Nirsevimab Updates

Hawaii Vaccines for Children Program

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Josephine Araki, RN

HOUSEKEEPING

- Please ensure you are muted throughout the presentation unless you are speaking.

- **Reminder for QA Team:**
- Please monitor the chat for questions you may be able to answer.

- **Reminder to Attendees:**
- Today's session is being recorded. Slides and webinar recordings will be uploaded to: https://health.hawaii.gov/docd/for-healthcare-providers/vaccination-resources/vaccines-for-children-program-vfc/

- To be added to the Hawaii VFC Program email list, please email your request to HawaiiVFC@doh.Hawaii.gov. In the subject line of the email, please write **EMAIL LIST.**

QUESTIONS?

During today's webinar, please use the chat to ask your questions so the Hawaii VFC Program subject matter experts can respond directly.

We will be answering your questions at the end of the presentation

OBJECTIVES

- By the end of this webinar, providers will understand:
  - The RSV season in Hawaii.
  - The appropriate immunizations for RSV prevention
  - Best practices for storing, handling, and administering these medications to ensure efficacy and safety

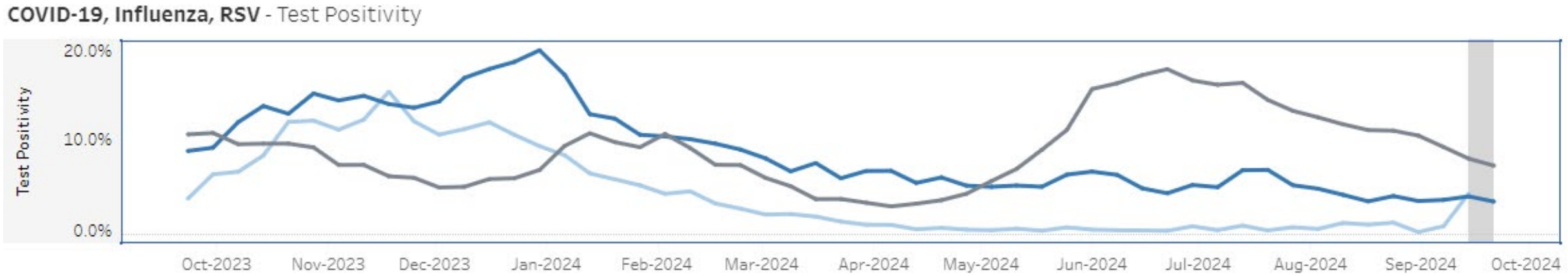
Respiratory Syncytial Virus (RSV)

- Most common cause of hospitalization in infants
- Most children infected during the 1st year of life
- Rate of RSV-associated hospitalization among infants born at ≤30 weeks' gestation (premature) is three times that of term infant
- Prematurity - important risk factor for severe RSV disease
- Among preterm infants, those born at less than 29 weeks of gestation have one of the highest risks of severe morbidity and hospitalization from RSV

RSV

- Leading cause of hospitalization among healthy term infants
- Can cause serious illness and death in infants and young children
- Severe RSV lower respiratory tract infection in infants can be prevented either by
  - Administering monoclonal antibody products to infants and young children
  - Administering RSV vaccine during pregnancy

RSV SEASON IS YEAR ROUND IN HAWAII



Data as of: 9/19/24

https://health.hawaii.gov/docd/disease-types/respiratory-viruses/

RSV protection is recommended year round in Hawaii

Protection

- Two injectable monoclonal antibody products that help protect infants and young children from lower respiratory tract infection caused by RSV
  - Nirsevimab (Beyfortus)
  - Palivizumab (Synagis)
- One RSV vaccine recommended for pregnant persons to prevent severe RSV lower respiratory tract infection in their infants
  - Abrysvo

Nirsevimab

- Not a vaccine
- Injectable monoclonal antibody that prevents severe RSV disease in infants and young children.
- Monoclonal antibodies do not activate the immune system, as would occur with infection or vaccination (active immunization).
- The antibodies themselves protect against disease (i.e., passive immunization).
- Protection is likely most effective the weeks after nirsevimab is given and wanes over time.
- Does not provide long-term immunity to RSV disease but provides protection to infants when they are most at risk of getting severe RSV disease.
- As children get older, they are less likely to get severe symptoms from RSV infection.

Nirsevimab Administration

- Administer intramuscularly (IM).
  - Preferred site of administration - anterolateral thigh region.
  - Do not administer intravenously (IV), intradermally (ID), or subcutaneously (SQ).
- **Number and Timing of Doses**
- Infants younger than 8 months of age who were born during or are entering their first RSV season should receive nirsevimab if
  - The mother did not receive RSV vaccine during pregnancy.
  - The mother's RSV vaccination status is unknown.
  - The infant was born within 14 days of maternal RSV vaccination.

Dosage

Age less than 8 months

- 50 mg for infants weighing <5 kg [<11 lb]
- 100 mg for infants weighing ≥5 kg [≥11 lb]

Age 8 through 19 months:

- 200 mg, administered as two 100 mg injections

Indications for Nirsevimab Use

- Infants aged <8 months
  - Whose pregnant parent did not receive Abrysvo vaccine
  - Whose pregnant parent's Abrysvo vaccination status is unknown
  - Who were born <14 days after the pregnant parent's Abrysvo vaccination
- Not needed for most infants aged <8 months whose pregnant parent received Abrysvo vaccine ≥14 days before giving birth.

Nirsevimab for Infants Born to Vaccinated Mothers

- Nirsevimab may be considered for infants born to a vaccinated pregnant parent in rare circumstances when, based on the clinical judgment of the health care provider, the potential incremental benefit of administration is warranted.
- These situations include, but are not limited to:
  - Infants born to pregnant people who might not have mounted an adequate immune response to vaccination (eg, persons with immunocompromising conditions)
  - Infants born to mothers who have conditions associated with reduced transplacental antibody transfer (eg, persons living with HIV infection
  - Infants who might have experienced loss of transplacentally acquired antibodies, such as those who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation (ECMO)
  - infants with substantially increased risk for severe RSV disease (eg, hemodynamically significant congenital heart disease or intensive care admission requiring oxygen at hospital discharge)

Indications for Nirsevimab Use

- Infants and children 8 through 19 months of age who are at increased risk of severe RSV disease, including those recommended by the AAP to receive palivizumab,[3] regardless of RSV vaccination status of the pregnant parent.
- This includes the following
  - Infants and children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen)
  - Infants and children who are severely immunocompromised.
  - Infants and children with cystic fibrosis who have manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or have weight-for-length that is less than the 10th percentile.
  - American Indian and Alaska Native children.

Administration Considerations

- Aim for administration of nirsevimab in the first week of life for infants who are recommended to receive nirsevimab
- Can be administered during the birth hospitalization or in the outpatient setting
- Infants with prolonged birth hospitalizations because of prematurity or other causes should receive nirsevimab shortly before or promptly after discharge from the hospital
- Nirsevimab should be administered to other eligible infants and toddlers as soon as nirsevimab is available

Administration Considerations

- If nirsevimab supply is limited and the patient is not eligible for palivizumab, nirsevimab should be prioritized to protect infants and children at the highest risk for severe RSV disease
  - First by high-risk conditions
  - Then by age, prioritizing the youngest infants first

Nirsevimab Administration with Other Products

- Can be administered without regard to timing of routine childhood vaccines.
  - This includes simultaneous administration (i.e., same clinic day) with vaccine products.
  - No interval between nirsevimab and live vaccines (such as MMR and Varicella) is necessary.
- Nirsevimab is not expected to interfere with the immune response to vaccine products.
  - In clinical trials, when nirsevimab was given concomitantly with routine childhood vaccines, the safety and reactogenicity profile of the co-administered regimen was similar to the childhood vaccines given alone.

Contraindications

Contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-alip or to a product component

Should be given with caution to infants and children with thrombocytopenia, any coagulation disorder or to individuals on anticoagulation therapy

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS) by telephone (1-800-822-7967) or online (https://vaers.hhs.gov)

Nirsevimab Storage and Handling

Nirsevimab is supplied as pre-filled syringes for one time use only.

It comes in two doses:

- 50 mg/0.5 ml
- 100 mg/ml

Pre-filled syringes

- Should be stored refrigerated between 2°C to 8°C (36°F to 46°F)
- May be kept at room temperature 20°C to 25°C (68°F to 77°F) for a maximum of 8 hours.
- Should be stored in the original carton to protect from light until time of use
- Do not freeze or expose to heat.

Do not use beyond the expiration date printed on the label.

Ordering

- Order using Nirsevimab Order Form
- CDC has implemented a new “top-off” strategy for VFC Nirsevimab supply, which involves replenishing doses allocated to the Hawai‘i VFC program every 2 weeks
- Please place orders with the Hawai‘i VFC Program to ensure maximum CDC replenishment of Hawaii VFC allocations every two weeks
- Note
  - If Hawai‘i’s VFC Nirsevimab allocation is above a CDC-determined threshold, no additional doses will be apportioned to the Hawai‘i VFC Program.
  - If VFC provider requests exceed available CDC VFC allocations, VFC provider orders will be waitlisted and/or partially fulfilled as supply permits.

Ordering for Birthing Hospitals

- Continue to order the amount of VFC 50mg doses needed for a two-week period
- The Hawai‘i VFC program will work with your facilities to distribute as many doses as possible for administration to VFC-eligible newborns

Ordering for Outpatient VFC Providers

- Please order the amount of 100mg doses needed to immunize VFC-eligible patient population aged 8 months or less and weighing ≥5kg for a one-month period
- If VFC provider requests exceed available VFC allocations, VFC provider orders may be waitlisted and/or processed for partial fulfillment as supply permits.

Palivizumab (Synagis)

- If nirsevimab is not available or not feasible to administer
  - High-risk infants who are recommended to receive palivizumab in the first or second year of life should receive palivizumab until nirsevimab becomes available
- High-risk infants whose pregnant parent received a recommended RSV vaccine ≥14 days prior to delivery do not require palivizumab, except in rare circumstances
- Should not be given to children who have already received nirsevimab

Palivizumab

Humanized mouse immunoglobulin G1 (IgG1 κ) monoclonal antibody produced by recombinant DNA technology

5 doses administered intramuscularly at a dosage of 15 mg/kg once a month

Does not contain preservative and vial cannot be stored once it is opened

Palivizumab Storage and Handling

Stored in refrigerator between 2°C and 8°C (36°F and 46°F) in its original container

DO NOT freeze

Palivizumab Preparation

DO NOT DILUTE THE PRODUCT.

DO NOT SHAKE OR VIGOROUSLY AGITATE THE VIAL.

Considerations: Palivizumab versus Nirsevimab Administration for High Risk Infants

- If nirsevimab is administered, palivizumab should not be administered
- If <5 doses of palivizumab were administered, the infant should receive 1 dose of nirsevimab.
  - No further palivizumab should be administered.
  - There is no minimum interval between the last dose of palivizumab and the dose of nirsevimab.
  - Because protection from palivizumab wanes after 30 days, nirsevimab should be administered no later than 30 days after the last palivizumab dose, when possible.
- If palivizumab was administered in the 1st year of life and the child is eligible for RSV prophylaxis in 2nd year of life, the child should receive nirsevimab, if available. If nirsevimab is not available, palivizumab should be administered as recommended

Maternal RSV Vaccination - Abrysvo

- Approved by ACIP for pregnant VFC eligible children within guidelines
- PreTo prevent severe RSV disease in infants, either maternal RSV vaccination or infant immunization with RSV monoclonal antibody is recommended.
- Most infants will not need both

Abrysvo Administration

- One dose of Pfizer's bivalent Abrysvo for people who are 32 through 36 weeks pregnant
- **Administer IM.**
  - Preferred site of administration is the deltoid region of the upper arm.
  - Do not administer RSV vaccine IV, ID, or SQ.
- **Number of Doses**
  - Abrysvo is currently approved and recommended for administration as a single dose
  - Sufficient evidence does not exist at this time to determine the need for additional doses in subsequent pregnancies

Administration with Other Vaccines

- Pregnant people can receive RSV, Tdap, COVID-19, and influenza vaccines at the same clinic visit when the vaccines are recommended.
- CDC's general best practice guidelines for immunization indicate that age-appropriate vaccinations can be given at the same visit, unless there is a specific reason not to.

Abrysvo Storage and Handling

Pfizer's vaccine is supplied in a kit with three components:

- Vial of Lyophilized Antigen Component (a sterile white powder)
- Prefilled syringe containing Sterile Water Diluent Component
- Vial adapter
- Refer to the manufacturer's package insert for specific instructions on reconstituting the vaccine: Package Insert – ABRYSVO (fda.gov).

Before reconstitution:

- Store vaccine and diluent refrigerated between 2°C and 8°C (36°F and 46°F).
  - Store these components in their original package and keep them together in the refrigerator to optimize organization.
- Never freeze the vaccine or diluent.

After reconstitution:

- Immediately administer the vaccine
- Prepare the vaccine only when ready for use.
- If you do not immediately administer the vaccine, there are some minor differences in storage:
  - Store the reconstituted vaccine ONLY at room temperature (15ºC to 30ºC / 59ºF to 86ºF).
  - Do NOT refrigerate. This is very different than other reconstituted vaccines. Typically, storage after reconstitution is refrigerated storage only or refrigerated or room temperature storage. For this vaccine, do NOT put it back in the refrigerator.
  - Once reconstituted, use within 4 hours

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- *Medical Advisories | Disease Outbreak Control Division*. (2024). Hawaii.gov. https://health.hawaii.gov/docd/for-healthcare-providers/medical-advisories/
- *Respiratory Viruses | Disease Outbreak Control Division*. (n.d.). https://health.hawaii.gov/docd/disease-types/respiratory-viruses/
- Synagis: Package Insert - Drugs.com
- Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. (2014). *PEDIATRICS*, *134*(2), 415–420. https://doi.org/10.1542/peds.2014-1665

Additional Resource

- CDC. (2024). *ACIP Evidence to Recommendations for Use of Nirsevimab in Children 8–19 months of age at increased risk of severe disease entering their second RSV season*. Advisory Committee on Immunization Practices (ACIP). https://www.cdc.gov/acip/evidence-to-recommendations/nirsevimab-season2-rsv-infants-children-etr.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/acip/recs/grade/nirsevimab-season2-rsv-infants-children-etr.html
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Post Webinar Satisfaction Survey

- Please use the following link to complete the satisfaction survey
  - https://forms.office.com/g/XStX9ewn6e

Questions

Contact Info

VFC Program & VFC Site Visits		
Josephine Araki, RN	josephine.araki@doh.hawaii.gov	808-723-1601
Loraine Lim, RN	loraine.lim@doh.hawaii.gov	808-723-0018
Kealohi Corpos	kealohi.corpos@doh.hawaii.gov	808-723-0091
Jazz Burns	jazz.burns.nsw@doh.hawaii.gov	808-723-0366
Sisilia Meli	sisilia.meli.nsw@doh.hawaii.gov	808-587-6588
Heather Winfield-Smith	h.winfield-smith@doh.hawaii.gov	808-586-8348
VFC Vaccine Orders		
Melvin Reyes	melvin.reyes@doh.hawaii.gov	808-586-8316
Elizabeth Ricon	elizabeth.ricon@doh.hawaii.gov	808-586-8301
Heather Winfield-Smith	h.winfield-smith@doh.hawaii.gov	808-586-8348
Ji Hyun Choi	jihyun.choi@doh.hawaii.gov	808-586-4585

Thank you!