



Implementation and Uptake of Nirsevimab and Maternal Vaccine

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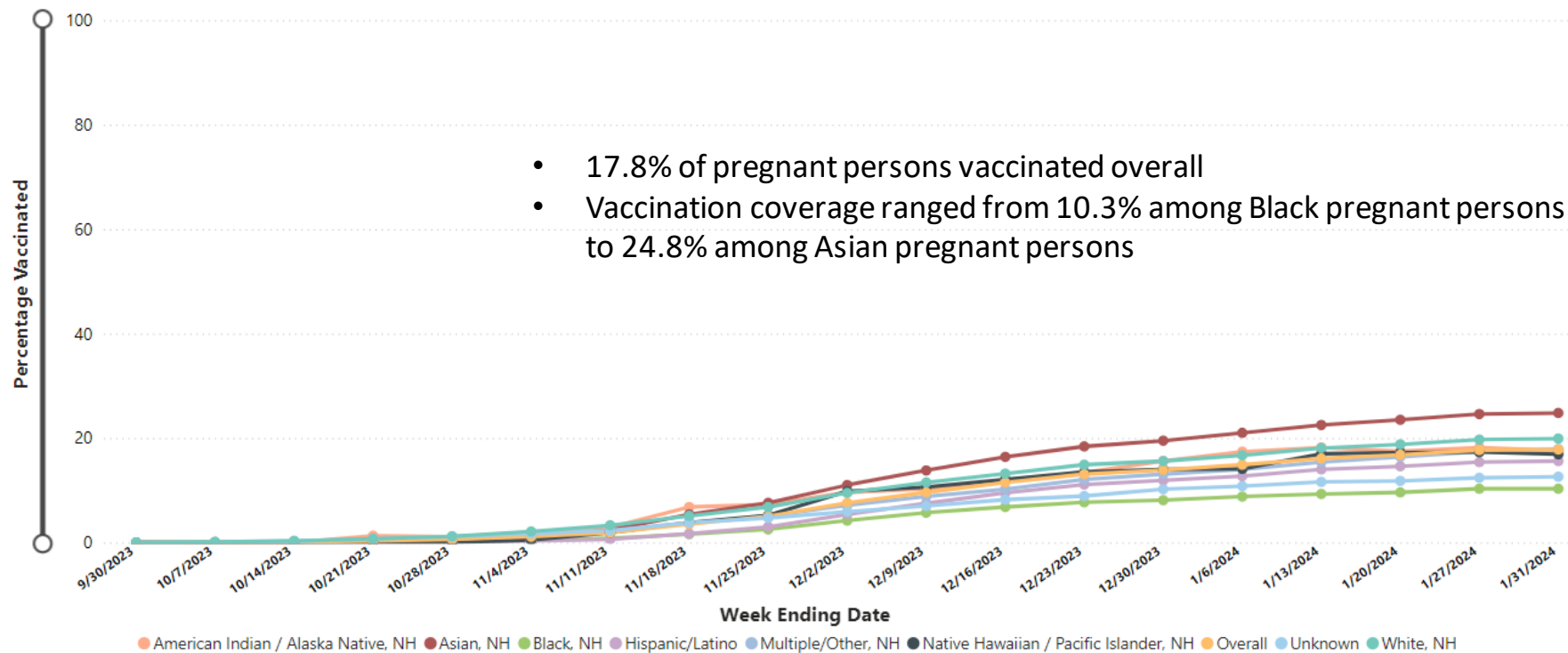
Immunization Services Division

National Center for Immunizations and Respiratory Diseases (NCIRD)

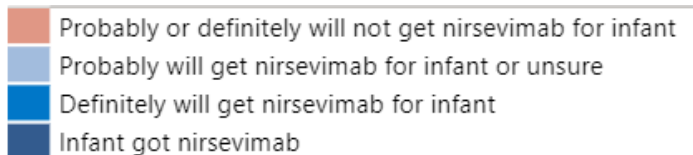
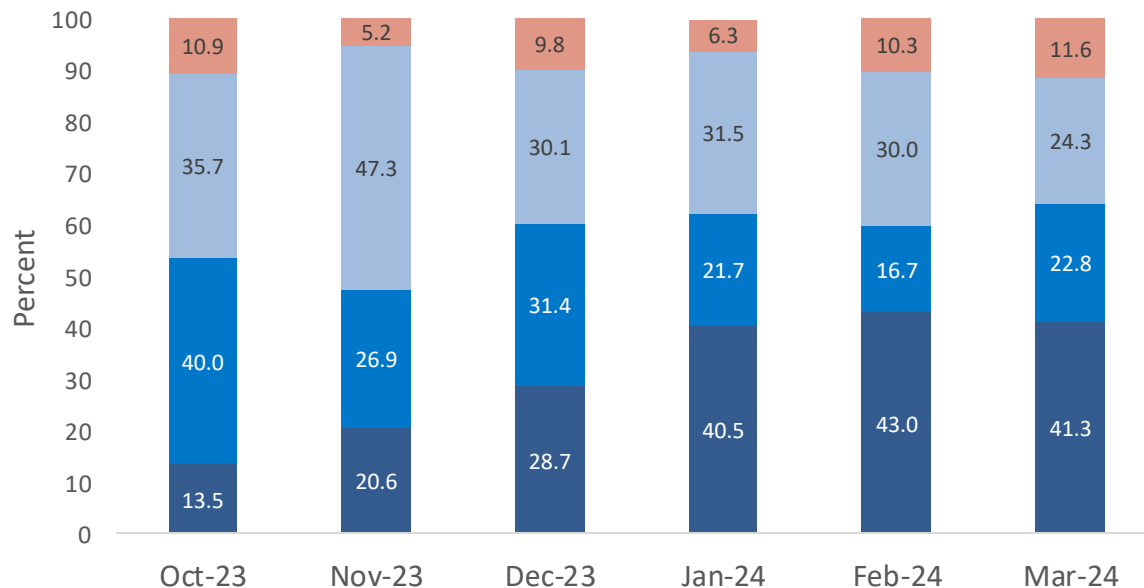
June 2024

2023-2024 Coverage for Nirsevimab and Maternal Vaccination

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



Monthly nirsevimab receipt and intent among women ages 18–49 years who have an infant <8 months, National Immunization Survey-Adult COVID Module (NIS-ACM)



Proportion of infants protected from RSV by receipt of nirsevimab or maternal RSV vaccination

- **51.2% of infants are estimated to be protected from RSV by either receipt of nirsevimab or maternal RSV vaccination.**
- Infants eligible for nirsevimab: 3,900,000
 - Those 0–7 months old during October 2023–March 2024
 - Born March 2023–March 2024
 - Assume 300,000 babies born each month
 - 43.0% received nirsevimab (from February NIS-ACM)
- Infants eligible for protection by maternal vaccination (a subset of infants eligible for nirsevimab): 1,800,000
 - Born October 2023–March 2024
 - Born to mothers 32-36 weeks' gestation and eligible for RSV vaccination September 2023–January 2024
 - 17.8% of mothers received RSV vaccination (from VSD data through January 2024)
- Estimated number of infants who received nirsevimab = $.430 \times 3,900,000 = 1,677,000$
- Estimated number of infants protect by maternal RSV vaccination = $.178 \times 1,800,000 = 320,400$
- **Percent protected by either = $1,677,000 + 320,400 / 3,900,000 = 51.2\%$**

Location of Maternal RSV Vaccine Administration

- **IQVIA* data:**
 - Among women ages 18-49 years in the U.S., during September 30, 2023, through April 20, 2024:
 - A total of 223,466 projected RSV vaccine doses were administered
 - 96,611 (43%) in physician medical offices**. Using a sample of 2,866 office-based physicians, vaccinations are projected to the ~700,000 office-based physicians in the U.S.
 - 126,865 (57%) in U.S. retail pharmacies. Using a sample of 40,469 pharmacies, vaccinations are projected to the ~57,000 pharmacies in the U.S.
- **NIS-ACM:**
 - National survey data
 - Among 1,483 pregnant women <50 years surveyed between December 2023-March 2024, 80 (5.4%) had already received the RSV vaccine
 - 15% in a pharmacy or drug store
 - 85% in a medical office (doctor's office/clinic/hospital/health dept)

*Data sources: Immunization Services Division's custom IQVIA Longitudinal Prescription Claims (LRx) + Medical Claims (Dx) data files (delivery date April 20, 2024). ** The projection to office-based physicians uses a list of US licensed office-based MDs and DOs maintained by the AMA.

Location of Maternal RSV Vaccine Administration: Limitations

- **IQVIA data limitations**

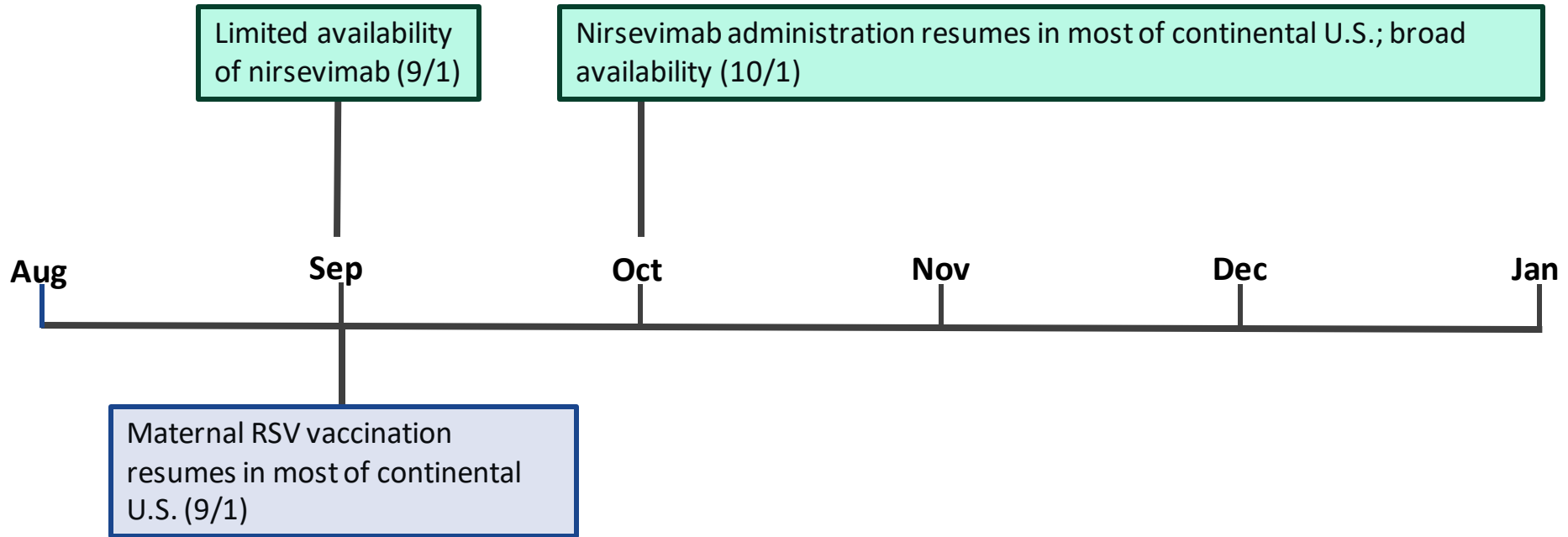
- May not be representative
 - Uninsured pregnant people are not represented in medical office estimates.
 - Projected physician medical office estimates are based on a small sample of physicians.
 - Data do not include vaccinations administered at other medical settings such as public health clinics and other settings including workplaces and community locations.
- There is no pregnancy variable in these IQVIA data
 - Estimates include women of reproductive age who received an RSV vaccine during September 2023–January 2024. This could include women who were not pregnant when vaccinated or were pregnant but vaccinated outside the recommended 32-36 weeks gestation period.

- **NIS-ACM data limitations:**

- Small sample size
- Gestational age at the time of vaccination is unknown
 - Pregnancy status at time of interview was known, but not gestational age; only some of those identified as pregnant would have been eligible for RSV vaccine at 32-36 weeks gestation during the September-January window for maternal RSV vaccination in most of the U.S. (e.g., in each month, many would have been at <32 weeks gestation when interviewed)

Implementation

Prospective 2024 RSV immunization timeline



Challenges with maternal RSV vaccination during the 2023-2024 season

- **New** immunization products
- Licensure/launch occurred in Aug/Sep, which prevented **planning** in advance of the season
- **Complex** clinical recommendations, nuanced communications
- Lack of **awareness** among healthcare providers
- Challenging have **provider/patient conversations** about vaccination in the context of nirsevimab **shortages**
- Cost and **reimbursement** issues during the first year
- **Access** issues—lack of supply at many OBGYN offices, denial at pharmacies, requirement of prescription
- Lack of data on **coadministration**
- No ability to link maternal and infant immunization **records**
- Concerns about **safety, efficacy**

Maternal vaccine supply for the 2024-2025 season

- **There is no anticipated supply/demand mismatch.**
- **The Pfizer RSV vaccine is already available in the field.**
 - However, providers who will vaccinate only pregnant persons may need to rebuild inventory for the 2024-2025 season.
 - Plans are to have vaccine available for administration September 2024–January 2025 for most of the U.S.

CDC Campaign: From Me, To You

From Me, To You.



Shared Experiences



Shared Immunity



Talk to a healthcare
provider you trust
about the vaccines that
are right for you
during your pregnancy.



*Your Recommendation
Makes A Difference.*

Share the benefits of vaccination during
pregnancy with patients in your care.



Challenges in initial implementation of nirsevimab targeting infants during the 2023-2024 season

- **Timing of policy decision**

- FDA licensure (July 17) of nirsevimab required special session of ACIP (August 3) leaving <2 months for distribution and roll out planning for October 1 launch
- Limited time for engagement with key stakeholders and implementing partners to ensure healthcare workers were aware of new product recommendations and could start procurement processes

- **Procurement and insurance coverage**

- Vaccines for Children (VFC) procurement expedited to ensure availability of nirsevimab for eligible infants and young children (~50% of US children); maternal vaccine for eligible pregnant people aged <19 years
- Healthcare providers were uncertain of need/demand given that private insurance companies have 12 months to adopt ACIP-endorsed vaccine recommendations
- Demand was strong from parents of young children, many of whom were willing to pay for nirsevimab/vaccine if insurance would not cover

Insufficient supply of nirsevimab to meet demand in 2023-2024 season

- Limited supply of nirsevimab (100mg and 50mg formulations) meant clinicians were uncertain how to ration or prioritize few available doses
- CDC issued an official Health Advisory notice via the Health Alert Network to prioritize available doses to high-risk infants and younger infants
- By January, demand had decreased and additional supply was available allowing return to original recommendations

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

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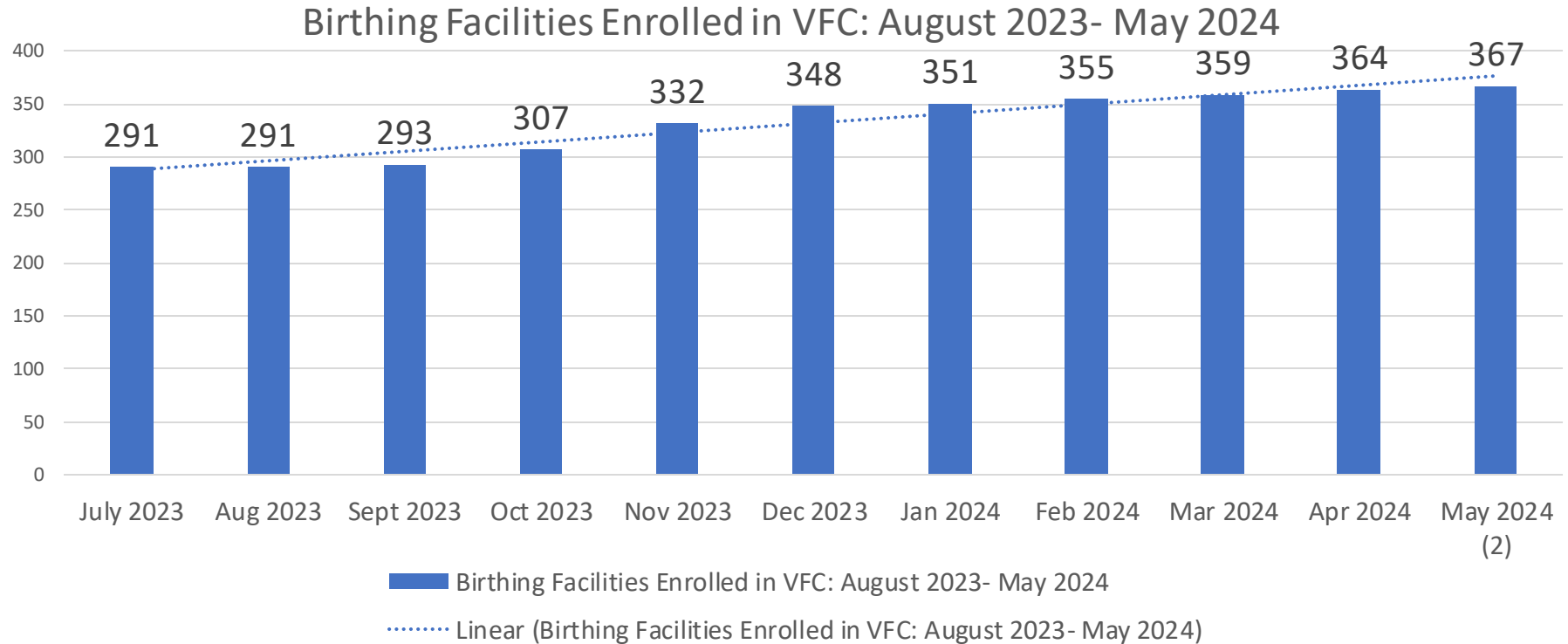
Distributed via the CDC Health Alert Network
October 23, 2023, 3:30 PM ET
CDCHAN-00499

[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](#)

Nirsevimab supply for the 2024-2025 season

- National shortage during 2023-24 due to faulty assumptions about uptake, presentation mix
- Manufacturer supply plan for 2024-25 is focused on
 - Increased volume of product
 - Frontloading of supply
 - Revised mix of presentations
- Requirements of supply plan include significant logistical actions, regulatory input and approvals, careful risk management
- Limited availability beginning early Sep, ramping up during Sep, **broadly available by Oct 1**
- Broadly available supply essential to promote confidence in vaccines/vaccine supply and program implementation
- Promoting vaccination *prior* to broadly available supply risks confusion, disappointment, and decreased confidence among providers and the public

Birthing Hospital Enrollment into VFC: Strategy



(1) These newly enrolled provider counts include 7 providers who were previously enrolled in the VFC program.

(2) Data for May 2024 is through May 8, 2024.

Activities to Increase Hospital VFC Enrollment

- **Engaging in data gathering activities:**
 - Held series of focus groups to identify facilitators and barriers to enrolling hospitals in VFC
 - National survey of birthing hospitals
 - Mapping hospitals by number of VFC-eligible births, VFC enrollment, and nirsevimab administration history
- **Planned activities to scale-up enrollment:**
 - Disseminating promising practices and success stories
 - Development of “Promising Practices” FAQ document
 - Working closely with immunization awardees to track process and provide support
- **Implementing activities to reduce enrollment burden:**
 - Awardees can enroll birthing hospitals as “specialty providers”; this allows birthing hospitals to offer only nirsevimab and HepB vaccination birth dose
- **Collaborating with partners**

Closing Slide / Disclaimer

For more information, contact CDC/ATSDR

1-800-CDC-INFO (232-4636)

TTY: 1-888-232-6348 www.cdc.gov www.atsdr.cdc.gov

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