



Respiratory Syncytial Virus Protection:

Insights from the inaugural year
of prenatal vaccination

October 18, 2024 | Marie Boller, MD and Karen Gibbins, MD, MSCI

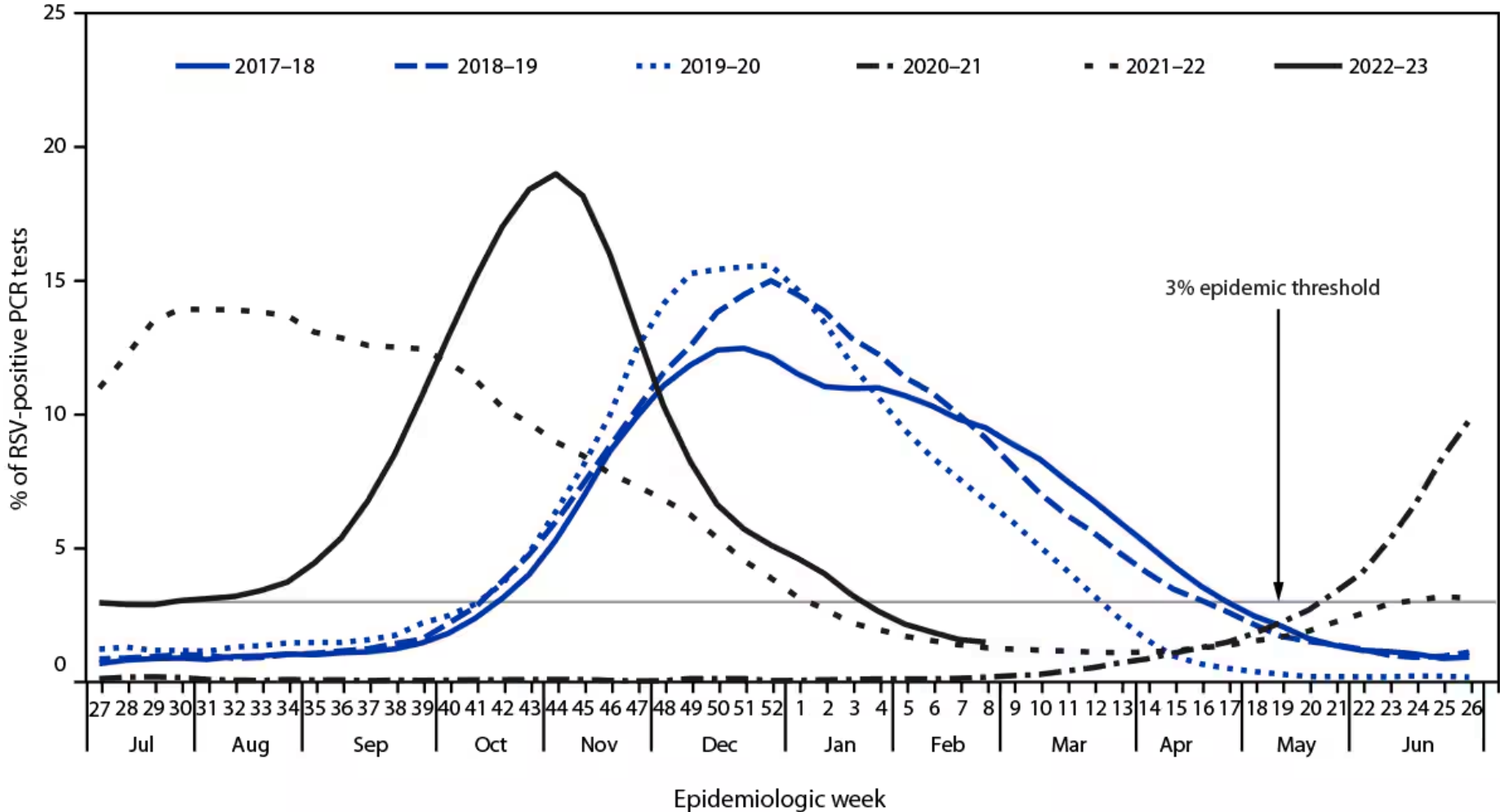


By the end of this presentation,
participants should be able to:

- Describe the evidence for prenatal and neonatal protection from Respiratory Syncytial Virus (RSV)
- Describe initial roll-out of prenatal vaccination and neonatal antibody administration during the 2023-2024 RSV season at OHSU
- Be aware of best practices for RSV protection during the current RSV season



FIGURE 1. Percentage* of polymerase chain reaction test results positive for respiratory syncytial virus, by epidemiologic week National Respiratory and Enteric Virus Surveillance System, United States, July 2017–February 2023



Hamid S, Winn A, Parikh R, et al. Seasonality of Respiratory Syncytial Virus — United States, 2017–2023. MMWR Morb Mortal Wkly Rep 2023;72:355–361. DOI: <http://dx.doi.org/10.15585/mmwr.mm7214a1>.



	RSV Vaccine in Pregnancy	Infant RSV Monoclonal Antibody
Description	RSVPreF Vaccine (Abrysvo)	Nirsevimab (Beyfortus)
Immunity	Recipient – active immunity Infant – passive immunity	Passive immunity
Administration	Single IM injection FDA approved: <ul style="list-style-type: none"> 32 0/7 to 36 6/7 weeks of pregnancy <p>Can receive other vaccines concurrently (Flu/COVID/Tdap)</p>	Single IM injection FDA approved: <ul style="list-style-type: none"> Birth to 8 months if birth parent did not receive Abrysvo 2+ weeks prior to delivery 8-19 months if increased risk of severe RSV disease
Seasonality	Beginning of September through end of January in most of US	Beginning of October to end of March in most of US
Safety	Local and systemic reaction: pain at injection site (41%), headache (31%), fatigue (46%), muscle pain (27%) Rare risk of severe allergic reaction	Local and systemic reaction: <1% rash and injection site reaction Rare risk of severe allergic reaction
Efficacy	**Timing of injection 2+ weeks prior to delivery** Medically attended severe lower respiratory tract illness: <ul style="list-style-type: none"> 81.8% relative risk reduction through 90 days after birth (6 cases in vaccine and 33 cases in placebo) 69.4% relative risk reduction through 180 days after birth (19 cases in vaccine and 62 cases in placebo) 	Medically attended severe lower respiratory tract illness: <ul style="list-style-type: none"> 74.9% relative risk reduction through 150 days after birth (12 cases in immunization and 25 cases in placebo)

Pfizer RSVpreF vaccine phase 3 trial

- 18 countries (including 45% US; 13% South Africa; 12% Argentina, 6% Japan)
- 1:1 ratio randomized to receive RSVpreF vaccine (Abrysvo) or placebo, double blinded
- Primary efficacy end points:
 - Medically attended severe RSV-associated respiratory tract illness
 - Medically attended RSV-associated respiratory tract illness in infants within 90, 120, 140, 180 days after birth
- Participants: 49 years or younger, uncomplicated, singleton pregnancy and no known increased risk of pregnancy complications.



RSV bivalent RSVpreF Vaccination (Abrysvo) Efficacy:

Medically attended **severe** lower respiratory tract illness
after birth:

- First 90 days: **81.8%** relative risk reduction
- First 180 days: **69.4%** relative risk reduction

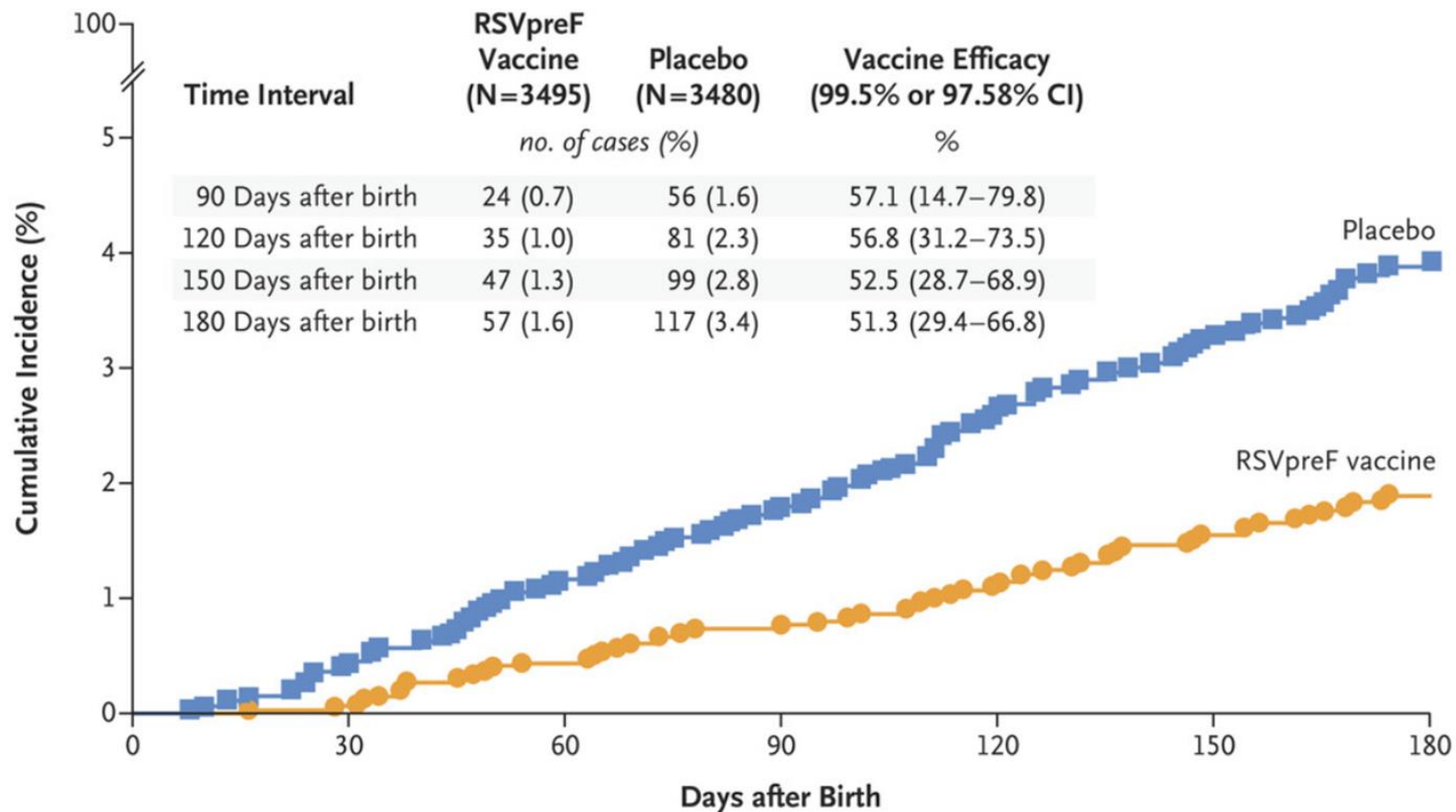
Nirsevimab (Beyfortus) Neonatal antibody **Efficacy:**

Medically attended
severe lower respiratory
tract illness:

**74.9% relative risk
reduction** through 150 days
after birth



Medically attended lower respiratory tract illness

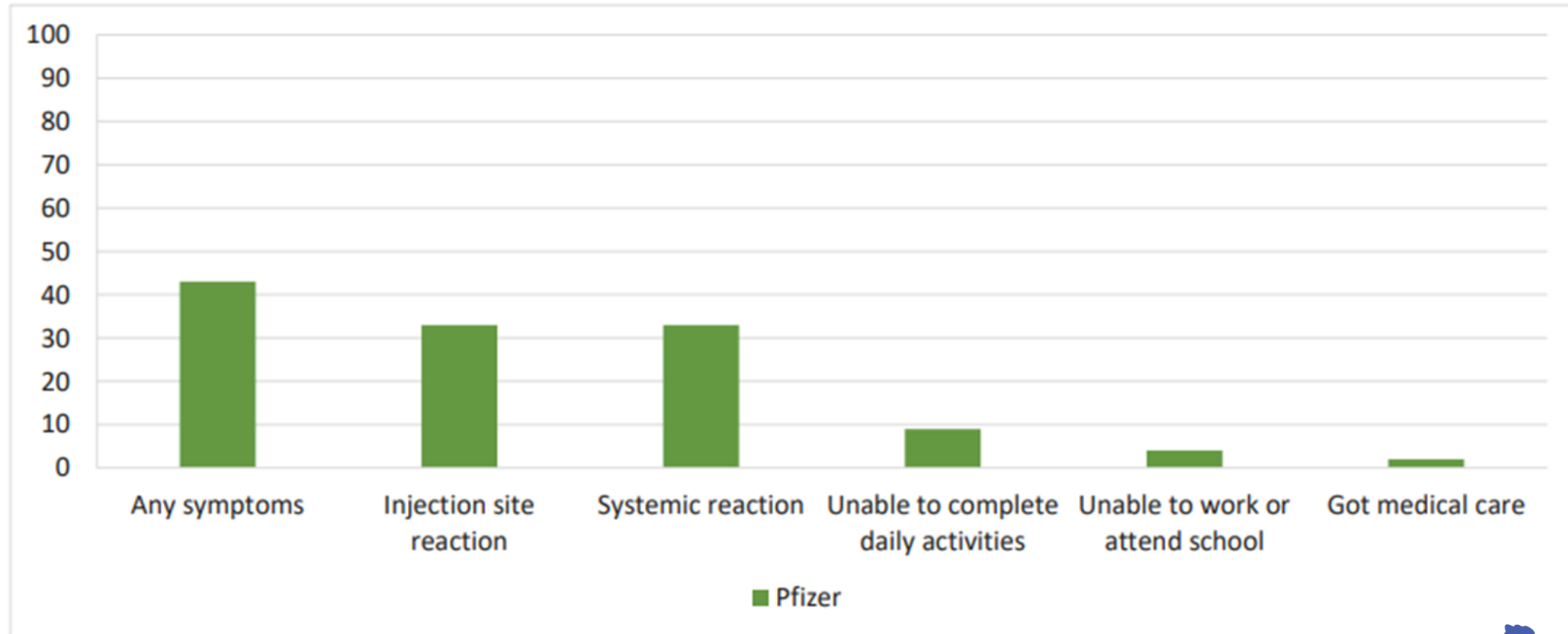


No. at Risk

Placebo	3480	3288	2964	2879	2804	2738	2700
RSVpreF vaccine	3495	3348	3035	2968	2898	2845	2792



RSV vaccination reported reactions and health impacts



For 1,116 V-safe participants aged 16-49 years enrolled in the maternal RSV protocol with ≥ 1 completed daily survey during August 21, 2023 – May 20, 2024

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-06-26-28/03-RSV-Mat-Peds-Moro-508.pdf>



Preterm Birth Signal

- Clinical trials of pregnant persons at 24–36 weeks' gestation preterm birth rates:
 - 5.7% in Abrysvo recipients vs 4.7% in placebo
 - RR 1.2 (95% CI 0.98-1.46)
 - When limited to 32-36 weeks': 4.2 vs 3.7%
 - When limited to high income countries: 5% vs 5%
- Cohort study of pregnant people who received RSVpreF vaccination 2023-2024, preterm birth rates:
 - 5.9% in Abrysvo recipients
 - 6.7% in those who did not receive vaccination



RSV bivalent RSVpreF Vaccination (Abrysvo) Recommendations:

- FDA approved: **32 0/7 to 36 6/7 weeks** in people who:
 - Do not have a planned delivery within 2 weeks
 - Did not receive the maternal RSV vaccine during 2023–2024 season
- Can receive other vaccines concurrently
- Early September – end of January

Fleming-Dutra KE, et al. Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR Morb Mortal Wkly Rep. ePub: 6 October 2023. DOI: <http://dx.doi.org/10.15585/mmwr.mm7241e1>.



Nirsevimab (Beyfortus) Neonatal antibody **Recommendations:**

FDA approved:

- Birth to 8 months *
- 8-19 months if increased risk of severe RSV disease

Early October – end of March



Relative Advantages and Disadvantages

	Advantages	Disadvantages
Abrysvo	<ul style="list-style-type: none">• Immediate protection after birth• Might be more resistant to potential mutations in F protein• Reduces the number of vaccines the infant receives at birth• Protection for pregnant person too	<ul style="list-style-type: none">• Potentially reduced protection in some situations (e.g., pregnant person is immunocompromised, or infant born soon after vaccination)
Beyfortus	<ul style="list-style-type: none">• Protection from monoclonal antibody may wane more slowly than from maternal RSV vaccine• Direct receipt of antibodies rather than relying on maternal transfer	<ul style="list-style-type: none">• Limited availability during 2023-2034 RSV season• Requires infant injection

Insurance coverage of Abrysvo

- OHP covers (requires documentation of active pregnancy)
- Private insurance:
 - Required to cover new vaccine recommendations in the next plan year
 - May have gestational age limits or other restrictions that will require an appeal



OHSU data from the
inaugural prenatal
vaccine season

2023-2024



Components of OHSU Roll-out

- **Vaccine champions**
- Collaboration with pediatric providers
- **Targeted campaign** – MyChart blasts, fliers, Babysteps emails
- Focus on both **provider and patient** education
- Epic smartphrases for patient education
- Delegation protocol for pharmacy to **administer without prescription**
- One vaccine clinic after ice storm



Examples

RSV Vaccine in Pregnancy

[Respiratory Syncytial Virus \(RSV\)](#) is a common illness in children. In the United States, it is the top reason infants end up in the hospital. Babies 1 year old and younger are at the highest risk for severe illness due to RSV. RSV season is typically during the fall to spring of each year. It peaks in the winter months.

To protect your baby from getting sick from RSV, we recommend **either**:

1. You receive an RSV vaccine ([Abrysvo](#)) between 32 to 36 weeks of pregnancy, during or just before the start of RSV season (September to January). You need to get the vaccine at least 2 weeks before delivery to be effective.

OR

2. Your baby receives an RSV antibody immunization, given as a shot in the hospital or in clinic. This option is for younger babies who are entering their first RSV season. Some older babies and toddlers at high risk for severe RSV through their second RSV season may also receive the immunization.

For most babies, we recommend either the RSV vaccine in pregnancy or the infant RSV antibody immunization, but not both.

About RSV vaccination in pregnancy

[Abrysvo](#) is the first vaccine approved for use in pregnant people to protect babies from severe illness caused by RSV. The RSV vaccine works by helping your body make antibodies to protect against RSV. Pregnant people who receive the vaccine pass these antibodies to their babies through the placenta. The antibodies help keep babies safe from severe illness caused by RSV during their first 6 months of life.

The most common side effects of the RSV vaccine are:

1. Pain at the injection site
2. Headache
3. Muscle pain
4. Nausea

Talk to your doctor or pregnancy care provider about [Abrysvo](#) and if it is right for you.

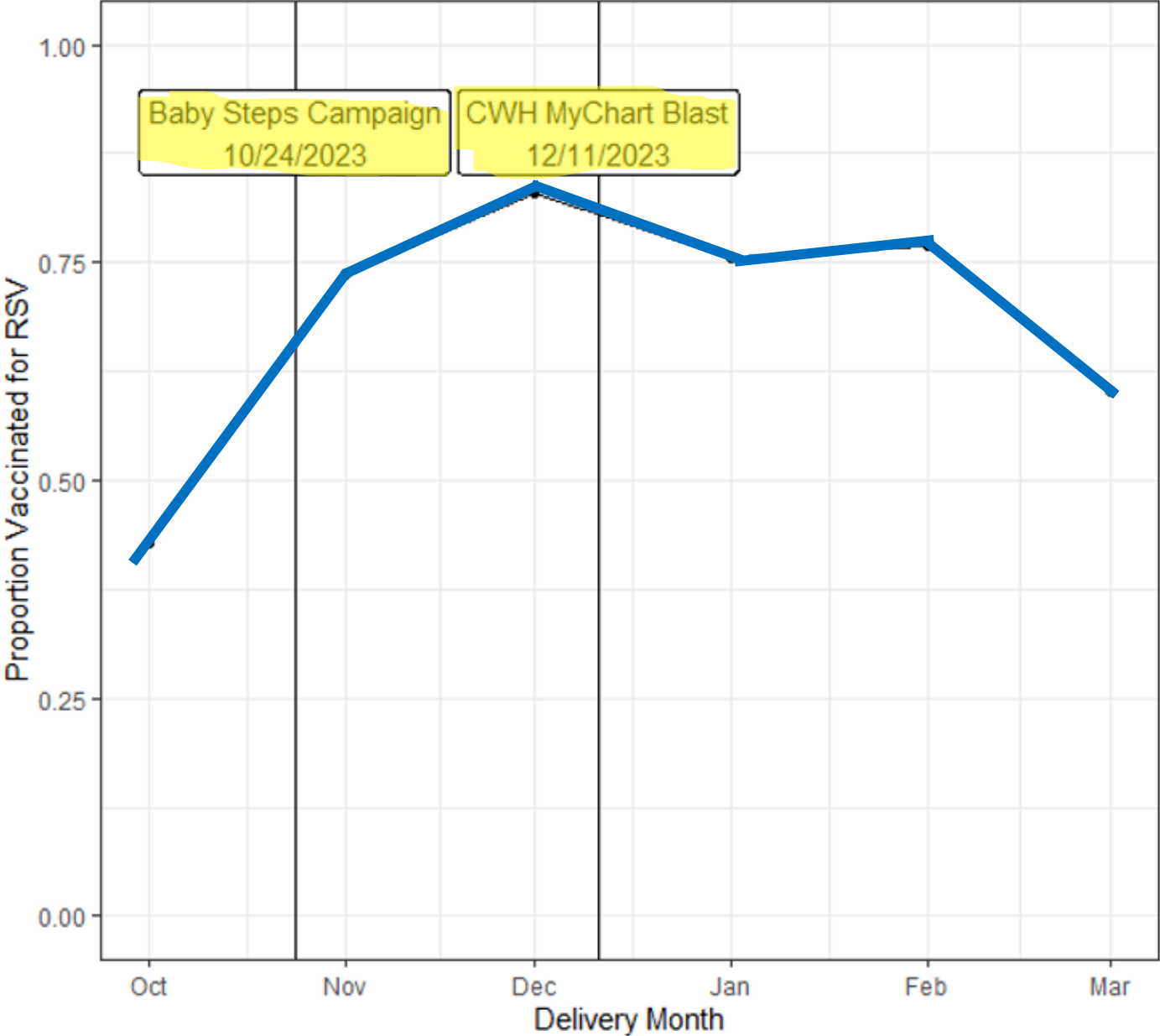
Insurance coverage for [Abrysvo](#) varies. Sometimes, insurance will not cover the RSV vaccine if given outside of 32 to 36 weeks of pregnancy or if given outside of the RSV season (September to January). [Before](#) getting [Abrysvo](#), contact your insurance to understand the cost.

Learn more about RSV and the RSV vaccine:

- ohsu.edu/health/rsv-respiratory-syncytial-virus
- cdc.gov/rsv/about/prevention.html
- acog.org/womens-health/faqs/the-rsv-vaccine-and-pregnancy
- acog.org/womens-health/experts-and-stories/ask-acog/should-i-get-the-rsv-vaccine-during-pregnancy

The logo for the Oregon Pregnancy Center (opc) is located in the bottom right corner. It consists of the lowercase letters "opc" in a white, sans-serif font, centered within a blue silhouette of the state of Oregon.

OHSU RSV Vaccination Rates, 2023-2024



Overall uptake **68.5%** (725/1059)

- 59.4% vaccination in pregnancy
- 36.1% neonatal antibody
- 4.4% both

**Retrospective observational cohort study of 2,973 pregnant people in NYC 2023-2024: 1,026 (34.5%) received prenatal RSV vaccination



RSV prophylaxis rates by care setting

CWH Generalist: 75.0%

Family Medicine: 70.9%

MFM: 58.5%

CNM: 65.2%

$p < 0.001$



Medicaid coverage associated with lower uptake

Rates of RSV protection by insurance
status:

- **OHP 63.6%**
- **Commercial 71.3%**

$p = 0.037$



What about preterm birth rates?

Rate of preterm birth <37 weeks:

- **9.9%** in those who received RSV protection
- **17.8%** in those who did not receive RSV protection

$p = 0.001$



Receipt of other prenatal vaccinations associated with increased uptake

Rates of RSV protection among people who received:

- Tdap: **73.9%**
 - in those who did not receive Tdap: 26.1%
- Flu vaccine: **78.5%**
 - In those who did not receive flu vaccine: 21.5%
- Covid vaccine: **85.0%**
 - In those who did not receive Covid vaccine: 15.4%

$p < 0.001$



Best Practice Points for Clinicians providing Prenatal Care

- Maternal RSV vaccine can be safely administered at the same time as other routine prenatal vaccines
- Document receipt or declination of maternal RSV vaccination in the patient's medical chart
- Encourage patients to register with V-safe:
<https://vsafe.cdc.gov>



Best Practice Points for Clinicians providing Prenatal Care: 2024-2025

- Prenatal RSV vaccine and monoclonal antibody nirsevimab are **safe and effective** ways to prevent severe lower respiratory tract infection caused by RSV in infants.
- 2nd RSV vaccine **not recommended** for pregnant patients vaccinated during 2023–2024 (infants should receive nirsevimab during this respiratory season).
- **No anticipated supply limitation** of the maternal RSV vaccine. No anticipated limitations to nirsevimab after October 2024.



<https://www.highriskpregnancyinfo.org/rsv>



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RSV Vaccine During Pregnancy

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opc

Pregnant?

Top 3 Reasons Why You Need the RSV Vaccine



1 Respiratory syncytial virus (RSV) can be dangerous for babies and young children. RSV illness is the most common reason that babies are hospitalized in the United States.

2 Getting the RSV vaccine during pregnancy helps protect your newborn from RSV right after birth and for the first 6 months of life.

3 The RSV vaccine is safe for both you and your fetus.



Thank you to Lisa Bayer

And all our RSV vaccine champions



Thank you



References

Fleming-Dutra KE, et al. Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. *MMWR Morb Mortal Wkly Rep*. ePub: 6 October 2023. DOI: <http://dx.doi.org/10.15585/mmwr.mm7241e1>.

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