Protection Against RSV infection:

Pregnancy or Neonatal Protection Strategies

Katie Mahuron, RN, Vermont Department of Health
Benjamin Lee, MD, Pediatric Infectious Disease
Marjorie Meyer, MD, Maternal Fetal Medicine
Whittney Barkhuff, MD, Neonatology

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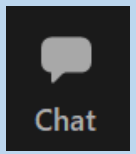

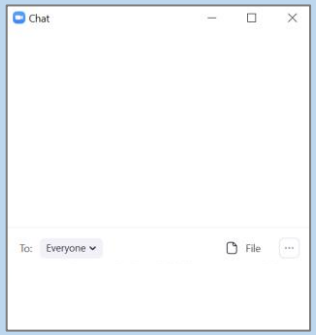

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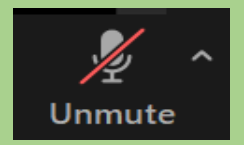

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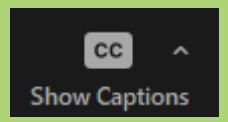

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Disclosures

- No disclosures

Collaborators

Objectives:

- Review RSV prevalence
  (*Benjamin Lee, MD, Pediatric Infectious Disease)*
- Review neonatal protection with newborn monoclonal antibody
  (*Benjamin Lee, MD, Pediatric Infectious Disease)*
- Review neonatal protection with maternal vaccine
  (Marjorie Meyer, MD, Maternal Fetal Medicine)
- Considerations around high-risk babies
  (Whittney Barkhuff, MD, Neonatology)
- Review Statewide Rollout & how to obtain both products for administration
  (Katie Mahuron, RN, Vermont Department of Health)

Avoid this

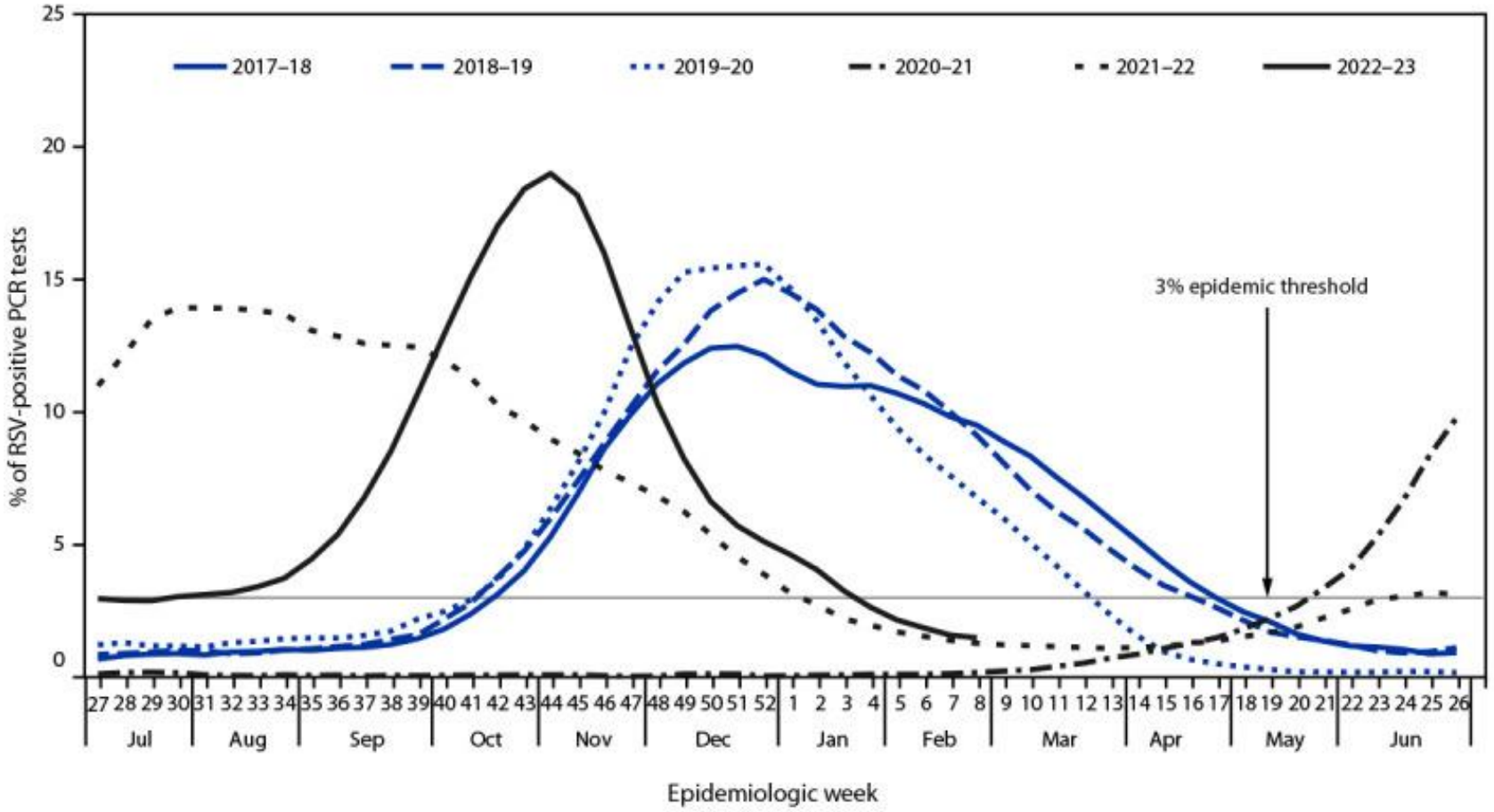
RSV treatment may prevent respiratory virus in babies

Visit ›

RSV burden and infant prevention

Benjamin Lee

RSV epidemiology: 5-year review



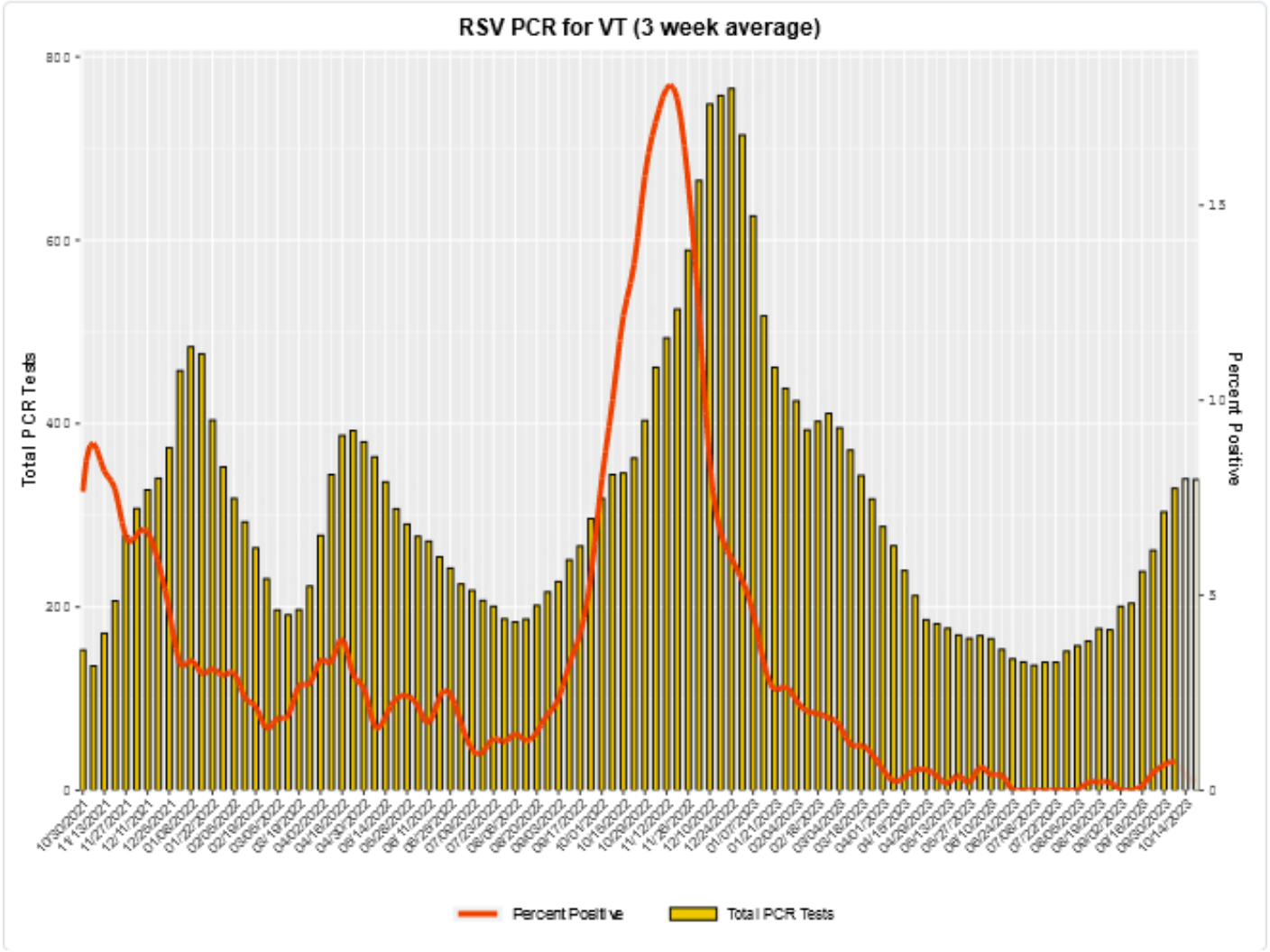
Hamid S, Winn A, Parikh R, Jones JM, McMorrow M, Prill MM, Silk BJ, Scobie HM, Hall AJ. Seasonality of Respiratory Syncytial Virus - United States, 2017-2023. MMWR Morb Mortal Wkly Rep. 2023 Apr 7;72(14):355-361. doi: 10.15585/mmwr.mm7214a1. PMID: 37022977; PMCID: PMC10078848.

RSV epidemiology: 5-year review

HHS region (headquarters) or state, RSV season	No. of laboratories reporting	No. of tests performed	Onset epidemiologic week[§] (mo)	Peak epidemiologic week[¶] (mo)	Offset epidemiologic week[**] (mo)	Epidemic duration, no. of wks[††]	% of annual detections in epidemic period[§§]
Region 1 (Boston)							
2017–18	9	38,902	44 (Nov)	52 (Dec)	17 (Apr)	26	97
2018–19	10	39,951	45 (Nov)	52 (Dec)	15 (Apr)	23	94
2019–20	12	53,441	44 (Nov)	52 (Dec)	12 (Mar)	21	96
2021–22	11	70,122	25 (Jun)	36 (Sep)	51 (Dec)	27	90
2022–23	10	184,128	35 (Sep)	44 (Nov)	50 (Dec)	16	81
Region 2 (New York City)							
2017–18	8	52,010	43 (Oct)	1 (Jan)	13 (Mar)	23	93
2018–19	9	62,066	44 (Nov)	51 (Dec)	13 (Mar)	22	89
2019–20	13	100,384	43 (Oct)	49 (Dec)	10 (Mar)	20	90
2021–22	9	186,986	30 (Jul)	39 (Oct)	50 (Dec)	21	78
2022–23	11	286,733	38 (Sep)	45 (Nov)	51 (Dec)	14	74

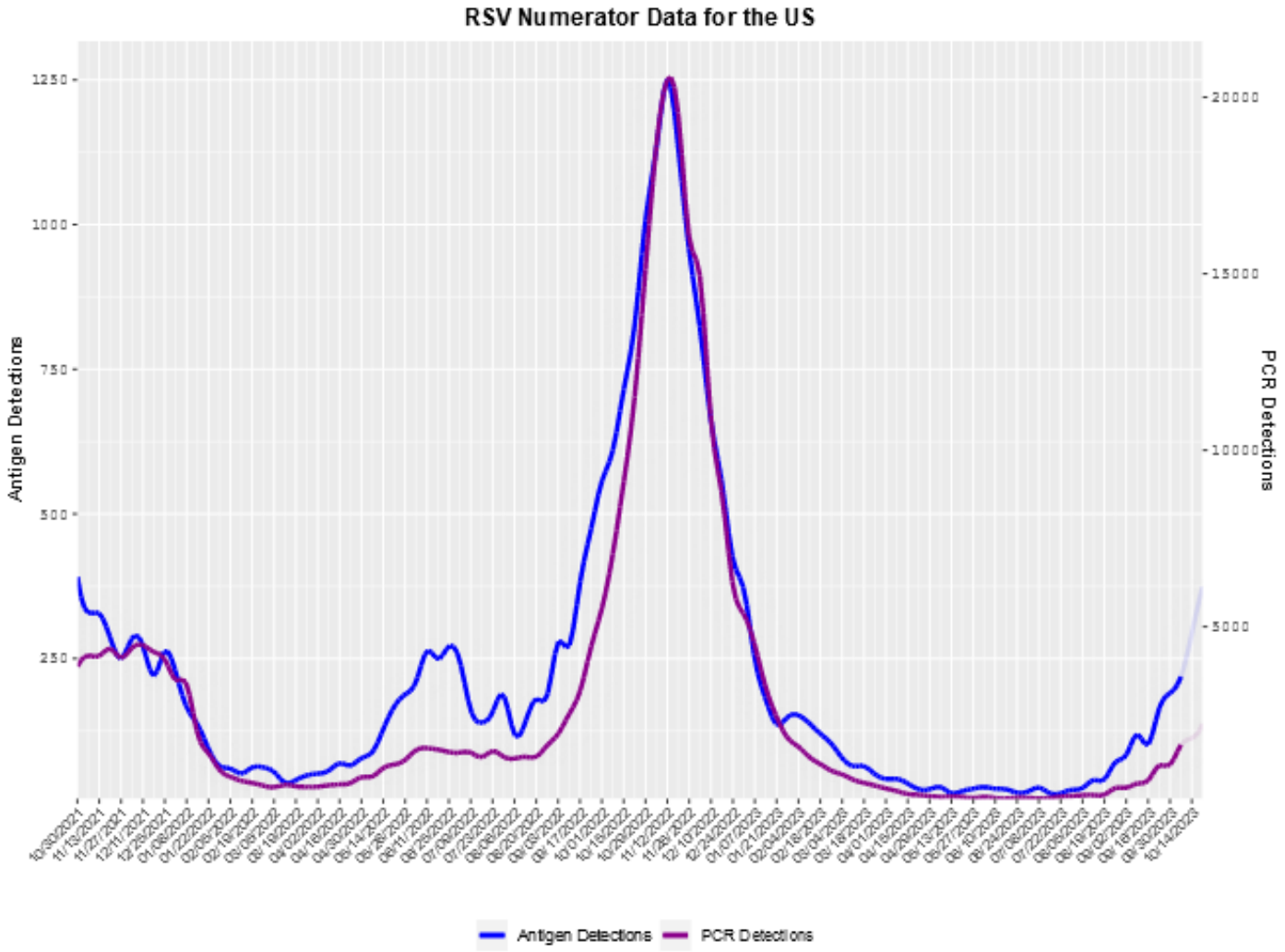
Hamid S, Winn A, Parikh R, Jones JM, McMorrow M, Prill MM, Silk BJ, Scobie HM, Hall AJ. Seasonality of Respiratory Syncytial Virus - United States, 2017-2023. MMWR Morb Mortal Wkly Rep. 2023 Apr 7;72(14):355-361. doi: 10.15585/mmwr.mm7214a1. PMID: 37022977; PMCID: PMC10078848.

RSV: Current trends, Vermont



https://www.cdc.gov/surveillance/nrevss/rsv/state.html#VT. Accessed online 30 Oct 2023.

RSV: Current trends, USA



https://www.cdc.gov/surveillance/nrevss/rsv/natl-trend.html. Accessed online 30 Oct 2023.

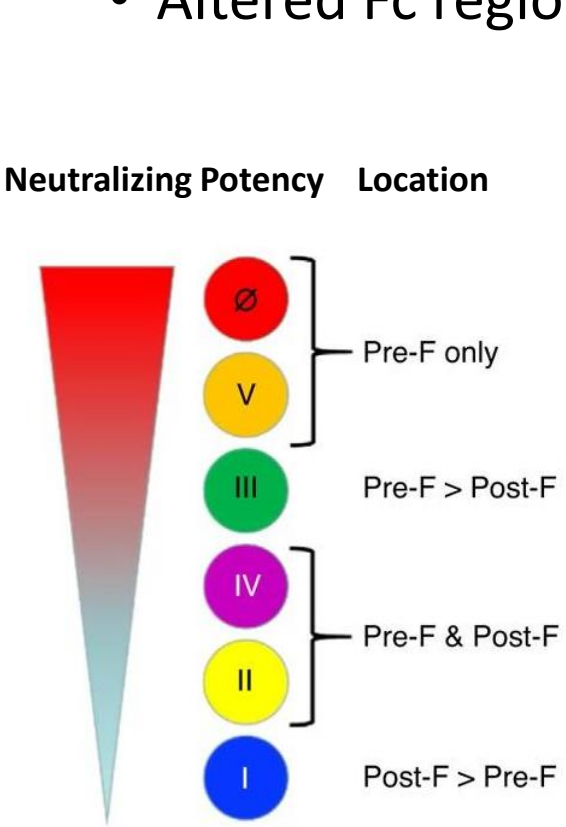
RSV: burden of illness

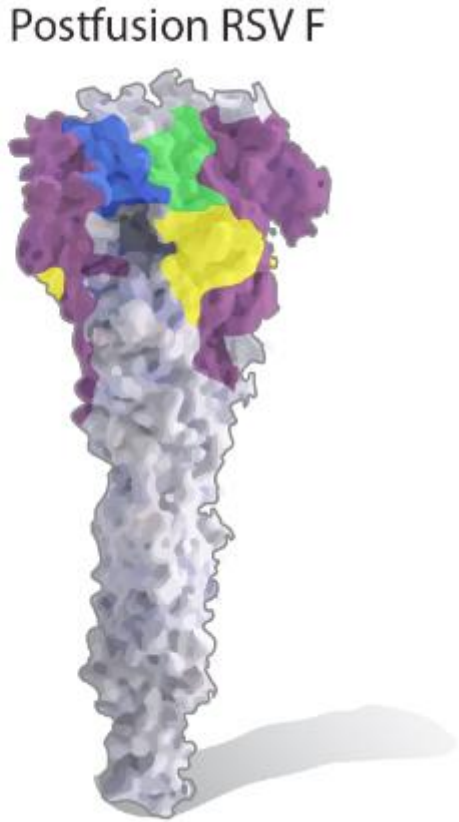
- 50,000-80,000 hospitalizations
- 100-300 deaths in children <5 years
- Leading cause of hospitalization among infants
  - 3X higher in preterm infants ≤30 weeks
  - Preterm infants with higher rates of ICU admission
- Only 5% of US infants eligible for palivizumab
  - High cost
  - Monthly dosing

Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR Morb Mortal Wkly Rep 2023;72:920–925. DOI: http://dx.doi.org/10.15585/mmwr.mm7234a4.

Nirsevimab (Beyfortus)

- Highly potent human monoclonal targeting pre-F
- Altered Fc region to extend half-life





Adapted from: Graham BS. Vaccine development for respiratory syncytial virus. Curr Opin Virol. 2017 Apr;23:107-112. doi: 10.1016/j.coviro.2017.03.012. Epub 2017 May 16. PMID: 28525878; PMCID: PMC5653266.

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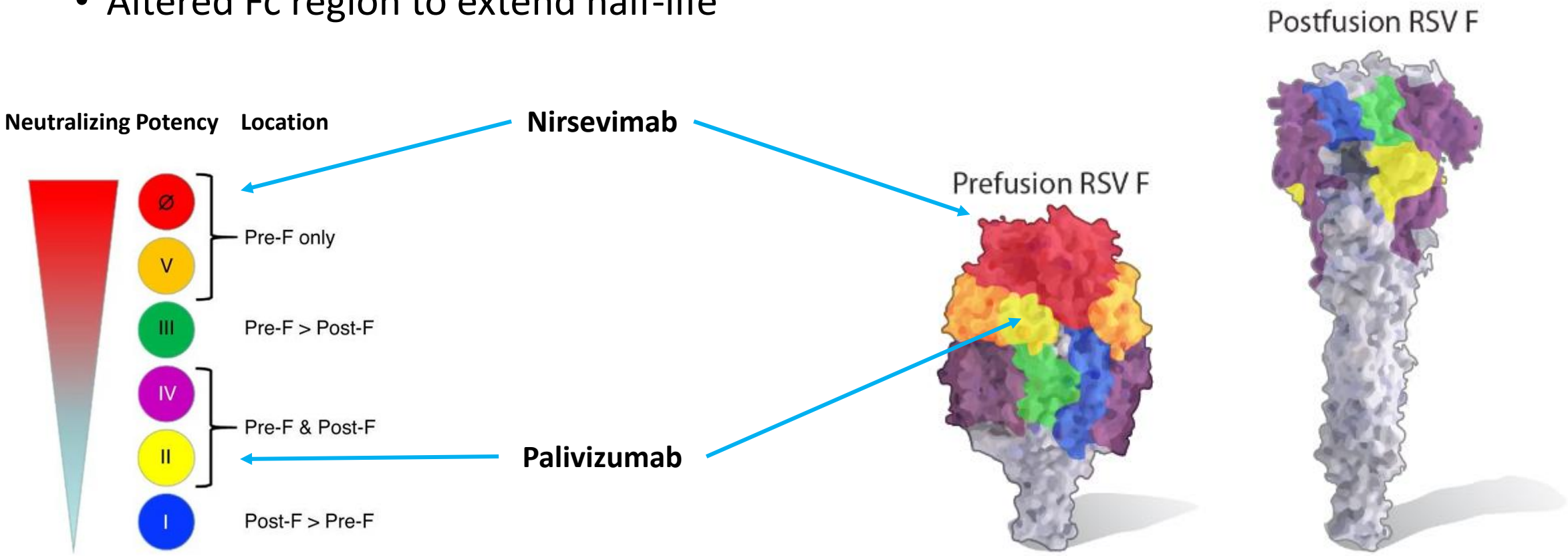
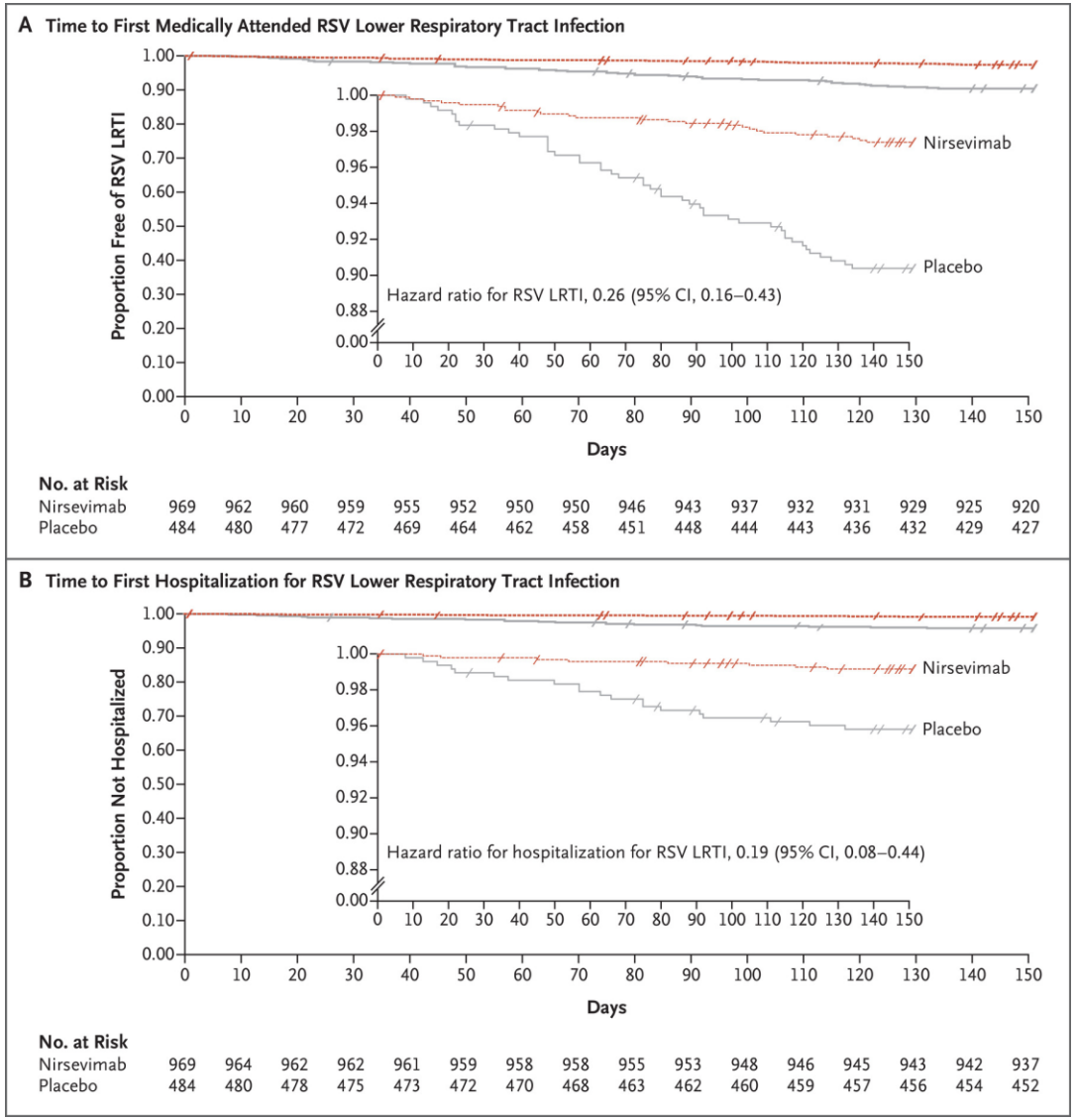


Adapted from: Graham BS. Vaccine development for respiratory syncytial virus. Curr Opin Virol. 2017 Apr;23:107-112. doi: 10.1016/j.coviro.2017.03.012. Epub 2017 May 16. PMID: 28525878; PMCID: PMC5653266.

Efficacy in preterm infants



Griffin MP, Yuan Y, Takas T, et al. Single-Dose Nirsevimab for Prevention of RSV in Preterm Infants. *New England Journal of Medicine*. 2020/07/30 2020;383(5):415-425. doi:10.1056/NEJMoa1913556

Efficacy: MELODY trial, late preterm and term

End Point	Placebo (N=1003)	Nirsevimab (N=2009)	Efficacy (95% CI)
	no. of participants with event (%)		
Medically attended RSV-associated LRTI	54 (5.4)	24 (1.2)	76.4 (62.3–85.2)
Hospitalization for RSV-associated LRTI	20 (2.0)	9 (0.4)	76.8 (49.4–89.4)
Very severe medically attended RSV-associated LRTI	17 (1.7)	7 (0.3)	78.6 (48.8–91.0)

Muller WJ, Madhi SA, Seoane Nuñez B, et al. Nirsevimab for Prevention of RSV in Term and Late-Preterm Infants. *New England Journal of Medicine*. 2023/04/20 2023;388(16):1533-1534. doi:10.1056/NEJMc2214773

Evidence summary

	Trial 03	Trial 04 (MELODY)	Pooled
Phase	2b	3	
Population	Preterm infants (29 – 34 6/7 weeks) entering first RSV season	Healthy infants ≥35 weeks entering first RSV season	Trial 03 + 04
Comparator	Placebo	Placebo	
Sample size			
Nirsevimab	969	1998	2579
Placebo/palivizumab	484	996	1293
Efficacy through day 150			
Medically-attended RSV LRTI	**70.1%** (95% CI, 52.3%-81.2%)	**76.4%** (95% CI, 62.3%-85.2%)	**79.0%** (95% CI, 68.5%-86.1%)
RSV-associated hospitalization	**78.4%** (95% CI, 51.9%-90.3%)	**76.8%** (95% CI, 49.4%-89.4%)	**80.6%** (95% CI, 62.3%-90.1%)
Comments	All children received 50 mg	100 mg for wt ≥ 5 kg	Only included those who received appropriate weight-based dose
Reference	1	2	3

1. Griffin MP, Yuan Y, Takas T, et al. Single-Dose Nirsevimab for Prevention of RSV in Preterm Infants. *New England Journal of Medicine*. 2020/07/30 2020;383(5):415-425. doi:10.1056/NEJMoa1913556
2. Muller WJ, Madhi SA, Seoane Nuñez B, et al. Nirsevimab for Prevention of RSV in Term and Late-Preterm Infants. *New England Journal of Medicine*. 2023/04/20 2023;388(16):1533-1534. doi:10.1056/NEJMc2214773
3. Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR Morb Mortal Wkly Rep 2023;72:920–925. DOI: http://dx.doi.org/10.15585/mmwr.mm7234a4
4. Domachowske J, Madhi SA, Simões EAF, et al. Safety of Nirsevimab for RSV in Infants with Heart or Lung Disease or Prematurity. *New England Journal of Medicine*. 2022/03/03 2022;386(9):892-894. doi:10.1056/NEJMc2112186

Evidence summary

	Trial 03	Trial 04 (MELODY)	Pooled	Trial 05 (MEDLEY)
Phase	2b	3		2/3
Population	Preterm infants (29 – 34 6/7 weeks) entering first RSV season	Healthy infants ≥35 weeks entering first RSV season	Trial 03 + 04	Preterm infants <35 weeks; children <24 months with CHD-CLD
Comparator	Placebo	Placebo		Palivizumab
Sample size				
Nirsevimab	969	1998	2579	406 preterm, 208 CHD-CLD
Placebo/palivizumab	484	996	1293	206 preterm, 98 CHD-CLD
Efficacy through day 150				
Medically-attended RSV LRTI	**70.1%** (95% CI, 52.3%-81.2%)	**76.4%** (95% CI, 62.3%-85.2%)	**79.0%** (95% CI, 68.5%-86.1%)	
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Comments	All children received 50 mg	100 mg for wt ≥ 5 kg	Only included those who received appropriate weight-based dose	Primarily for safety PK demonstrated similar antibody levels as in MELODY
Reference	1	2	3	4

1. Griffin MP, Yuan Y, Takas T, et al. Single-Dose Nirsevimab for Prevention of RSV in Preterm Infants. *New England Journal of Medicine*. 2020/07/30 2020;383(5):415-425. doi:10.1056/NEJMoa1913556
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HARMONIE phase 3b

- France, UK, Germany Aug 2022-June 2024
- Infants ≥ 29 weeks entering first RSV season aged 0-12 months
- Primary efficacy analysis after 2022-23 RSV season
  - RSV hospitalization 83% (95% CI 68%-92%)
  - Severe disease (Sa02<90% and oxygen given) 76% (95% CI 33-93%)

https://www.astrazeneca.com/media-centre/medical-releases/new-beyfortus-data-reinforce-efficacy-against-infant-rsv-hospitalisations.html.
Published 12 May 2023. Accessed online 10/30/23.

RSV Vaccine: Pregnancy or Neonatal Protection Strategies

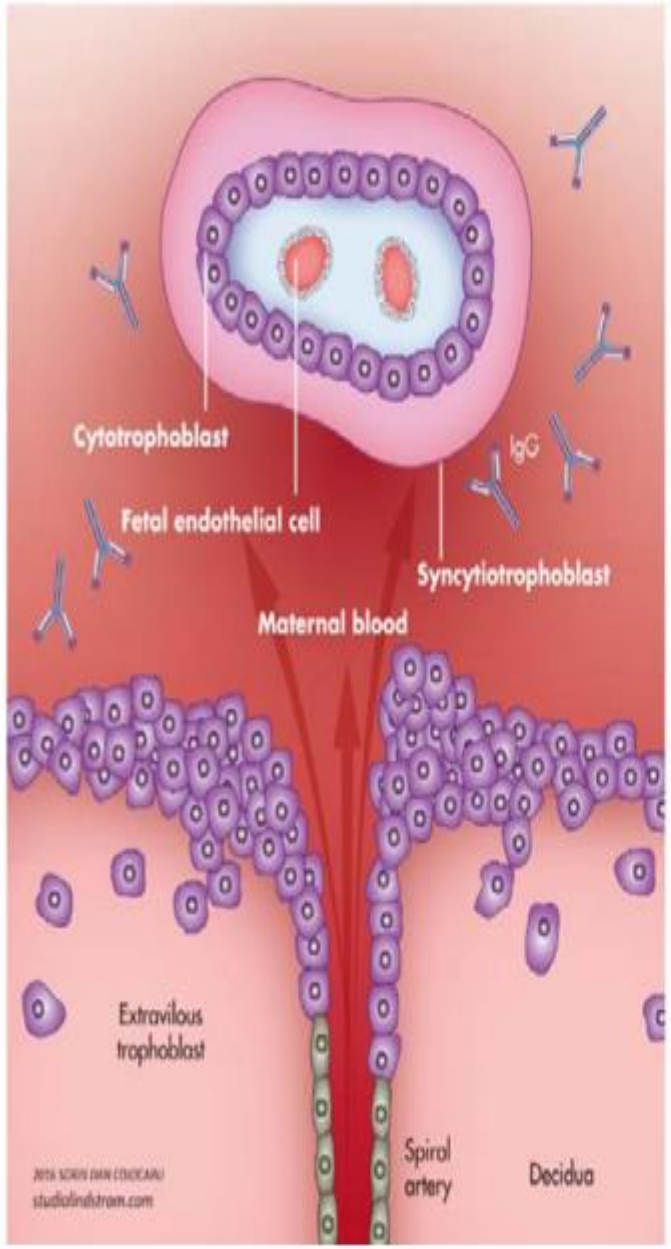
Marjorie Meyer MD, Maternal Fetal Medicine

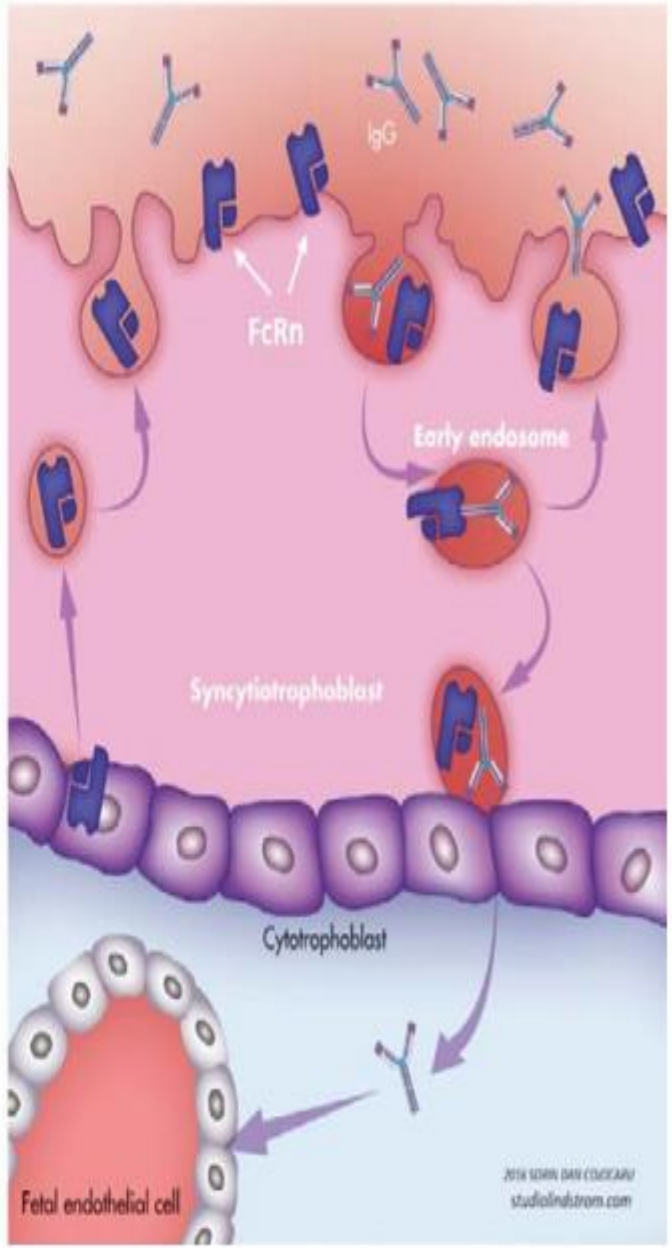
<u>Protection:</u>

Provide neonates with antibodies to RSV

(1) Giving monoclonal antibody after birth (Nirsevimab, Beyfortus)

(2) Give pregnant person a vaccine which boosts production of IgG antibodies that cross the placenta to the neonate in the third trimester (same model of TDaP for pertussis) (Abrysvo)





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(1) Giving monoclonal antibody after birth (Nirsevimab, Beyfortus)

(2) Give pregnant person a vaccine which boosts production of IgG antibodies that cross the placenta to the neonate in the third trimester (same model of TDaP for pertussis)

(3) Note: not a high prevalence (2% neonates severe RSV)

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 20, 2023 VOL. 388 NO. 16

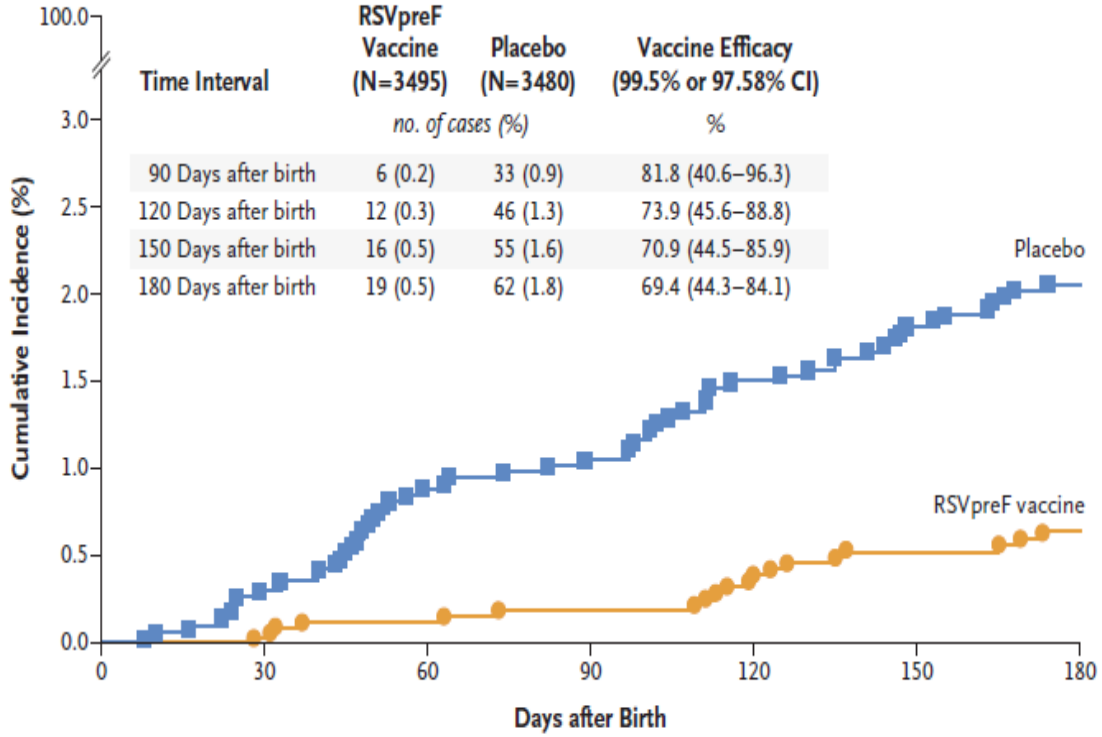
Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants

B. Kampmann, S.A. Madhi, I. Munjal, E.A.F. Simões, B.A. Pahud, C. Llapur, J. Baker, G. Pérez Marc, D. Radley, E. Shittu, J. Glanternik, H. Snaggs, J. Baber, P. Zachariah, S.L. Barnabas, M. Fausett, T. Adam, N. Perreras, M.A. Van Houten, A. Kantele, L.-M. Huang, L.J. Bont, T. Otsuki, S.L. Vargas, J. Gullam, B. Tapiero, R.T. Stein, F.P. Polack, H.J. Zar, N.B. Staerke, M. Duron Padilla, P.C. Richmond, K. Koury, K. Schneider, E.V. Kalinina, D. Cooper, K.U. Jansen, A.S. Anderson, K.A. Swanson, W.C. Gruber, and A. Gurtman, for the MATISSE Study Group*

- Medically attended severe lower respiratory tract illness occurred within 90 days after birth:
  - 6/3682 pts that received vaccine
  - 33/3676 pts that received placebo (vaccine efficacy, 81.8%; 99.5% CI, 40.6 to 96.3);
- 19 cases and 62 cases, respectively, occurred within 180 days after birth (vaccine efficacy, 69.4%; 97.58% CI, 44.3 to 84.1).

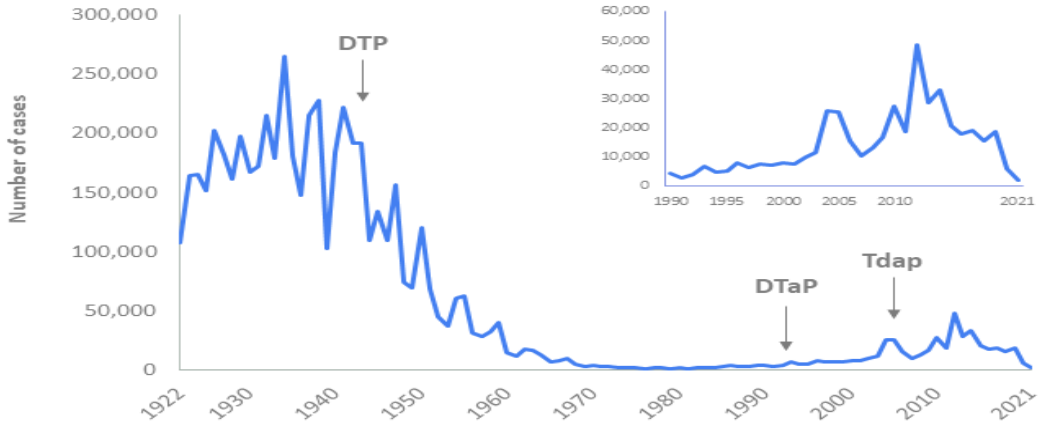
A Medically Attended Severe RSV-Associated Lower Respiratory Tract Illness

Time Interval	RSVpreF Vaccine (N=3495)	Placebo (N=3480)	Vaccine Efficacy (99.5% or 97.58% CI)
	no. of cases (%)		%
90 Days after birth	6 (0.2)	33 (0.9)	81.8 (40.6–96.3)
120 Days after birth	12 (0.3)	46 (1.3)	73.9 (45.6–88.8)
150 Days after birth	16 (0.5)	55 (1.6)	70.9 (44.5–85.9)
180 Days after birth	19 (0.5)	62 (1.8)	69.4 (44.3–84.1)



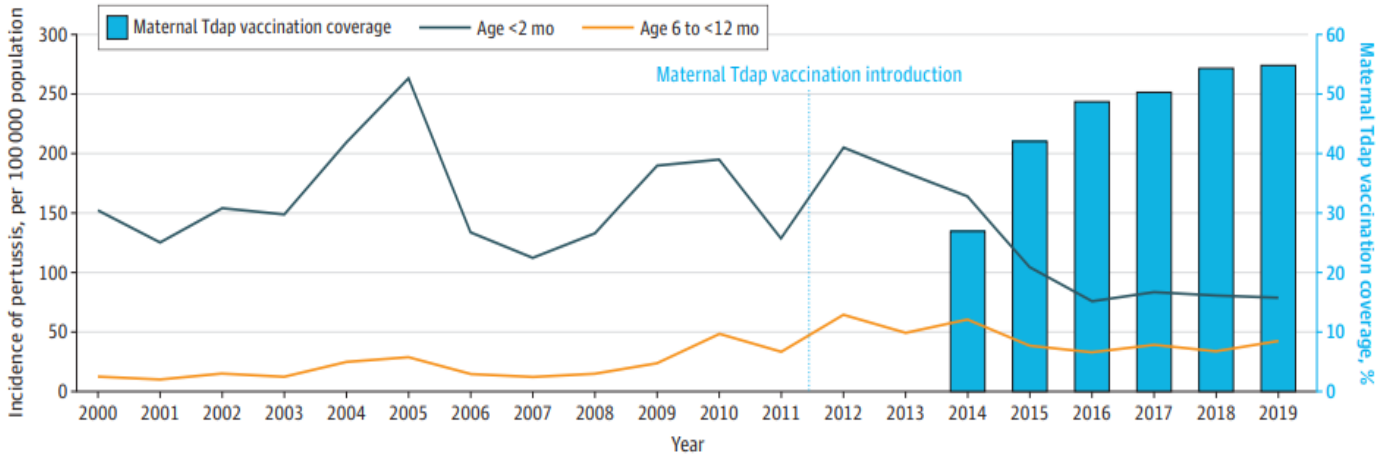
No. at Risk							
Placebo	3480	3292	2973	2899	2833	2776	2749
RSVpreF vaccine	3495	3349	3042	2981	2916	2867	2820

Reported NNDSS pertussis cases: 1922-2021



Pertussis vaccine works

Figure 1. Annual Incidence of Reported Pertussis Among Infants Younger Than 2 Months and Infants Aged 6 Months to Less Than 12 Months, 2000-2019



Maternal tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccination during pregnancy was introduced in the US in 2011. National coverage estimates of maternal Tdap vaccination for available years (beginning in 2014) were obtained through the Centers for Disease Control and Prevention's internet panel survey.[12,20-22] Changes in the internet panel survey methods may limit the ability to compare estimates for 2017 to 2018 with estimates from previous seasons.

Pertussis incidence among infants younger than 2 months declined following maternal Tdap vaccination introduction; no similar decrease occurred among infants aged 6 months to less than 12 months.

(NNT: 1000 (low disease prevalence in US but can be high other countries)

ABRYSVO vs Beyfortus for infant protection against respiratory syncytial virus (RSV) infection

ABRYSVO (Mother)

What is ABRYSVO?

- **A vaccine** for pregnant women given to protect their newborns from RSV infection
- Given ONCE at 32-36 weeks to women delivering shortly before or during RSV season (~Oct-Mar)

How well does it work?

- In babies whose mothers were vaccinated at 32-36 weeks, it was **77% effective** at preventing severe medically attended RSV through 6 months of life

How safe is the vaccine?

- In clinical trials where vaccination started at 24 weeks, slightly more vaccinated mothers experienced preterm birth or pre-eclampsia. This difference was not statistically significant but will receive further evaluation after licensure. Vaccinating at 32-36 weeks reduces these risks

Advantages of ABRYSVO

- Newborn protection is immediate from birth
- Reduces the number of shots for infants

Disadvantages of ABRYSVO

- Potential for very small increased risk to mother and fetus related to preterm birth
- Duration of protection is likely only ~3 months

Other comments

- Also approved for adults ≥ 60
- The only RSV vaccine approved during pregnancy
- If ABRYSVO is given, with rare exceptions, your baby will not be eligible for Beyfortus

Beyfortus (nirsevimab) (Baby)

What is Beyfortus?

- A **monoclonal antibody** given to newborns and infants to protect against RSV infection
- Given ONCE to any infant <8 months of age entering or born during their first RSV season (~Oct-Mar), ideally at <1 week of life for newborns
- Certain high-risk children 8-19 months also eligible

How well does it work?

- The shot was **81% effective** at preventing RSV-associated hospitalization for the 5 months following injection in babies <8 months old

How safe is the shot?

- In clinical trial, the rate of adverse events was similar in children receiving Beyfortus and those receiving a placebo

Advantages of Beyfortus

- It is arguably slightly more effective than ABRYSVO
- The duration of protection is ~5 months; 1-2 months longer compared to ABRYSVO
- There are arguably fewer concerns about safety

Disadvantages of Beyfortus

- It is an additional injection for your baby
- Depending on where you deliver, it may not be available in the newborn nursery,

Other comments

- There is another monoclonal antibody (Synagis) that is also approved, but only for certain high-risk premature infants and requires monthly injection
- With rare exceptions, babies whose mothers who received ABRYSVO will not be eligible for Beyfortus

Which is best for me?

There are advantages and disadvantages to each product, and earlier in the season, product availability may be a limiting factor. This is an individualized decision that should be made after discussion with your family, your doctor, and other people you trust.

Fleming-Dutra KE, Jones JM, Roper LE, et al. 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 Morb Mortal Wkly Rep 2023;72:1115–1122. DOI: http://dx.doi.org/10.15585/mmwr.mm7241e1

Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR Morb Mortal Wkly Rep 2023;72:920–925. DOI: http://dx.doi.org/10.15585/mmwr.mm7235e1

Infant protection against respiratory syncytial virus (RSV) infection:
A vaccine for pregnant patients vs an antibody shot for newborns

Pregnant person vaccine (ABRYSVO)

- Given at 32-36 weeks
- 77% effective against more severe cases of RSV
- Protects for about 3 months

Benefits:

- No newborn injection

Downsides:

- Slightly less effective
- Slightly shorter protection
- Some trials have higher risk of premature delivery (less than 37 weeks)

Newborn antibody shot (Beyfortus)

- Given in first week of life (newborn office visit)
- 81% effective against infant hospitalization due to RSV
- Protects for about 5 months

Benefits:

- Maybe slightly more effective and longer protection

Downsides:

- Newborn injection required before 1 week

The baby can receive one method of protection but not both
The pregnant patient can choose (based on product availability)

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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

Print

HAN HEALTH ALERT NETWORK

This is an official CDC HEALTH ADVISORY

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.

Considerations around high-risk babies

- Nirsevimab is recommended for all infants younger than 8 months of age who are born during or who are entering their first RSV season (unless their mother was vaccinated during pregnancy)

- Recommended for some children age 8 – 19 months who are at increased risk for severe RSV disease and entering their second RSV season

https://www.cdc.gov/vaccines/vpd/rsv/public/child.html

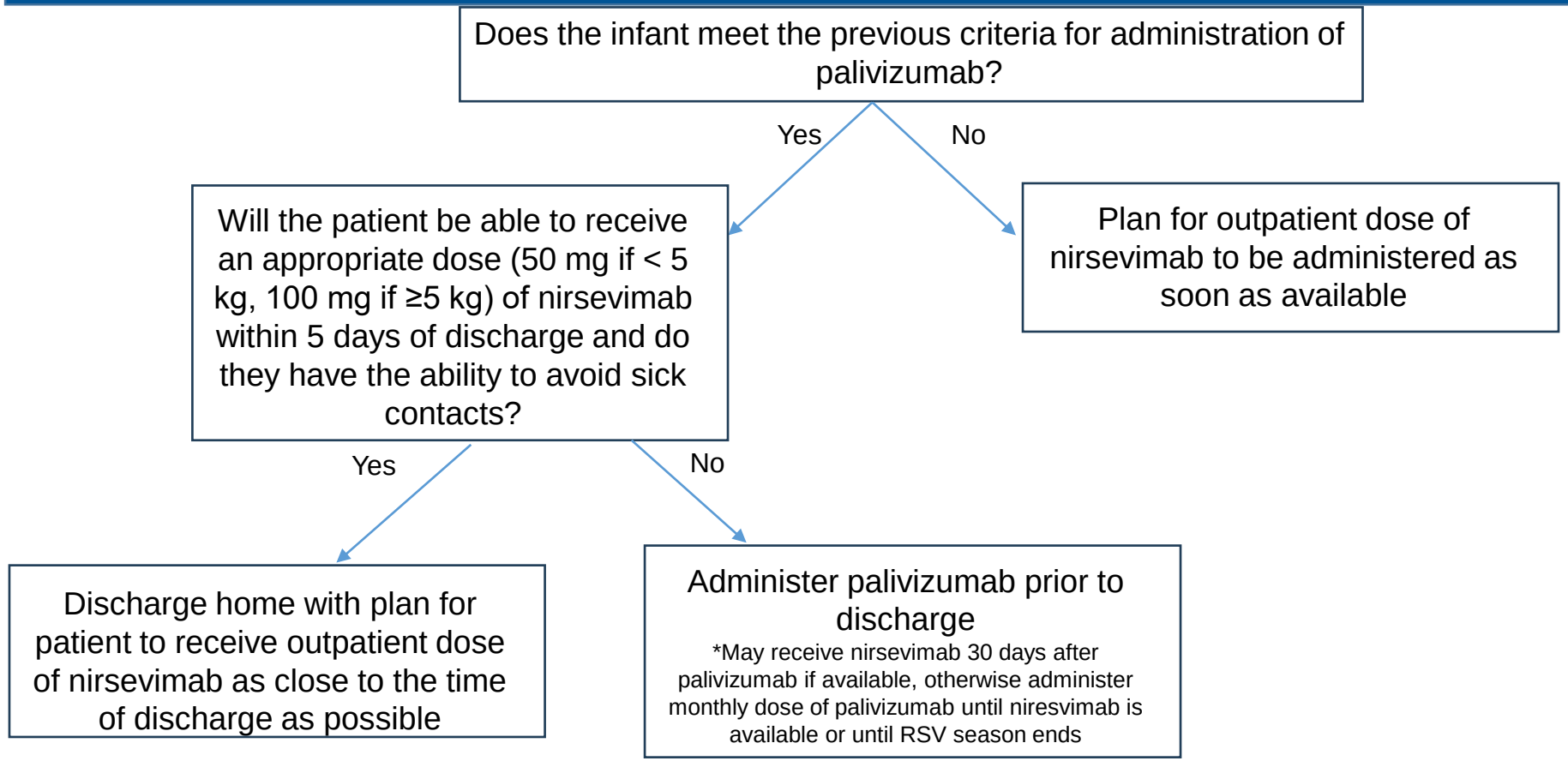
Are we done giving palivizumab (Synagis)?

- Guidance from the AAP for the use of palivizumab prophylaxis against RSV first published in a policy statement in 1998
- AAP recommendations updated to reflect the most recent literature regarding children at greatest risk of severe RSV disease
  - Born ≤ 29 weeks GA
  - Born 29 - 32 weeks GA with additional risk factors
  - Congenital heart disease (unrepaired, hemodynamically significant)
  - Severe immunosuppression, neuromuscular disease, pulmonary disease, Down syndrome
- First dose often administered prior to discharge from the NICU during RSV season

Not yet….

- Nirsevimab shortages – not yet available in UVMMC inpatient units
- Maternal vaccine not yet widely available/being administered

Palivizumab or nirsevimab workflow for high-risk (previously palivizumab-eligible) infants being discharged from the UVMMC NICU/NTS during the 2023-2024 RSV season

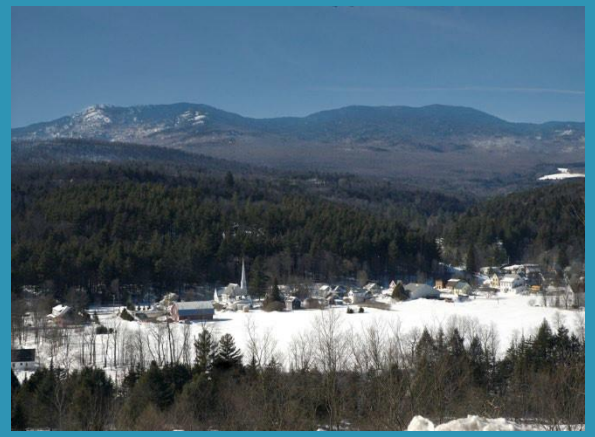


Updated recommendations

- For infants weighing 5 kg and born before October 2023, administer a 50 mg dose of nirsevimab (how prioritize these doses?)
- For infants weighing ≥ 5 kg, prioritize using 100 mg nirsevimab doses in infants at highest risk of severe RSV disease:
  - Infants < 6 months of age
  - American Indian and Alaska Native infants aged < 8 months
  - Infants aged 6 to < 8 months with conditions that put them at the highest risk of severe RSV disease
- In palivizumab-eligible infants aged 8 – 19 months, suspend using nirsevimab for the 2023-2024 RSV season and give palivizumab per AAP recommendations

Summary and future directions

- Will continue to administer palivizumab to eligible infants until adequate supply of nirsevimab
- Plan to communicate with PCP's prior to discharge to determine whether nirsevimab is available to be given or not
- If there is any doubt, palivizumab will be administered
- Working on VFC enrollment – timing unclear
- Providing information to families re: nirsevimab
- Waiting for supply of 50 mg and 100 mg doses to improve



RSV Products

November 1, 2023

Katie Mahuron, RN – *Adult Coordinator*

VERMONT
DEPARTMENT OF HEALTH

Agenda

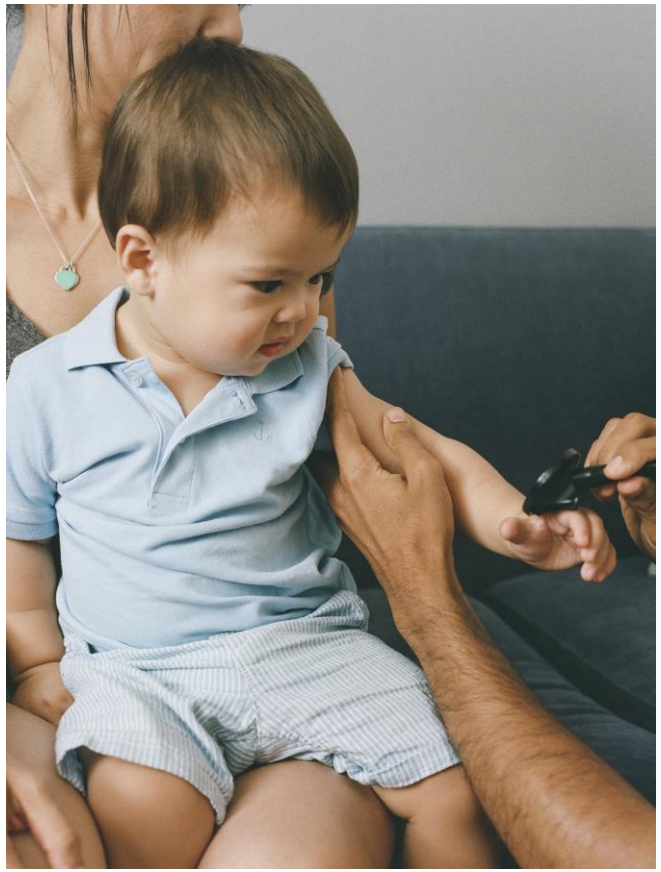
- Vermont Vaccine Program
- Enrollment into Vermont Vaccine Program
- RSV Monoclonal Antibody for Infants
- RSV Vaccine for Pregnant Individuals

Contact Information

- Ordering, vaccine storage and handling, vaccine-specific information: AHS.VDHImmunizationProgram@vermont.gov
- Immunization registry and reporting questions: IMR@vermont.gov
- Merideth Plumpton – Immunization Program Manager Merideth.Plumpton@vermont.gov
- Katie Mahuron – Adult Immunization Coordinator Katie.Mahuron@vermont.gov

Vermont Vaccine Program

Vermont Vaccine Program



Vaccines for Children (VFC) is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay.

Vaccines for Adults (VFA) is a Vermont run program that serves all Vermonters aged 19-64.

All birthing hospitals are eligible to enroll in VFC.

All OBGYN offices are eligible to enroll in VFC and VFA.

Vermont Vaccine Program

Vermont is a universal vaccine state

Vermont Vaccine Purchasing Program (VVPP) collects funding from health insurers. Insurer funding is combined with federal funding to support the purchase of vaccines from the CDC federal contract at the lowest price.

As a result, funding from insurers and other payers, the VVPP makes it possible for:

- Health care providers to receive state-supplied vaccines at no charge
- Children to have easy access to all recommended vaccines
- Adults (19 to 64 years**) to have access to all recommended vaccines through their health care provider
- All payers to participate in an efficient, cost-effective system for purchasing and distributing vaccines.

**we are unable to include people ages 65+ because Medicare does not pay into VVPP

Enrollment in Vermont Vaccine Program

Enrollment Requirements

Requirements for join one or both of our Vaccine Programs

1. Medical Director with prescribing authority
2. Two vaccine contacts that work at this practice (do not need any license or specific titles) to be the liaison of the program and manage the vaccine.
3. Must be willing to use the state-temperature monitoring devices for the vaccine units.
4. Be able to report all immunization to the IMR within 7 days (Immunization Documentation Guidance (healthvermont.gov))

For more in-depth requirements provider agreement located on page 3 of the VCVP.VAVP Vermont Provider Agreement_2022.2024.pdf (healthvermont.gov)

To get more information or start the process reach out to Samantha Metcalf the VFC Coordinator at Samantha.Metcalf@vermont.gov

RSV Monoclonal Antibody for Infants

Immunization Program's Plan for Nirsevimab

- Available as part of the VFC Program
  - All enrolled PCP offices will be able to order
- Information going out in Provider Updates

- IZ Program is reaching out to Birthing Hospitals
  - SVMC, Gifford, Rutland, Brattleboro & NMC are already enrolled
  - UVMMC is in final stages of enrollment for NICU and Obstetrics Unit
  - Porter, NVRH exploring enrollment
  - Waiting to hear back from all others

Beyfortus (Nirsevimab)

- Available in a 50 mg/0.5mL and 100 mg/mL pre-filled syringe
  - 2nd RSV season: single 200 mg dose administered as 2 IM injections
- Considerations when ordering:
  - Number of younger infants weighing less than 5 kg
  - Number of increased risk kids needing 2 of the 100 mg
  - Awareness of birthing hospital plans and OB/GYN plans for Abrysvo administration
  - Ordered in multiples of 5 (each box contains 5 doses)

Recommended Dose of BEYFORTUS in Infants Aged <8 months Born During or Entering Their 1st RSV Season	
Body Weight at Time of Dosing	**Recommended Dosage**
Less than 5 kg	50 mg by IM injection
5 kg and greater	100 mg by IM injection

Recommended Dose of BEYFORTUS in Children 8-19 Months at Increased Risk of Severe RSV Disease Entering Their 2nd RSV Season	
Recommended Dosage	200 mg by IM injection

Beyfortus (Nirsevimab) Ordering

- Ordering opening 10/10 for birthing hospitals and 10/11 for providers
  - No birthing hospitals were prepared to administer
- Ordering paused by CDC as of 10/13
  - Orders submitted prior to 10/13 were placed on backorder
  - Orders placed on 10/13 were cancelled by CDC
  - Several large pediatric offices were left without any supply

- Submitted orders started arriving week of 10/16
  - Immunization Program reached out to providers asking them to hold administration (except for high-risk children) until we could determine if we would need to reallocate doses

Reallocation of Nirsevimab

- Immunization Program worked with data analyst team to review data including
  - who ordered
  - ordered quantities
  - Immunization Registry (IMR) information regarding patient population

- Nirsevimab was picked up and redistributed week of 10/23
  - Limited doses were placed at District Offices throughout state to be transferred to providers who did not receive any supply

- Supply remains inadequate and providers must make challenging decisions on how to prioritize patient panel
  - Approximately 1,300 doses in state

CDC HAN Recommendations

CDC HAN

Recommendations:

1. Infants <5kg, ACIP recommendations unchanged.
    - Infants born before October 2023, administer a 50mg dose of nirsevimab now.
    - Infants born during October 2023 and throughout RSV season, administer 50 mg dose of nirsevimab in first week of life.
2. Infants >5kg, prioritize using 100mg nirsevimab doses in infants at highest risk of severe RSV disease:
    - Young infants aged <6 months
    - American Indian & Alaska Native infants aged <8 months
    - Infants aged 6 to <8 months with conditions that place them at high risk of severe RSV disease: premature birth at <29 weeks' gestation, chronic lung disease of prematurity, hemodynamically significant congential heart disease, severe immunocompromise, severe cystic fibrosis (either manifestations of severe lung disease or weight-for-length less than 10th percentile), neuromuscular disease or congenital pulmonary abnormalities that impair the ability to clear secretions

CDC HAN Recommendations Continued

CDC HAN

Recommendations:

3. Suspend use of nirsevimab in palivizumab-eligible children aged 8-19 months for 2023- 2024 RSV season

4. Continue to offer to American Indian and Alaska Native children who are not palivizumab-eligible

5. For palivizumab-eligible infants aged <8 months, when nirsevimab is unavailable follow AAP recommendations.

6. Avoid using two 50mg doses for infants weighing >5 kg

7. Providers should encourage pregnant people to receive RSVpreF vaccine (Abrysvo).

8. Either RSVpreF vaccination during pregnancy or nirsevimab immunization for infants is recommended, but administration of both products is not needed in most cases.

Nirsevimab: What's Next?

- CDC has stated some jurisdictions did not place any orders or placed very limited orders and those jurisdictions will be prioritized as ordering resumes
  - Will be under allocation when ordering resumes
  - Additional product will be made available to CDC every 2 to 3 weeks and they will determine when VT is approved to order again

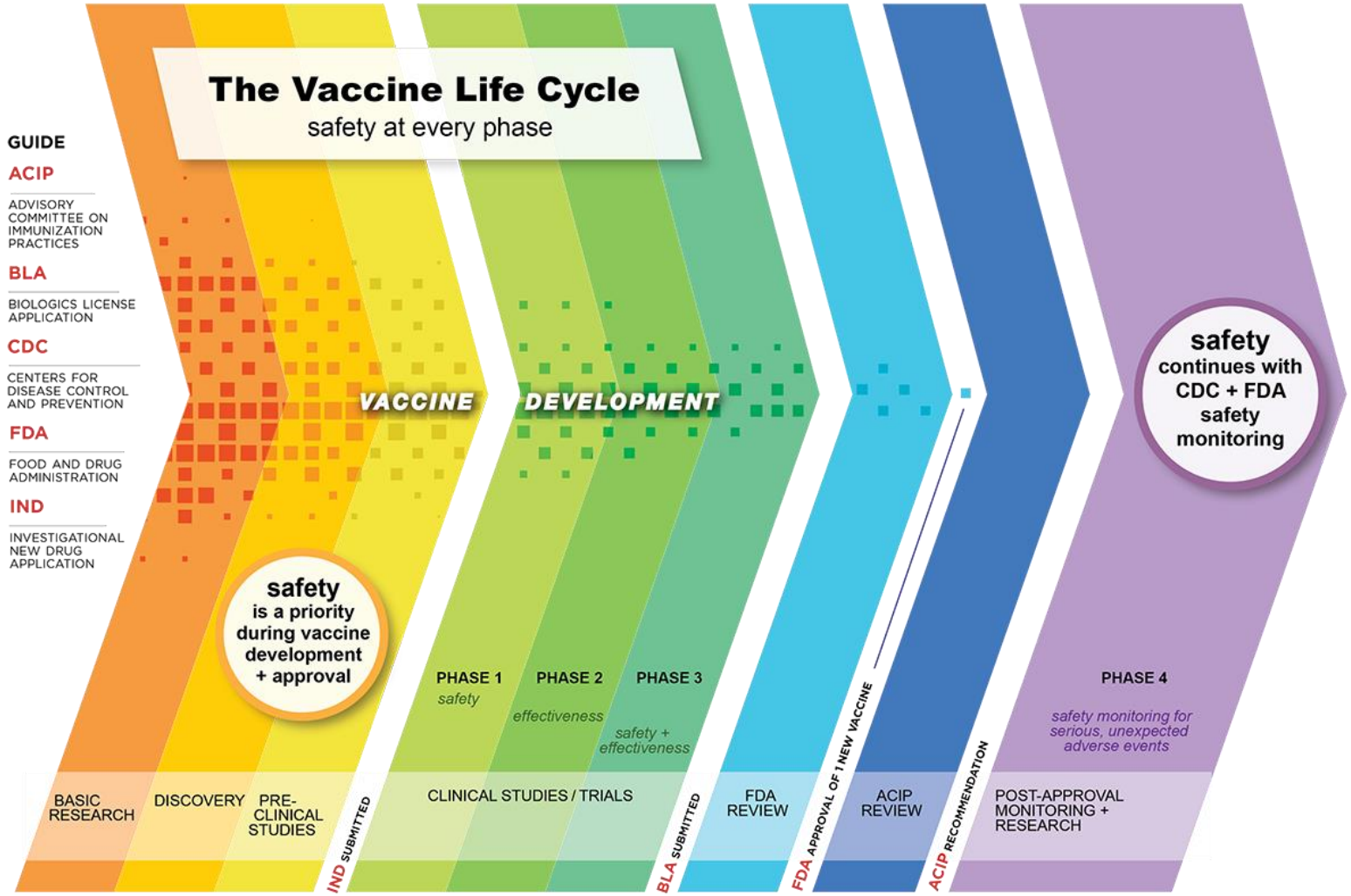
- When ordering reopens, goal is to prioritize birthing hospitals that are prepared to administer for 50 mg dose

- Sanofi has indicated that for private supply orders are backordered until December or January

- CDC and Sanofi have indicated there is less availability for 100 mg dose

RSV Vaccine for Pregnant Individuals

Vaccine Approval Process



- CDC Director reviews ACIP recommendation and makes an official recommendation
  - Recommendation becomes official CDC public health guidance for safe use of the vaccine in the United States.
- Published in CDC's MMWR
  - Offers additional clinical guidance
- **CDC makes vaccine available on CDC contracts for VDH Immunization Program to purchase and distribute**

Immunization Program's Plan for Abrysvo

- Once available on CDC contract will be available to order for enrolled VFC/VFA providers.
- Immunization Program is conducting outreach to OB/GYNs to assess interest in enrolling VFC/VFA.
- Currently enrolled OB/GYNs include:
  - NMC OB/GYN
  - SVMC – Womens & Childrens Services
  - Art of Birth Midwifery
  - North Country OB/GYN
  - Gifford Medical Center OB/GYN & Midwifery
  - UVMHN Porter Women's Health
  - SVMC OB/GYN
  - Women's Wellness Center
  - Rutland Women's Healthcare
  - Four Seasons OB/GYN & Midwifery
  - The Women's Center
  - Maitri Health Care for Women

Plan for Abrysvo

- Likely will be under allocation when first available to order
- Do not have a date for when Abrysvo will be available through Immunization Program
- Determining strategies for prioritization of providers serving pregnant individuals

Abrysvo Access at Pharmacies

- Individual pharmacies are approaching differently.
  - Walgreens online scheduler allows RSV vaccine for pregnant individuals
- Vermont Drug Utilization Review Board approved with criteria stating “Abrysvo: Covered if ≥ 60 years of age OR the vaccine will be administered during weeks 32 through 36 of pregnancy during September through January.”
  - Of note, for those under 60 a prior authorization will be needed from the prescriber.
- Potentially some pharmacy concerns due to the package insert: Warning and Precautions: Potential Risk of Preterm Birth information:

> "To avoid the potential risk of preterm birth with use of ABRYSVO before 32 weeks of gestation, administer ABRYSVO as indicated in pregnant individuals at 32 through 36 weeks gestational age. Pregnant individuals who were at increased risk of preterm birth were generally excluded from clinical studies of ABRYSVO"

Kinney Drugs open to collaborating on a vaccine clinic or opening up Abrysvo for pregnant individuals in a controlled single-store setting to allow proper "shared decision making"

Contact DVHA Pharmacy Unit at ahs.dvhaph@vermont.gov if interested

Questions?

Contact Information

- Ordering, vaccine storage and handling, vaccine-specific information: AHS.VDHImmunizationProgram@vermont.gov
- Immunization registry and reporting questions: IMR@vermont.gov
- Program updates and e-mailed communications available on the Vaccine Information for Health Care Professionals Page:
  - Updates: www.healthvermont.gov/disease-control/immunization-providers#vvpupdate
  - E-mails: www.healthvermont.gov/disease-control/immunization-providers#vvpmemo

Q&A

Questions?

Thank you

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