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

November 13, 2024

Association of Immunization Managers

HOUSEKEEPING

- We encourage discussion but please remain muted when not speaking
- This call is being recorded
- Please introduce yourself in the chat and tell us your role in these efforts
- All slides and resources will be sent after the call
- Use the chat box for any questions

Agenda

- Purpose of the Learning Collaborative
- Understand how replacement models have been successfully implemented in birthing hospitals to improve VFC program participation.
- Guest Speakers:
  - Virginia:
    - Beth Miller, VVSA Field Operations Supervisor, IQIP Coordinator
    - Mark Vestal, PharmD, MMCi, BCPS, Pharmacist Coordinator, Pharmacy Supply Chain
    - Josh Crawford, PharmD, BCPS, System Director, Clinical Pharmacy Services
  - Utah
    - Kayla Strong. MA –VFC Program Manager
  - New York State
    - Lyndsey Hoyt, MPH
      Director, Bureau of Vaccine Programs
    - Matthew Groth, PharmD, MS
      Director for Pharmaceutical Supply Chain Management
- Discussion
- 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

Virginia

- Beth Miller
  VVSA Field Operations Supervisor
  IQIP Coordinator
  - VDOH
- Mark Vestal, PharmD, MMCi, BCPS
  Pharmacist Coordinator, Pharmacy Supply Chain
  - UVA
- Josh Crawford, PharmD, BCPS
  System Director, Clinical Pharmacy Services
  - Bon Secours

REDUCING BARRIERS TO VFC PARTICIPATION IN VIRGINIA

Virginia Department of Health
University of Virginia Health System
Bon Secours Mercy Health

VFC Vaccine Ordering Replacement Model

- What is the Vaccine Ordering Replacement Model?
- What is needed to implement the Vaccine Ordering Replacement Model
- Proposal for the Vaccine Ordering Replacement Model
- Exception for Influenza vaccine
- Virginia's past and present experience with the Vaccine Ordering Replacement Model
- Challenges and Barriers
- Questions and Contact Information

What is the Vaccine Ordering Replacement Model (Replacement)?

- Providers supply the initial stock of vaccines for their patient population
- Private and public vaccine stock may be co-mingled
- As VFC-eligible children receive doses, awardees replace those doses
- All VFC requirements must be met
- Providers must operate within CDC's depot policy

Refer to pages 48-50 in the 2022-23 VFC Operations Guide v. 3.0 for full guidance

What is needed to implement Replacement

- Provider:
  - Financial means
  - Electronic means for recording eligibility at the dose level
  - Ability to submit data to the awardee monthly

- Awardee:
  - Ability to verify eligibility
  - Oversight – Temperature Monitoring
  - Ensure doses replaced reflect the provider's VFC-eligible patients

Proposal for Replacement

- Awardee must submit a proposal for CDC approval

- Eligibility screening at every encounter
- Awardee must have an electronic system (IIS) to capture eligibility at the dose level
- Doses must be documented within 30 days
- Awardee must include a sample report that will be used to verify doses administered data
- Data to review
  - Actual doses being replaced
  - Patient-level data
- Reports must be submitted monthly
- Doses must be shipped directly to provider locations
  - Providers with centralized pharmacies must follow CDC's Depot policy
  - Providers may not ship vaccines from a Centralized pharmacy to other sites throughout the state
- Inventory must be submitted to VTrckS based on public portion of population
- Vaccine returns must be submitted based on public portion of population

Full guidelines available on page 49 of the 2023-24 VFC Operations guide (last updated 1.18.24

Exception for Influenza Vaccine

- CDC does not allow for inclusion of Influenza Vaccine
- Use the VFC-eligible patient portion to identify Influenza doses needed
- Influenza returns must reflect VFC-eligible patient portion
- Although not included in Replacement, doses may be co-mingled

Virginia's past and present experience

- Birthing hospitals utilized Replacement in the early 2010s
  - Office of the Inspector General (OIG) report and changes CDC implemented in 2014
  - Reduced Birthing Hospital VFC participation

- Virginia currently has two providers utilizing Replacement
  - Kaiser Permanente (19 sites) – approved in 2019
  - University of Virginia (12 sites) – Previously enrolled 2015-2018, recently re-approved January 2024

Challenges and Barriers

- Replacement approval is a process
- Replacement is not right for every VFC provider
- The depot policy may challenge providers with Centralized pharmacies
- Purchasing/maintaining supply of vaccine when allocations are in place
- Data reporting and oversight

University of Virginia (UVA) – Mark Vestal

Successes

- Enrolled in VFC Vaccine Ordering Replacement model January 2024
- Expanding to other clinics within the UVA Health System

Barriers/Challenges

- Coordination with off-campus clinics
- Replenishment of inpatient administration for eligible VFC patients (e.g., differences in billing requirements)

Bon Secours – Joshua Crawford

Barriers/Challenges

- In-patient Reimbursement
  - DRG-based
- VFC only covers some patients
  - Would need to offer to all patients
- Administrative burden of VFC
  - Who would determine eligibility internally?
- Closure of Labor & Delivery centers
  - Not generally profitable
  - Three closed in Bon Secours since 2020
- Manufacturer's messaging
  - Pushed for hospital administration
  - Led HCPs to believe nirsevimab would be reimbursed/covered
  - Focus should be directed toward MD office setting for administration

Statistics

- Annual Births = 23,578
  - Potential nirsevimab doses = 11,789
- Nirsevimab cost = ~$470/dose
  - $5,540,830 annual potential cost
- Margin per birth
  - Varies by market
    - Half of our hospitals lose money per birth
  - Relatively low to no margin
  - Unsure of Medicaid % in L&D

Questions?

Crista Sullivan
Virginia Vaccine Supply and Assessment Program Director
crista.sullivan@vdh.virginia.gov
Beth Miller
Virginia Vaccine Supply and Assessment Field Operations Supervisor
beth.miller@vdh.virginia.gov
Virginia Department of Health
Division of Immunization

Utah

- Kayla Strong, MA
  VFC Coordinator

New York State

- Lyndsey Hoyt, MPH
  Director, Bureau of Vaccine Programs
- Matthew Groth, PharmD, MS
  Director for Pharmaceutical Supply Chain Management

NEW YORK STATE | Department of Health

1994-2024 30TH ANNIVERSARY Vaccines for Children

New York State Vaccines for Children

Birthing Hospital Engagement and Replacement Model Implementation

Lyndsey Hoyt
New York State Department of Health
Division of Vaccine Excellence, Bureau of Vaccine Programs
November 13, 2024

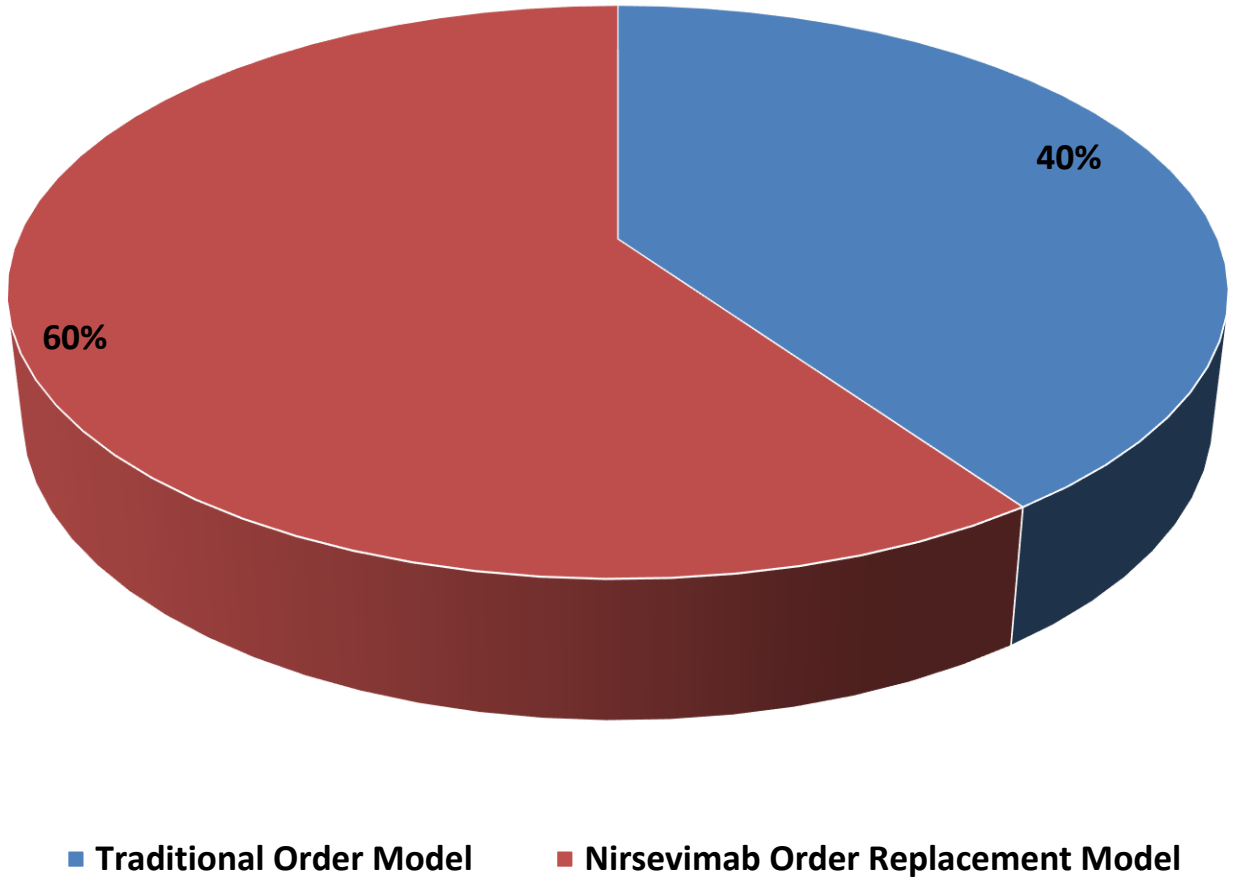
Background

- 79 birthing hospitals in New York State
- Long standing Universal Hepatitis B program – vaccine for all infants regardless of insurance
  - State funded
  - Not required to enroll in VFC
  - Not all birthing hospitals participate
- October 2023 sent information to enroll in VFC for nirsevimab
  - Shortly after supply constraints announced; prioritized birthing hospitals for distribution
  - 21 hospitals enrolled by March 2024; only 13 ordered nirsevimab

May 2024: Replacement Model Interest Survey

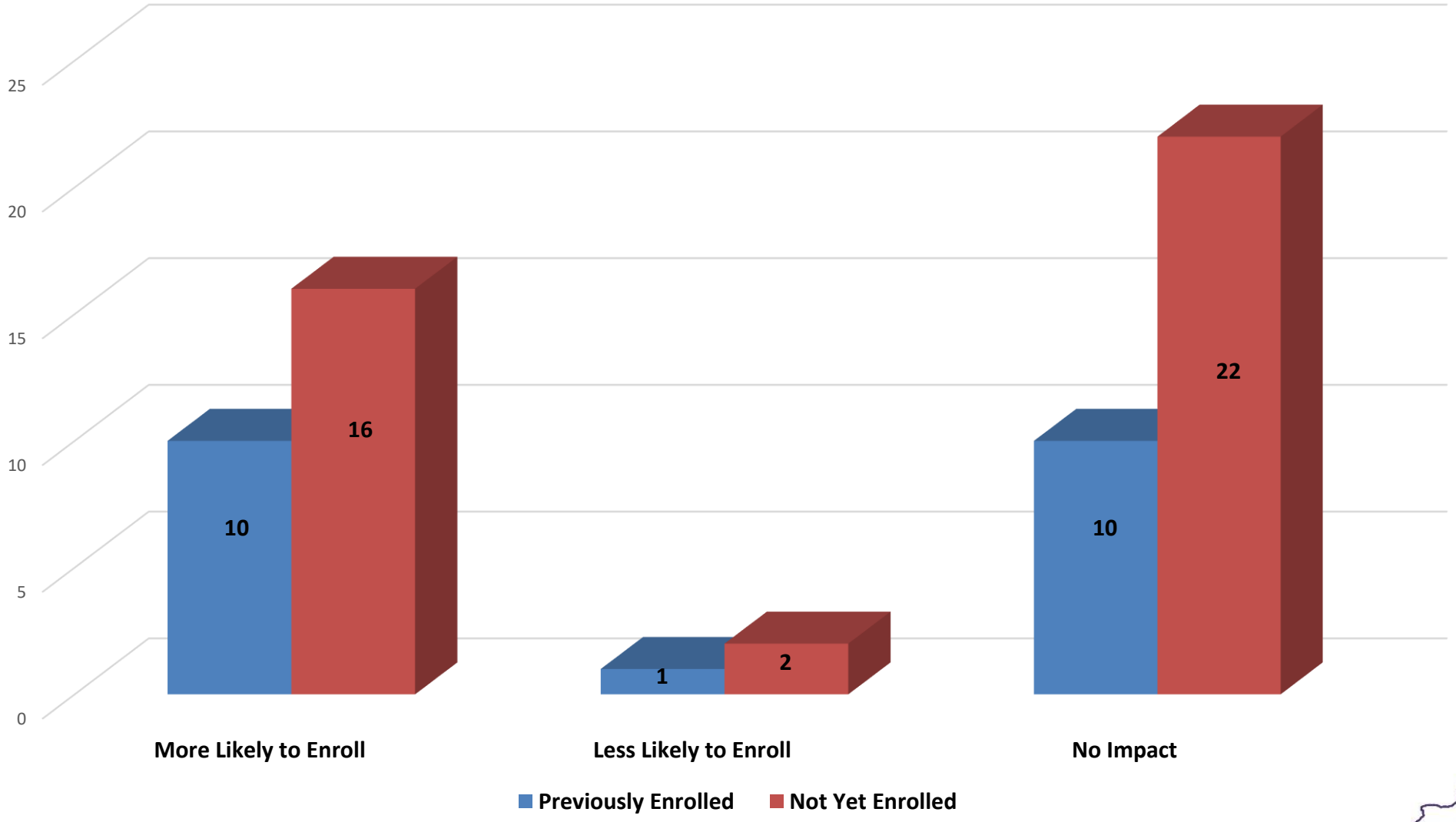
- Described how a potential Nirsevimab Ordering Replacement Model would differ from traditional ordering.
- At this time, we were considering an all-in-one approach for birthing hospitals (either all must use replacement or traditional).
- Questions included ordering model preference, impact on enrollment, and barriers.
- Response rate = 77% (61 of 79)

Ordering Model Preference



NEW YORK STATE | Department of Health

Impact of Replacement Model Availability on Enrollment Decision



NEW YORK STATE | Department of Health

Sample: NYS Nirsevimab Order Model Selection

- Vaccine Ordering Replacement Model. In addition to the terms of the Vaccines for Children Provider Agreement, we understand the following requirements for using the Vaccine Ordering Replacement Model:

1. Both VFC eligible and privately insured infants will be immunized.
2. Initial supply will be privately purchased to cover at least six weeks of administration to all infants.
3. All doses, with VFC eligibility type, will be documented in NYSIIS within 14 days of administration.
4. New York State VFC Program will automatically place replacement orders monthly (November through April) for doses administered to VFC eligible infants. These doses do not require separate labeling and may be administered to any infants.
5. Publicly funded vaccine may not be repackaged or redistributed.
6. In the event any doses of nirsevimab expire or become non-viable prior to administration, the proportion of public vaccine eligible supply will be returned to CDC's centralized distributor, McKesson, for Federal Excise Tax credit.
7. Upon request, we will make procurement records (vaccine orders/invoices/payment records) for a 12-month period available to the NYS Vaccines for Children Program.

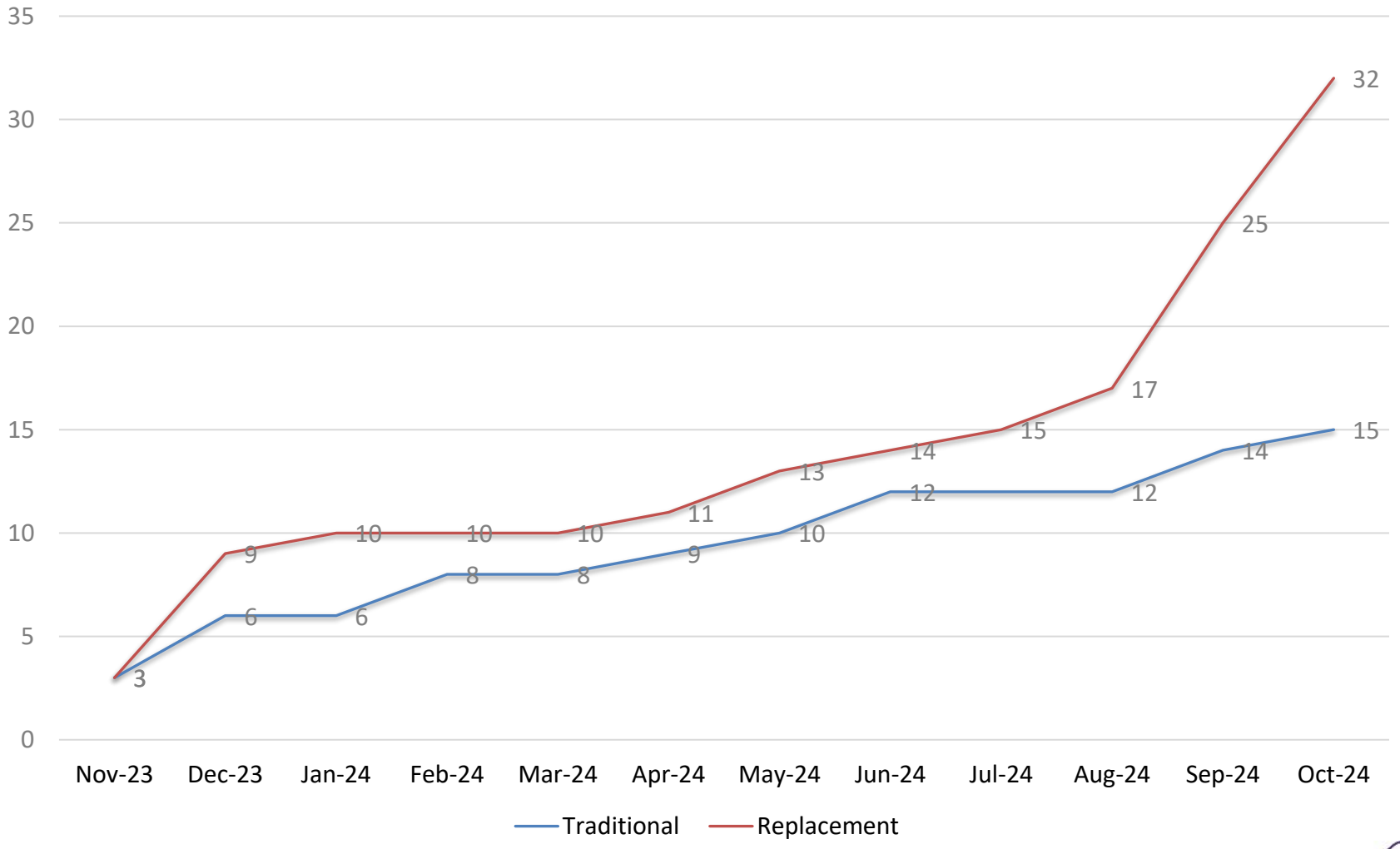
Engagement calls w/ Replacement Model Hospitals

- Compare provider profile on enrollment to NYSDOH data on total births and Medicaid births
- Explain requirement to privately purchase initial supply and add to NYSIIS inventory module
- The replacement model can only be used if you also plan to vaccinate your privately insured newborns. The DRG bundled birth payment does not include the cost of nirsevimab.
  - Have you made any contractual agreements with health insurance plans to cover?
  - If no, are you prepared to incur this expense for privately insured infants?
- Review of Public Health Law requirement to report all immunizations to children 0-18 within 14 days to NYSIIS
  - Are you reporting manually or through data exchange from EMR?
  - If using EMR, is nirsevimab entered as a medication or immunization?
  - Who will ensure reporting within 14 days?

RSV Replacement Dose vs Traditional Model

	Traditional	Order Replacement
Separation of public and private stock	**YES**	**NO**
VFC eligibility screening **before** vaccination	**YES**	**NO** (providers have 14 days to determine eligibility)
Hospital staff reports dose in NYSIIS within 14 days with accurate eligibility	**YES**	**YES**
Hospital staff orders VFC vaccine	**YES**	**NO** (NYS VFC Program sends replacement doses automatically)

Enrollment Trend



NEW YORK STATE Department of Health

Challenges

- In-patient reimbursement from health plans for non-VFC eligible
- Reporting
  - Hepatitis B birth dose is reported to vital records, who in turn reports to NYSIIS; Reporting responsibility of hospital from EMR to NYSIIS (or manual reporting to NYSIIS) for nirsevimab is new.
  - Knowing baby's name prior to discharge to get dose into NYSIIS. Cannot report without name due to this causing "orphan" immunization records.
- NYSIIS Inventory
  - Not built to deduct inventory in which fund type and eligibility don't match
  - Requires manual cleaning via NYSIIS Inventory Not Deducted module

University of Rochester Medical Center
Matt Groth

- Successes/Solutions

- Barriers/Challenges

Questions?

Lyndsey Hoyt, MPH

Director, Bureau of Vaccine Programs

New York State Department of Health

Division of Vaccine Excellence

Lyndsey.hoyt@health.ny.gov

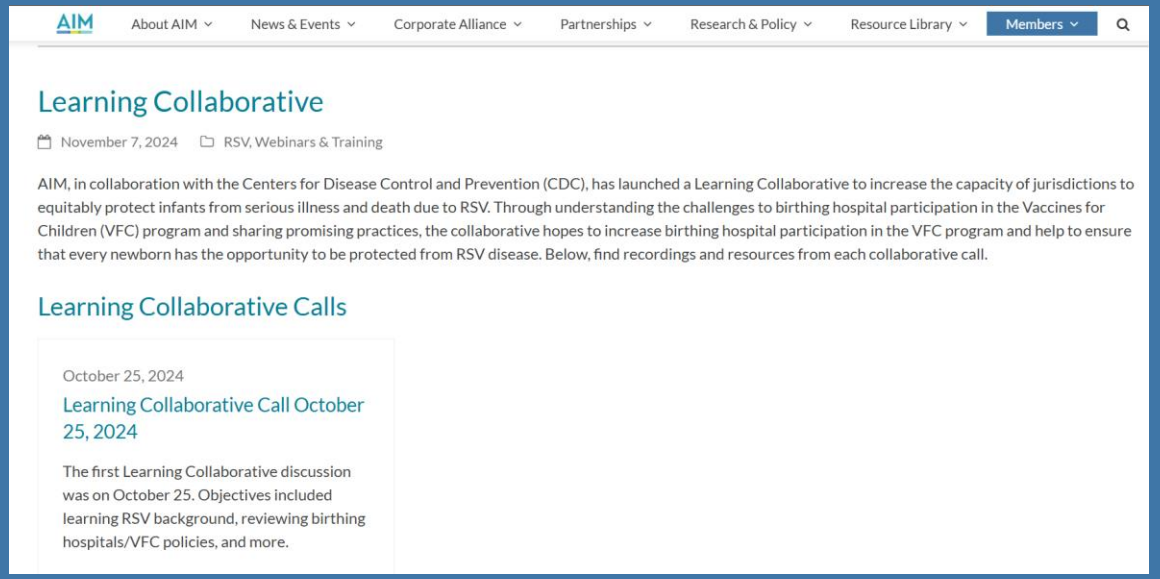
nyvfc@health.ny.gov

NEW YORK STATE | Department of Health

Speaker Q&A
&
Discussion

Resources

Learning Collaborative on the AIM Website!
https://www.immunizationmanagers.org/resources/learning-collaborative/



New York State Department of Public Health:
Vaccine Replacement Model

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

- Previous Call Resources
  - November 13: https://www.immunizationmanagers.org/resources/learning-collaborative/
- Future Calls:
  - December 19, 2024 at 2:00-3:00 PM ET
  - January: TBD

Register Now!
Dec. 19, 2024

https://us06web.zoom.us/meeting/register/tZ0qce6hpz8jE915DI5qR6MXfedgLZus2C62

Thank you!

immunizationmanagers.org

@AIMimmunization

Association of Immunization Managers

AIM | Association of Immunization Managers