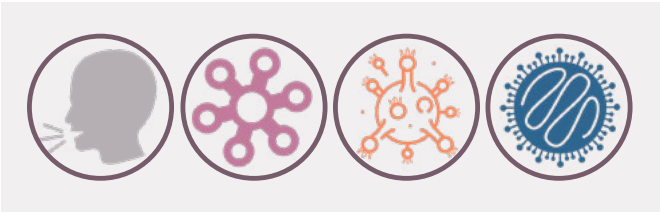
IMMUNISATION COALITION

2024 VACCINATION DURING PREGNANCY GUIDE

FOR HEALTHCARE PROFESSIONALS

ABOUT PREGNANCY AND VACCINATIONS

People are particularly vulnerable during pregnancy and should receive the whooping cough (pertussis) vaccine, the **influenza** vaccine, and now a **COVID-19** vaccine and an **RSV** vaccine to protect themselves and their baby.



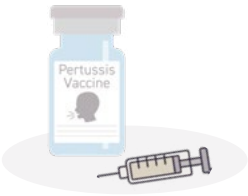
As **the immune system is naturally suppressed during pregnancy**, pregnant patients face an increased risk of contracting influenza or COVID-19 and associated complications.

Influenza, whooping cough and COVID-19 are serious illnesses that can affect both the birth parent and baby.

Most children will contract RSV at least once before they turn two years of age.[1]

Vaccination can help keep birth parents and babies healthy and protect the newborn in the first 6 months of life.

WHOOPING COUGH VACCINATION DURING PREGNANCY



Whooping cough is a highly infectious bacterial disease that causes severe bouts of coughing.

In adults the symptoms can be mild, but for a baby who is not yet vaccinated it can be life-threatening.

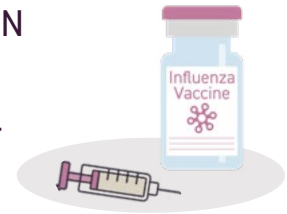
Vaccination during pregnancy (preferably between 20-32 weeks) allows the body to produce antibodies that are passed on to the baby before birth. These antibodies will protect the baby until they are able to **receive their own vaccination at 6 weeks of age**.

Studies have found that whooping cough vaccination during pregnancy is safe and effective for both parent and baby.

Studies from the US and UK involving more than **40,000 pregnant patients** found only mild side effects, such as pain or redness in the arm where the vaccination was given. It does not increase the risk of serious pregnancy complications such as premature birth.

The National Health and Medical Research Council (NHMRC) recommends vaccination during the mid-2nd trimester and early 3rd trimester (ideally at 20–32 weeks).

INFLUENZA VACCINATION DURING PREGNANCY



HOW DOES INFLUENZA AFFECT THE PARENT AND BABY?

Influenza is a potentially severe disease that can affect both the parent and baby.

It can impact the parent during the **second and third trimesters** and the baby in the **first few months** after birth, even causing death.

WHAT IS THE RISK?

On average each year in Australia, influenza causes approximately 100 deaths and 5,100 hospitalisations.[2] **Contracting influenza while pregnant results in a disproportionate amount of this burden.**

In Australia, the 2009 epidemic of influenza A(H1N1) pdm09 (commonly known as 2009 H1N1) resulted in increased admissions to intensive care. The highest excess ICU admission rate was in Aboriginal and / or Torres Strait Islander peoples (17out of 100,000) and during pregnancy (14 out of 100,000):[3]

- Overall, nearly 10% of those admitted to ICU with AH1N1v while pregnant died
- Over 10% suffered pregnancy losses
- More than 50% of the remaining individuals delivered preterm, emphasising the severity of the disease in pregnancy[4]

Considerable decreases in influenza cases have been reported since April 2020 due to the COVID-19 epidemic in Australia. Physical distancing, travel restrictions, emphasis on hygiene, changes in testing priorities, and the diversion of resources to the COVID-19 response may all have affected the numbers.[5][6] With the reopening of international borders in November 2021 and the increase in population movement, there was a notable resurgence of influenza activity in 2022 with the virus circulating early in the season. The persistent seasonal spread of influenza observed in 2023 is likely to continue, underscoring the importance of vaccination for vulnerable populations who are at a heightened risk of complications from the flu.[2]

WHAT ARE THE COMPLICATIONS?

The natural suppression of the immune system during pregnancy may increase the risk of contracting influenza.

Additionally, there is an increased risk of severe complications during pregnancy, including stillbirth, premature birth, and suboptimal foetal growth.

HOW CAN PARENTS PROTECT THEMSELVES AND THE BABY?

Influenza vaccination protects against these complications. Although vaccination rates have recently increased, the risk of influenza to the unborn baby is often underestimated.

> Not enough people understand that the baby cannot be vaccinated against influenza in the first 6 months of life.

Multiple studies show that influenza vaccination at any stage of pregnancy is associated with a **20% reduction** in the risk of stillbirth.

WHAT DO PARENTS NEED TO KNOW DURING PREGNANCY?

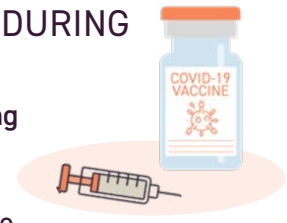
According to Elizabeth McCarthy, Senior Lecturer Department of Obstetrics and Gynecology, University of Melbourne Perinatal Centre, Mercy Hospital for Women:

The influenza vaccine is nationally approved and free during pregnancy. The vaccine is the best way to protect the mother and baby. Vaccinating against influenza during pregnancy gives a 3 for 1 benefit:

- Protects the parent during pregnancy and in the early months of parenthood
- Protects the unborn baby by transplacental antibodies
- Protects the young infant by antibodies in breast milk

WATCH OUR PREGNANCY & IMMUNISATION VIDEO

COVID-19 VACCINATION DURING PREGNANCY



COVID-19 can cause harm during pregnancy.

People who contracted COVID-19 during pregnancy are:

- 4.37 times more likely to have complications while pregnant[7]
- More likely to require care in an intensive care unit (ICU), to need a ventilator (for breathing support), or to die from the illness
- More likely to have a caesarean birth, preeclampsia or eclampsia, and blood clots[8]

When compared to the babies from pregnancies with no COVID-19, the babies of COVID-19 patients are:

- More likely to be born prematurely
- More likely to be admitted to a hospital newborn care unit
- More likely to be stillborn
- More likely to experience distress during birth

COVID-19 VACCINATION

Real-world evidence has demonstrated that the original mRNA vaccines from *Pfizer* and *Moderna* are safe for use during pregnancy and breast/chest-feeding.

While data on the newer variant vaccines during pregnancy is limited, there are no additional safety concerns compared to the original vaccines. However, there is currently less information available about the use of the *Novavax* vaccine during pregnancy.[9]

The *Pfizer* vaccine can be given as two doses, 3–6 weeks apart, and the Moderna vaccine can be given as two doses, 4–6 weeks apart.[24][25][26]

COVID-19 VACCINATION EFFECTIVENESS DURING PREGNANCY

Results from a vaccination program in Israel show that the *Pfizer* COVID-19 vaccine is effective in preventing COVID-19 during pregnancy.[10]

Research shows that antibodies produced during vaccination cross the placenta and may provide some protection to newborn babies.

In the UKOSS study of COVID-19 from 1 February to 30 September 2021, 1,714 people were admitted to hospital with symptomatic COVID-19 while pregnant:[11]

- 98.1% of these individuals were unvaccinated
- 1.5% had received one vaccine dose
- 0.4% had received two doses

14% of the people hospitalised (235 individuals) were admitted to intensive care:

- 98.7% of these individuals were unvaccinated
- 1.3% (3 people) had received a single dose of vaccine
- None had received two doses

During the third wave (Delta wave) of COVID-19 in the UK, the pregnancy-related deaths were mainly seen in unvaccinated people.

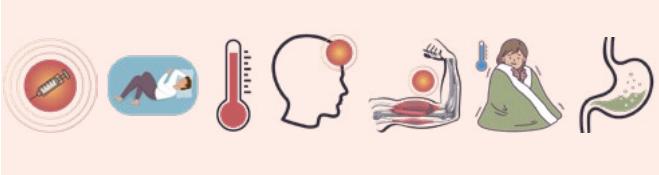
Data from vaccination programs across several countries indicate that the *Pfizer* and *Moderna* vaccines are effective in preventing SARS-CoV-2 infection and severe outcomes during pregnancy. To achieve optimal protection against the Omicron variant, it is necessary to receive two initial doses followed by a booster dose. Studies have shown that **receiving an additional booster dose while pregnant leads to lower rates of severe illness** compared to those who receive only the initial two doses. During the Omicron surge, a two-dose vaccination regimen reduced the risk of severe COVID-19 complications by 48%, while three doses (including the booster) reduced the risk by 76% compared to the unvaccinated.[9]

COVID-19 VACCINE SAFETY DURING PREGNANCY

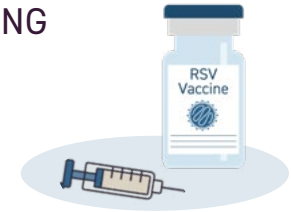
Evidence from other countries shows that the *Pfizer* and *Moderna* COVID-19 vaccines are safe during pregnancy.

A U.S. study[12] involving more than 35,000 pregnant individuals found that the side effects after vaccination were similar in both pregnant and non-pregnant participants.

The possible side effects include **pain at the injection site, tiredness, fever, headache, muscle and joint pain, chills,** and **diarrhoea.**



RSV VACCINATION DURING PREGNANCY



RSV is a highly infectious virus, and most children will get it at least once before they turn 2 years of age.[13]

From 2006–2015, there were **63,814 hospitalisations** with an RSV-specific principal diagnostic code; **60,551** (**94.9%**) were in **children under 5 years** of age.[14]

Between 2016 and 2019 there were more than **115,000 hospitalisations** with an RSV diagnosis in Australia, of which approximately **75%** were in **children aged less than 5 years**. Most of these children were otherwise healthy. For **infants aged less than 6 months**, the annual RSV hospitalisation rate over this period was approximately **6,200 per 100,000 population**, with the **highest rates** in **infants aged 0–2 months** (approximately **7,200 per 100,000 population**).[15]

Between 2021 (when RSV became a notifiable disease) and 6 June 2024, there have been **314,432 cases** reported to the National Notifiable Disease Surveillance System, with **51.6%** being **children aged 4 and under**.[16]

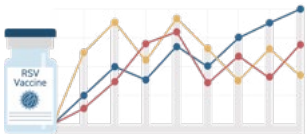
RSV is associated with increased morbidity among preterm babies and infants born with chronic health conditions such as respiratory and/or cardiac complications.[17]

VACCINES

ABRYSVO is a recombinant respiratory syncytial virus (RSV) pre-fusion F protein vaccine formulated to actively immunise pregnant patients, particularly between **24–36 weeks of gestation**, to prevent lower respiratory tract disease caused by RSV in infants from **birth–6 months** of age.[18]

VACCINE EFFECTIVENESS

Vaccination during pregnancy reduces the risk of severe RSV disease in infants under 6 months of age by around 70%. (See vaccine information)



This protection results from the passive transfer of RSV-specific antibodies from the birth parent to the foetus during pregnancy via the placenta.[19]

TIMING OF VACCINATION

The **recommended** time for RSV vaccination during pregnancy is between **28–36 weeks gestation**. Although *Abrysvo* is registered from 24–36 weeks gestation, **administration from 24–<28 weeks of gestation is not routinely recommended** until more safety and efficacy data is available for people at this stage of pregnancy and their newborn infants.[19] RSV vaccine can be given at any time of the year, regardless of when a patient is expected to deliver.

RSV PREVENTION IN HIGH-RISK INFANTS

High-risk infants are those who are more likely to develop complications from RSV. This group includes premature infants, those with heart or lung problems, and those who are immunocompromised.

MONOCLONAL ANTIBODIES

Palivizumab

Palivizumab is an injectable monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. It is given intramuscularly and is directed at a protein in RSV. **It has been shown to reduce intensive care unit admissions for babies who have been hospitalised for RSV.**[20][21]

Nirsevimab *(Currently available through state-based programs in WA, QLD and NSW as of August 2024)*

Nirsevimab is an injectable, long-acting monoclonal antibody that provides protection against RSV disease for **at least 5 months** after a single dose. It is indicated for the prevention of RSV lower respiratory tract disease to **protect all infants** against severe disease during or entering their first RSV season, **and young children under 24 months** who are vulnerable to severe disease during their 2nd RSV season.[22][23]

As with RSV vaccines, RSV monoclonal antibody medications should only be prescribed by a medical practitioner and used according to the approved TGA indication.

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