Immunization Updates
November 8, 2023

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1

Nirsevimab

2

Nirsevimab Efficacy and Safety

- Nirsevimab provides short-term protection to infants through their first RSV season when they are at highest risk of severe RSV infection.
- Nirsevimab is shown to be over 80% effective at preventing RSV lower respiratory tract infection hospitalizations.
- Study side effects were generally mild, including pain, redness, and swelling at the injection site.
- Nirsevimab should be administered at the same time as other recommended immunizations.

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3

Nirsevimab Availability

Both strengths (50mg/0.5mL and 100mg/1mL) are in extremely short supply and will have limited availability throughout the 2023-2024 respiratory syncytial virus (RSV) season.

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4

Nirsevimab Interim Recommendations

Due to limited supply for the 2023-2024 RSV season, the CDC has recommended these priority groups for nirsevimab:

1. All babies weighing <5kg born during RSV season (October-March) should receive a 50mg/0.5mL dose in the first week of life.
2. All babies <5k born prior to October 2023 should receive a 50mg/0.5mL dose.
3. For infants weighing ≥5kg, prioritize using 100mg/1mL doses in infants at highest risk of severe RSV, including:
   - Infants aged <6 months
   - **American Indian** and Alaska Native children aged <8 months
   - Infants aged 6 to 8 months with conditions that place them at high risk of severe RSV disease:

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5

Nirsevimab Interim Recommendations

Infants aged 6 to 8 months with conditions that place them at high risk of severe RSV disease include:

- Premature infants born at <29 weeks' gestation
- Infants with severe immunocompromise
- Infants with chronic lung disease of prematurity who required medical support any time during the six-month period before the second RSV season
- Infants with cystic fibrosis who have manifestations of severe lung disease or weight-for-length <10th percentile
- Infants with neuromuscular disease or congenital pulmonary abnormalities that impair the ability to clear secretions

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6

Nirsevimab Interim Recommendations

What if the maternal RSV vaccine was not given and nirsevimab is not available?

- First RSV Season:
  - Palivizumab remains available for children at highest risk of severe RSV based on American Academy of Pediatrics (AAP) guidelines, including infants born during or entering their **first RSV season** with:
    - Chronic lung disease of prematurity
    - Hemodynamically significant congenital heart disease
    - Neuromuscular disorders that impair the ability to clear secretions from the upper airway

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7

Nirsevimab Interim Recommendations

What if the maternal RSV vaccine was not given and nirsevimab is not available?

- Second RSV Season:
  - Palivizumab remains available for children at highest risk of severe RSV based on American Academy of Pediatrics (AAP) guidelines, including preterm infants born at <32 weeks, 0 days' gestation entering their **second RSV season** who required at least 28 days of oxygen after birth and who continue to require supplemental oxygen, chronic systemic corticosteroid therapy, or bronchodilator therapy within 6 months of the start of the second RSV season

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8

VFC Nirsevimab in North Dakota

Due to limited supply for the 2023-2024 RSV season, the North Dakota Department of Health and Human Services has:

- Estimated likely county level nirsevimab needs based on historical rotavirus vaccine utilization.
- Reviewed which sites have and have not ordered and received nirsevimab.
- Determined which sites have surplus nirsevimab supply based on their anticipated need for this point in the RSV season.
- Made arrangements to reallocate nirsevimab from sites with surplus to sites with shortfall to ensure equitable access throughout the state without unreasonable patient travel requirements.

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9

Nirsevimab Do's and Don'ts

- **DON'T** use 2 - 50mg/0.5mL syringes to give a 100mg dose.
- **DON'T** give a 50mg dose to a child who would (by weight or by age) be recommended to receive a 100mg dose.
- **DO** use the doses you have available based on the Interim Recommendations for the 2023-2024 RSV season. **DON'T** "save" them in your fridge.
- **DON'T** borrow from VFC supply. The likelihood of being able to repay doses is very low, so this is not permitted at this time.
- **DO** educate pregnant women about the maternal RSV vaccine, Abrysvo™, and the current low supply of nirsevimab.

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10

Nirsevimab – What you can do!

01	02	03
If you have supply, get infants weighing <5k immunized now. • Call parents of recent births to bring infant in while 50mg/0.5mL dose still appropriate	Work with your OB partners to establish a process for offering and providing maternal RSV vaccine.	Call in older, highest-risk children who would need the 100mg/1mL dose if you have it available.

11

Nirsevimab – What you can do!

- If you do not have any nirsevimab in stock, assist parents in finding a location with stock.
- The ND VFC locator now shows nirsevimab locations for VFC eligible children: https://www.hhs.nd.gov/health/diseases-conditions-and-immunization/immunizations/public

12

Maternal RSV Vaccine

13

Maternal RSV Vaccine

- Abrysvo™ is readily available.
- Approved for use in pregnant women 32-36 weeks gestation during the months of September through January
- 91% effective in preventing severe medically attended RSV-associated lower respiratory tract infections in infants from birth through 90 days and 76% effective from birth through 180 days
- It takes about 14 days from the time of maternal vaccination for best maternal antibody development and transfer to the infant to occur.
- The maternal RSV vaccine may be given at the same time as other recommended vaccines.

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14

Maternal RSV Vaccine

- If maternal RSV vaccine received during pregnancy, infant typically will not require RSV immunization after birth unless:
  - Mother received RSV vaccine <14 days prior to delivery.
  - Per the clinical judgment of the medical provider, the potential incremental benefit is warranted.
- There was a small increase in preterm births observed in the clinical trial patients receiving the vaccine between 24-36 weeks' gestation compared to those receiving placebo.
  - Unclear if this is a true safety issue related to the vaccine or if it was unrelated to vaccination.
  - To reduce the potential risk of preterm birth and complications from RSV disease, the U.S. Food and Drug Administration (FDA) approved the maternal RSV vaccine only for use later in pregnancy during 32 through 36 weeks' gestation while additional studies are conducted.

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15

Maternal RSV Vaccine

- As an Advisory Committee on Immunization Practices (ACIP) recommended vaccine, insurance plans are required to cover the maternal RSV vaccine.
  - Insurance providers have 1 year to comply, but many plans are already covering the maternal RSV vaccine.
- The maternal RSV vaccine is covered by North Dakota Medicaid.
- ACIP approved including the maternal RSV vaccine in the Vaccines for Children (VFC) program for uninsured, under-insured, Medicaid-eligible, and American Indian children 18 and younger, though CDC has not yet added it to VFC.

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16

Maternal RSV Vaccine

- Where can a pregnant women get the maternal RSV vaccine?
  - She can discuss with her OB/GYN care provider. She may be able to get the vaccine during one of her regular visits.
  - She can ask her OB/GYN care provider if there is a pharmacy they are referring patients to for the Maternal RSV Vaccine.
  - She can check with her preferred pharmacy to see if they are offering Abrysvo™ during pregnancy and ask if they require a prescription.
  - She can check with her local Public Health Unit to see if they are offering Abrysvo™ during pregnancy.

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17

Infant RSV Immunization Options

Immunize.Org has created and made available on their website:

- Standing Orders for Administering Pfizer RSV Vaccine (Abrysvo) during Pregnancy
- Standing Orders for Administering Nirsevimab RSV Preventive Antibody to Infants (2023-24 Season Only)

18

October ACIP Meeting

19

October ACIP Meeting

The Advisory Committee on Immunization Practices (ACIP) met October 25-26, 2023 and discussed:

- **Meningococcal Vaccines**
- **Mpox Vaccines**
- RSV – Adults
- **Influenza Vaccines**
- **Vaccine Safety Update**
- **Combined Immunization Schedules**
- Chikungunya Vaccine
- Dengue Vaccines
- **COVID-19 Vaccines**
- Pneumococcal Vaccines

20

Pentavalent Meningococcal Vaccine

- On October 20, 2023, the U.S. FDA approved Penbraya for individuals ages 10 – 25.
  - Serogroups A, B, C, W-135 and Y
  - Trumenba and Nimenrix (MCV4 vaccine used in other countries)
  - Licensed as a 2-dose series (6-month interval) for individuals aged 10–25 years
- Penbraya cost:
  - $210 - $250 private market
  - $157.50 - $187.50 public market

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21

Pentavalent Meningococcal Vaccine

- The FDA based its approval on results from a pivotal phase 3 trial (NCT04440163) that evaluated more than 2400 patients from the United States and Europe.
  - The FDA based its approval on results from a pivotal phase 3 trial (NCT04440163) that evaluated more than 2400 patients from the United States and Europe.
  - The trial achieved all primary and secondary endpoints, as Penbraya demonstrated non-inferiority to licensed vaccines for the 5 meningococcal serogroups.

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22

Pentavalent Meningococcal Vaccine

- A single dose of the vaccine achieved non-inferiority criteria for serogroups A, C, W, and Y compared to a single dose of Menveo.
  - Among participants who were not previously administered a meningococcal vaccine, the proportion of those with ≥4-fold increases in immune responses was higher after receiving either 1 or 2 doses of Penbraya for serogroups A, C, W and Y compared to 1 dose of Menveo, according to the study.
  - The proportion of participants with ≥4-fold increases in immune responses was higher against all 4 serogroup B strains after 2 doses of Penbraya vs 2 doses of Trumenba.
  - Penbraya was also found to be well-tolerated, with a safety profile consistent with licensed vaccines, according to Pfizer.

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23

Pentavalent Meningococcal Vaccine

ACIP discussion questions:

- Should pentavalent vaccine be included as an option for MenACWY/MenB vaccination in people currently recommended to receive both vaccines?
- Should pentavalent vaccine be included as an option for people currently recommended to receive MenACWY only?
- Should pentavalent vaccine be included as an option for people currently recommended to receive MenB only?

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24

Previous Meningococcal Recommendations

- MenACWY dose 1 at 11-12 years, booster at 16
- MenB (shared clinical decision making): two doses at age 16-23 years
- Other high risk: travelers, microbiologists, certain medical conditions

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25

New Meningococcal Recommendations

ACIP voting results:

- Pfizer's MenABCWY vaccine may be used when **BOTH** MenACWY and MenB are indicated at the same visit.
- Sample schedule:
  - MenACWY at age 11
  - MenABCWY at age 16
  - MenB
- Pentavalent vaccine will be included in VFC Program.
- Providers do not have to use the pentavalent vaccine.

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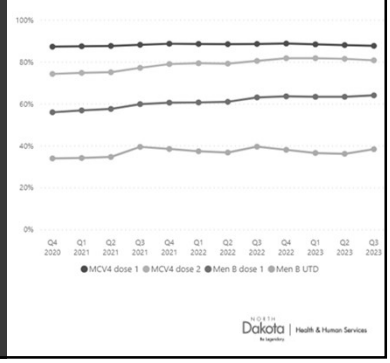
26

ND Meningococcal Rates

- **NDIIS**



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27

Future Meningococcal Discussions

- The ACIP workgroup will be revisiting the new meningococcal schedule. Discussions will include:
  - Whether 11-12 year old dose is still needed given recent epidemiology
  - Shared clinical decision making for meningococcal B vaccines
  - Opportunity to reduce the number of vaccines
- ACIP vote anticipated in February of 2025

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28

Mpox Vaccine Recommendations

- ACIP recommends vaccination with the 2-dose JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox.
- This is an interim recommendation, to be revisited in 2-3 years.
- Dose 2 should be administered 28 days after dose 1.

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29

Mpox Vaccine Recommendations

- Persons at risk:
  - Gay, bisexual , and other men who have sex with men, transgender or nonbinary people who in the past 6 months have had one of the following:
    - A new diagnosis of ≥ 1 sexually transmitted disease
    - More than one sex partner
    - Sex at a commercial sex venue
    - Sex in association with a large public event in a geographic area where mpox transmission is occurring
  - Sexual partners of persons with the risks described in above
  - Persons who anticipate experiencing any of the above

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30

JYNNEOS Commercialization

- JYNNEOS is currently only available through federal stockpile.
- Will be commercialized in "several months"
- Private market cost: $200-$270 per dose

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31

2024 Immunization Schedules

- ACIP voted to approve the 2024 Child/Adolescent Immunization Schedule and Adult Immunization schedule.
- The 2024 Schedules include nirsevimab, maternal RSV vaccine, mpox vaccine recommendations, PCV20 recommendations, updated COVID-19 vaccines, etc.

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32

Influenza Vaccines

- Safety findings:
  - The quadrivalent recombinant influenza vaccine is safe during pregnancy.
  - Simultaneous administration of mRNA COVID-19 and quadrivalent inactivated influenza vaccines: no safety concerns compared to sequential administration.
  - Simultaneous administration of zoster recombinant and quadrivalent inactivated influenza vaccines: no safety concerns.

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33

COVID/FLU VACCINE SAFETY – ICSHCEMIC STROKE

- A statistical signal for ischemic stroke after Pfizer-BioNTech bivalent mRNA COVID-19 vaccine was detected in CDC's Vaccine Safety Datalink (VSD) in persons aged ≥65 years during fall 2022.
- Available data do not provide clear and consistent evidence of a safety problem for ischemic stroke with bivalent mRNA COVID-19 vaccines when given alone or given simultaneously with influenza vaccines, or when influenza vaccine is given alone.

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34

COVID/FLU VACCINE SAFETY – ICSHCEMIC STROKE

- Looking at a VSD Rapid Cycle Analysis (RCA) and various safety studies from Kaiser, Medicare claims data, UK NHS data, additional international data, etc., there were variable and inconsistent results obtained in some analyses of risk of ischemic stroke following bivalent COVID-19 vaccination, simultaneous bivalent COVID-19 and influenza vaccination, and influenza vaccination alone.
- However, the most common findings across studies are findings of no association.

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35

COVID/FLU VACCINE SAFETY – ICSHCEMIC STROKE

- Available data do not provide clear and consistent evidence of a safety problem for ischemic stroke with bivalent mRNA COVID-19 vaccines when given alone or given simultaneously with influenza vaccines, or when influenza vaccine is given alone.
- Most study results have not shown an association between vaccination and ischemic stroke, and no clear pattern demonstrating increased risk has emerged.
- CDC will continue to conduct additional safety analysis and continue vigilant safety monitoring for the 2023-2024 COVID-19 vaccine.

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36

COVID-19 Vaccine

- Updated interchangeability:
  - In the following circumstances, an age-appropriate COVID-19 vaccine from a different manufacturer may be administered:
    - The same vaccine is not available at the vaccination site at the time of the visit.
    - Previous dose manufacturer unknown
    - The person would otherwise not receive a recommended vaccine dose.
    - The person started but is unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication.
- February ACIP Meeting: additional COVID-19 dose in older adults?

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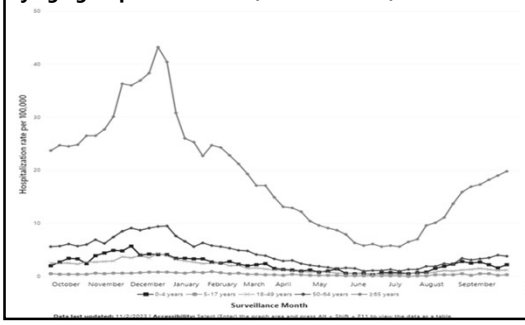
37

Weekly population-based rates of COVID-19 associated hospitalization by age group – COVID-NET, United States, October 2022-October 2023



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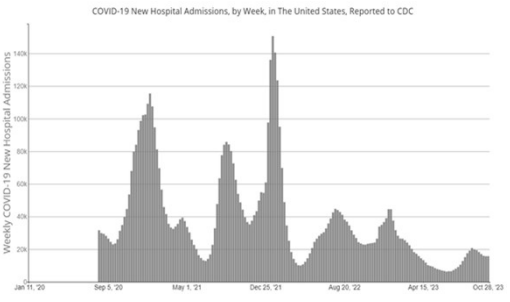
38

Weekly COVID-19 new hospital admissions – National Healthcare Safety Network (NHSN), United States, September 2022-October 2023



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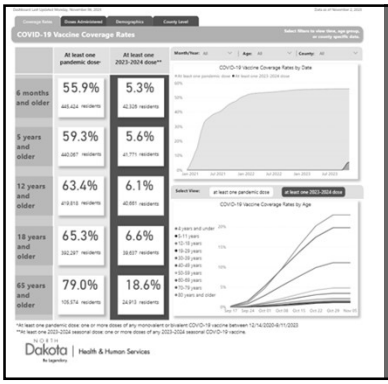
39



- **ND COVID-19 Immunization Rates**
  - **65 and older population at high-risk for complications**
  - **Anecdotal reports from parents having trouble finding pediatric vaccine**

40

Other Discussions

- RSV Vaccine for adults ages 50-59?
- Chikungunya Vaccine
  - Valneva vaccine could be licensed 4th quarter 2023
  - Possible recommendations for travelers, laboratory workers, outbreak response
- Dengue Vaccine – application for approval was pulled by manufacturer
- Pneumococcal Vaccine
  - PCV-21 (Merck) anticipated licensure in first half of 2024

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41

Nirsevimab – Trinity

42

BEYFORTUS ROLL OUT

Tiffany Smith

43

FIRST STEPS

- Focused on getting info to pediatricians to get them on board.
- All the providers were in agreement with going forward. As last years RSV season saw a lot of infants very sick and hospitalized.
- Made sure the Sanofi rep contacted our pharmacy buyer to get them the info they needed to have the meetings to go forward.
- Was in contact with the Sanofi rep to schedule a lunch with all of our pediatric staff.

44

STARTING THE PROCESS

- Ordered state vaccine first, before ordering was stopped
- Ordered what we could for private vaccine
- Got the info to all of our pediatric nurses on dosing and ICD-10 codes
- Communicated with our pharmacy to get our EMR ready to be able to add in our inventory of Beyfortus and have the caresets added

45

PREPARING TO START GIVING

- Once the caresets were available and we had state and private vaccine, we started offering it to patients
- Started offering at all newborn checks and any well checks for infants under 8 months.
- Made sure we had VIS printouts for all parents available.

46

47

THANK YOU

IF YOU HAVE QUESTIONS, YOU CAN EMAIL OR CALL ME

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701-857-3062

47

Post-Test

Post-Test

- Nurses interested in continuing education credit, visit https://ndhealth.co1.qualtrics.com/jfe/form/SV_7OpniIvWJy9IHHg
  Successfully complete the five-question post-test to receive your certificate
- Credit for this session will not expire until December 12, 2023.

- This presentation will be posted to our website: www.hhs.nd.gov/immunizations

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48

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49

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50