November 2023

**LEARNING FORUM** 



# AWHONN/KPQC FALL CONFERENCE: A SUCCESS!!!!



## AWHONN/KPQCFALL CONFERENCE: A SUCCESS!!!!

• 123 attendees, 18 speakers, 10 vendors, 54 different organizations represented:

AdventHealth Shawnee Mission

Amberwell Hiawatha

Ascension Medical Group, MFM Wichita

**AWHONN** 

Blue Cross Blue Shield of Kansas City

Centura St Catherine's Dodge City Children's Mercy Hospitals and Clinics

Citizens Medical Center

Clay County Medical Center

Community Healthcare System

**Emporia State University** 

Grow Midwives, LLC

Hays Medical Center

High5 for Mom & Baby

**Hutchinson Regional Medical Center** 

IOWA AWHONN Reg. Chapter Leader

Kansas Action for Children Kansas Birth Equity Network Kansas Breasfeeding Coalition Kansas Hospital Association

Kansas Infant Death and SIDS Network

Kansas Service Children's League

Kansas Department of Health and

Environment

**KFMC** 

Lawrence Memorial Hospital

McPherson Center for Health

Neosho Memorial Reg Med Ctr

Newman Regional Health

Olathe Health

PeriGen

Pratt Regional Medical Center

Reno County Health Department

Republic County Health Department

Rice County District Hospital

Riley County

**Rockhurst University** 

Salina Regional Medical Center

Saline County Health Department

SE Kansas Multi-County Health Dept.

Sedgwick County Health Department

**Smith County Memorial Hospital** 

St. Luke's East

Stormont Vail Health Flint Hills

Stormont Vail Health Topeka

Sunflower

Topeka Doula Project

United Healthcare

United Methodist Health Ministry Fund

University Health Truman Med Center

University of Kansas Health Systems- Great

Bend

University of Kansas School of Nursing (Salina)

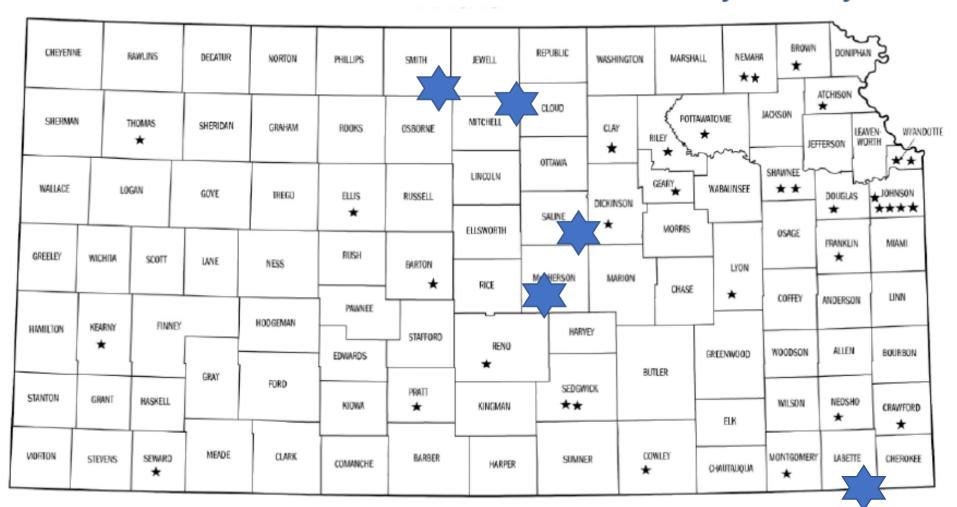
University of Kansas Topeka

Wyandotte County Health Department



## Enrolled FTI Sites = Impact 90% of Kansas Births!

## Fourth Trimester Initiative Locations by County



## FTI Updates

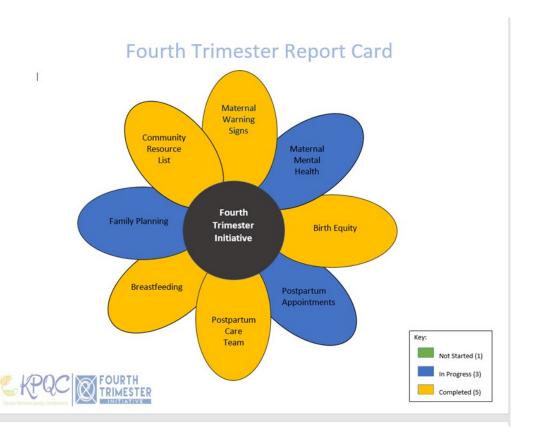
- □ POSTBIRTH trainings- Last date for group training: December 1 at 0830 via Teams
- ☐ Birth Equity trainings-

Hutchinson & Hiawatha-nearing end of training

No Longer enrolling any additional FTI sites



## **Survey Completions:**





## Thank you:

### **Birth Facilities**

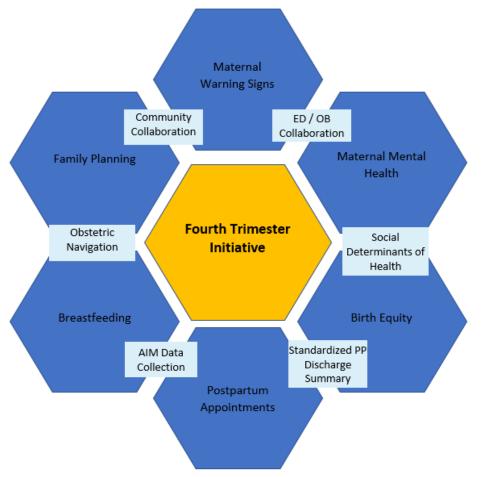
AdventHealth Shawnee Mission Amberwell Hiawatha Community Hospital Ascension Via Christi Pittsburg Ascension Via Christi Wichita Amberwell Atchison Citizens Medical Center Clay County Medical Center Community Healthcare System **Hutchinson Regional Medical Center** Lawrence Memorial Hospital McPherson Center for Health Nemaha Valley Community Hospital Neosho Memorial Regional Medical Newman Regional Health Sabetha Community Hospital Smith County Memorial Hospital Stormont Vail Health Stormont Vail Health Flint Hills University of KS Health System-Great Bend

### **KS Birth Centers**

New Birth Company-Overland Park, KS



## **Fourth Trimester Projects**







## Rapid Response: Premature Deliveries

www.kdhe.ks.gov/DocumentCenter/View/13579/PrematurityAction-Alert-PDF



Rates of premature births are continuing to climb in the United States, with 1 in 10 babies being born before 37 weeks gestation.

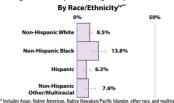


While births before 34 weeks gestation have remained relatively steady in recent years, preterm birth rates (under 37 weeks gestational age) remain highest among the Black, non Hispanic; American Indian or Alaska Native; Native Hawaiian or Other Pacific Islander; and Hispanic populations."

While Kansas falls slightly below the national average for prematurity at 10.1%, large disparities exist with Black mothers experiencing premature deliveries 51% more often than those of other races. Factors such as inadequate health care coverage, poverty, chronic disease and smoking, as well as inadequate prenatal education are identified as being contributing factors for premature births. To learn more about contributing factors and reducing disparities in preterm birth, please see November's Did You Know and the Preterm Births in Kansas Infographic.

### Prevalence of Preterm Birth, Among Kansas Women with a Recent Live Birth

Data were gathered from the Kansas Pregnancy Risk Assessment Monitoring System (PRAMS), 2017-2019. PRAMS is a survey in which women who have recently given birth are interviewed about their health and experiences before, during, and shortly after pregnancy.



\*Includes Asian, Native American, Native Hawaiian/Pacific Islander, other race, and multiracial.

A higher proportion of non-Hispanic Black mothers gave birth to a preterm infant, compared to non-Hispanic White mothers, non-

Hispanic mothers of other race, and Hispanic mothers. The estimated prevalence of preterm birth was significantly higher (p<0.05) among non-Hispanic Black women, compared to non-Hispanic White women, Hispanic women, and non-Hispanic women of other/miked race.

### By Self-Reported Health Insurance Status During Pregnancyiv\*\*



The prevalence also varied by the type of health insurance that women reported having for their prenatal care. Women whose primary insurance for prenatal care was Medicaid had a significantly higher prevalence of preterm birth, compared to women who had private insurance or who were uninsured.



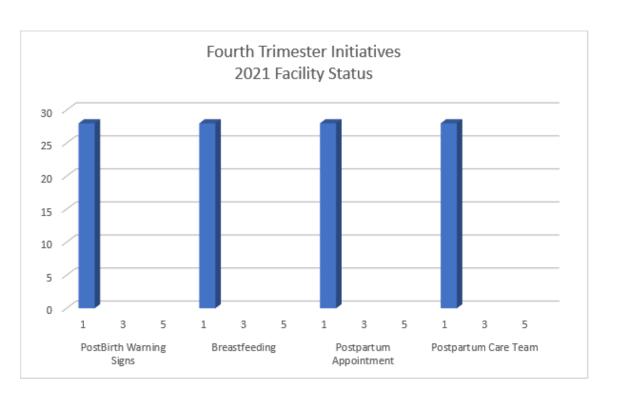


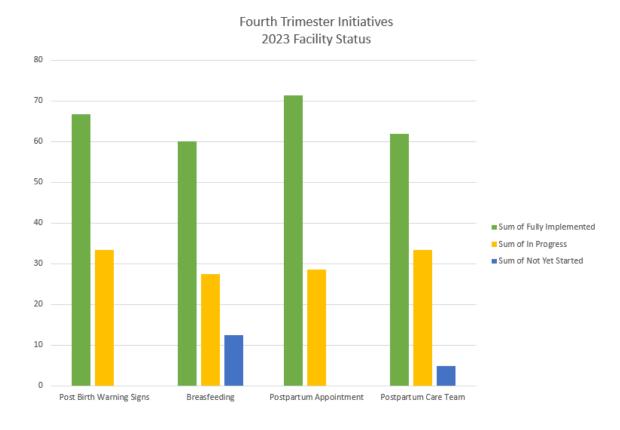
# But... Look what you've done!

Data!



## **AIM Enrollment: Project Start vs Now**









# No guilt. Full throttle finish.

We are ALMOST done, and great change has been started.

Stay tuned with facility updates for projects to complete in 2024!



# **Featured Speakers**





Becky Prall, Immunization Program
Section Chief
KDHE | Kansas Immunization
Program

Helay Hassas, PharmD Medical Science Liaison Sanofi Pharmaceuticals









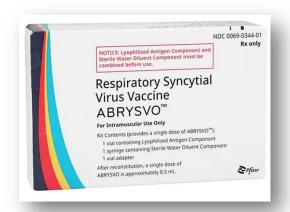


## **Objectives**

- Review of available RSV products
- Approved RSV vaccine during pregnancy
- Nirsevimab (Beyfortus) supply and recommendation
- Prevention of Administration Errors
- Vaccines for Children Program brief overview
- Resources, product information and job aids



## RSV Vaccines Approved for 60 Years and Older



Source: FDA



- Two RSV vaccines are licensed and recommended for persons 60 years and older.
- Recommendation is based on shared clinical decision-making.
- Recommendation is a single dose of either product. Currently there is not sufficient evidence for additional doses.

Source: FDA



## **RSV Vaccines Approved for 60 Years and Older**

Shared Clinical Decision-Making (SCDM)

### **RSV Vaccination for Adults 60 Years and Older**

- · Respiratory syncytial virus (RSV) is a cause of severe respiratory illness across the lifespan. Each year in the United States, RSV leads to approximately 60,000-160,000 hospitalizations and 6,000-10,000 deaths among adults 65 years and older.
- Adults 60 years of age and older now have the option to receive one dose of RSV vaccine based on a SCDM process between a patient and their health care provider.
- · Consider multiple factors when discussing RSV vaccination with your patients. SCDM recommendations are optional and are informed by whether the patient has any risk factors for severe RSV disease; a patient's risk of exposure to RSV; a patient's preferences for RSV vaccination; and the clinical discretion of the health care provider.

#### Underlying medical conditions associated with increased risk for severe RSV disease include:



Chronic lung disease (e.g., COPD and Chronic cardiovascular

disease (e.g., CHF and



Chronic kidney



Moderate or severe mmunocompromise





Chronic hematologic



Any underlying condition that a provider determines



Chronic or progressive neurologic or neuromuscular



night increase the risk of severe RSV disease

#### Other factors associated with increased risk for severe RSV disease include



Frailty or advanced age, as determined by the





Any underlying factor

#### Other points to consider:

- Serious neurologic conditions, including Guillain-Barré syndrome (GBS), have been reported after RSV vaccination in clinical trials. However, it is unclear whether the vaccine caused these events.
- · Persons with history of severe allergic reaction (e.g., anaphylaxis) to any component of RSV vaccine should not receive the vaccine



### Storing RSV vaccines

 Abrysvo kit (vial of lyophilized antigen component, prefilled syringe containing sterile water diluent, and a vial adapter) must be refrigerated at 36°E to 46°E (2°C to 8°C) in the original carton. Do not freeze. Discard

en frozen.

#### Who is most likely to benefit from RSV vaccination?

Adults ages 60 years and older who are at highest risk for severe RSV disease are most likely to benefit from vaccination. This includes persons with:

antigen component vials must be refrigerated s from light. Do not freeze. Discard if the

### Respiratory Syncytial Virus vaccines (RSV)

### **Fact Sheet for Healthcare Providers**

CDC recommends that adults ages 60 years and older may receive a single dose of RSV vaccine using shared clinical decision-making (SCDM).

If you vaccinate, either approved RSV vaccine (Abrysvo™ or Arexvy®) can be used.

### **Patients**

**60**<sup>+</sup> Years Old

About RSV vaccines

### Doses

How do shared clinical decision-making recommendations (SCDM) difference utine,

. SCDM vaccination recommendations are individually based rather than population based and informed by

. Consider multiple factors when discussing RSV vaccination with your patients. The decision to vaccinate is informed by whether the patient has any risk factors for severe RSV disease, a patient's risk of exposure to RSV, a patient's preferences for RSV vaccination, and the clinical discretion of the health care provider.

Abrysvo is a recombinant stabilized prefusion F protein vaccine approved for the prevention of lower

· Arexvy is an adjuvanted recombinant stabilized prefusion glycoprotein F vaccine approved for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals ages 60 years and older.

respiratory tract disease (LRTD) caused by RSV in individuals ages 60 years and older.



catch-up, and risk-based immunization recommendations?

a decision process between the health care provider and the patient.

### Administer



Storage

Refrigerate at 36°F to 46°F (2°C to 8°C)

termines might increase the risk for severe

re and coronary artery disease

disease and asthma

rmines might increase the risk for severe

has ever had a severe allergic reaction, such as

r RSV vaccination

afety profile. The most common side effects in

ne (GBS), were reported after RSV vaccination

urveillance clarifying the existence of any those who are at highest risk for severe RSV onent (a sterile white powder) with the diluent component.

perature at 59°F to 86°F (15°C to 30°C) and use

conditions at 36°F to 46° F (2°C to 8°C). nstituted vaccine has been frozen.

onent (a sterile white powder) with the alescent, colorless to pale brownish sterile

light in the refrigerator at 36°F to 46° F (2°C to within 4 hours.

stituted vaccine has been frozen.

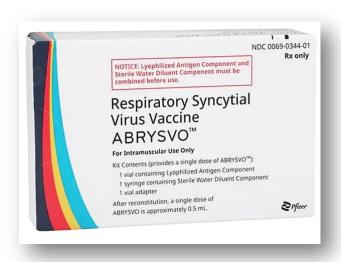
larly in the deltoid region of the upper arm

Vaccine Adverse Event Reporting System nt adverse event – even if it is uncertain able online on how to submit a VAERS report





## **RSV Vaccine Approved for Maternal Use**



Source: FDA

- One RSV vaccine is licensed and recommended for use during pregnancy.
- Recommended to be administered between 32- and 36-weeks gestation using seasonal administration (from September through January in most of the continental U.S.).
- Recommendation is a single dose.



## **Options for Infant RSV Prevention**

# Respiratory Syncytial Virus vaccines (RSV) Options for Infant RSV Prevention At-a-Glance

Two immunization products are available for the prevention of severe Respiratory Syncytial Virus (RSV) disease in infants: maternal RSV vaccine and infant RSV monoclonal antibody. All infants should be protected against severe RSV disease through use of one of these products.

Either maternal RSV vaccination or use of RSV monoclonal antibody in the infant is recommended.

Administration of both products is not needed for most infants.

Maternal RSV vaccination: Use ONLY Pfizer RSVPreF vaccine (trade name Abrysvo™)

#### Maternal RSV Vaccine

RSVPreF vaccine (trade name Abrysvo<sup>™</sup>) is recommended for people during weeks 32 through 36 of pregnancy, using seasonal administration, to prevent severe RSV disease in infants. In clinical trials, there was a small increase in the number of preterm birth events in vaccinated pregnant people after vaccination. It is not clear if this is a true safety problem related to RSV vaccine or if this occurred for reasons unrelated to vaccination.

### Infant RSV Monoclonal Antibody'

RSV monoclonal antibody (generic name nirsevimab, trade name Beyfortus™) is recommended for the following:

- . Infants less than 8 months of age born during or entering their first RSV season if:
  - ° Mother did not receive maternal RSV vaccine or it is unknown if mother received RSV vaccine

#### OR

Infant was born less than 14 days after maternal RSV vaccination<sup>†</sup>

In rare circumstances, nirsevimab may be considered for infants born to mothers vaccinated 14 or more days before birth when the health care provider believes the potential incremental benefit is warranted. These situations include, but are not limited to:

- Infants born to mothers who might not have mounted an adequate immune response to vaccination (e.g., people with immunocompromising conditions)
- Infants born to mothers who have conditions associated with reduced transplacental antibody transfer (e.g., people living with HIV infection)
- Infants who might have experienced loss of maternal antibodies, such as those who have undergone cardiopulmonary bypass of extracorporeal membrane oxygenation (ECMO)
- Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission with the requirement for oxygen at hospital discharge)
- Some infants and children aged 8 through 19 months who are at increased risk of severe RSV disease entering their second RSV season.
  - American Indian/Alaska Native children
  - Children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season
  - Children with severe immunocompromise
  - Children with severe cystic fibrosis

\*Note: A different monoclonal antibody, palivizumab, is used in children under 24 months of age with certain conditions that place them at high risk for severe RSV disease Please see <u>ABP oxidatines for polivizumab, Parh par published considerations on the use of inservimab and palivizumab; <a href="https://publications.aan.gov/redobod/respures/25372">https://publications.aan.gov/redobod/respures/25372</a>. Oxiding the same RSV season.</u>

From time of maternal vaccination, at least 14 days are needed for the development and transplacental transfer of maternal antibodies to protect the infant

## Clinical Considerations for Use of Maternal RSV Vaccine or Infant RSV Monoclonal Antibody

(Administration of both products is not needed for most infants)

| Product  | Maternal RSV Vaccine  | RSV Monoclonal Antibody  |
|--|---|--|
| Description  | RSVPreF vaccine<br>Trade name: Abrysvo™   | Generic name nirsevimab<br>Trade name: Beyfortus™  |
| Immunity   | Mother – Active immunity<br>Infant – Passive immunity   | Passive immunity   |
| Duration of Protection                                       | Approximately 3 to 6 months for infant  | Approximately 5 months or more   |
| How Supplied   | A kit that includes a vial of lyophilized<br>antigen component, a prefilled syringe<br>containing sterile water diluent, and<br>a vial adapter. The lyophilized antigen<br>component is reconstituted with the sterile<br>water diluent to form a single dose.  | Single dose pre-filled syringe with a<br>purple (for 50 mg dosage) or light blue<br>(for 100 mg dosage) plunger rod. No<br>reconstitution needed.  |
| Recommended<br>Dosage  | 0.5 mL Currently recommended for administration as a single dose. It is not yet known whether additional doses might be needed in later pregnancies.  | Age less than 8 months  • Less than 5 kg: 50 mg (0.5mL)  • 5 kg and greater: 100 mg (ImL)  Age 8 through 19 months <sup>a</sup> • 200 mg (administered as two IM injections)   |
| Number of Doses  | One   | One <sup>5</sup>   |
| How Administered   | IM injection  | IM injection   |
| Coadministration   | Can be administered without regard to<br>timing of other routine immunizations,<br>including simultaneous administration  | Can be administered without regard to<br>timing of other routine immunizations,<br>including simultaneous administration   |
| Gestation or Age for<br>Immunization                         | 32 through 36 weeks   | Less than age 8 months depending on<br>mother's RSV vaccination status     Ages 8 through 19 months if at<br>increased risk for severe RSV disease.‡   |
| When to Administer<br>(Seasonality)                          | Beginning of September through end of<br>January in most of the continental United<br>States.   | Beginning of October through end of<br>March in most of the continental United<br>States.  |
|  | In jurisdictions with RSV seasonality that differs from most of the continental United States, including Alaska, southern Florida, Cuam, Hawaii, Puerto Rico, U.Saffiliated Pacific Islands, and U.S. Virgin Islands, healthcare providers should follow state, local, or territorial guidance on timing of maternal RSV vaccination. | In jurisdictions with RSV seasonality that differs from most of the continental United States, including Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.Saffiliated Pacific Islands, and U.S. Virgin Islands, healthcare providers should follow state, local, or territorial guidance on timing of nirsevimab administration. |
| Contraindications<br>(Product Should Not<br>Be Administered) | History of severe allergic reaction (e.g.,<br>anaphylaxis) to any component of the<br>maternal RSV vaccine  | History of severe allergic reaction (e.g.,<br>anaphylaxis) after a previous dose or to a<br>component of nirsevimab  |

## Clinical Considerations for Use of Maternal RSV Vaccine or Infant RSV Monoclonal Antibody

(Administration of both products is not needed for most infants)

| Precautions (Administration Should Typically Be Deferred)  Safety  - Local and systemic reactions in clinical trials, the most common reactions after maternal RSV vaccine in pregnant people were pain at the injection site, headache, muscle pain, and nausea.  - Severe allergic reactions As with any medicine or vaccine, there is a remote chance of RSV vaccine causing a severe allergic reaction.  - Preterm birth In clinical trials, among people who were vaccinated during weeks 24 through 36 weeks of pregnancy, more preterm births were reported among maternal RSV vaccine recipients than among placebo recipients. This difference was not statistically different. Available data are insufficient to establish or exclude a causal relationship between preterm birth and maternal RSV vaccine, EDA approved the vaccine for use during weeks 32 through 36 of pregnancy. The vaccine studies did not include people who already had a higher risk of preterm births.  - Hypertensive disorders of pregnancy Although not common, in the clinical trials, hypertensive disorders of pregnancy (including pre-eclampsia) occurred in 1,8% of pregnant people who received a placebo.   | (Administration of both products is not needed for most infants) |  |   |  |
|--|--|--|---|--|
| Administration Should Typically Be Deferred  | Product  | Maternal RSV Vaccine   | RSV Monoclonal Antibody   |  |
| In clinical trials, the most common reactions after maternal RSV vaccine in pregnant people were pain at the injection site, headache, muscle pain, and nausea.  • Severe allergic reactions  As with any medicine or vaccine, there is a remote chance of RSV vaccine causing a severe allergic reaction  • Preterm birth  In clinical trials, among people who were vaccinated during weeks 24 through 36 weeks of pregnancy, more preterm birth were reported among maternal RSV vaccine recipients. This difference was not statistically different. Available data are insufficient to establish or exclude a causal relationship between preterm birth when administering maternal RSV vaccine, EDA approved the vaccine for use during weeks 32 through 36 of pregnancy. The vaccine store for use during weeks 32 through 36 of pregnancy. The vaccine store for use during weeks 32 through 36 of pregnancy. The vaccine store for use during weeks 32 through 36 of pregnancy. The vaccine store of pregnancy (including pre-eclampsia) occurred in 1,8% of pregnant people who received the RSV vaccine compared to 1,4% of pregnant people who received a large of the vaccine and the proposed to the vaccine compared to 1,4% of pregnant people who received a large of the vaccine and the proposed to the vaccine compared to 1,4% of pregnant people who received a large of the vaccine and the proposed to the vaccine to the vaccine studies are compared to 1,4% of pregnant people who received a large of the vaccine to 1,4% of pregnant people who received a large of the vaccine to 1,4% of pregnant people who received a large of the vaccine to 1,4% of pregnant people who received a large of the vaccine to 1,4% of pregnant people who received a large of the vaccine to 1,4% of pregnant people who received a large of the vaccine to 1,4% of pregnant people who received a large of the vaccine to 1,4% of pregnant people who received a large of the vaccine to 1,4% of pregnant people who received a large of the vaccine to 1,4% of pregnant people who received a large of the v | (Administration Should   |  |   |  |
|  | Safety   | In clinical trials, the most common reactions after maternal RSV vaccine in pregnant people were pain at the injection site, headache, muscle pain, and nausea.  As with any medicine or vaccine, there is a remote chance of RSV vaccine causing a severe allergic reaction  Preterm birth In clinical trials, among people who were vaccinated during weeks 24 through 36 weeks of pregnancy, more preterm births were reported among maternal RSV vaccine recipients than among placebo recipients. This difference was not statistically different. Available data are insufficient to establish or exclude a causal relationship between preterm birth and maternal RSV vaccine. To reduce the potential risk of preterm birth when administering maternal RSV vaccine, FDA approved the vaccine for use during weeks 32 through 36 of pregnancy. The vaccine studies did not include people who already had a higher risk of preterm births.  Hypertensive disorders of pregnancy Although not common, in the clinical trials, hypertensive disorders of pregnancy (including pre-eclampsia) occurred in 1.8% of pregnant people who received the RSV vaccine compared to 1.4% of pregnant people who received a | In clinical trials, the most common adverse events after nirsevimab were rash and injection-site reactions, each occurring in <1% of infants and young children.  Severe allergic reactions As with any medicine or vaccine, there is a remote chance of nirsevimab causing a severe allergic reaction.  Serious adverse event The incidence of serious adverse events was not increased in the nirsevimab arm compared with that in the placebo arm. No serious allergic reactions or immune complex disease |  |

IChildren 8-19 months who are at increased risk of severe RSV disease (American Indian and Alaska Native children; children who are severely immunocompromised; children with cystic fibrosis with severe disease; and children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season) should receive inservimab 200 mg dose administered as two IM injections (2 x IOO mg loikb thus plunoer root shortly before the start of their second RSV season.

\$One dose for each RSV season except for children undergoing cardiac surgery with cardiopulmonary bypas where an additional dose is recommended as soon as the child is stable after surgery. See <u>label (ida gov)</u>.





## **Beyfortus (nirsevimab)**



### Respiratory syncytial virus immunization

(minimum age: birth [Nirsevimab, RSV-mAb (Beyfortus™)

#### Routine vaccination

^

- . Infants born October March in most of the continental United States\*
  - Mother did not receive RSV vaccine OR mother's RSV vaccination status is unknown: administer 1 dose nirsevimab within 1 week of birth in hospital or outpatient setting
  - o Mother received RSV vaccine less than 14 days prior to delivery: administer 1 dose nirsevimab within 1 week of birth in hospital or outpatient setting
  - Mother received RSV vaccine at least 14 days prior to delivery: nirsevimab not needed but can be considered in rare circumstances at the discretion of healthcare providers (see special populations and situations at <a href="mailto:cdc.gov/vaccines/vpd/rsv/hcp/child-fags.html">cdc.gov/vaccines/vpd/rsv/hcp/child-fags.html</a>)
- · Infants born April-September in most of the continental United States\*
  - Mother did not receive RSV vaccine OR mother's RSV vaccination status is unknown: administer 1 dose nirsevimab shortly before start of RSV season\*
  - Mother received RSV vaccine less than 14 days prior to delivery: administer 1 dose nirsevimab shortly before start of RSV season\*
  - Mother received RSV vaccine at least 14 days prior to delivery: nirsevimab not needed but can be considered in rare circumstances at the discretion of healthcare providers (see special populations and situations at <a href="mailto:cdc.gov/vaccines/vpd/rsv/hcp/child-fags.html">cdc.gov/vaccines/vpd/rsv/hcp/child-fags.html</a>)

Infants with prolonged birth hospitalization\*\* (e.g., for prematurity) discharged October through March should be immunized shortly before or promptly after discharge.

### Special situations

- Ages 8–19 months with chronic lung disease of prematurity requiring medical support (e.g., chronic corticosteroid therapy, diuretic therapy, or supplemental
  oxygen) any time during the 6-month period before the start of the second RSV season; severe immunocompromise; cystic fibrosis with either weight for length
  <10th percentile or manifestation of severe lung disease (e.g., previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on</li>
  - 1 dose nirsevimab shortly before start of second RSV season\*
- · Ages 8-19 months who are American Indian or Alaska Native:

chest imaging that persist when stable)\*\*:

- o 1 dose nirsevimab shortly before start of second RSV season\*
- Age-eligible and undergoing cardiac surgery with cardiopulmonary bypass\*\*: 1 additional dose of nirsevimab after surgery. For additional details see special
  populations and situations at <a href="https://www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html">www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html</a>

\*Note: While the timing of the onset and duration of RSV season may vary, nirsevimab may be administered October through March in most of the continental United States. Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, jurisdiction with tropical climate) should follow guidance from public health authorities (e.g., CDC\_health\_departments) or radional medical centers on timing of administration based on local RSV seasonality. Although optimal timing of administration is just before Nicevimab 100 mg Dose Priori... rsevimab may also be administered during the RSV season to infants and children who are age-eligible.

\*\*Note: Nirsevimab can be administered to children who are eligible to receive palivizumab. Children who have received nirsevimab should not receive palivizumab for the same RSV season.

For further guidance, see <a href="https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm">www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm</a> and <a href="https://www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.htm">www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm</a> and <a href="https://www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.htm">www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.htm</a>



## Nirsevimab 100 mg Dose Prioritization

Español | Other Languages





**Emergency Preparedness and Response** 

**Emergency Preparedness and Response Home** 

Limited Availability of Nirsevimab in the United States— Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season





Distributed via the CDC Health Alert Network October 23, 2023, 3:30 PM ET CDCHAN-00499

### Summary

The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to provide options for clinicians to protect infants from respiratory syncytial virus (RSV) in the context of a limited supply of nirsevimab . a long-acting monoclonal antibody immunization product recommended for preventing RSV-associated lower respiratory tract disease in infants.

In the context of limited supply during the 2023–2024 RSV season, CDC recommends prioritizing available nirsevimab 100mg doses for infants at the highest risk for severe RSV disease: young infants (age <6 months) and infants with underlying conditions that place them at highest risk for severe RSV disease. Recommendations for using 50mg doses remain unchanged at this time. Avoid using two 50mg doses for infants weighing ≥5 kilograms (≥11 pounds) to preserve supply of 50mg doses for infants weighing <5 kilograms (<11 pounds). Providers should be aware that some insurers may not cover the cost of two 50mg doses for an individual infant.

CDC further recommends that providers suspend using nirsevimab in palivizumab-eligible children 2 aged 8–19 months for the 2023–2024 RSV season. These children should receive palivizumab per American Academy of Pediatrics (AAP) recommendations 2. Nirsevimab should continue to be offered to American Indian and Alaska Native children aged 8–19 months who are not palivizumab-eligible and who live in remote regions, where transporting children with severe RSV for escalation of medical care is more challenging or in communities with known high rates of RSV among older infants and toddlers. Prenatal care providers should discuss potential nirsevimab supply concerns when counseling pregnant people about RSVpreF vaccine (Abrysvo, Pfizer) as maternal vaccination is effective and will reduce the number of infants requiring nirsevimab during the RSV season.

### KS-HAN



October 24, 2023

From: KDHE Immunization Program

To: Vaccines for Children (VFC) Program Providers

RE: Limited Availability of Nirsevimab in the United States – Interim CDC Recommendations

Today, the Centers for Disease Control and Prevention (CDC) issued a notice via the <u>Health Alert Network (HAN)</u> recommending that healthcare settings that are currently experiencing shortages of Nirsevimab prioritize available 100mg doses to infants at the highest risk for severe RSV disease. This includes all infants aged <6 months and select groups of older babies who have certain risks factors. Recommendations for the 50mg doses of Nirsevimab remain unchanged at this time. Please refer to the <u>CDC HAN</u> for additional dosing recommendations.

We appreciate your support in spreading awareness of this notice and in helping families understand other prevention strategies they can employ to help protect babies from severe RSV illness, including the RSV vaccine that can be give during weeks 32 to 36 of pregnancy, and everyday health and hygiene practices like handwashing and staying home when sick.

Thank you for your continued support in keeping Kansans protected.



## Beyfortus (nirsevimab)



### STANDING ORDERS FOR

Administering Nirsevimab RSV Preventive Antibody to Infants (2023–24 Season Only)

## **Purpose**

To reduce morbidity and mortality from respiratory syncytial virus (RSV) by immunizing all infants who meet the criteria established by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) with a long-acting monoclonal antibody against RSV.

2023-24 Season Note: Due to strong early demand and limited supply of nirsevimab (Beyfortus, Sanofi), particularly 100-mg manufacturer-filled syringes (MFS), on October 24, 2023, CDC issued a Health Advisory with revised recommendations for use of nirsevimab during the 2023-24 season (see CDC Health Alert at https://emergency.cdc.gov/han/2023/han00499.asp). ACIP recommendations for infants weighing less than 5 kg are unchanged. This template follows CDC's limited nirsevimab recommendations for infants weighing 5 kg or more for the 2023-24 season. A routine template will be posted once restricted use is no longer recommended by CDC. Interim CDC recommendations are subject to change as new information becomes available.

RSV Vaccine Note: Between September 1 and January 31 each season, prevention of severe RSV disease in infants is recommended through administration of RSVpreF vaccine (Abrysvo, Pfizer) to the pregnant person between gestational week 32 and week 36 and 6 days, as an alternative to nirsevimab. If conditions (e.g., product availability) allow for the option of maternal vaccination or nirsevimab, the pregnant person may choose the preferred option. The standing order template for maternal vaccination with Abrysvo is available at www.immunize.org/p3096.pdf.



## Prevention of Vaccine Administration Errors



### **Vaccine Administration: Preventing Vaccine Administration Errors**

A vaccine administration error is any preventable event that may cause or lead to inappropriate medication use or patient harm. Vaccine administration errors can have many consequences, including inadequate immunological protection, possible injury to the patient, cost, inconvenience, and reduced confidence in the health care delivery system. Take preventive actions to avoid vaccine administration errors and establish an environment that values reporting and investigating errors as part of risk management and quality improvement.

Vaccine administration errors may be due to causes such as

- Lack of standardized protocols
- Distraction
- Changes in recommendations

Insufficient staff training

- (e.g. DTaP, DT, Tdap, Td) Patient misidentification Using nonstandard or error-prone abbreviations

Fasily misidentified products

If an error occurs, determine how it occurred and take the appropriate actions to put strategies in place to prevent it from happening in the future. The following table outlines common vaccine administration errors and possible preventive actions you

#### Error(s)

### Wrong vaccine. route, site, or dosage (amount);

### **Possible Preventive Actions**

Circle important information on the packaging to emphasize the difference between the vaccines.

Include the brand name with the vaccine abbreviation whenever possible (e.g., PCV13 [Prevnar13]) in orders, medical screens, etc.

Separate vaccines into bins or other containers according to type and formulation. Use color-coded identification labels on vaccine storage containers.

Store look-alike vaccines in different areas of the storage unit (e.g., pediatric and adult formulations of the same vaccine on different shelves in the unit).

Do not list vaccines with look-alike names sequentially on computer screens, order forms, or medical

Consider using "name alert" or "look-alike" stickers on packaging and areas where these vaccines

Consider purchasing products with look-alike packaging from different manufacturers, if possible.

Establish "Do NOT Disturb" or no-interruption areas or times when vaccines are being prepared or

Prepare vaccine for one patient at a time. Once prepared, label the syringe with vaccine name.

Do not administer vaccines prepared by someone else.

Triple-check work before administering a vaccine and ask another staff member to check.

Keep reference materials on recommended sites, routes, and needle lengths for each vaccine used in your facility in the medication preparation area.

Clearly identify diluents if the manufacturer's label could mislead staff into believing the diluent is the

Integrate vaccine administration training into orientation and other appropriate education

Provide education when new products are added to inventory or recommendations are updated.

Use standing orders, if appropriate

National Coordinating Council for Medication Error Reporting and Prevention, https://www.nccmerp.org/about-medication-errors

vaccine administration, see COVID-19 Vaccine Administration Errors and Deviations at www.cdc.gov/vaccines/covid-19/clinical-considerations/ terim-considerations-us-appendix.html#appendix-c

### Don't Be Guilty of These Preventable Errors in Vaccine Administration!

reported errors in administering vaccines? Although some of these errors are much more serious than others, none of them should occur. Be sure those who administer vaccines are not making any of these preventable errors in vaccine administration.

Note: Information about reporting vaccine administration errors is found at the end of this article.

ERROR: Not using a screening checklist to identify patients' contraindications and precautions to vaccination

How to Avoid This Error: Always use a reliable screening question naire to consistently avoid either 1) giving a vaccine to a patient for whom it is contraindicated (a serious, potentially life-threatening situation), or 2) missing opportunities to vaccinate because of lack of knowledge of pre-existing medical conditions or false contraindications (which can also be life-threatening, leaving a patient exposed to a vaccine-preventable disease

Helpful Resources: Use Immunize.org's screening checklists, such as Screening Checklist for Contraindications to Vaccines for Children and Teens (see www.immunize.org/catg.d/p4060.pdf) and Screening Checklist for Contraindications to Vaccines for Adults (see www. immunize.ore/cate.d/p4065.pdf). CDC's Vaccine Contraindications and Precautions web page: www.cdc.gov/vaccines/hcp/acip-recs/ general-recs/contraindications.html

ERROR: Administering the wrong vaccine due to similarities in vaccine names (e.g., DTaP for Tdap, zoster for varicella,

How to Avoid This Error: Check the vial label 3 TIMES! Such errors often involve vaccines whose generic or trade names look or sound alike (e.e., Tdap and DTaP, Adacel and Daptacel), or that have similar packaging, so store such vaccines separately and mark them clearly in your storage unit as well as on the patient's vaccine tray. Other times, vaccines are mixed up when vaccinating multiple family members, such as siblines, on the same visit, Prepare vaccines needed for one family member at a time, and always verify names and birthdates for the patient receiving the vaccines.

What to do after such an error: The parent/patient should be told the wrong vaccine was given. Provide the correct vaccine, if necessary, with correct spacing, if necessary (for more details about specific situations, check Ask the Experts I www.immunize.org/ask experts | under the relevant vaccine section, or email CDC nipinfo@ cdc.gov for advice). Assess how this error happened to ensure it will not happen again.

Helpful Resource: Institute for Safe Medication Practices' (ISMP) Recommendations for Practitioners to Prevent Vaccine Errors Part 2: Analysis of ISMP Vaccine Errors Reporting Program: www.ismp.org/ newsletters/acutecare/showarticle.aspx?id=104

ERROR: Using the wrong diluent or administering the diluent only

How to Avoid This Error: Use careful labeling in your vaccine storage unit. Keep vaccines and their diluents together if storage requirements are the same. Check the vial and diluents labels 3 TIMES before reconstituting vaccine. Administering the diluent only is most likely to happen with the two vaccines that include antigen in their liquid component, Menveo and Pentacel.

What to do after such an error: Diluent errors could affect the potency of the vaccine antigen administered, or the patient might not get the full benefit of the vaccine if the diluent not given contains antigen. If the wrong diluent is used, the vaccine needs to be repeated (except in the case of mixing up the diluent between MMR MMRV, varicella, and zoster vaccines which are all made by Merck and use the same sterile water diluent).

If an INACTIVATED vaccine is reconstituted with the wrong diluent and is administered, the dose is invalid and should be repeated ASAP. If a LIVE vaccine is reconstituted with the wrong diluent and is administered, the dose is invalid and if it can't be repeated on the same clinic day, it needs to be repeated no earlier than four weeks after the invalid dose. This spacing is due to the effects of generating a partial immune response that could suppress the live replication of subsequent doses, even of the same live virus vaccine.

Menyeo IGSKI vaccine for the prevention of Neisseria meninaltidis sergeroups A. C. Y. and W-135 is available in two different formulations: 1) a single vial of liquid containing all four serotypes and 2) a two-vial presentation comprised of the MenCYW-135 liquid conjugate component and a vial containing the MenAlyophilized conjugate component. If using the two-vial presentation and the patient receives only the diluent, he or she is not protected against invasive menineococcal disease caused by Neisseria menineitidis serogroup A. Serogroup A disease is very rare in the United States but common in some other countries. If the recipient of the MenCYW-135 diluent-only dose does not plan to travel outside the U.S., then the dose does not need to be repeated. Otherwise, the dose should be repeated with either correctly reconstituted Merryeo or with a dose of Menactra or MenQuadfi. There is no minimum interval between the incorrect dose and the repeat dose.



FOR PROFESSIONALS www.immunize.org / FOR THE PUBLIC www.vaccineinformation.org



### RSV (Pfizer/ABRYSVO)

**Ages:** 60 years and older

Pregnant people at 32-36 weeks gestation

Route: Intramuscular (IM) injection

Reconstitute RSV powder ONLY with manufacturer-supplied sterile water diluent

Do Not Freeze

Beyond Use Time: If not used immediately after reconstitution, store at room temperature [15°C to 30°C (59°F to 86°F)] and discard if not used within 4 hours.

### RSV (GSK/AREXVY)

**Ages:** 60 years and older

Route: Intramuscular (IM) injection

Reconstitute RSV powder ONLY with manufacturer-supplied adjuvant suspension

Do Not Freeze

Beyond Use Time: If not used immediately after reconstitution, store refrigerated at 2°C to 8°C (36°F to 46°F) or at room temperature up to 25°C (77°F). Discard if not used within 4 hours.



## sas Immunization Programs Overview – Vaccines for Children



The VFC Program provides vaccines at no cost to children who might not otherwise be vaccinated due to the inability to pay.

Congress created the VFC program in response to the 1989-1991 measles outbreak in the United States. Upon investigation, CDC found that more than half of the children who had measles had not been immunized.



## sas Immunization Programs Overview – Vaccines for Children



# VFC Program Overview Birth through 18 years of age

## **Eligibility**

- American Indian or Alaskan Native
- Uninsured
- Medicaid Title 19 (must specify)
- Underinsured\*
  - Cap due to age
  - Cap on total vaccine coverage
  - Specific vaccine that is not covered
- Medicaid Title 21 CHIP (must specify)

<sup>\*</sup>Underinsured doses may only be given at a deputized local health department, Federally Qualified Health System, or a Rural Health Clinic.



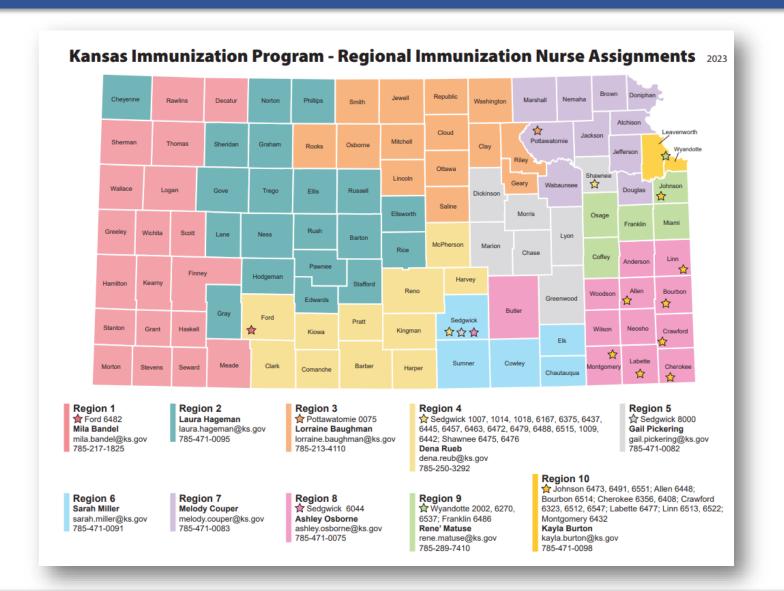
## sas Immunization Programs Overview – Enrollment



If you would like to enroll in the VFC or Bridge Access Program, please contact the Regional Public Health Immunization Nurse or email KDHE.Vaccine@ks.gov for more information.



## ansas Immunization Programs Overview – Enrollment





## Resources and Product Information – Adults 60+

<u>Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)</u>

CDC Recommends RSV Vaccine For Older Adults | CDC Online Newsroom | CDC

RSV Vaccination: What Older Adults 60 Years of Age and Over Should Know | CDC

ABRYSVO™ (Respiratory Syncytial Virus Vaccine) | Safety Info

RSV Vaccination | AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted) (arexvyhcp.com)

<u>Adult Immunization Schedule – Healthcare Providers | CDC</u>

RSV Vaccination for Adults 60 Years and Older (cdc.gov)

Respiratory Syncytial Virus Vaccines (RSV)-Fact Sheet for Healthcare Providers (cdc.gov)



## Resources and Product Information – Pregnancy

<u>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 (cdc.gov)</u>

CDC recommends new vaccine to help protect babies against severe respiratory syncytial virus (RSV) illness after birth

RSV Vaccination for Pregnant People | CDC

ABRYSVO™ (Respiratory Syncytial Virus Vaccine) | Safety Info

Adult Immunization Schedule – Healthcare Providers | CDC

<u>Standing Orders for Administering Pfizer Respiratory Syncytial Virus (RSV) Vaccine (Abrysvo) During Pregnancy (immunize.org)</u>

Options for Infant RSV Prevention At-a-Glance (cdc.gov)



## Resources and Product Information – Infants/Children

<u>Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children:</u>

<u>Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)</u>

CDC Recommends a Powerful New Tool to Protect Infants from the Leading Cause of Hospitalization | CDC Online Newsroom | CDC

Healthcare Providers: RSV Immunization for Children 19 Months and Younger | CDC

Beyfortus™ (nirsevimab-alip) | Now Approved for RSV Prevention

<u>Birth-18 Years Immunization Schedule – Healthcare Providers | CDC</u>

Standing Orders for Administering Nirsevimab RSV Preventive Antibody to Infants (2023-24 Season Only) (immunize.org)

Health Alert Network (HAN) - 00499 | Limited Availability of Nirsevimab in the United States—Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season



## **Additional Resources**

Vaccine Label Examples (cdc.gov)

Vaccine Administration: Preventing Vaccine Administration Errors (cdc.gov)

Don't Be Guilty of These Preventable Errors in Vaccine Administration! (immunize.org)

Vaccine Administration Protocols | CDC

RSV (Respiratory Syncytial Virus) Immunizations | CDC

Kansas Health Alert Network (KS-HAN) | KDHE, KS

Email Updates | Health Alert Network (HAN) (cdc.gov)

Immunizations | KDHE, KS



## Questions



Becky Prall, RN Immunization Program Section Chief (c) 785-213-2972 Becky.Prall@ks.gov

KDHE.Vaccine@ks.gov 877-296-0464

# Helay's slides



# Thank you for joining us today!

\*Reminder-There is no December Learning Forum. See you January 23, 2024.

# **Happy Holidays from KPQC!**

