

Babies in Western Australia will soon be immunized against RSV, but not with a vaccine

March 7 2024, by Christopher Blyth and Allen Cheng



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This week, Western Australia <u>announced</u> a state government-funded immunization program against respiratory syncytial virus (RSV). It's the



first Australian state or territory to do so.

All babies under 8 months old and those aged 8 to 19 months at increased risk of severe RSV infection will be eligible for the immunization in WA this year.

RSV can cause serious illness in children, and news headlines have welcomed WA's impending rollout of "<u>vaccinations</u>" against the virus.

But this immunization differs from other routine childhood vaccines.

Why is RSV important?

RSV is the <u>most common cause</u> of respiratory infection in young children. By the age of two, almost all children show <u>evidence</u> they've been exposed to the virus.

RSV can also be a problem for the elderly and people with underlying health conditions such as those with weakened immune systems.

How do we protect children against RSV?

Antibodies are a key part of the immune system that protect people against many viral infections, including RSV. They're usually generated in response to infection or a <u>vaccine</u>, and work by attaching to proteins on the surface of RSV, therefore preventing the virus from invading the



cells that line the airways and lungs.

The problem in newborn babies (who are at the highest risk of severe RSV infection) is that previous vaccines have not generated sufficient antibodies to provide protection.

So two strategies have been developed to protect young children against RSV. These strategies are both referred to as <u>passive immunization</u>, because children receive protective antibodies from outside the body. This is different to active immunization where we give a child a vaccine so they can generate their own antibodies.

Vaccination in pregnancy

One way to deliver passive immunity to young infants is by vaccinating their mothers during pregnancy. Maternal immunization has been shown to be effective at protecting infants from other infections, including influenza, whooping cough (pertussis), tetanus and COVID.

By delivering a single RSV vaccine to <u>pregnant women</u>, antibodies are generated by the mother and transported across the placenta, providing passive immunity and protection to the baby for around the first six months of life. In a <u>clinical trial</u>, giving an RSV vaccine in late pregnancy reduced RSV in young infants by approximately 70%. But RSV vaccines for pregnant women are <u>not yet available</u> in Australia.

What are monoclonal antibodies?

The other passive immunization strategy relies on manufactured longacting antibodies (known as monoclonal antibodies), which can be delivered by injection to young children.



This is what will be offered in WA. Nirsevimab (also known as Beyfortus) is a long-acting antibody that Australia's Therapeutic Goods Administration (TGA) <u>approved</u> in November 2023.

Nirsevimab binds specifically to RSV and remains in the body for several months after injection. In a key <u>clinical trial</u> nirsevimab was shown to reduce RSV infections by about 75% for up to five months.

Several European countries have recently implemented infant programs with nirsevimab and are <u>reporting</u> significantly lower RSV hospitalization rates in babies.

Antibody therapies in various forms have been used for more than a century for the prevention and treatment of a range of conditions, dating from "serotherapy" for tetanus, diphtheria and snake bite in the late 1800s.

Licensed antibody products are rigorously tested in <u>clinical trials</u> and through post-marketing surveillance to ensure their safety.

For <u>nirsevimab</u> specifically, the <u>clinical trial</u> mentioned above included more than 1,400 infants. Adverse events were reported at similar rates in the nirsevimab and placebo groups, and no serious adverse events relating to treatment were reported. No significant safety concerns have been identified in the real-world rollout in the northern hemisphere either.

When does RSV occur?

RSV <u>usually takes hold</u> just before the flu season in southern states, and circulates year-round in tropical areas. While influenza almost disappeared during the <u>COVID</u> pandemic, there were <u>ongoing cases</u> of RSV, albeit with a disruption to the normal seasonal pattern.



Since 2022, RSV has resumed its normal seasonal pattern. The WA government says the immunisations will be available <u>from April</u>, which is timely in anticipation of the 2024 season.

What about other states and territories?

Free access to an immunization against RSV should significantly benefit young children and families in WA, keeping children out of hospital this winter.

Whether other states will follow WA's lead is uncertain at this stage, and we don't yet know whether nirsevimab will in time become part of the <u>National Immunization Program</u>, meaning it would be available for free nation-wide.

Ensuring equitable access, particularly for those at greatest risk of severe RSV <u>infection</u>, must be prioritized to ensure maximum benefit for all children and families.

Nirsevimab is likely to be the first of many tools to prevent RSV in children. A maternal RSV vaccine is currently under assessment by the TGA and Pharmaceutical Benefits Advisory Committee (PBAC). A vaccine for older Australians, Arexvy, is registered and is also being assessed by the PBAC, with additional vaccines expected to be available in the future.

These developments highlight the future of RSV prevention and also the significant potential for <u>monoclonal antibodies</u> to play a greater role in preventing infections as part of public health programs.

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Provided by The Conversation

Citation: Babies in Western Australia will soon be immunized against RSV, but not with a vaccine (2024, March 7) retrieved 29 April 2024 from https://medicalxpress.com/news/2024-03-babies-western-australia-immunized-rsv.html

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