



INDIAN COUNTRY ECHO: NIRSEVIMAB PROVIDER UPDATE & INCREASING UPTAKE

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Overview

- RSV signs and symptoms
- Disease burden
- Current landscape of Nirsevimab + Dosing Guidelines
- Quick note on Palivizumab
- Abrysvo: RSV vaccination for Pregnant People
- Provider talking points
- Contraindications/precautions & Safety
- FAQs



Source: <https://www.npaihb.org/maternal-and-child-health/>

RSV Signs & Symptoms

- Common virus that affects the lungs
- RSV season starts in the fall and peaks in the winter in most regions of the U.S.
- Spreads through coughing, sneezing, touching surfaces and then touching face (can live up to 6 hours on hard surfaces)
- Symptoms include cough, fever, wheezing, congestion, increased work of breathing, decreased appetite/feeding

HOW TO TELL THE DIFFERENCE BETWEEN FLU, RSV, COVID-19, AND THE COMMON COLD

Common symptoms may include cough, headaches, sneezing, runny nose, and congestion. Different symptoms may include:

| | COLD | FLU | COVID-19 | RSV |
|------------------------|------|-----|----------|-----|
| ACHES | ○○ | ××× | ○○ | ● |
| DIFFICULTY BREATHING | ● | ● | ××× | ○○ |
| FATIGUE | ○○ | ××× | ××× | ● |
| FEVER | ● | ××× | ○○ | ○○ |
| LOSS OF TASTE OR SMELL | ● | ● | ○○ | ● |
| SORE THROAT | ××× | ○○ | ××× | ● |
| WHEEZING | ● | ● | ● | ××× |

Legend: ● Rarely, ○ Sometimes, × Often

National Foundation for Infectious Diseases

Disease Burden

- RSV is the leading cause of infant hospitalization in the US¹
 - Up to 3% of children in their first year of life are hospitalized due to RSV infection³
 - Approximately 75% of infants hospitalized for RSV were born healthy and at term with no underlying conditions⁴
- RSV is the most common cause of bronchiolitis & pneumonia in babies <1 year old
- Most children will get an RSV infection before the age of 2 years, and 20-30% will develop a lower respiratory tract infection (bronchiolitis or pneumonia)³
- 68% of parents said an RSV hospitalization of their child affected their mental health²
- 66% of interviewed parents described RSV as a financial burden or crisis²

About Nirsevimab 'Beyfortus'



- Approved by FDA July 2023
 - Clinical trials **began Nov 2016**
- Monoclonal antibody product = passive immunization
- Protection expected to last at least 5 months
- It is part of the Vaccines for Children Program
- Approved for all infants aged < 8 months who are born during or entering their first RSV season, whose mother did NOT receive RSV vaccine 14 days or more prior to birth

Nirsevimab Efficacy

Pooled efficacy from phase 2 and 3 clinical trials in preventing medically attended RSV-associated lower respiratory tract infection (LRTI) was **79.0%**

Efficacy in preventing RSV-associated LRTI with hospitalization was **80.6%**

Efficacy in preventing RSV-associated LRTI with admission to an intensive care unit (ICU) was **90.0%**

The Shortage



Nirsevimab is produced by Sanofi and Astra Zeneca

Sanofi estimated production based on rotavirus vaccine and pneumococcal conjugate vaccine

- Rotavirus vaccine and pneumococcal conjugate vaccine, respectively, had about **10 percent and 11 percent immunization rates in their first 6 months of launch.**

Sanofi estimated that exceptional demand for Beyfortus could lead to uptake by as much as **30 percent** of the birth cohort in the first six months

- 30% = 1.1 million doses for the US

The Response



Ordering quickly surpassed the expectations

230,000 additional doses of Nirsevimab will be released in **January 2024**

- This will allow for up to **40%** of the eligible population to receive Nirsevimab during the 23-24 RSV season
- **1.4 million babies offered protection against RSV**, a 27 percent increase over the initial supply forecast for the season

What this means for Washington

Nirsevimab ordering was paused in October 2023

- WA had received 14,000 total doses

November 2023: The CDC allocated an additional 7,700 doses of the 50mg nirsevimab product and 600 doses of the 100mg product for WA

- This is a total of **22,300 doses** for the season

Doses for ~40% of WA babies





January 5, 2024

Updated Guidance for Healthcare Providers on Increased Supply of Nirsevimab to Protect Young Children from Severe Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season

Infants and children recommended to receive nirsevimab should be immunized as quickly as possible. Healthcare providers should not reserve nirsevimab doses for infants born later in the season when RSV circulation and risk for exposure to RSV may be lower. RSV activity remains elevated nationwide and is continuing to increase in many parts of the country, though decreased activity has been observed in the Southeast.



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Respiratory Syncytial Virus Infection (RSV)



Healthcare providers are [encouraged to administer nirsevimab](#) to protect infants against severe RSV. Do not save doses for later in the season. More nirsevimab is expected in early 2024.

Recommended Timing of Immunization

| Month of birth | Recommended timing of nirsevimab immunization |
|-----------------|--|
| October–March | Within 1 week of birth |
| April–September | Beginning in October, for example at a 2-, 4-, or 6-month well child visit |

Current Recommendations

- **Age < 8 months**
 - 50 mg for infants weighing <5 kg
 - 100 mg for infants weighing ≥5 kg
- **Age 8 - 19 months & at increased risk**
 - 200 mg, administered as two 100 mg injections
 1. Chronic lung disease of prematurity
 2. Severe immune compromise
 3. Severe cystic fibrosis
 4. **American Indian or Alaskan Natives:** incidence of RSV-associated hospitalization among AI/AN children aged 12–23 months was 4 -10 times that of similar-aged children

For healthcare providers who continue to have limited supply, prioritize infants at the highest risk for severe RSV disease using the following principles: **first by high-risk conditions and then by age, prioritizing the youngest infants first.**

Nirsevimab to replace Palivizumab (“Synagis”)

- Previous RSV immunization for premature infants born <29w0d, premature infants with chronic lung disease, and infants with hemodynamically significant heart disease, neuromuscular or pulmonary abnormalities that impair secretion clearance
- Required monthly doses x 5
- **Children who receive Nirsevimab should not receive palivizumab during the same RSV season**
- **There had been a recommendation in the fall from the CDC to suspend using Nirsevimab in Palivizumab-eligible children aged 8-19 months; however currently if Nirsevimab is available it should be used instead of Palivizumab**

Abrysvo: for pregnant people

- Recommended during weeks 32-36 of pregnancy
- September to January
- Infant is protected if born >14 days after mother receives Abrysvo (**NOT recommended for infant to also receive Nirsevimab**)
 - Exceptions:
 - Pregnant person is immunocompromised or has condition associated with reduced transplacental antibody transfer (HIV)
 - Infant requiring ECMO/cardiopulmonary bypass
 - Infant with substantial increased risk for severe RSV disease (hemodynamically significant congenital heart disease, ICU admission with a requirement of oxygen at discharge)

Abrysvo: recommended through January

Seasonal administration of maternal RSV vaccine is only recommended [through the end of January](#) for most of the continental United States

- Infants born to unvaccinated mothers during RSV season should receive nirsevimab [through the end of March](#) (i.e., February 1–March 31)
- After January 31, infants will be born when RSV activity is expected to be lower, and there is less benefit relative to the financial cost of Abrysvo

Relative Advantages and Disadvantages of Each Product

Advantages

Disadvantages



Maternal RSV vaccine

- Immediate protection after birth
- Might be more resistant to potential mutations in F protein

- Potentially reduced protection in some situations (e.g., pregnant person is immunocompromised or infant born soon after vaccination)
- Potential risk for preterm birth and hypertensive disorders of pregnancy



Nirsevimab

- Protection from nirsevimab may wane more slowly than from maternal RSV vaccine
- Direct receipt of antibodies rather than relying on transplacental transfer
- No risk for adverse pregnancy outcomes

- Potentially limited availability during 2023–24 RSV season
- Requires infant injection

RSV Vaccine Administration Errors

- CDC has received reports of vaccine administration errors with RSV vaccines.
- Pfizer's [Abrysvo](#) is the only RSV vaccine recommended for use in pregnant people. [GSK's Arexvy](#) is not recommended for use in pregnant people.
- [Nirsevimab](#) is the only RSV immunization approved and recommended for infants.

Q: If a dose of maternal RSV vaccine is inadvertently administered after January 31st, is it considered valid?

Yes, even if vaccination occurs after January 31st, the dose is considered valid. Nirsevimab is not recommended for the infant after they are born. Either maternal RSV vaccination during pregnancy or Nirsevimab administration to the infant is recommended to prevent RSV.

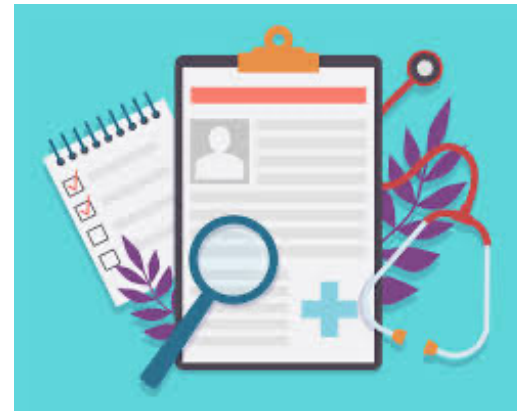
Avoid Vaccine Administration Errors

1. Order and stock the vaccine product that fits best with your patient population.
2. Avoid stocking multiple products, if possible.
3. If multiple RSV vaccine products are stocked, label each with the correct indications.
4. Educate staff on vaccine recommendations. If multiple RSV products are stocked, train staff about the differences in preparation and indications.
5. Follow medication administration best practices—read and check the vaccine product label at least 3 times and ask another staff member to confirm that it is the correct vaccine product for the patient.
6. If referring pregnant people to another vaccine provider, tell them to get Abrysvo (Pfizer) vaccine and confirm the vaccine product prior to administration.



Further Guidance

- If Arexvy is given to a pregnant person instead of Abrysvo: Do not give the pregnant person a dose of Abrysvo
 - Experts suggest no special monitoring for the pregnant person beyond routine prenatal care is needed
- **After birth the infant should receive nirsevimab shortly before or during their first RSV season (at age less than 8 months) for RSV prevention**



Further Guidance

- If Arexvy or Abrysvo is given to an infant instead of nirsevimab, the infant should receive nirsevimab to prevent severe RSV disease, if otherwise eligible
- **Administration of nirsevimab may be done as soon as the error is identified** (no minimum interval), but it could be reasonable to consider waiting 48 to 72 hours between administration of the vaccine and nirsevimab administration
- If nirsevimab will be administered at the same visit or within 72 hours, nirsevimab should be administered at a different anatomic site

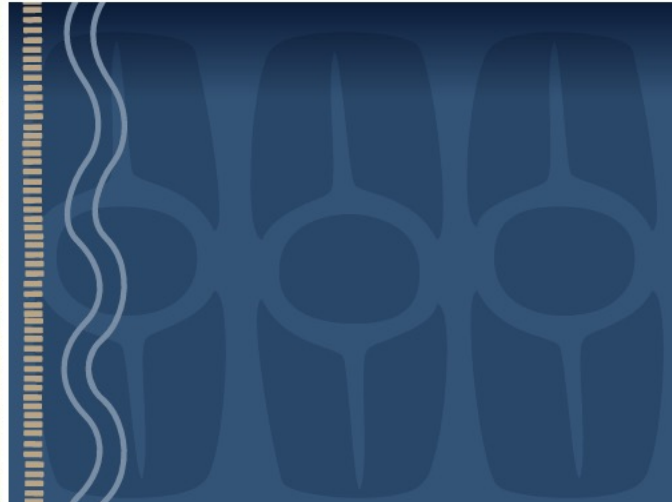
ACIP RSV Immunization Seasonal Recommendations Summary*

| | Sept | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug |
|--|---|---|-----|-----|-----|--|-----|---|-----|-----|-----|-----|
| Infants and children (nirsevimab) | | Administer during October–March in most of the continental U.S. | | | | | | Providers can adjust administration schedules based on local epidemiology.† | | | | |
| Pregnant people (Pfizer, Abrysvo) | Administer during September–January in most of the continental U.S. | | | | | ONLY jurisdictions whose seasonality differs from most of the continental US may administer outside of September–January.† | | | | | | |
| Adults 60+ (Pfizer, Abrysvo; GSK, Arexvy) | Offer as early as vaccine is available using shared clinical decision making; continue to offer vaccination to eligible adults who remain unvaccinated. | | | | | | | | | | | |

| | |
|-------------------------------------|--|
| Recommended timing for immunization | Timing NOT recommended for immunization, except in limited situations (as indicated in chart) |
|-------------------------------------|--|



A Medical Provider's Guide



Talking to Families about Vaccines: Use Positive Phrases

Talk with families about vaccines in the context of their goals and values.

- Communicate the ways in which vaccines help families accomplish their goals and align with their values.

Use positive phrases and messaging

- “We have some vaccines to do today”
- “Billy is due for vaccines today”
- You can then follow up with: “Do you have any questions about these vaccines?” or “Would you like information about these vaccines?”

This language expresses that vaccines are a routine part of pediatric preventive care and that the majority of families do choose to vaccinate

What if Parents Refuse to Vaccinate?

Ask parents about their concerns. Do not interrupt them. Give them an opportunity to fully express themselves so that they know you are taking them seriously.

- Repeat back what you have heard: “I understand that you think vaccines aren’t safe,” or “I hear your concern that vaccines cause autism.”
- In your response, **keep the patient at the center of everything**: “I am here to care for Sally, and I want the best for her.”

Ask parents for feedback: “How do you feel about that?” or “What do you think?”

- Give them an opportunity to learn from you and to ask more questions if necessary. Focus on the child’s (and parents’) quality of life.

We want parents to feel good about choosing to vaccinate their children because they believe it’s the right decision, not because they are frightened into doing so.

Nirsevimab Provider Talking Points

- **Reminder:** RSV is the leading cause of infant hospitalization; providers should share with families they are **EXCITED** there is now a way to reduce the risk of hospitalization!
- Nirsevimab = pre-made antibodies against RSV, provides **immediate protection** that lasts 5 months
 - Antibodies are infection fighting cells naturally made by our body
- Instead of baby's body having to learn how to make antibodies (traditional vaccines), Nirsevimab is pre-formed antibodies
- These antibodies last longer than antibodies made by the baby's body
- Safe to give with other vaccines! Will have same efficacy

Contraindications/Precautions

- History of severe allergic reaction (e.g., anaphylaxis) after a previous dose of Nirsevimab or to a product component
- Use with caution in infants and children with bleeding disorders
- In accordance with CDC [General Best Practice Guidelines for Immunization](#), children who have a moderate or severe acute illness should usually wait until they recover before getting Nirsevimab

Safety

- Adverse events reported in only 1.2% of participants
- Rash occurring within 14 days of injection and injection site reactions (pain, swelling, redness) were the 2 adverse reactions reported that occurred significantly more than in the placebo arm
- No anaphylaxis was reported



FREQUENTLY ASKED QUESTIONS

For children ages 8-19 mns who are recommended to receive Nirsevimab during their second RSV season, what is minimal interval between doses?

Only one dose of Nirsevimab is recommended for each season. Each dose of Nirsevimab provides protection for at least 5 months, and a second dose of Nirsevimab is not recommended to be given within 5 months of the first dose.

Can I give Nirsevimab to children ages 20 mns and older who are at increased risk for RSV disease?

Nirsevimab is not recommended for any child who is age 20 months and older.

How long after an RSV infection should I wait to give Nirsevimab?

Nirsevimab recommendations are the same regardless of prior RSV infection or RSV-associated hospitalization.

Can it be given with routine childhood vaccines?

Table 1 Recommended Child and Adolescent Immunization Schedule for Age

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination. To determine the minimum intervals between doses, see the catch-up schedule (Table 2).

| Vaccine and other immunizing agents | Birth | 1 mo | 2 mos | 4 mos | 6 mos | 9 mos | 12 mos | 15 mos | 18 mos | 19 mos |
|--|--|--------------------------|----------------------|----------------------|--------------------------|---|--|--------------------------|--------|--------|
| Respiratory syncytial virus (RSV-mAb [Nirsevimab]) | 1 dose depending on maternal RSV vaccination status, See Notes | | | | | 1 dose (8 through 19 months), See Notes | | | | |
| Hepatitis B (HepB) | 1 st dose | ← 2 nd dose → | | | ← 3 rd dose → | | | | | |
| Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series) | | | 1 st dose | 2 nd dose | See Notes | | | | | |
| Diphtheria, tetanus, acellular pertussis (DTaP <7 yrs) | | | 1 st dose | 2 nd dose | 3 rd dose | | | ← 4 th dose → | | |
| Haemophilus influenzae type b (Hib) | | | 1 st dose | 2 nd dose | See Notes | | ← 3 rd or 4 th dose, See Notes → | | | |
| Pneumococcal conjugate (PCV15, PCV20) | | | 1 st dose | 2 nd dose | 3 rd dose | | ← 4 th dose → | | | |
| Inactivated poliovirus (IPV <18 yrs) | | | 1 st dose | 2 nd dose | ← 3 rd dose → | | | | | |
| COVID-19 (1vCOV-mRNA, 1vCOV-aPS) | | | | | 1 or more doses of | | | | | |

Yes!

Nirsevimab in Preterm Infants?

Preterm infants (born before 37 weeks) regardless of birth weight, should receive it at their chronological age using same guidance for full-term infants and young children

**What if a young infant is in our office and diagnosed with RSV that day or are within 48 hours of illness onset?
Would a dose of nirsevimab be helpful to them to reduce the severity of the illness?**

Nirsevimab has not been studied as a treatment in infants with RSV and is not licensed for treatment of RSV disease. Nirsevimab should be given prior to onset of the RSV season or as soon as possible after birth for infants born during the season to prevent severe RSV disease.

Northwest Portland Area Indian Health Board Immunization Projects



*Strengthening Vaccine Confidence through
Communication, Education and Outreach*



Vaccination information for Natives by Natives

VacciNative & Native Boost Resources

- Fact sheets & Flyers
- Provider PPT Presentations
- Childhood immunization flip guide
- Social Media Tool Kits
- Video & Radio PSAs

Protecting Against RSV

Our ancestors taught us the importance of caring for one another and prioritizing the well-being of our communities. One way they can protect themselves and others is by getting vaccinated against RSV. RSV is a cold-spreading virus that causes symptoms in people of all ages ranging from mild coughs to difficulty breathing and even lung infections. It's especially dangerous for infants and Elders.

The booklet is designed to help you understand the use and use of RSV, so you can take care of yourself, your family, and your community.

“For the well-being of your immune system, get the RSV vaccine. I have witnessed a family member suffer with RSV in the hospital, and it hurts to watch. By making sure that everyone who can get vaccinated against RSV does, we can continue to build a healthier community.”
—Catherine “Gully” Buckner, Texas Public Health

What is RSV?
RSV is a respiratory viral illness, like common colds, that affects our lungs and breathing passages. It usually causes mild, cold-like symptoms. Most people recover in a week or two, but RSV can cause severe infection and difficulty breathing in certain individuals.

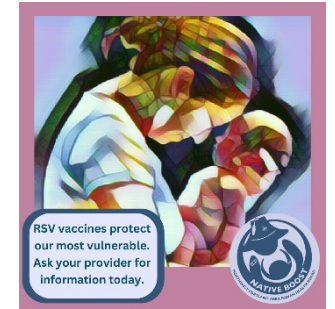
Common RSV Symptoms
People with RSV commonly show symptoms that include:

- Runny nose
- Fever
- Coughing
- Wheezing
- Sneezing
- Decreased appetite

How RSV Spreads
RSV spreads when:

- An infected person coughs or sneezes and you breathe in the air droplets.
- You touch an object with droplets on it, then touch your eyes, nose, or mouth.
- You have direct contact, like kissing, with someone who has RSV.

“Symptoms of RSV usually appear in stages rather than all at once. Some people with RSV develop the breathing symptoms, like trouble breathing and severe lung infection.”
—Dr. Jill Pitt, Ph.D., M.D., M.P.H., Division of Biomedical Sciences, Oregon Health & Science University, Oregon Health & Science University, Oregon Health & Science University, Oregon Health & Science University



2023-24 Vaccines & Prevention for Flu, COVID-19, & RSV

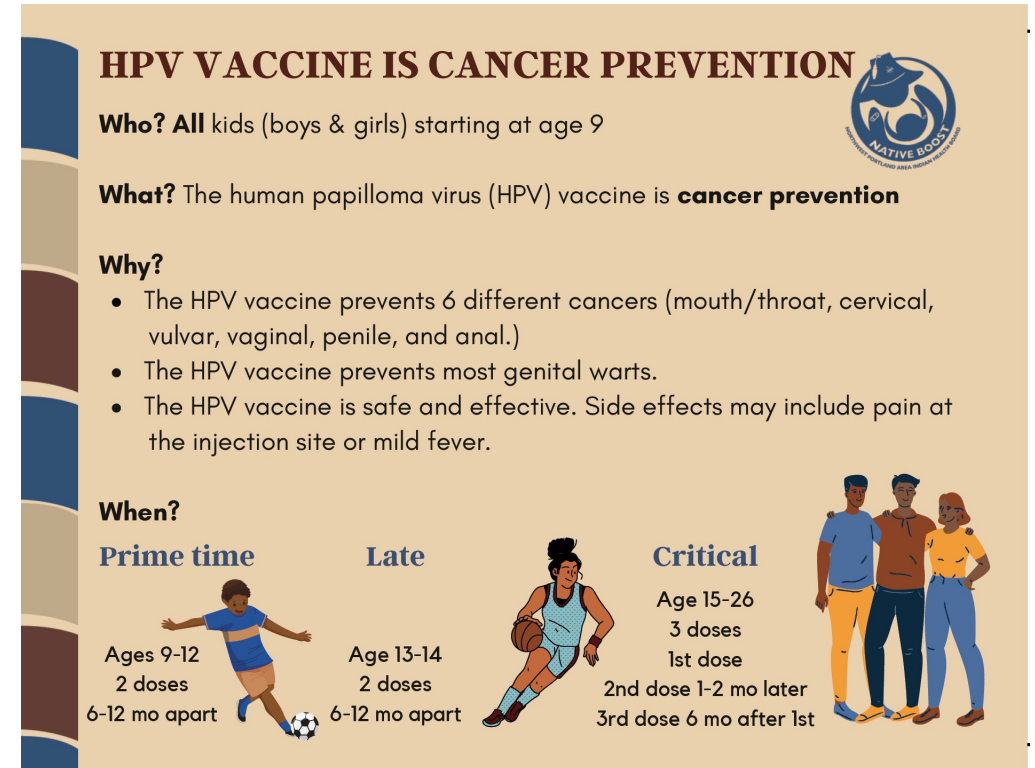
| | FLU | COVID-19 | RSV for 60+ | RSV Pediatric |
|------------------------|---|-------------|--|--|
| Why is this important? | Updated for current season | | No RSV vaccine existed before 2023 | |
| Distribution timing | | Now | | Early October |
| Who should get it? | Everyone 6 months and older who has never been vaccinated and those who had been fully vaccinated | | Age 60+ | Birth-8mo, & 8-19mo if AI/AN or at higher risk |
| When should I get it? | | Fall Season | All three vaccines can be given at same time | |
| What is it? | | Vaccine | | Protection |

VACCINATIVE
Vaccination information for Nations by Nations

Keeping Safe During Respiratory Illness Season

What else would be helpful for RSV Immunizations?

- Fact sheets & Flyers
- Childhood immunization flip guide
- Social Media Tool Kits
- Video & Radio PSAs
- Computer cards for clinics



HPV VACCINE IS CANCER PREVENTION

Who? All kids (boys & girls) starting at age 9




What? The human papilloma virus (HPV) vaccine is **cancer prevention**

Why?

- The HPV vaccine prevents 6 different cancers (mouth/throat, cervical, vulvar, vaginal, penile, and anal.)
- The HPV vaccine prevents most genital warts.
- The HPV vaccine is safe and effective. Side effects may include pain at the injection site or mild fever.

When?

| Prime time | Late | Critical |
|---------------------------------------|---------------------------------------|--|
| Ages 9-12 2 doses 6-12 mo apart | Age 13-14 2 doses 6-12 mo apart | Age 15-26 3 doses 1st dose 2nd dose 1-2 mo later 3rd dose 6 mo after 1st |

Contact Us

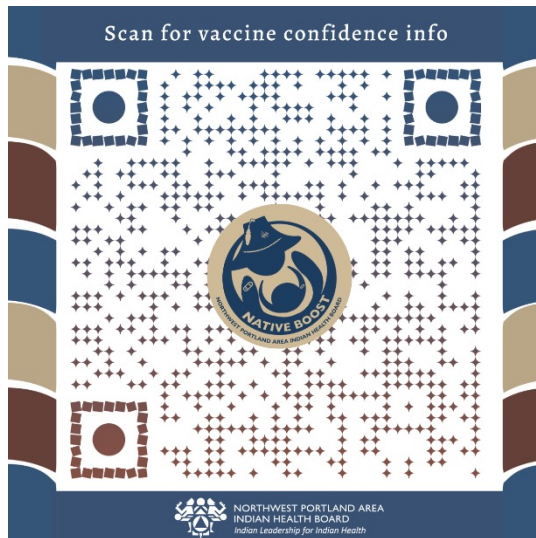
Native Boost

Email:

nativeboost@npaihb.org

Website:

npaihb.org/native-boost/



Vaccinative

Email:

vaccinative@npaihb.org

Website:

<https://www.indiancountryecho.org/vaccinative/>



Links and Resources

- Report vaccine administration errors: [Vaccine Adverse Event Reporting System \(VAERS\)](#). In the event that a vaccine administration error occurs, please reach out to CDC at NIPINFO@cdc.gov for further guidance.
- [RSV \(Respiratory Syncytial Virus\) Immunizations | CDC](#)
- [Healthcare Providers: RSV Immunization for Children 19 Months and Younger | CDC](#)
- [Frequently Asked Questions About RSV Immunization with Monoclonal Antibody for Children 19 Months and Younger | CDC](#)
- [RSV Vaccination: What Parents Should Know | CDC](#)
- [ACIP and AAP Recommendations for Nirsevimab | Red Book Online | American Academy of Pediatrics](#)
- [Health Alert Network: Limited Availability of Nirsevimab in the United States – Interim CDC Recommendations to Protect Infants from RSV During the 2023-2024 Respiratory Virus Season](#)
- Vaccines For Children Program (VFC): <https://www.cdc.gov/vaccines/programs/vfc/index.html>

Thank you!

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