

Maternal Immunisation against Respiratory Syncytial Virus (RSV) during Pregnancy



Evidence Review

Key Points

1. Maternal vaccination against RSV during pregnancy is safe and effective.
2. Vaccination against RSV during pregnancy protects newborns against RSV during the first 6 months of life.

Background

The Australian Technical Advisory Group on Immunisation (ATAGI) recommends the maternal RSV vaccine, Abrysvo[®], to all women between 28 to 36 weeks of pregnancy.¹ Abrysvo[®] is available for free under the National Immunisation Program for pregnant women.² It works by generating protective antibodies against RSV in women, which move across the placenta into their infants' bloodstream to protect them against RSV. It takes at least 2 weeks after vaccination with Abrysvo[®] for women to make enough antibodies to protect their newborn infant against RSV.³

Burden of illness

Infants and children

RSV infects the majority of children by the age of 2 years-old,¹ with at least two out of every 100 Australian infants hospitalised with RSV by the age of 2 months.⁴ Globally in 2019, about one in 28 deaths among children aged between 28 days to 6 months was attributable to RSV, occurring predominantly in low and middle-income countries,⁵ with approximately 26,700 RSV-attributable deaths occurring in preterm babies.⁶

Infants who are most vulnerable to severe RSV infection^{1, 4, 6, 7} are those who:

- are born prematurely
- of Aboriginal and Torres Strait Islander origin
- have low birthweight
- have congenital heart disease
- have an impaired immune system
- have immature lung development
- have severe chronic lung condition(s)
- have Down's Syndrome.

RSV causes inflammation of children's small airways, called bronchioles, leading to wheeze and breathlessness. It can also cause cough, runny nose and watery eyes. In very young infants, especially preterm babies, RSV can interrupt their regular breathing cycles.⁸ RSV infection in infancy is associated with long-term respiratory complications such as repeated lung infections, asthma and lung function deterioration that continue into adulthood.⁹

The presence of maternal antibodies through vaccination with Abrysvo® is critical to protect infants against RSV during a period when they are most at risk of severe RSV disease and hospitalisation and while their own immune system matures.^{10, 11} Studies have demonstrated that higher maternal RSV antibody levels in infants are associated with reductions in infection severity and hospitalisation rates from RSV.^{3, 12-15}

Adults

RSV also leads to serious disease in older adults. Within the Australian adult population, those who are above 65 years-old have the highest risk of being hospitalised from RSV.⁴ This is still substantially lower than the RSV hospitalisation rate among infants.⁴

Effectiveness

Protection of infants

A large multi-national placebo-controlled randomised clinical trial of Abrysvo® which recruited 7,400 healthy pregnant women below the age of 49 years-old, between 24 to 36 weeks of gestation, demonstrated vaccine efficacy of 70% (95% CI, 51%-83%) against severe RSV infection among infants in the first 6 months of life.³ This trial also discovered that infants born to vaccinated women were 55% less likely (95% CI, 24%-75%) to be hospitalised from RSV infection within the first 6 months of life.³ A real-world implementation study of Abrysvo® in Argentina during the 2024 RSV season illustrated similar vaccine efficacy of 68% (95% CI, 56%-76%) against hospitalisations from RSV among infants less than 6 months-old.¹⁶ Following the roll-out of a year-round maternal RSV vaccination program in Australia, a modelling study predicts that RSV hospitalisation rates would decline by 60% (from 3.0 to 1.2 per 100 persons) among infants less than 3 months-old, and 40% (from 1.9 to 1.1 per 100 persons) among 3 to 5-month-old infants.¹⁷

Maternal protection

It is currently unknown whether Abrysvo® protects pregnant women from RSV.¹

Safety

Abrysvo® is well-tolerated among vaccine recipients. The most common side effects reported were injection site pain and fatigue, but these symptoms occurred at similar rates among those who received placebo injections.¹ In addition, the rates of low birthweight, preterm birth, developmental delay and maternal hypertensives disorders of pregnancy, were similar between infants born to Abrysvo® recipients and placebo.^{3, 18} There were no maternal deaths, stillbirths, Guillain-Barre syndrome or inflammatory neuropathies associated with Abrysvo® vaccination.^{3, 19}

Vaccination timing

Abrysvo® can be administered concurrently with other maternal vaccines such as the pertussis, influenza and COVID-19 vaccines.¹ In addition, maternal vaccination against RSV is recommended year-round despite the seasonality of RSV infections because severe RSV disease in infants can occur anytime during the year.¹

Abrysvo® is not recommended for pregnant women below 28 weeks of gestation, as its safety and efficacy in this group of women and their newborns are still uncertain.¹ There is also insufficient evidence to recommend Abrysvo® for breastfeeding women.¹ Furthermore at this time, there is no safety and efficacy data to recommend additional doses of Abrysvo® for subsequent pregnancies.^{1, 19}

Given the 2 weeks delay in protection after receiving Abrysvo®, infants born within 2 weeks of Abrysvo® administration should receive nirsevimab, a RSV-specific antibody, to protect them against RSV.¹

References

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