



COVID-19 AND RSV VACCINE UPDATES WEBINAR

October 24, 2023

Before We Start

- All participants will be muted for the presentation.
- You may ask questions using the Q&A box, and questions will be answered at the end of the presentation.
- Continuing education is available for nurses and medical assistants.
- If you're watching in a group setting and wish to claim CE credit, please make sure you register for the webinar and complete the evaluation as an individual.
- You can find more information here: <u>COVID-19 Vaccine Updates Webinar</u>
 <u>October 24, 2023 | Washington State Department of Health</u>
 (https://doh.wa.gov/you-and-your-family/immunization/immunization-training)

Continuing Education

- This nursing continuing professional development activity was approved by Montana Nurses Association, an accredited approver with distinction by the American Nurses Credentialing Center's Commission on Accreditation. Upon successful completion of this activity, 1.0 contact hours will be awarded.
- This program has been granted prior approval by the American Association of Medical Assistants (AAMA) for 1.0 administrative continuing education unit.

Disclosures

The planners and speakers of this activity have no relevant financial relationships with any commercial interests pertaining to this activity.

Learning Objectives

- Describe updated COVID-19 vaccine recommendations
- Discuss RSV vaccine recommendations for older adults and pregnant persons
- Explain recommendations for the use of nirsevimab in infants
- Identify relevant resources

Presenters

Heidi Kelly, RN-BC, MS
Public Health Nursing Consultant

Frank Bell, MD Swedish Pediatric Infectious Disease

COVID-19 VACCINE UPDATES HEIDI KELLY, RN-BC, MS

COVID-19 Recommendations

- Everyone ages 5 years and older is recommended to receive 1 dose of a 2023-2024 mRNA COVID-19 vaccine.
- Children ages 6months-4 years should completed a multi-dose initial series (2) doses of Moderna or 3 doses of Pfizer-BioNtech mRNA COVID-19 vaccine) with at least one dose of the 2023-2024 COVID-19 vaccine.
- People who are moderately or severely immunocompromised should complete a 3-dose initial series with at least one dose of the 2023-2024 COVID-19 vaccine and may receive 1 or more additional 2023-2024 COVID-19 vaccine doses.
- Bivalent mRNA COVID-18 vaccines are no longer recommend for use in the **United States.**

Key Changes from bivalent mRNA recommendations

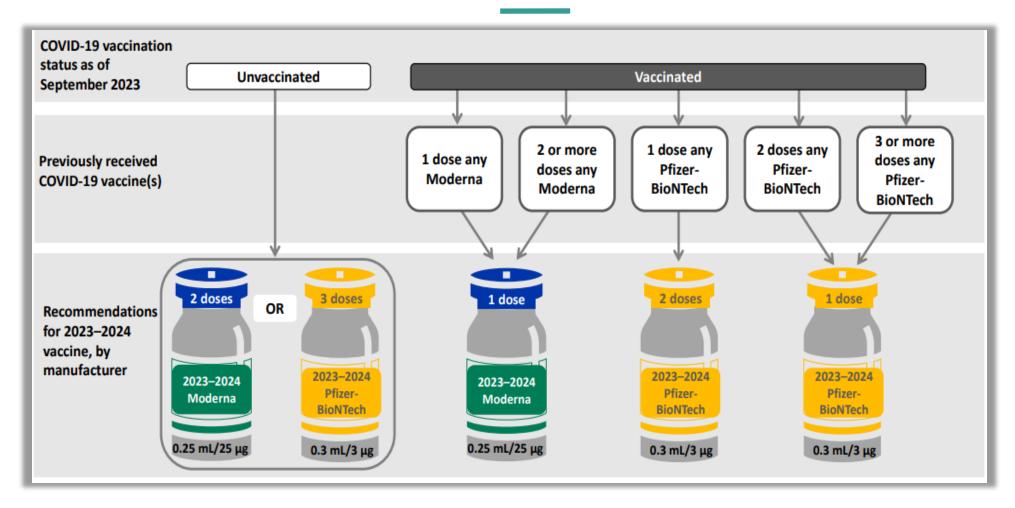
Bivalent recommendations	Proposed 2023 – 2024 vaccine recommendations	Rationale
Everyone ages 6 years and older recommended for a single bivalent dose	Everyone ages 5 years and older recommended for a single 2023 – 2024 dose	Eliminates complex recommendations for 5-year-olds
Two Moderna dosages authorized for 6 months – 5 years, depending on vaccination history and immune status	All Moderna doses in ages 6 months – 11 years are now 25 μcg	Reduces the number of COVID-19 vaccine products in use
Optional 2 nd bivalent dose for those ages 65 years and older	No additional dose recommendation at this time	Will monitor epidemiology and vaccine effectiveness to determine if additional doses are needed

SOURCE: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/11-COVID-Wallace-508.pdf

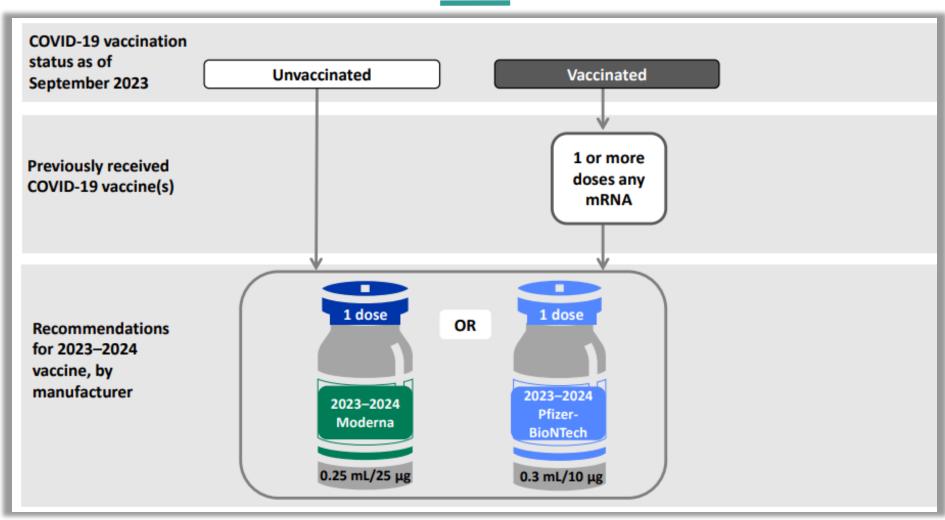
Simultaneous administration of COVID-19 and other vaccines

- In accordance with <u>General Best Practice Guidelines for Immunization</u>, routine administration of all age-appropriate doses of vaccines simultaneously is recommended for children, adolescents, and adults if there are no contraindications at the time of the healthcare visit.
- Providers may simultaneously administer COVID-19, influenza, and respiratory syncytial virus (RSV) vaccines to eligible patients; the Health Alert Network (HAN) <u>published on September 5, 2023</u> may be consulted for additional information about simultaneous administration of these vaccines.
- Simultaneous administration of COVID-19 vaccine and nirsevimab (a long-acting monoclonal antibody for certain infants and young children for prevention of RSV) is recommended.
- Coadministration of COVID-19 and RSV vaccine for older adults is acceptable.
- There are additional considerations if administering an orthopoxvirus vaccine and COVID-19 vaccine.

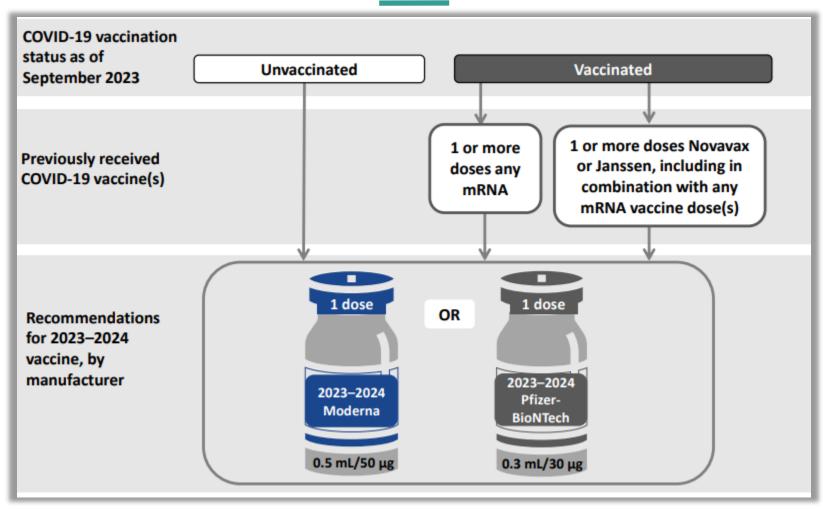
Recommended 2023-2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged 6 months-4 years



Recommended 2023–2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged 5–11 years



Recommended 2023–2024 COVID-19 mRNA vaccines for people who are NOT immunocompromised, aged ≥12 years



Recommendations for moderately or severely immunocompromised people 6mo and older

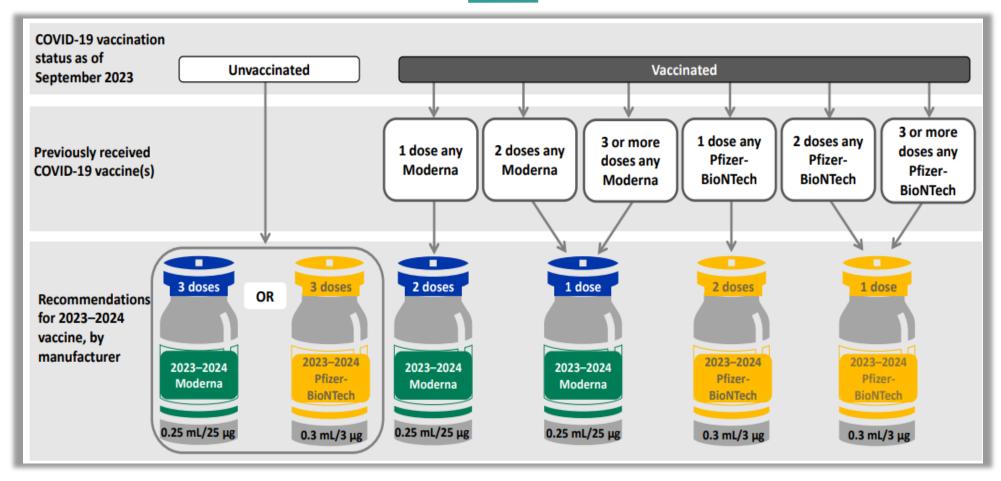
Doses recommended:

- Initial COVID-19 vaccine series*
- At least 1 2023–2024 COVID-19 vaccine dose
- May receive 1 or more additional 2023-2024 mRNA COVID-19 vaccine doses**

SOURCE: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/11-COVID-Wallace-508.pdf

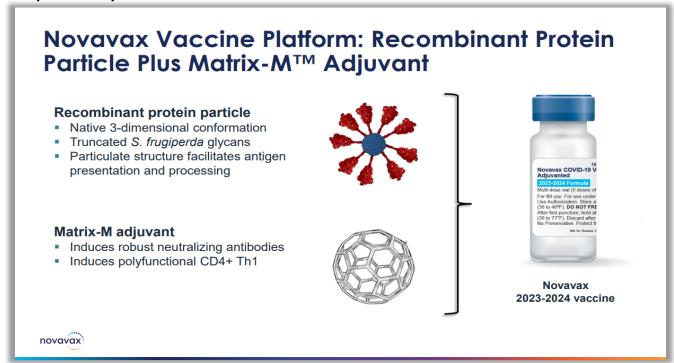
^{*}Series of 3 homologous mRNA COVID-19 vaccine doses at the time of initial vaccination. This could also include a history of receipt of 1 or more doses of Novavax or Janssen, including in combination with mRNA vaccine dose(s).
**Further additional dose(s) may be administered, informed by clinical judgement of a healthcare provider and personal preference and circumstances. Further additionall doses should be administered at least 2 months after the last 2023-2024 COVID-19 vaccine dose.

Recommended 2023–2024 COVID-19 vaccines for people who ARE moderately or severely immunocompromised, aged 6 months–4 years



Novavax

- New Formulation with XBB .1.5 variant has been authorized for use
 2 dose initial series, 3-8 weeks apart
- Booster dose available in limited situations at least 8 weeks after last dose of primary series

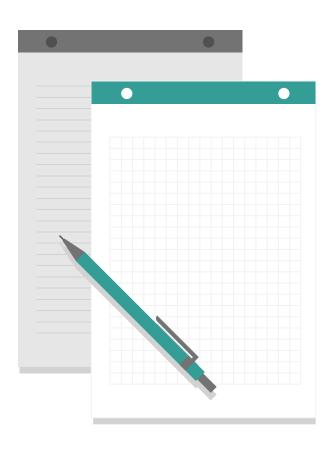


SOURCE: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/09-COVID-Dubovsky-508.pdf

2023-2024 COVID-19 Vaccine Up to Date Definition

- Everyone aged 5 years and older are recommended get one 2023–2024 COVID-19 vaccine to be up to date.
- Children aged 6 months–4 years and people who are moderately or severely immunocompromised need multiple doses, including at least one 2023–2024 COVID-19 vaccine dose to be up to date.
- People who are moderately to severely immunocompromised may get additional doses of the 2023-2024 COVID-19 vaccine.

COVID-19 Administrative Factors



VIS/EUA

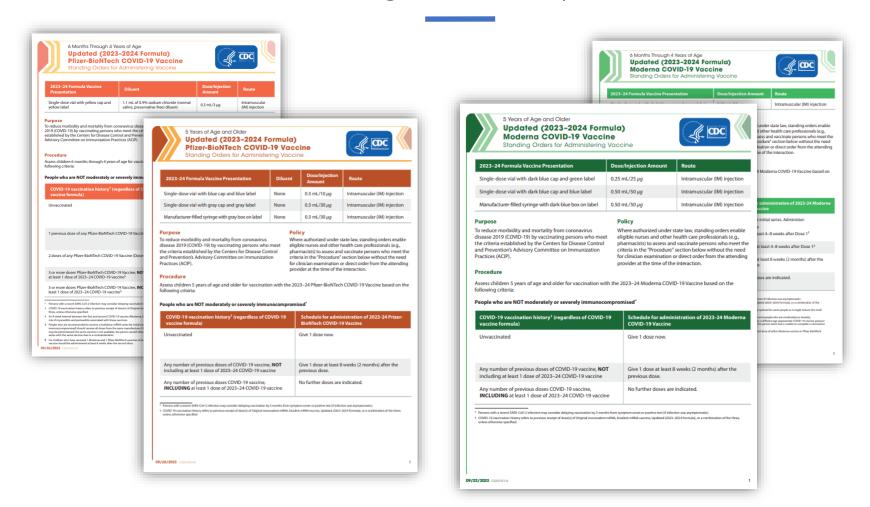
Can be found on FDA COVID-19 vaccine site For:

- Pfizer 6mo-4y/o
- Moderna 6mo-11 y/o
- Spikevax
- Comirnaty-found within the package insert (last 3 pages)

CDC Guidance on VIS:

"Until a VIS is available for a particular vaccine, a provider may use the manufacturer's package insert, written FAQs, or any other document – or produce their own information materials – to inform patients about the benefits and risks of that vaccine."

Standing Order Templates



SOURCE: https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

WAIIS

- 2023-2024 COVID-19 vaccines have been added to WAIIS (WA Immunization Information System)
- The forecast for the new recommendations will be added early quarter 4
- Providers may notice a forecasting error for these vaccines
 Inadverdent Dose Error
- Error message due to lack of forecasting and does not impact data being recorded in the IIS

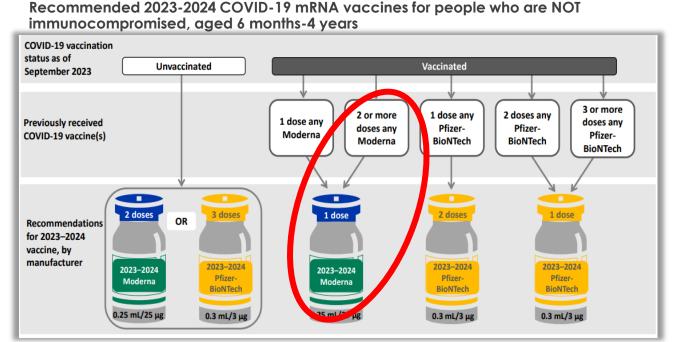
Knowledge Check 1

A healthy 4 y/o child arrives to the clinic to receive routine childhood vaccines. Parent is asking about COVID-19 vaccines. Child received a complete 2 dose Moderna initial monovalent series-no bivalent doses. What is the best response to her request?

- a. Administer one dose of 2023-2024 Moderna COVID-19 vaccine for children 6mos-11 y/o to be given with the other childhood vaccines received that day.
- b. Ask parent to return in 4 weeks for the COVID-19 vaccine, since the child is receiving routine vaccines today.
- c. Give a dose of 2023-2024 Moderna COVID-19 vaccine for children 6mos-11 y/o now and then schedule for a second dose in 4 weeks.

Knowledge Check Answer 1

Answer: A. Administer one dose of 2023-2024 Moderna COVID-19 vaccine for children 6mos-11 y/o to be given with the other childhood vaccines received that day.



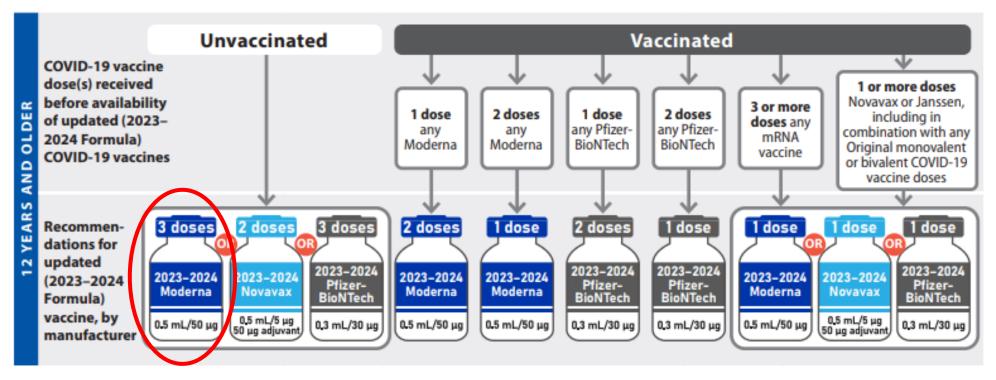
Knowledge Check 2

An immunocompromised 25 y/o client some into the clinic requesting a Moderna COVID-19 vaccine. They have never received a COVID-19 vaccine, what is the best course of care for this client?

- a. Provide one dose of 2023-2024 mRNA COVID-19 vaccine now and schedule a follow-up appointment for their second dose to complete their primary series in 4 weeks.
- b. Provide one dose of 2023-2024 mRNA COVID-19 vaccine to complete their primary series.
- c. Provide one dose of 2023-2024 mRNA COVID-19 vaccine now and schedule 2 follow-ups for 2 more doses in 4 week intervals, to complete their primary series.
- d. Provide Pfizer 2023-2023 mRNA COVID-19 vaccine for their second and third dose for better coverage.

Knowledge Check 2

Answer: C. Provide one dose of 2023-2024 mRNA COVID-19 vaccine now and schedule 2 follow-ups for 2 more doses in 4 week intervals, to complete their primary series.



SOURCE: Recommend updated (2023-2024 Formula) COVID-19 vaccines for people who are moderately or severely immunocompromised (cdc.gov)

VAERS is the nation's early warning system for vaccine safety





Vaccine Adverse Event **Reporting System**

http://vaers.hhs.gov



Source: T Shimabukuro, Advisory Committee on Immunization Practices presentation; 04/20/2022 meeting. Available at ACIP April 20, 2022 Presentation Slides | Immunization Practices | CDC

FRANK BELL, MD SWEDISH PEDIATRIC INFECTIOUS DISEASE

Immunization against RSV

Immunization for older adults, & in pregnancy, monoclonal antibody for infants

Respiratory Syncytial Virus (RSV) infection

- RSV causes acute respiratory tract infections in people of all ages
- Immunity to RSV is incomplete, reinfection is common



RSV in infants

- Almost all infants are infected by the end of their second winter
- 1 to 3% of all infants will require admission to hospital
- 50,000 80,000 hospitalizations/year in the U.S.
- 100 300 deaths/year

Infants at increased risk of severe RSV-LRTI include those with:

 Prematurity, chronic lung disease of prematurity, severe immune compromise; certain congenital heart, lung & neurologic disorders

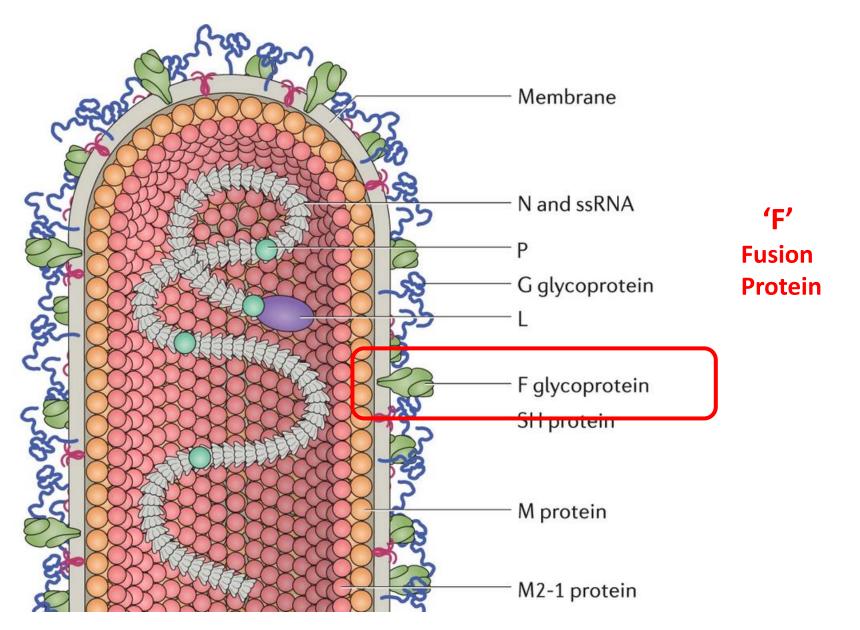
RSV in adults

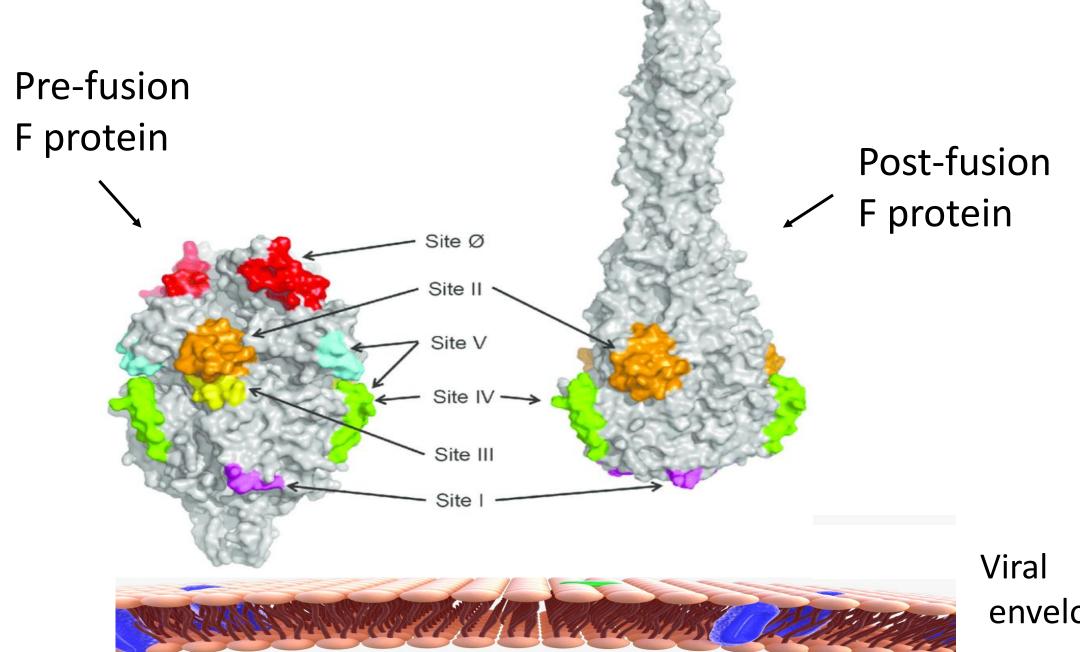
- 60,000 160,000 hospitalizations/year
- 6,000 10,000 deaths/year in those aged ≥65 yrs

Adults at increased risk include those with:

- Chronic lung, heart or neurologic disease, diabetes, chronic kidney disease, frailty, residence in a congregate setting
- Compromised immunity, including transplant recipients, patients taking immunosuppressive medications
- Persons of advanced age (aged ≥75 yrs)

RSV





envelope

Two products to protect older adults in 2023

- 'RSVPreF3' recombinant protein (GSK) (aka Arexvy®)
 - + adjuvanted (AS01_E) monophosphoryl lipid A (MPL) and saponin QS-21
- 'RSVPreF' recombinant protein (Pfizer) (aka Abrysvo®)

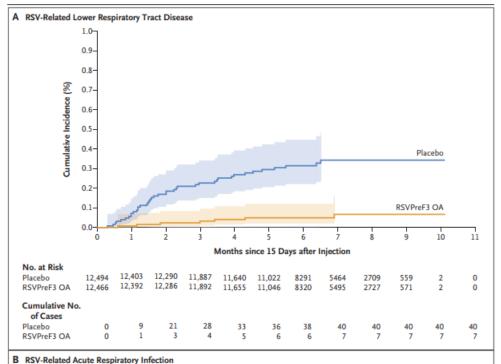
Adult Vaccination in Clinical Trials

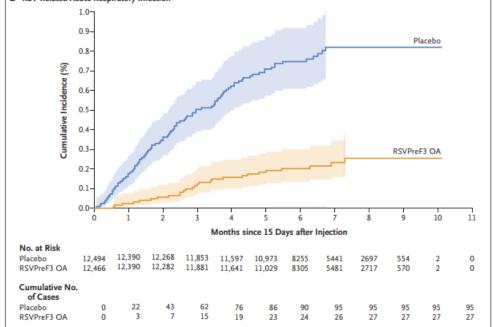
- Efficacy against LRTI & ARI over 6+ months of follow-up
 - efficacy against RSV A & B subtypes -
- Immunogenic
- Adverse-effects 'acceptable' (GSK/adjuvant > Pfizer > placebo)
- Safety
 - No safety signals

GSK adjuvanted

LRTI





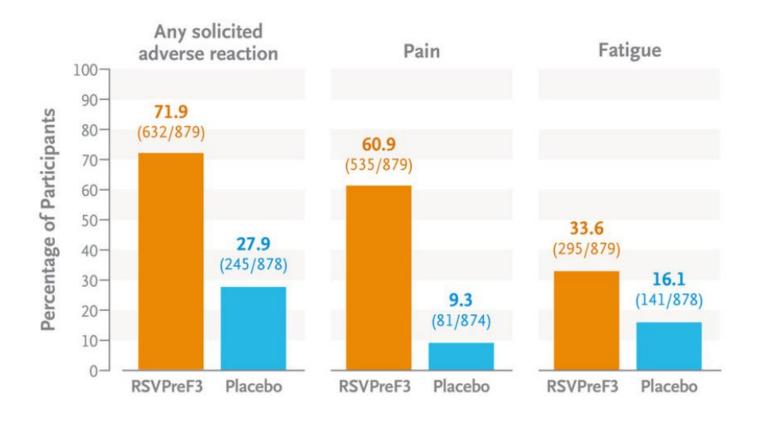


Vaccine efficacy at 6mo = **82%**

Vaccine efficacy at 6mo = **72%**

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GSK adjuvanted



Most solicited reactions were mild or moderate and resolved within the 4-day solicitation period (mean duration, 1 to 2 days)

Recommendations: RSV Vaccination in Adults

Use shared clinical decision-making

Administer 1 dose to adults >60yrs, before the onset of the RSV season Coadministration with other vaccines at the same visit is acceptable

Vaccination of older adults against RSV

- A) is not really necessary; RSV is for babies
- B) will help to protect their grandchildren from getting bronchiolitis
- C) will diminish response to vaccines for influenza and COVID-19
- D) may offer useful protection for those with medical co-morbidities

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Challenges with Pediatric Vaccines for RSV

- Trials of early inactivated vaccines showed enhanced disease
- Current approaches provide infants with RSV-specific IgG

Experience with Passive Immunization

- Immune globulin (tetanus TIG, rabies RIG, varicella VZIG)
- Moms to their babies, across the placenta
- Actively-immunized moms to babies (tetanus, measles, influenza, GBS)
- Monoclonal antibodies (COVID-19, Ebola, RSV)

Two products are available to protect infants in 2023

• Maternal immunisation – 'RSVPreF' recombinant protein (Pfizer)

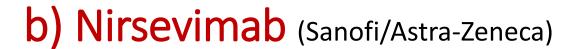
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(aka Abrysvo®)
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Monoclonal antibody – nirsevimab (Astra-Zeneca w/ Sanofi)

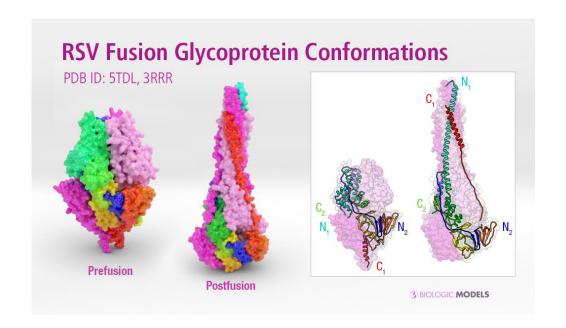
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(aka Beyfortus®)
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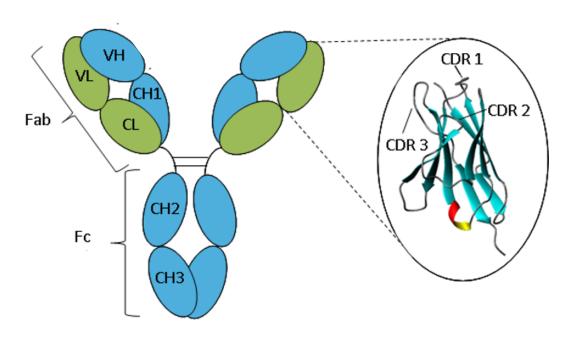
a) RSVPreF (Pfizer)

A recombinant **RSV Fusion protein** stabilized in the prefusion conformation Administered to the **pregnant person**



A recombinant human IgG monoclonal **RSV antibody**, binding to the prefusion conformation of the Fusion protein Administered directly to the **infant**





One product is available to vaccinate moms in 2023

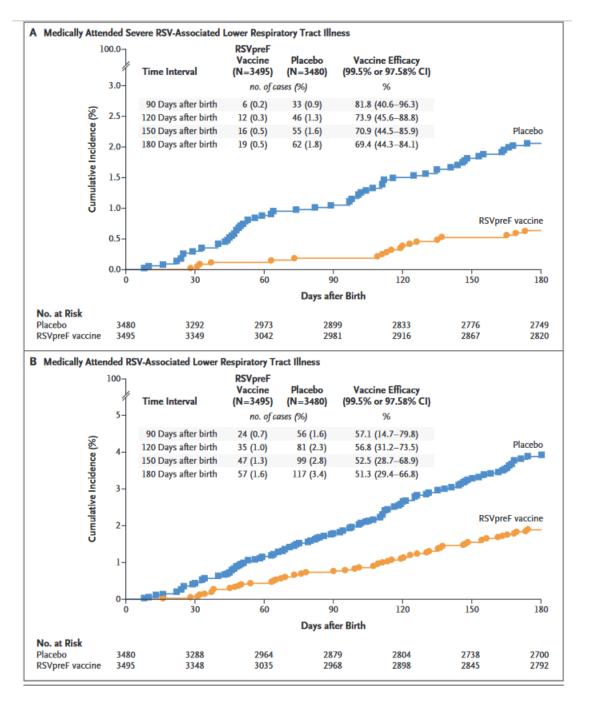
• 'RSVPreF' recombinant F protein, non-adjuvanted (Abrysvo®, Pfizer)

a) RSV Vaccination in Pregnant Persons

- Efficacy: in preventing infant disease to age 6 months
 - over the full RSV season
- Safety
 - mild reactogenicity

Severe LRTI

LRTI



Vaccine efficacy at 150d = **71%**

Vaccine efficacy at 150d = **52%**

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Recommendations: RSV Vaccination in Pregnancy

Administer 1 dose of RSV vaccine during weeks 32 through 36 of pregnancy during the months from September through January

Vaccination of pregnant persons against RSV

- A) is an experimental approach
- B) is intended to protect the recipient against RSV-LRTI in pregnancy
- C) will help protect the newborn against RSV-LRTI over the first winter
- D) should be offered year-round at 24 36 weeks of pregnancy

Vaccination of pregnant persons against RSV

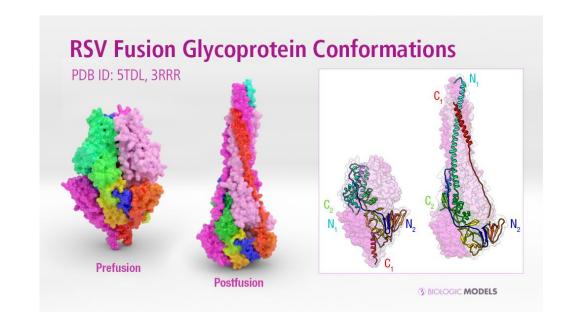
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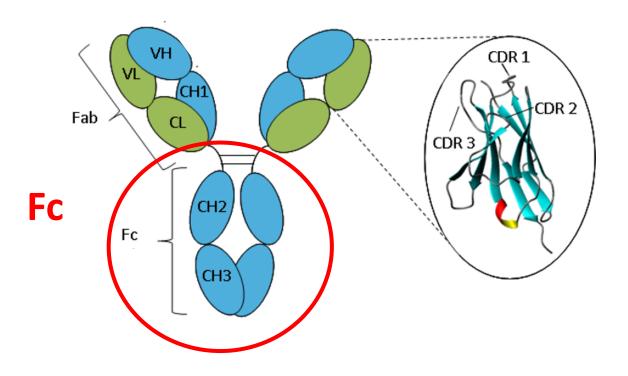
b) Nirsevimab for infants

A recombinant human IgG_{1k} monoclonal antibody

binding to the highly-conserved site \emptyset epitope present on the *prefusion* conformation of the RSV Fusion protein

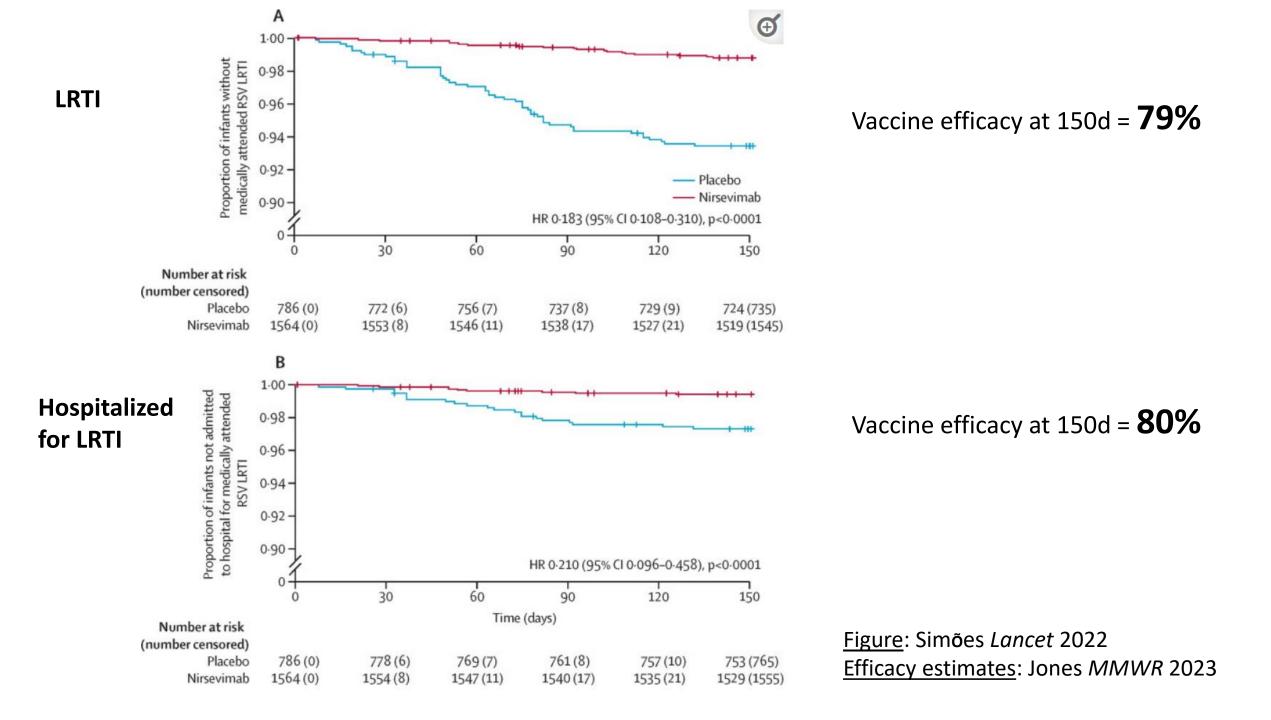
+with a modification to the Fc portion of the antibody to extend the half-life





Nirsevimab in Clinical Trials

- Efficacy over the entire RSV season
- No resistance to nirsevimab
- Safety no concerns for hypersensitivity
- No problems from anti-nirsevimab antibodies



Efficacy of nirsevimab in 2 large clinical trials

- 80% reduction in RSV-related medical visits, hospitalization
 AND significant reductions in:
- Hospital admissions for <u>any-cause</u> respiratory illness
- Any-cause medically attended LRTI / LRTI outpatient visits
- Antibiotic prescriptions

Recommendations: Who should get nirsevimab?

<u>All</u> infants under the age of 8 months entering their first RSV season (i.e. October through March)

Recommendations: Who should get nirsevimab?

All infants under the age of 8 months entering their first RSV season

& Children aged 8–19 months at increased risk for severe RSV disease who are entering their <u>second</u> RSV season

(Washington RSV season: October through March)

Who should NOT get nirsevimab?

An infant whose mother received the RSV vaccine > 14d prior to delivery

Who should get a further dose of RSV mAb in season #2?

Children between the ages of 8 & 19 months with

- Chronic Lung Disease of prematurity
- Severe immune compromise
- Severe Cystic Fibrosis
- American Indian or Alaskan Natives

RSV immunization of infants under the age of 8 months

- A) mounts an effective cell-mediated response to RSV infection
- B) protects the younger infant through their period of greatest risk
- C) will diminish immune-responses to later encounter with RSV
- D) should be given in addition to palivizumab (Synagis®) for those at risk

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Immunization against RSV

- *New* options for protecting individuals at risk of severe RSV-LRTI
- 3 new products ... more on the way
- 3 population groups targeted for immunization
- Active & passive approaches to protection against RSV-LRTI
- Potential to assist healthcare systems over the Respiratory Season

Immunization against RSV: Resources

- Washington State Department of Health (DOH)
 https://doh.wa.gov/you-and-your-family/immunization/diseases-and-vaccines/respiratory-syncytial-virus-rsv
- Washington Chapter of the American Academy of Pediatrics (WCAAP) https://wcaap.org/webinars/nirsevimab-webinar/
- National American Academy of Pediatrics (AAP)
 https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/
- Centers for Disease Control and Prevention (CDC) https://www.cdc.gov/rsv/index.html
- Morbidity and Mortality Weekly Report (MMWR)
 Nirsevimab: https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm
 Older Adults: https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm

Pregnancy: https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm

Reserve Slide

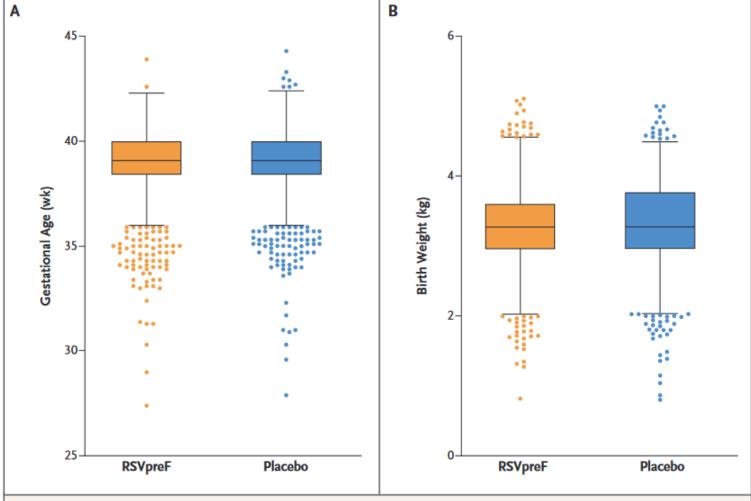


Figure 1. Gestational Age and Birth Weight of Infants Born to Mothers Who Received RSVpreF or Placebo.

In the box-and-whisker plots, the horizontal line indicates the median, the top and bottom of the box indicate the interquartile range, and the whiskers indicate 1.5 times the interquartile range. The outliers are represented as dots. The median gestational age (Panel A) was 39 weeks (interquartile range, 38 to 44) in each group, as a continuous variable. The median birth weight (Panel B) was 3.3 kg (interquartile range, 3.0 to 3.6) in each group, as a continuous variable. RSVpreF denotes respiratory syncytial virus prefusion F protein—based vaccine.

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Obtaining Continuing Education

- Continuing education is available for nurses and medical assistants
- There is no cost for CEs
- Expiration date is 01/24/24
- Successful completion of this continuing education activity includes the following:
 - Attending the entire live webinar or watching the webinar recording, and completing the evaluation
 - On the evaluation, please specify which type of continuing education you wish to obtain
- •Please note: CE certificates are NOT generated after evaluation completion—CE certificates will be sent by DOH via email within a few weeks after evaluation completion
- •If you have any questions about CEs, contact Trang Kuss at trang.kuss@doh.wa.gov

Questions?



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