximises antibody transfer.

Pregnant women who are not vaccinated prior to 32 weeks' gestation should still receive a dose of vaccine as soon as possible at any time up until delivery, given that pertussis vaccination may still provide some protection to the newborn albeit less than if the mother is vaccinated earlier.[29] Pregnant women who inadvertently receive pertussis vaccination earlier than 20 weeks' gestation do not need a repeat dose during the same pregnancy as antibodies are detected in newborns of women who are vaccinated as early as 13 weeks' gestation.[30] Maternal antibodies begin to wane several months post-vaccination and therefore will be insufficient by the time of a subsequent pregnancy, even if the pregnancies are closely spaced or the woman has received a vaccination in the pre-pregnancy period. It is therefore recommended that a pertussis vaccine is given in each pregnancy.[5]

Adverse events following pertussis vaccination are not more common in pregnant women than in non-pregnant adults,[31] and large cohort studies of pregnant women have not found any safety signal for adverse birth outcomes following maternal pertussis vaccination.[32,33]

Ongoing challenges in maternal immunisation

Despite comprehensive safety and efficacy data for both influenza and pertussis vaccines, uptake in pregnant women remains suboptimal, particularly of influenza vaccine.[34–36] Globally, in 2015, there were still 113 World Health Organization member states that did not have an influenza vaccine policy in place for pregnant women.[37] In Australia, there are marked variations in influenza vaccine coverage ranging from 25% in one study in New South Wales[35] to 61% in a study conducted in Western Australia.[36]

Broadly speaking, three factors need to be considered in order to address the problem of low vaccine coverage. Pregnant women's understanding of the importance and safety of the vaccines has been shown to influence their vaccine uptake.[38–41] For example, of 75 studies included in a literature review, perception of vaccine safety was the most commonly identified barrier to vaccination in pregnant women.[38] Efforts to address this concern are important to enhance women's confidence in the safety of receiving vaccines during pregnancy. Furthermore,

healthcare provider recommendation has consistently been shown to be the key determinant in encouraging women to receive vaccines.[38,40,42] In a study conducted in South Australia, pregnant women who received a recommendation from their healthcare provider had three times greater odds of receiving influenza vaccination than women who did not receive a healthcare provider recommendation.[42] Lastly, integrating maternal vaccination into routine antenatal care can improve pregnant women's access to vaccines, and thereby improve vaccine coverage.[43–45]

Travel vaccines that may be recommended for pregnant women

When considering travel vaccines in pregnant women, a number of principles need to be considered including assessing the risk of exposure, risk of disease depending on the stage of pregnancy, and data on the efficacy and safety of travel vaccines in pregnant women.

Efficacy of travel-related vaccines in pregnancy

While there is limited vaccine efficacy data specifically in pregnant women for a number of travel-related vaccines, these may still be recommended for pregnant women on the basis of the risk of potential exposure and available safety data (Table 1).[5]

Safety of travel-related vaccines in pregnancy

Inactivated vaccines routinely recommended for travel are considered safe in pregnancy.[5] Live vaccines are generally not recommended but are not absolutely contraindicated.[5] Vaccine providers should consider the risk of exposure based on the itinerary, potential risks of maternal infection in the absence of vaccination, and available safety data in pregnancy. For example, if a pregnant woman cannot avoid travel to a yellow fever–endemic area, the benefit of the vaccine to protect the mother against yellow fever is likely to outweigh the potential risk to the fetus.[5] In two studies of 704 pregnant women who were either inadvertently administered the yellow fever vaccine or received the vaccine during an outbreak, there was no increased risk of congenital malformations,[46,47] miscarriage[47] or premature delivery.[47] While there are rare reports of infants with likely serological evidence of transplacental transmission of yellow fever virus from their mothers following vaccination, the clinical implication of this finding is uncertain.[47,48]

Table 1 summarises the recommendations in Australia, the UK and the USA for vaccines in pregnant women planning to travel. It lists vaccines that are not routinely included in the national immunisation program but may be indicated for pregnant women who are travelling.

Risk from receiving live vaccines during pregnancy

To date, there have been no congenital syndromes reported as a consequence of inadvertent vaccination with a live vaccine around the time of conception or in early pregnancy. In two studies reporting on a total of 211 pregnant women who received live attenuated rubella vaccine inadvertently, there were no cases of congenital rubella syndrome.[49,50]

Congenital varicella syndrome has not been reported among the 928 cases of pregnant women who inadvertently received varicella vaccine between 1995 and 2012.[51]

Inadvertent administration of any live vaccine during pregnancy should be discussed with the woman and their antenatal care provider, but no additional investigations such as ultrasonography are indicated.

Maternal vaccines in development

Respiratory syncytial virus

Respiratory syncytial virus (RSV) causes significant morbidity and mortality in infants, with the greatest burden of disease in low- and middle-income countries.[52] Globally, 33.1 million RSV-associated acute lower respiratory infections (RSV-ALRIs) occurred in children aged <5 years in 2015.[52] It has been estimated that 3.2 million children were admitted to hospital, and 59,600 died in hospital.[52] In an Australian study, children aged <5 years accounted for 95% of those admitted to hospital with RSV, with infants aged 0–2 months having the highest rate of hospitalisation (2778 per 100,000 population).[53] The significant impact of RSV on infant mortality and morbidity globally, particularly in very young infants, is the impetus for efforts to develop a maternal RSV vaccine.

RSV vaccine development

In the most recent phase III trial of an RSV vaccine, 4636 women were randomised to receive the vaccine or placebo at 28–36 weeks' gestation.[54] This study did not statistically meet its primary outcome, which was prevention of medically significant RSV-ALRI in infants (estimated vaccine efficacy 39.4%; 95% CI: −1%, 63.7%). It also did not statistically meet its secondary objective of prevention of RSV-ALRI with severe hypoxemia (estimated vaccine efficacy 48.3%; 95% CI: −8.2%, 75.3%). However, it was protective against RSV-associated hospitalisation (44.4%; 95% CI: 19.6%, 61.5%).[43] In this phase III study, there were similar rates of adverse events and adverse obstetric outcomes (eg preterm birth, stillbirth) in pregnant women who received the vaccine and those who received placebo.[54]

Group B streptococcus

Globally in 2015, there were an estimated 33,000 cases of invasive Group B streptococcus (GBS) disease in pregnant or postpartum women, >300,000 cases of early- and late-onset GBS disease in infants, and an estimated 147,000 stillbirths and infant deaths attributable to GBS.[55]

GBS: Strategies for disease prevention and vaccine development

Screening for GBS colonisation of the vaginal tract during pregnancy and administration of intrapartum antibiotic prophylaxis to women who are colonised is the current strategy for preventing neonatal infection in many high-income countries.[56] However, implementing a

Table 1. Inactivated (non-live) and live vaccines that may be indicated in pregnant women who are planning to travel

Vaccine	Australian Immunisation Handbook	Advisory Committee on Immunization Practices (ACIP) – US	Immunisation against infectious diseases – UK
Bacillus Calmette–Guérin (BCG)*	The BCG vaccine has not been shown to harm the fetus but is generally not recommended to pregnant women.	Although no harmful effect has been documented, the BCG vaccine is not recommended, as further studies are required.	The BCG vaccine should not be given during pregnancy. Even though no harmful effects on fetuses have been observed, further studies are required.
Cholera vaccine (oral)†	The cholera vaccine is not routinely recommended, as there are limited data on its safety.	There is no specific recommendation in pregnant women.	No data are available on the safety of cholera vaccine. If the risk of cholera is high, the vaccine could be considered.
Hepatitis A†	There are limited data available; vaccination should be recommended to women travelling to areas of moderate-to-high endemicity.	Safety during pregnancy has not been determined. However, given hepatitis A is an inactivated vaccine, the theoretical risk to the fetus is low. The risk of vaccination should be weighed against the risk of hepatitis A in pregnant women.	The hepatitis A vaccine may be given when clinically indicated. There is no evidence of risk from vaccination.
Japanese encephalitis (JE)‡	There are limited data on use in pregnant women. However, since JE is associated with miscarriage, pregnant women at high risk of JE are recommended to receive inactivated JE virus vaccines.	There are no data on JE vaccine in pregnant women.	Inactivated JE vaccine should be avoided; however, risk assessment must be made against the risk of acquiring JE, which is associated with miscarriage.
MenACWY (quadrivalent meningococcal conjugate vaccine)†	Pregnant women can receive this vaccine if at increased risk of the disease.	Pregnancy should not preclude vaccination with MenACWY vaccine.	Meningococcal vaccines may be given to pregnant women when indicated. There is no evidence of risk to pregnancy.
Rabies†	Pregnant or breastfeeding women are recommended to receive rabies vaccine and human rabies immunoglobulin, if required, after a potential exposure to rabies virus.	Pregnancy is not considered a contraindication to post-exposure prophylaxis. If the risk of exposure to rabies is substantial, pre-exposure prophylaxis might be indicated in pregnancy.	Pregnant women should be given vaccines pre-exposure if risk is high. Pregnant women should be given vaccine if indicated post-exposure.
Typhoid (parenteral Vi polysaccharide)†	Pregnant women can receive typhoid Vi vaccine if they are travelling to endemic countries where water quality and sanitation are poor.	There are no data on the use of typhoid vaccine in pregnant women. It should be given to pregnant women only if clearly needed.	There is no evidence of risk from vaccinating pregnant women.
Yellow fever*	Pregnant women should be advised against travelling to rural areas where yellow fever is endemic. However, if travel to a country with a risk of yellow fever virus transmission is unavoidable, pregnant women should receive yellow fever vaccine.	If travel is unavoidable and the risk for exposure outweighs the vaccination risk, a pregnant woman should be vaccinated.	If travel is unavoidable and risk of exposure is high, then immunisation may be considered.

**Live vaccine*
†Inactivated vaccine
‡There is a live attenuated JE vaccine that is not recommended in pregnancy.[20]

similar strategy is challenging in settings with limited resources.[56]

There are 10 capsular polysaccharide serotypes of GBS, with most GBS disease attributable to six serotypes.[56,57] Covering all serotypes is challenging for vaccine development. However, trivalent GBS polysaccharide-protein conjugate vaccines have been administered to pregnant women as part of phase II clinical trials. These have been shown to be immunogenic, safe and well tolerated.[58–61] Phase I and II clinical trials of hexavalent GBS vaccines are currently underway.

Conclusion

Maternal influenza and pertussis vaccinations in pregnancy are two safe interventions that should be part of routine antenatal care for all pregnant women. With the potential for RSV and GBS vaccines being recommended during pregnancy in the future, maternal immunisation will have an increasingly important role in improving maternal and child health in Australia and globally. However, challenges remain, the most important being achieving high vaccine coverage. To address this, efforts need to be directed towards improving maternal knowledge and addressing maternal concerns about vaccine safety, facilitating healthcare provider recommendation of vaccines, and ensuring access to maternal vaccines at the point of antenatal care.

Key points

- All pregnant women are recommended to receive influenza and pertussis vaccinations in each pregnancy.
- Influenza vaccination in the antenatal period protects both the woman and the newborn.
- Pertussis vaccination at 20–32 weeks' gestation, or as close as possible to these dates, maximises maternal antibody transfer to the neonate.
- As part of pre-travel counselling and management, pregnant women who wish to travel should have a detailed and thorough assessment and discussion to inform the need for pre-travel vaccination.
- Travel vaccinations are provided following consideration of the risk of exposure, risk from disease according to the stage of pregnancy, and safety/efficacy data.

Authors

Khai Lin Kong MBBS, FRACP, Infectious Diseases Physician, Department of Obstetrics and Gynaecology, Monash University, Vic

Sushena Krishnaswamy MBBS, FRACP, PhD, Infectious Diseases Physician, Department of Infectious Diseases, Monash Health, Vic; Adjunct Lecturer, Department of Obstetrics and Gynaecology, Monash University, Vic

Michelle L Giles MBBS, FRACP, PhD, Infectious Diseases Physician, Department of Infectious Diseases, Alfred Health and Royal Women's Hospital, Vic; Associate Professor, Department of Obstetrics and Gynaecology, Monash University, Vic. michelle.giles@monash.edu

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correspondence **ajgp@racgp.org.au**