Birthing Hospitals and VFC:
A Learning Collaborative to Protect Infants from RSV

October 25, 2024

AIM Association of Immunization Managers

Agenda

- Purpose of this learning collaborative
- RSV background and recommendations for prevention
- Birthing hospitals and VFC policies
- Discussion: What do birthing hospitals need to ensure success?
- Resources
- Next steps

Purpose

- Increase the capacity to equitably protect infants from serious illness and death due to RSV infection by
  - Understanding challenges to hospital participation in the VFC program
  - Sharing promising practices to overcome these challenges
  - Increasing birthing hospital participation in the VFC program

Poll Question:

How do you best define your roll in the effort to protect infants from RSV?

- Hospital administrator
- Hospital pharmacist/pharmacy staff
- Clinician (ordering nirsevimab for administration to infants)
- Clinical staff (administering nirsevimab to infants in the hospital)
- Immunization program manager/staff (enrolling providers in the VFC program and providing nirsevimab for VFC-eligible infants
- Partner organization (providing support/guidance to hospitals engaged in this effort (e.g. perinatal quality collaboratives, national membership organizations, CDC, etc.)
- Public health (other than immunization programs)
- Other

RSV : Background and Recommendations for Prevention

Jefferson Jones, MD MPH
CDC/NCIRD/CORVD

RSV background and ACIP recommendations for prevention of severe RSV in infants

Jefferson Jones MD MPH FAAP

CDR, USPHS

Co-Lead ACIP Maternal/Pediatric RSV Workgroup

Coronavirus and Other Respiratory Viruses Division

Outline

- Burden and seasonality of RSV
- ACIP nirsevimab recommendations
- 2023-24 RSV real world effectiveness estimates

Burden and seasonality of RSV

RSV is the leading cause of hospitalization in U.S. infants[1]

- Majority of infants are infected in the first year of life and nearly all by age 2 years[2]
- 2-3% of young infants will be hospitalized for RSV[3,4,5]
  - Highest RSV hospitalization rates occur in first months of life and risk declines with increasing age in early childhood[3,5]
  - 79% of children hospitalized with RSV aged <2 years had no underlying medical conditions[3]

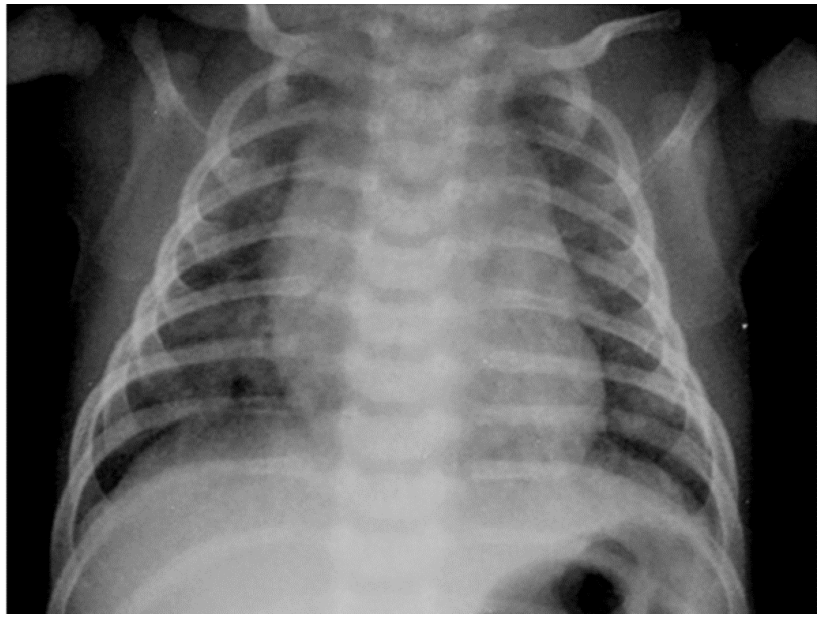
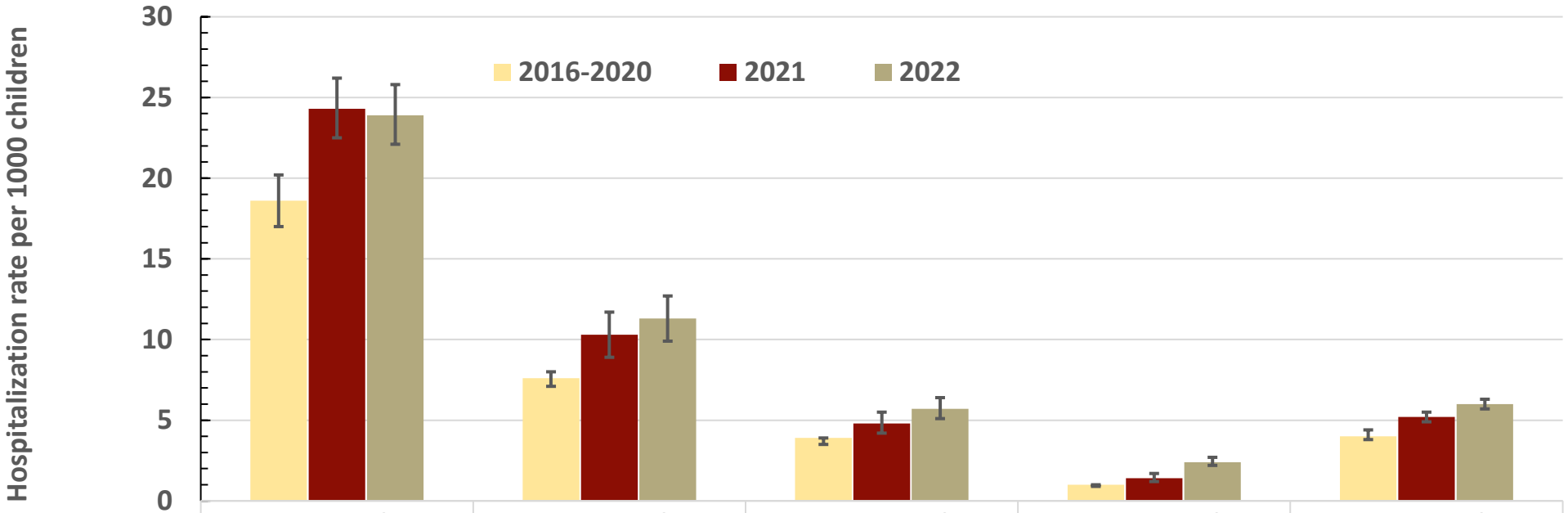


Image: Goncalves et al. Critical Care Research and Practice 2012

[1]Suh et al. JID 2022; [2]Glezen et al, Arch Dis Child, 1986; 3Hall et al, Pediatrics, 2013; 4Langley & Anderson, PIDJ, 2011; [5]Curns et al. Pediatrics, 2024

RSV-associated hospitalization rates highest in younger infants



	0-5 months	6-11 months	12-23 months	24-59 months	0-59 months
2016-2020	18.6	7.6	3.9	1.0	4.0
2021	24.3	10.3	4.8	1.4	5.2
2022	23.9	11.3	5.7	2.4	6.0

2016-2020: Curns et al, Pediatrics (2024): https://doi.org/10.1542/peds.2023-062574; 2021, 2022: McMorrow et al, Pediatrics (in press)
New Vaccine Surveillance Network; *average annual rate per 1000 children over 4 seasons: Dec 2016-Sep 2017, Oct 2017-Sep 2018, Oct 2018-Sep 2019, and Oct 2019-Sep 2020; †annual rate per 1000 children during Jan – Dec 2021; ‡ annual rate per 1000 children during Jan – Dec 2022

RSV burden is high in children aged <5 years

Each year in the United States, RSV leads to approximately:

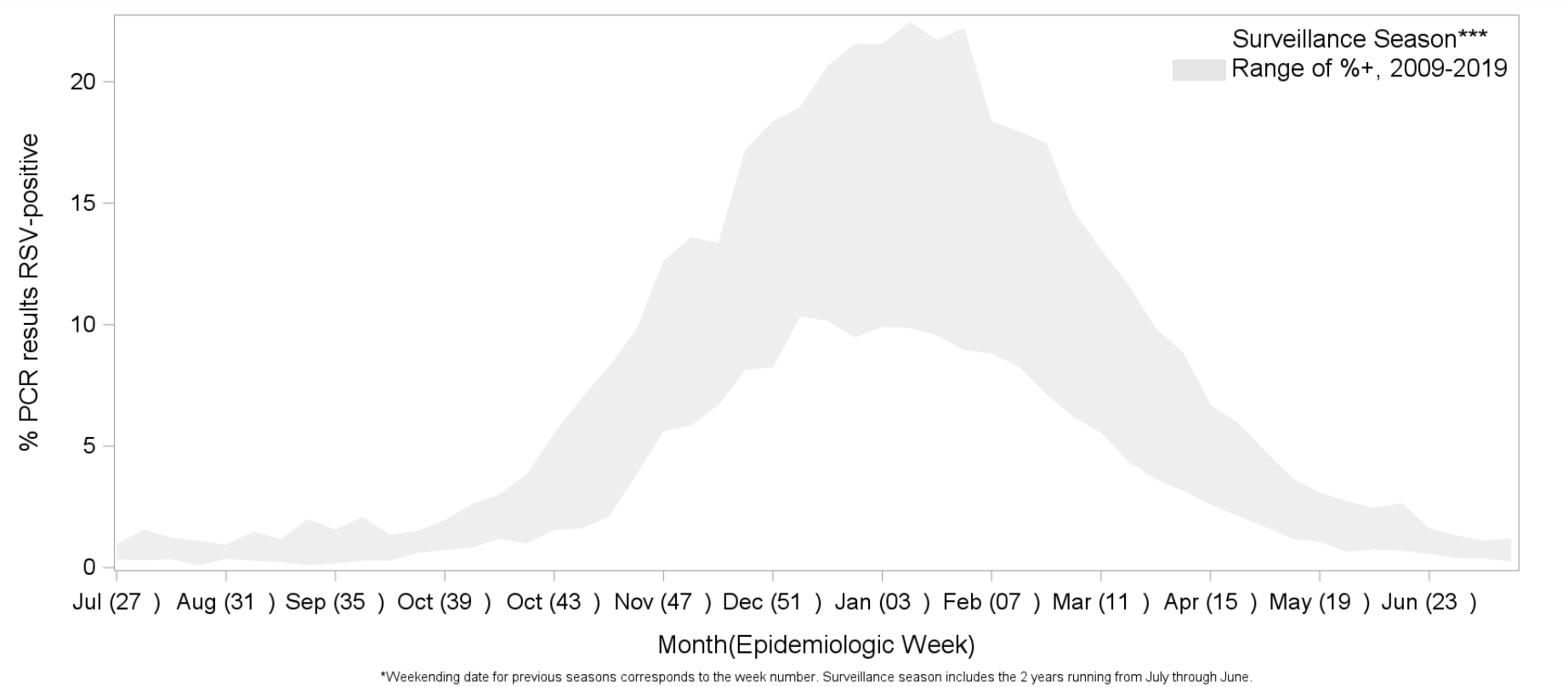
~2,000,000 medical encounters[1]

58,000–80,000 hospitalizations[1,2,3]

100–300 deaths[4,5,6]

1. Hall et al, NEJM (2009): https://doi.org/10.1056/NEJMoa0804877
2. McLaughlin et al, J Infect Dis (2022): https://doi.org/10.1093/infdis/jiaa752
3. CDC RSV-NET, unpublished data.
5. Matias et al, Influenza Other Respi Viruses (2014): https://doi.org/10.1111/irv.12258
6. Hansen et al, JAMA Network Open (2022): https://doi.org/10.1001/jamanetworkopen.2022.0527

Pre-pandemic, RSV circulation was highly seasonal in the U.S. with peak activity during December – February



Pre-pandemic seasonality shown by grey shaded area

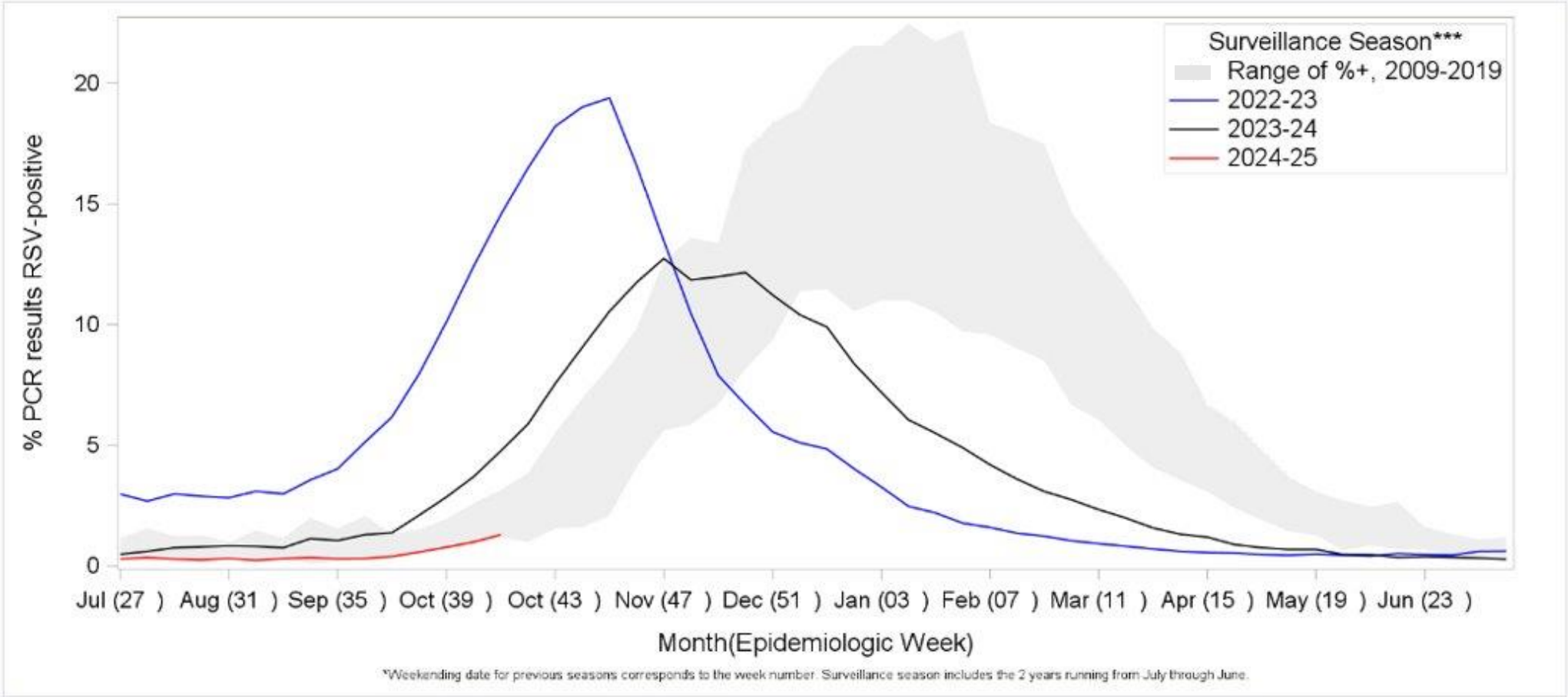
Report was last updated on: 5/9/2024.

*All results presented are from nucleic acid amplification tests which represent >90% of the diagnostic tests reported to NREVSS. The last three weeks of data in 2023-24 may be less complete. NREVSS is an abbreviation for the National Respiratory and Enteric Virus Surveillance System. For more information on NREVSS, please visit National Respiratory and Enteric Virus Surveillance System | CDC.

**Respiratory syncytial virus types A and B are not shown separately in this report.

***The NREVSS surveillance season runs from the first week in July through June of the following year.

After several years with atypical seasonality, recent data suggest a return to pre-pandemic seasonality



Report was last updated on: 10/16/2024.

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Protect infants and young children against severe RSV disease with either

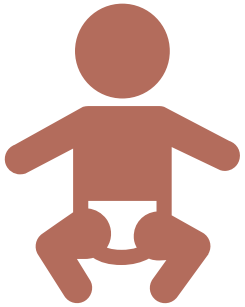
Maternal RSV vaccine or nirsevimab

Maternal vaccine

32 through 36 weeks' gestation

September through January in most of the continental United States

Nirsevimab



All infants <8 months*

Second season dose for children ages 8–19 months at increased risk of severe RSV disease

October through March in most of the continental United States (earlier the better)

**Either* maternal RSV vaccine or nirsevimab is given to protect infants against severe RSV disease – only one is needed for most infants

ACIP recommendations for nirsevimab

Infant RSV Immunization–Nirsevimab

- **Long-acting monoclonal antibody**
  - Not a vaccine; passive immunization
  - Beyfortus is trade name
- **Approved for prevention of RSV LRTD in infants and some young children**
- **50 mg/0.5 mL or 100 mg/1.0 mL**
- **Covered under Vaccines for Children program**

Package Insert (2024). https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761328s007lbl.pdf

LRTD: lower respiratory tract disease

Recommendations for Use of Nirsevimab in Infants

- **One dose to infants younger than 8 months of age during their 1st RSV season (October through March) if:**
  - The mother did not receive RSV vaccine during pregnancy
  - The mother's RSV vaccination status is unknown
  - The infant was born less than 14 days after maternal RSV vaccination

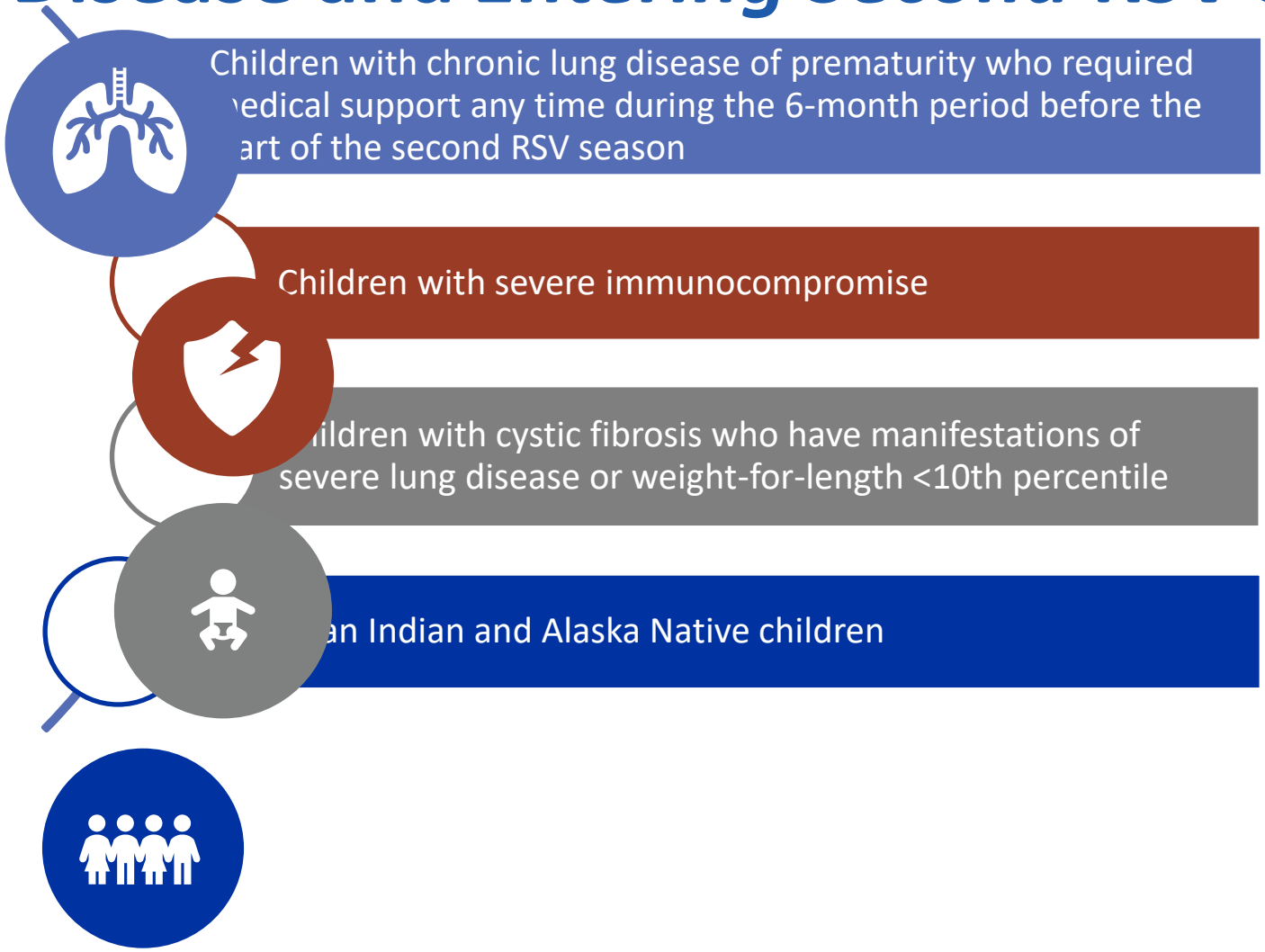
Jones JM, Fleming-Dutra KE, Prill MM, et al. (2023). http://dx.doi.org/10.15585/mmwr.mm7234a4.
Package Insert (2024). https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761328s007lbl.pdf

When to Use Nirsevimab in Young Children

- **One dose for some children ages 8 through 19 months who are at increased risk of severe RSV disease and entering their second RSV season**
  - Dose is administered regardless of maternal receipt of RSV vaccine
  - Dose is administered regardless of receipt of nirsevimab during their first RSV season

ACIP and AAP Recommendations for Nirsevimab | Red Book Online | American Academy of Pediatrics (2023). https://publications.aap.org/redbook/resources/25379.
Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

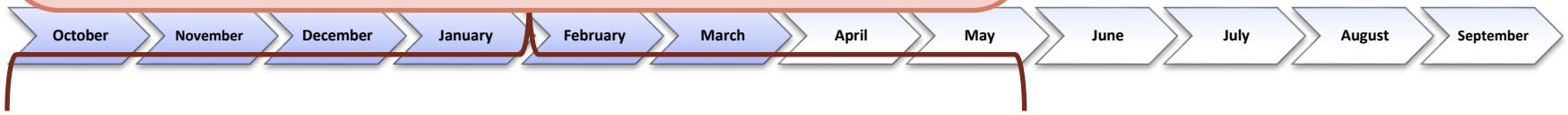
Ages 8 through 19 Months at *Increased Risk* for Severe RSV Disease and *Entering Second* RSV Season



Jones JM, Fleming-Dutra KE, Prill MM, et al. https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Nirsevimab Timing by Birth Month: 1st RSV season

Infants born October through March are recommended to receive nirsevimab, within one week of birth, ideally during birth hospitalization



Infants born April through September are recommended to receive nirsevimab from October through March, ideally shortly before the RSV season begins

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)

RSV Seasonality Differs Based on Climate

In jurisdictions with differing seasonality (e.g., Alaska, southern Florida, Puerto Rico, and other jurisdictions with tropical climates), providers should follow state, local, or territorial guidance on the timing of administration.

This presentation covers nirsevimab timing for most of the continental U.S.

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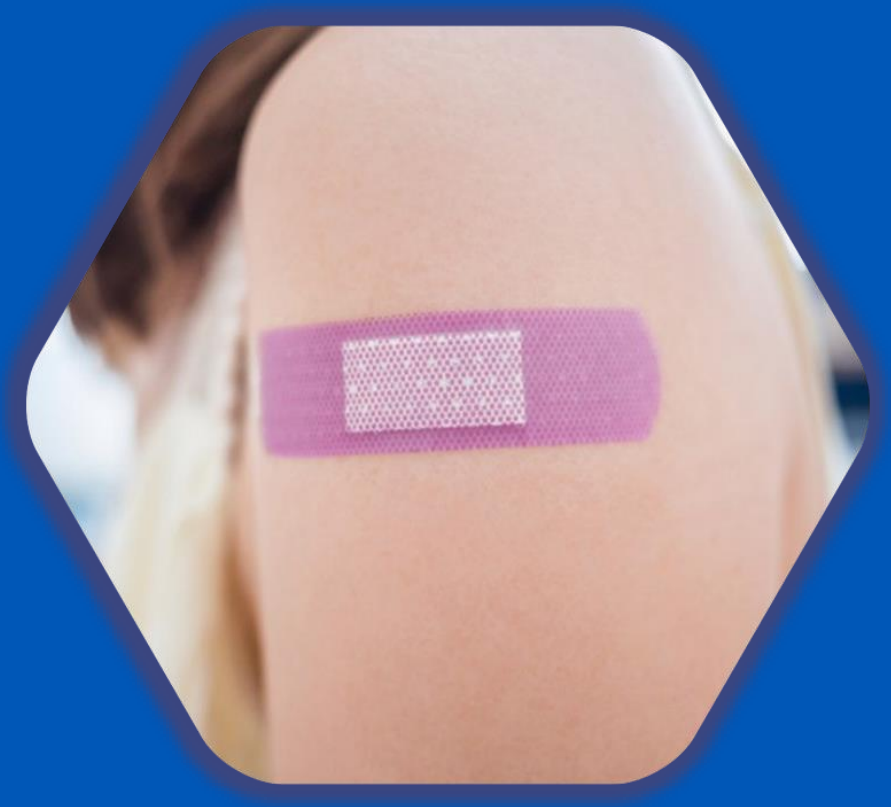
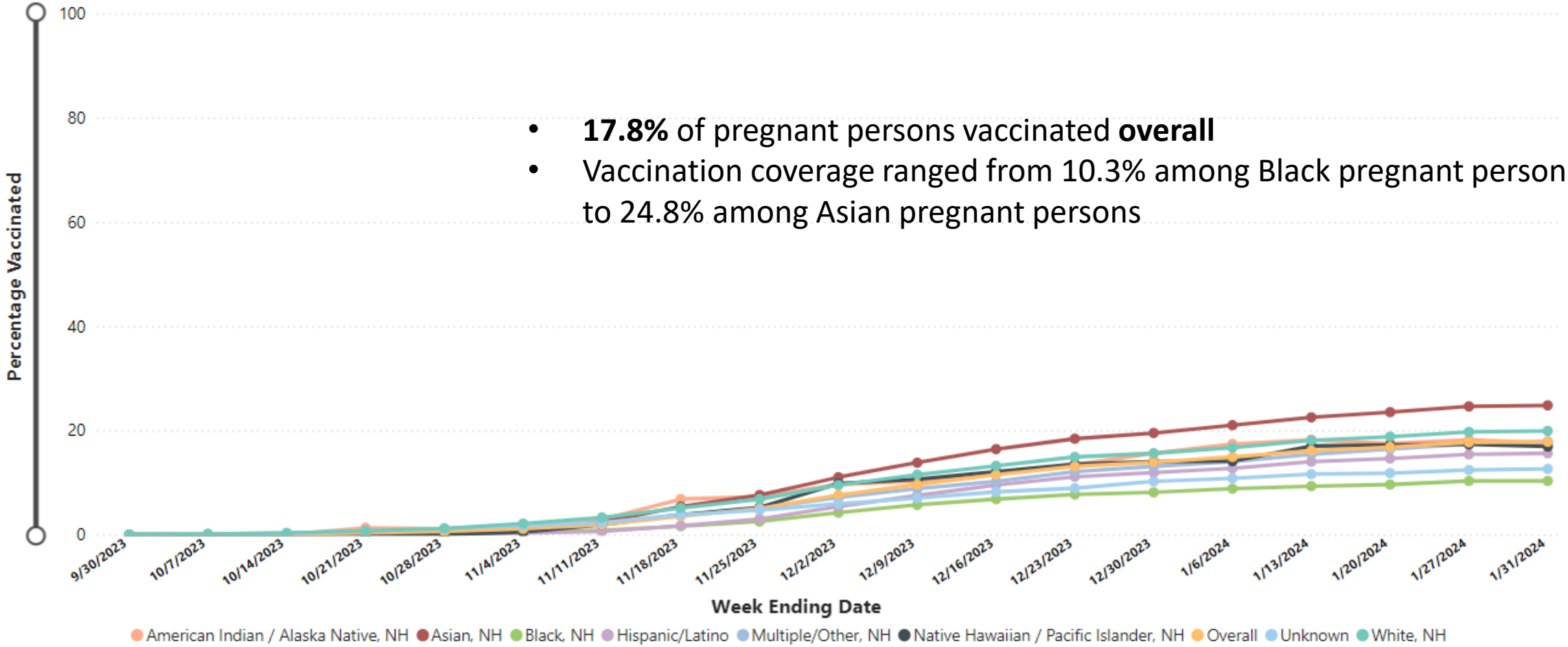


2023-24 uptake and effectiveness estimates

Percent of pregnant persons ages 18–49 years vaccinated with RSV vaccine overall and by race and ethnicity

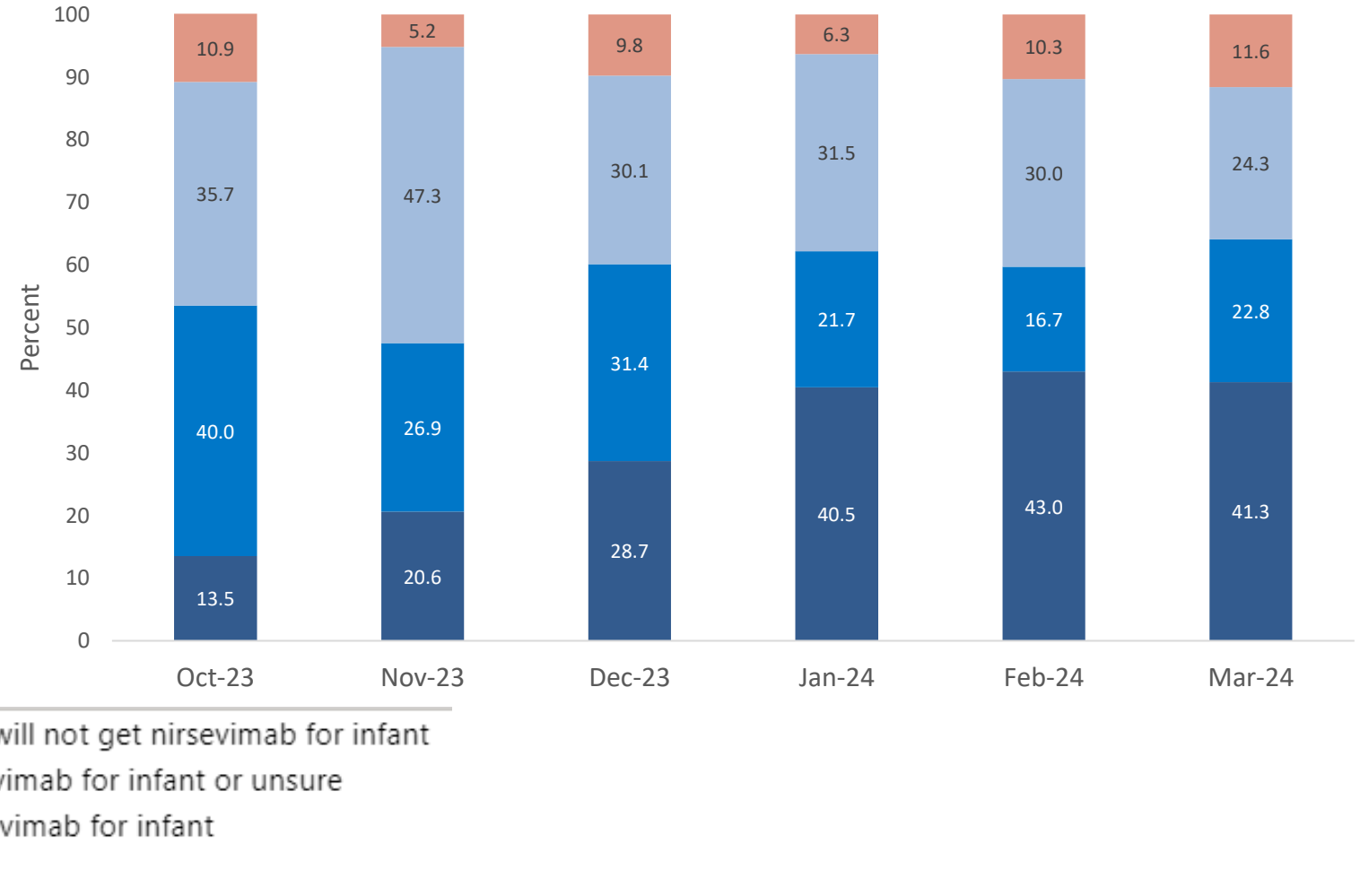
- **17.8%** of pregnant persons vaccinated **overall**
- Vaccination coverage ranged from 10.3% among Black pregnant persons to 24.8% among Asian pregnant persons



Data source: Vaccine Safety Datalink https://www.cdc.gov/vaccines/imz-managers/coverage/rsvvaxview/pregnant-persons-coverage-intent.html

Slide source: S. Stokely. Implementation and Uptake of Nirsevimab and Maternal Vaccine. ACIP, June 2024.

Monthly nirsevimab receipt and intent among women ages 18–49 years who have an infant aged <8 months

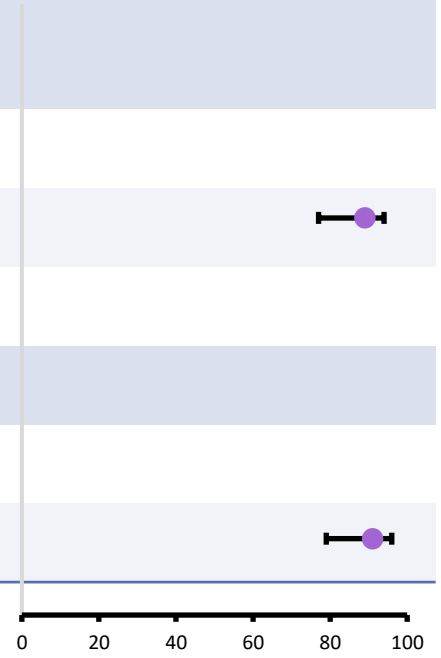


Data source: National Immunization Survey, Adult COVID Module (NIS-ACM) https://www.cdc.gov/vaccines/imz-managers/coverage/rsvvaxview/nirsevimab-coverage.html

Slide source: S. Stokely. Implementation and Uptake of Nirsevimab and Maternal Vaccine. ACIP, June 2024.

First season nirsevimab product effectiveness (PE) against medically attended RSV-associated ARI and RSV-associated hospitalization – NVSN, October 2023 – March 2024*

Outcome | Nirsevimab dosage pattern	Total encounters	RSV-positive encounters N (Row %)	Median days since dose (IQR)	Adjusted PE (95% CI)†
Medically Attended RSV-associated ARI episode‡				
No nirsevimab doses	1,575	755 (48)	N/A	ref
Nirsevimab, ≥7 days prior§	120	9 (8)	42 (21-73)	89 (77-94)
RSV-associated hospitalization				
No nirsevimab doses	807	526 (65)	N/A	ref
Nirsevimab, ≥7 days prior	63	6 (10)	38 (15-67)	91 (79-96)



Nirsevimab was effective against medically attended RSV-associated ARI episodes and RSV-associated hospitalization.

*State-level RSV RT-PCR percent positivity thresholds of 3% were used to define the beginning and end weeks of the analysis by site

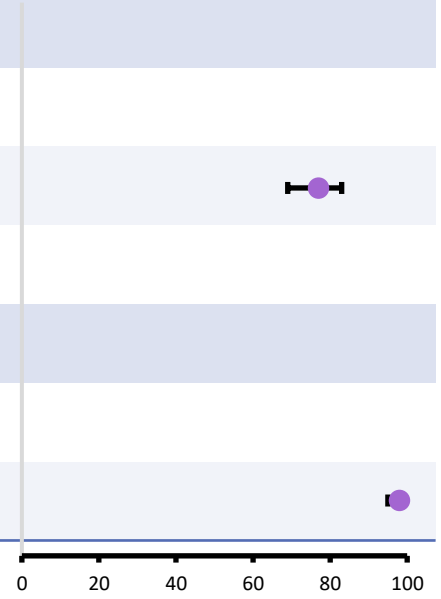
†Multivariable logistic regression models compared the odds of vaccination among RSV case and control patients while adjusting for site, age in months, month of enrollment, and presence of >1 high-risk medical condition for severe RSV disease.

§Immunization defined as one nirsevimab dose ≥7 days prior to symptom onset.

ARI = acute respiratory illness | N/A = not applicable | ref = reference group

First season nirsevimab product effectiveness (PE) against RSV-associated ED encounters and hospitalization – VISION, October 8, 2023 – March 31, 2024

Outcome | Nirsevimab dosage pattern	Total encounters	RSV-positive encounters N (Row %)	Median days since dose (IQR)	Adjusted PE (95% CI)*
RSV-associated ED encounter				
No nirsevimab doses	4,610	1,988 (43)	N/A	ref
Nirsevimab, ≥7 days prior	442	63 (14)	53 (27-84)	77 (69-83)
RSV-associated hospitalization				
No nirsevimab doses	927	601 (65)	N/A	ref
Nirsevimab, ≥7 days prior	93	4 (4)	48 (25-84)	98 (95-99)



Nirsevimab was effective against RSV-associated ED encounters and hospitalization among infants in their first RSV season.

*Odds ratio used to calculate VE estimate was adjusted for age, race and ethnicity, sex, calendar day (days since Oct 8, 2023), and geographic region
N/A = not applicable | ref = reference group

Estimating maternal RSV vaccine effectiveness

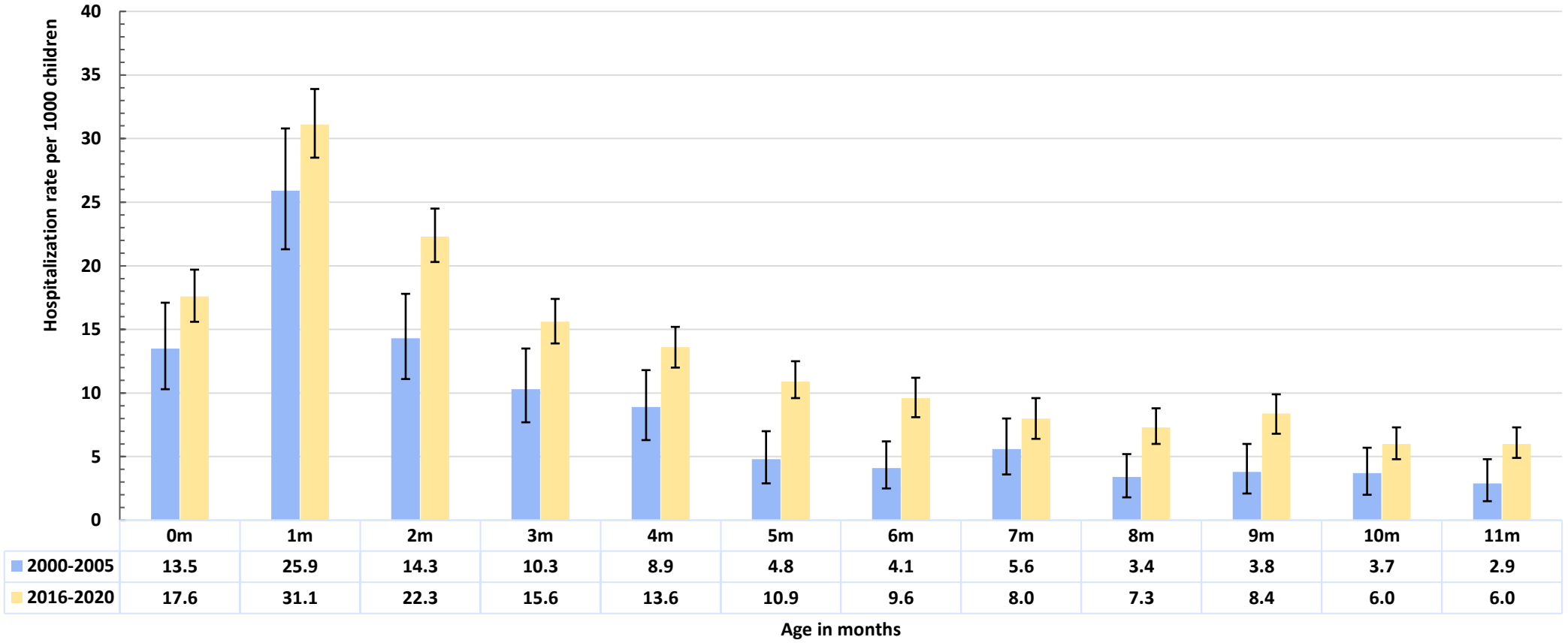
- **CDC's ability to estimate maternal RSV vaccine effectiveness this first season was limited by**
  - Uptake of maternal RSV vaccine
  - Timing of the 2023-2024 RSV season
  - Timing of vaccine rollout

- **CDC will continue to monitor maternal RSV vaccine effectiveness in future seasons**

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

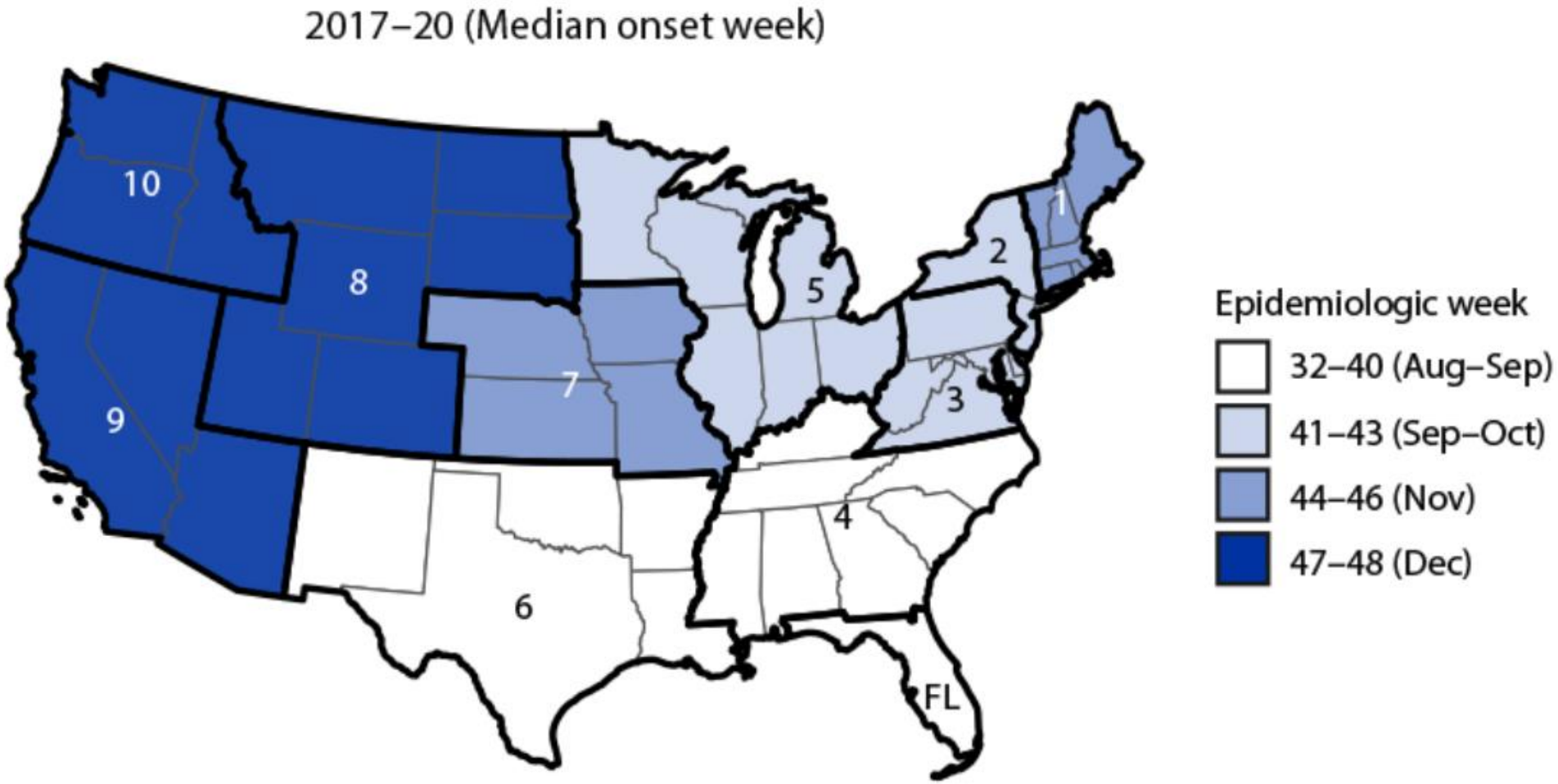
RSV-associated hospitalization rates highest in children less than 8 months



	0m	1m	2m	3m	4m	5m	6m	7m	8m	9m	10m	11m
2000-2005	13.5	25.9	14.3	10.3	8.9	4.8	4.1	5.6	3.4	3.8	3.7	2.9
2016-2020	17.6	31.1	22.3	15.6	13.6	10.9	9.6	8.0	7.3	8.4	6.0	6.0

2000–2005: Adapted from Hall et al, Pediatrics 2013,
2016–2020: CDC unpublished data, larger age groups published in McMorrow et al, Pediatrics 2024

RSV activity typically starts in the southeast and moves northwest



https://www.cdc.gov/mmwr/volumes/72/wr/mm7214a1.htm

Birthing Hospitals and VFC Policies

Sam Graitcer, MD
Provider Compliance and Quality Assurance Team Lead
Immunization Operations Services Branch
CDC/NCIRD/ISD

VFC Program

For **30 years** the VFC Program has provided vaccines at no cost to children who are:

- Uninsured
- Under-insured
- Eligible for Medicaid
- American Indian or Alaska Native

1994-2024 30TH ANNIVERSARY Vaccines for Children

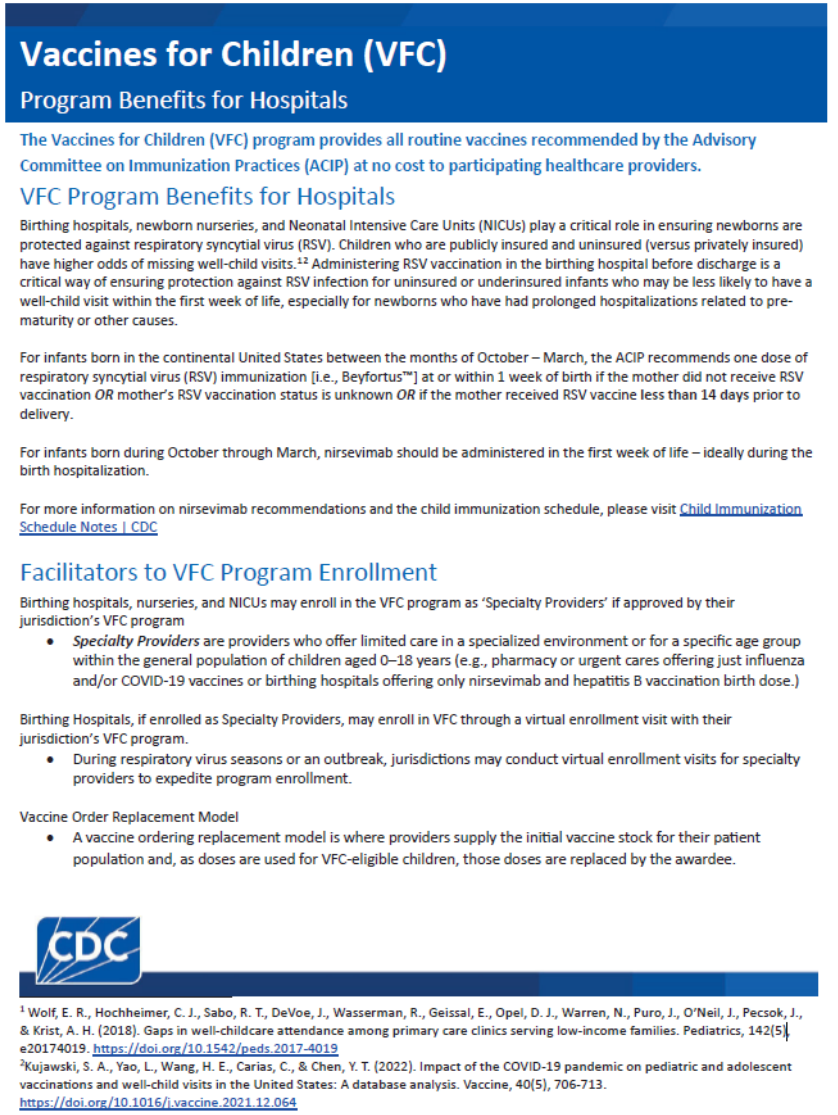
Protecting Newborns

- Birthing facilities and their staff are CRITICAL to ensuring newborns are protected against RSV ***BEFORE*** hospital discharge, including newborns who qualify for the VFC program

- Children who are publicly insured and uninsured (i.e. VFC-eligible children) have higher odds of missing well-child visits (e.g. 1 week-old visit with outpatient pediatrician)

Protecting Newborns

"For infants born during October through March, nirsevimab should be administered in the first week of life– ***ideally during the birth hospitalization***."



Vaccines for Children (VFC)

Program Benefits for Hospitals

The Vaccines for Children (VFC) program provides all routine vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) at no cost to participating healthcare providers.

VFC Program Benefits for Hospitals

Birthing hospitals, newborn nurseries, and Neonatal Intensive Care Units (NICUs) play a critical role in ensuring newborns are protected against respiratory syncytial virus (RSV). Children who are publicly insured and uninsured (versus privately insured) have higher odds of missing well-child visits.[1,2] Administering RSV vaccination in the birthing hospital before discharge is a critical way of ensuring protection against RSV infection for uninsured or underinsured infants who may be less likely to have a well-child visit within the first week of life, especially for newborns who have had prolonged hospitalizations related to pre-maturity or other causes.

For infants born in the continental United States between the months of October – March, the ACIP recommends one dose of respiratory syncytial virus (RSV) immunization [i.e., Beyfortus™] at or within 1 week of birth if the mother did not receive RSV vaccination ***OR*** mother's RSV vaccination status is unknown ***OR*** if the mother received RSV vaccine less than 14 days prior to delivery.

For infants born during October through March, nirsevimab should be administered in the first week of life – ideally during the birth hospitalization.

For more information on nirsevimab recommendations and the child immunization schedule, please visit Child Immunization Schedule Notes | CDC

Facilitators to VFC Program Enrollment

Birthing hospitals, nurseries, and NICUs may enroll in the VFC program as 'Specialty Providers' if approved by their jurisdiction's VFC program

- ***Specialty Providers*** are providers who offer limited care in a specialized environment or for a specific age group within the general population of children aged 0–18 years (e.g., pharmacy or urgent cares offering just influenza and/or COVID-19 vaccines or birthing hospitals offering only nirsevimab and hepatitis B vaccination birth dose.)

Birthing Hospitals, if enrolled as Specialty Providers, may enroll in VFC through a virtual enrollment visit with their jurisdiction's VFC program.

- During respiratory virus seasons or an outbreak, jurisdictions may conduct virtual enrollment visits for specialty providers to expedite program enrollment.

Vaccine Order Replacement Model

- A vaccine ordering replacement model is where providers supply the initial vaccine stock for their patient population and, as doses are used for VFC-eligible children, those doses are replaced by the awardee.

CDC

[1] Wolf, E. R., Hochheimer, C. J., Sabo, R. T., DeVoe, J., Wasserman, R., Geissal, E., Opel, D. J., Warren, N., Puro, J., O'Neil, J., Pecsok, J., & Krist, A. H. (2018). Gaps in well-childcare attendance among primary care clinics serving low-income families. Pediatrics, 142(5), e20174019. https://doi.org/10.1542/peds.2017-4019

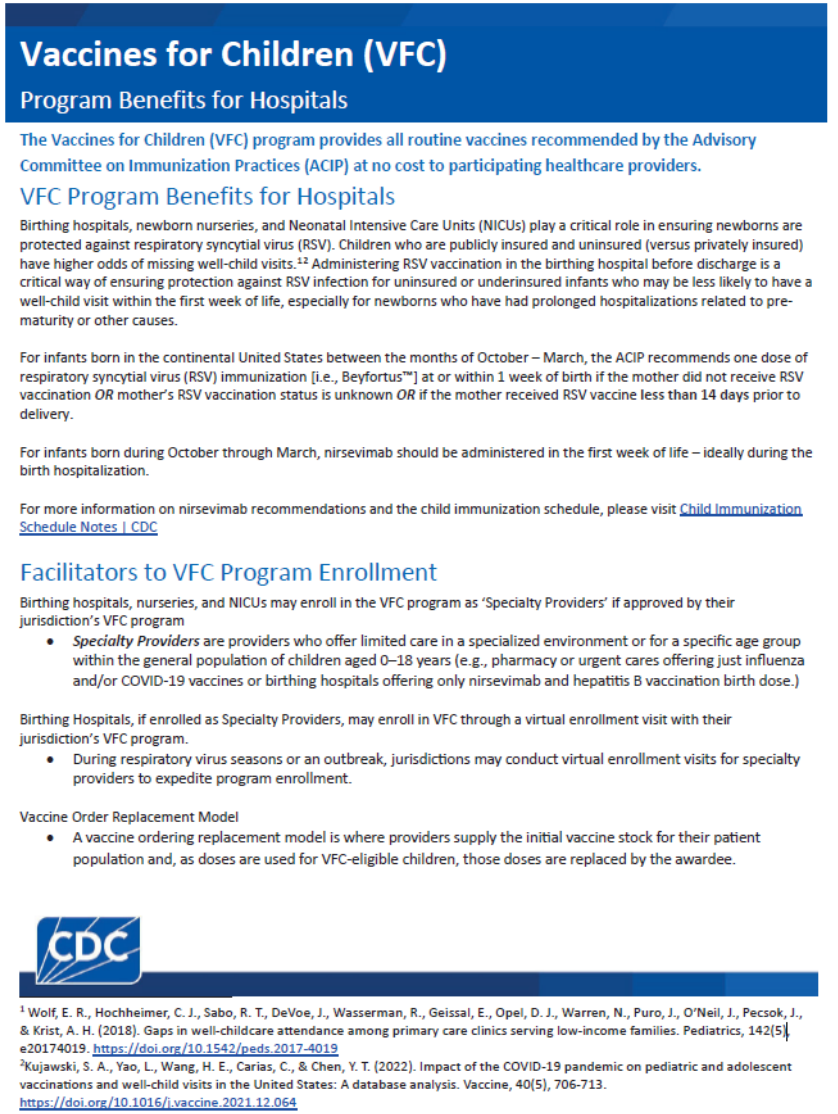
[2]Kujawski, S. A., Yao, L., Wang, H. E., Carias, C., & Chen, Y. T. (2022). Impact of the COVID-19 pandemic on pediatric and adolescent vaccinations and well-child visits in the United States: A database analysis. Vaccine, 40(5), 706-713. https://doi.org/10.1016/j.vaccine.2021.12.064

*RSV vaccines in the continental United States should be administered between the months of October – March. Administrating may potentially differ outside the continental United States.

Benefits for Hospitals

Participation in the VFC Program:

- Reduces your hospital's up-front costs
  - Hospitals do not pay for nirsevimab or hepatitis B vaccines for VFC-eligible children
- Promotes equitable access to all ACIP-recommended vaccines
  - Enables newborns at your facility to receive the immunizations they need before hospital discharge
- Helps provide quality care to all infants who are at risk for RSV infection, regardless of insurance status



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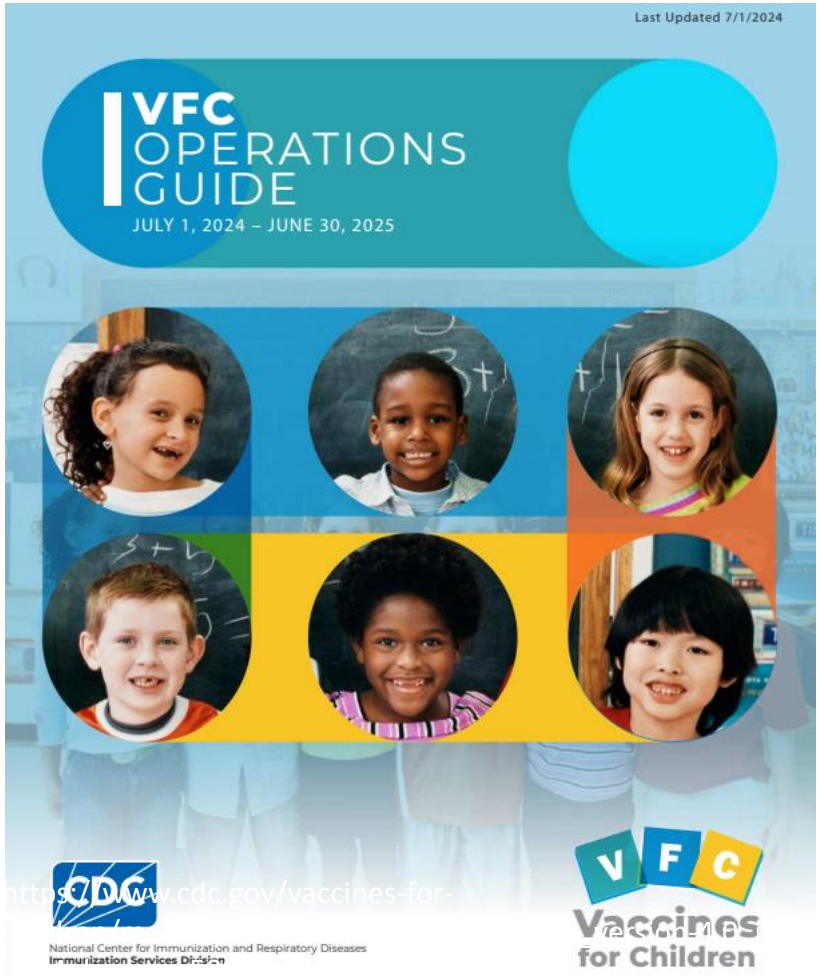
VFC POLICIES

At the discretion of the immunization program:

- Birthing hospitals may qualify as “specialty providers”
  - Only required to stock and administer vaccines for the population they serve (i.e., nirsevimab and hepatitis B vaccine)

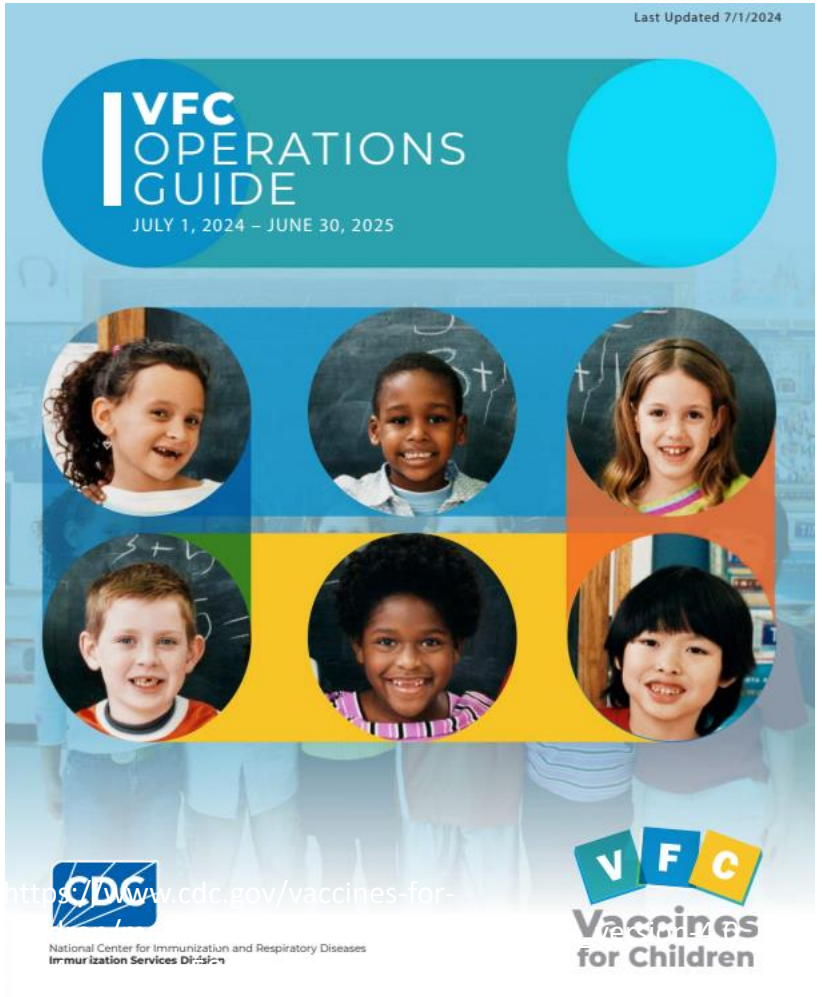
- VFC enrollment visits may be conducted virtually



VFC POLICIES (cont.)

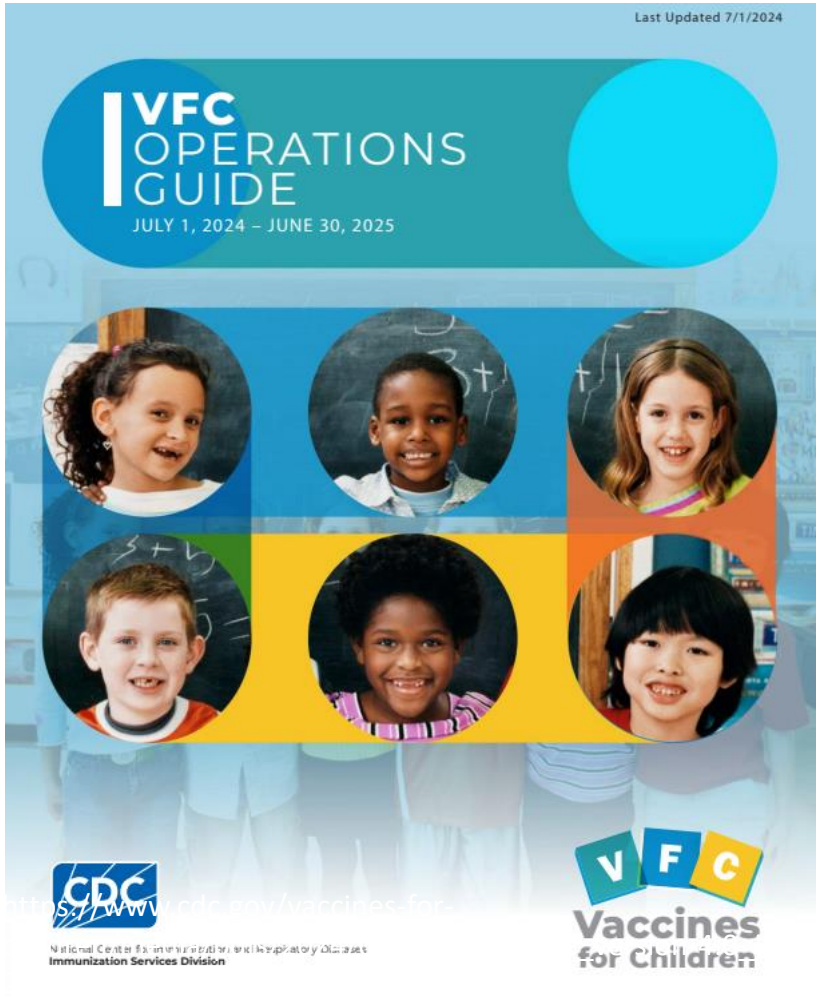
At the discretion of the immunization program:

- Hospitals may work with jurisdiction immunization programs to institute a CDC-approved "**replacement model**"
  - Hospital purchases and administers one stock of nirsevimab
    - Electronic accounting of inventories in lieu of separate physical stock
  - VFC program replaces doses given to VFC-eligible infants
  - Intended to allow hospitals with financial means to establish an initial stock of the product to provide to all newborns
  - Allows hospitals time to verify insurance without concern for the inappropriate use of federally-provided product



VFC POLICIES (cont.)

- At the discretion of the immunization program:
  - Hospitals may borrow between VFC and commercial stock, but repayment of the borrowed dose must occur within 1 month or after 5 doses
- Immunization programs may NOT penalize providers for loss of nirsevimab due to dose expiration
- VFC providers will be required to meet all the normal private stock requirements by August 31, 2025



https://www.cdc.gov/vaccines-for-children/media/pdfs/2024/08/operations-guide-covid-19-addendum-2024-4-2_002-508.pdf

Resources

Checklist for Birthing Hospitals

AIM Resource Library

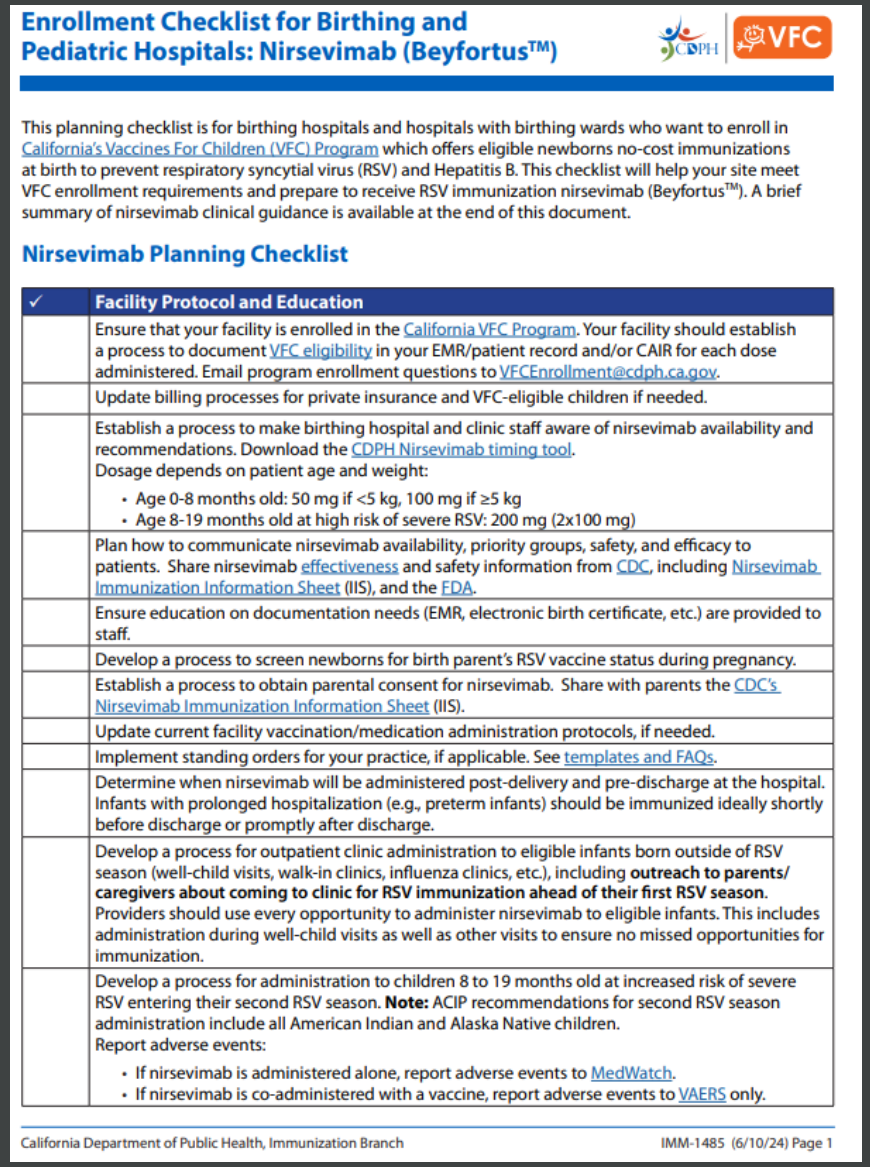
https://www.immunizationmanagers.org/resources/north-dakota-nirsevimab-implementation-planning-checklist/

California Checklist

https://www.immunizationmanagers.org/content/uploads/2024/06/California-Department-of-Public-Health-Enrollment-Checklist-for-Birthing-and-Pediatric-Hospitals-Nirsevimab-BeyfortusTM.pdf

North Dakota Checklist

https://www.immunizationmanagers.org/content/uploads/2023/09/North-Dakota-Nirsevimab-Planning-Checklist_2023.pdf



Enrollment Checklist for Birthing and Pediatric Hospitals: Nirsevimab (Beyfortus™)

CDPH | VFC

This planning checklist is for birthing hospitals and hospitals with birthing wards who want to enroll in California's Vaccines For Children (VFC) Program which offers eligible newborns no-cost immunizations at birth to prevent respiratory syncytial virus (RSV) and Hepatitis B. This checklist will help your site meet VFC enrollment requirements and prepare to receive RSV immunization nirsevimab (Beyfortus™). A brief summary of nirsevimab clinical guidance is available at the end of this document.

Nirsevimab Planning Checklist

✓	Facility Protocol and Education
	Ensure that your facility is enrolled in the California VFC Program. Your facility should establish a process to document VFC eligibility in your EMR/patient record and/or CAIR for each dose administered. Email program enrollment questions to VFCEnrollment@cdph.ca.gov.
	Update billing processes for private insurance and VFC-eligible children if needed.
	Establish a process to make birthing hospital and clinic staff aware of nirsevimab availability and recommendations. Download the CDPH Nirsevimab timing tool. Dosage depends on patient age and weight: • Age 0-8 months old: 50 mg if <5 kg, 100 mg if ≥5 kg • Age 8-19 months old at high risk of severe RSV: 200 mg (2x100 mg)
	Plan how to communicate nirsevimab availability, priority groups, safety, and efficacy to patients. Share nirsevimab effectiveness and safety information from CDC, including Nirsevimab Immunization Information Sheet (IIS), and the FDA.
	Ensure education on documentation needs (EMR, electronic birth certificate, etc.) are provided to staff.
	Develop a process to screen newborns for birth parent's RSV vaccine status during pregnancy.
	Establish a process to obtain parental consent for nirsevimab. Share with parents the CDC's Nirsevimab Immunization Information Sheet (IIS).
	Update current facility vaccination/medication administration protocols, if needed.
	Implement standing orders for your practice, if applicable. See templates and FAQs.
	Determine when nirsevimab will be administered post-delivery and pre-discharge at the hospital. Infants with prolonged hospitalization (e.g., preterm infants) should be immunized ideally shortly before discharge or promptly after discharge.
	Develop a process for outpatient clinic administration to eligible infants born outside of RSV season (well-child visits, walk-in clinics, influenza clinics, etc.), including **outreach to parents/caregivers about coming to clinic for RSV immunization ahead of their first RSV season.** Providers should use every opportunity to administer nirsevimab to eligible infants. This includes administration during well-child visits as well as other visits to ensure no missed opportunities for immunization.
	Develop a process for administration to children 8 to 19 months old at increased risk of severe RSV entering their second RSV season. **Note:** ACIP recommendations for second RSV season administration include all American Indian and Alaska Native children. Report adverse events: • If nirsevimab is administered alone, report adverse events to MedWatch. • If nirsevimab is co-administered with a vaccine, report adverse events to VAERS only.

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Discussion:

What do birthing hospitals need to ensure success?

Next Steps

Next Steps:

- Birthing hospitals and immunization programs can work together to troubleshoot challenges and process VFC program enrollment
- CDC and AIM can assist with challenges
- Future Calls:
  - November 13 at 3:00-4:00 PM ET
  - December: TBD
  - January: TBD

Register Now!

Nov. 13, 2024

https://us06web.zoom.us/meeting/register/tZAvdu-ppz8oEtJoXfvWx_1r2948Da8wMHWf

Thank you!

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