Washington State Department of Health

VACCINE ADVISORY COMMITTEE MEETING

October 12th, 2023

Today's Agenda

Time	Agenda Item	Facilitator
11:00 – 11:15	**I. Welcome, Announcements, Introductions, Land Acknowledgement**	**Tao Sheng Kwan-Gett**
11:15 – 11:20	**II. Conflict of Interest Declaration**	**Meghan Cichy**
11:20 – 11:25	**III. Approval of Last Meeting Minutes (Handout)**	**Tao Sheng Kwan-Gett**
11:25 – 11:35	**IV. Public Comment**	**Tao Sheng Kwan-Gett** **Phillip Wiltzius**
11:35 – 11:45	V. Immunization Billing	Christopher Chen Korrina Dalke
11:45 – 11:55	VI. Office of Immunization Program Director Updates	Jamilia Sherls-Jones
11:55 – 12:05	VII. COVID-19 Vaccine Director Updates	Heather Drummond
12:05 – 12:10	VIII. Director Update Discussion	Jamilia Sherls-Jones Heather Drummond
12:10 – 12:25	IX. Excess Mortality in the COVID Pandemic	Jonathan Downs
12:25 – 12:55	X. Respiratory Syncytial Virus	Elyse Bevers Janel Jorgenson Trang Kuss
12:55 – 1:00	XI. Future Agenda Items XII. 2024 VAC Meeting Dates: Jan 11th, April 11th (hybrid), July 11th, Oct 10th XI. Adjourn	Tao Sheng Kwan-Gett

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Respiratory Virus Season Immunization Reimbursement

VAC Committee Meeting

October 12, 2023

Many recent changes in payment of immunizations

- **COVID vaccine** moving from federal purchase to commercialization
- New immunizations for **RSV**
- **Inflation Reduction Act** requirements for coverage of ACIP recommended vaccines including travel vaccines
- Usual **flu season** updates
- **Shifts** in where individuals seek immunizations, providers are able to administer them, and supply is available

Overview of Apple Health Immunization Reimbursement

- Apple Health **covers all immunizations** on the Centers for Disease Control and Prevention (CDC) **Advisory Committee on Immunization Practices (ACIP) Recommended Immunization Schedule** for adults and children
- Immunizations are made available to **Apple Health clients ages 18 and younger** at no cost from the Department of Health (DOH) through the **Childhood Vaccine Program** (which administers the state VFC program) in conjunction with the Washington Vaccine Association. For this population:
  - Apple Health reimburses clinics and hospitals **only for the administration* of the immunizations** and not for the immunizations themselves
  - Apple Health **does not reimburse for immunization products administered outside of the VFC program**; pharmacies in WA, for the most part, are not enrolled in VFC

* Clinics are reimbursed for administrative costs for VFC rather than an administration fee at this time

NOTES: For more information on the VFC program, see the VFC webpage. Immunizations covered by the program are listed in the Professional Administered Drug Fee Schedule.

Overview of Apple Health Immunization Coverage

Population	Setting	Administration covered?	Product covered?
0 – 18	**Pharmacies**	**No**	**No**
0 – 18	**Clinics**	**Yes***	**Yes,** through VFC (-SL modifier)
0 – 18	**Hospitals****	**Yes**	**Yes**
19 +	**Pharmacies**	**Yes*****	**Yes**
19 +	**Clinics**	**Yes**	**Yes**
19 +	**Hospitals**	**Yes**	**Yes**

NOTE: *Clinics are reimbursed for administrative costs for VFC rather than an administration fee at this time
**Immunizations administered during an inpatient episode of care are not separately reimbursed outside of the DRG, where applicable
***Apple Health FFS does not currently pay for administration in pharmacies, but MCOs do

Questions?

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Office of Immunization Program Director Updates

- Nirsevimab & WVA Funding Decision
- Flu Vaccine Campaign
- Increasing Vaccine Rates in LTCFs
- Respiratory Illness Data Dashboard
- Change to IPV IIS Forecast
- Immunization Exemptions Toolkit for Health Care Providers
- Personnel Updates

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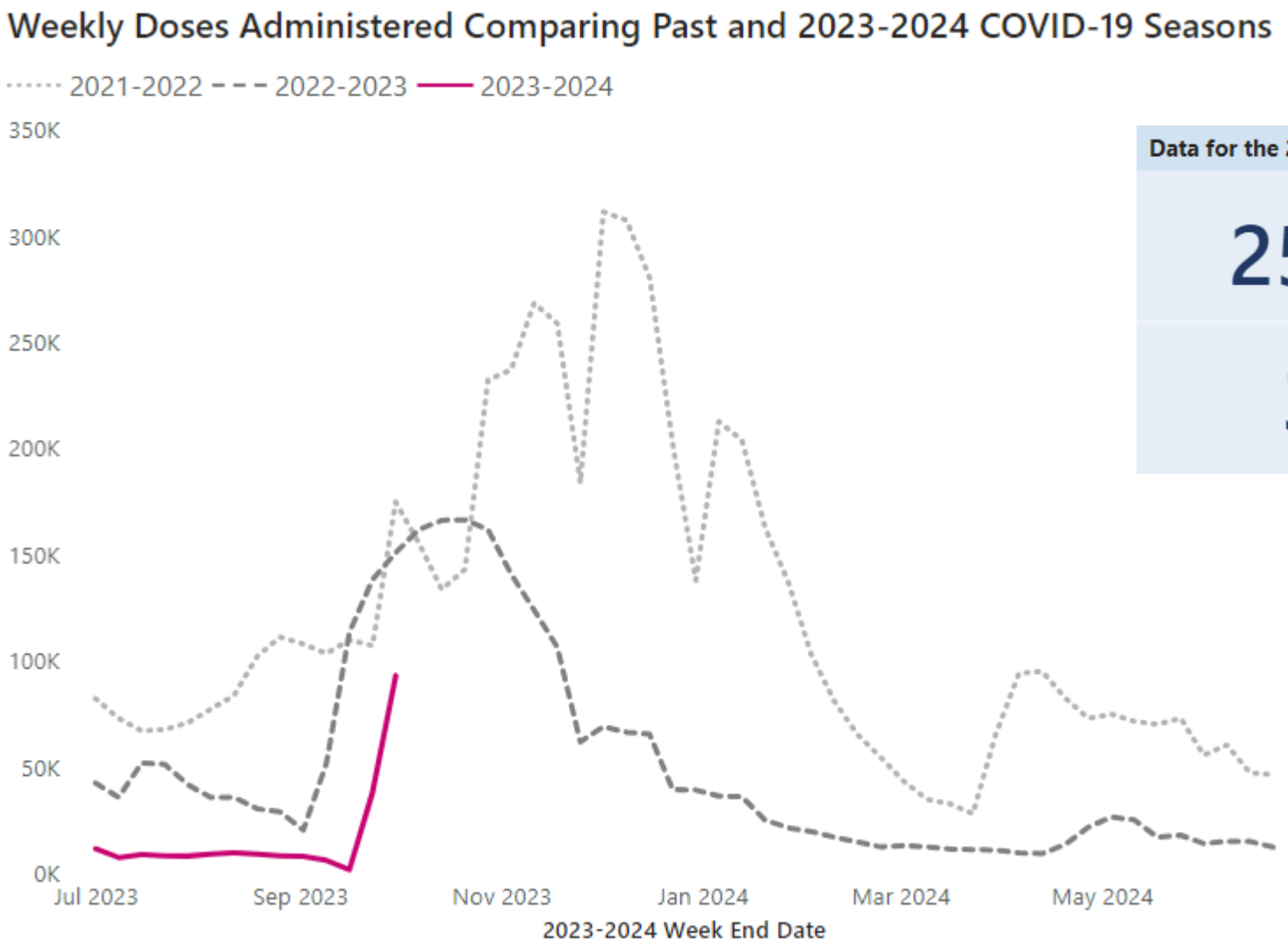
Washington State Department of HEALTH

COVID-19 Vaccine Program Update
October 12, 2023

COVID-19 Vaccinations in Washington



Data for the 2023-2024 COVID-19 Season

250,830	Doses administered
3,189	Doses administered per 100,000 people

[Respiratory Illness Data Dashboard | Washington State Department of Health]

Changing Landscape of COVID-19 Vaccines

	Past: Dec 2020 – Sept 2023	Present & future: September 12, 2023
Overview	Federal government purchased and distributed COVID-19 vaccines for free to any enrolled provider.	• COVID-19 vaccines are a commercial product. • Public health programs obtain and distribute similarly to flu and other vaccines.
Supply Line	• Free to any enrolled provider	• Providers can purchase vaccine directly from manufacturers and distributors. • Federal government supplies vaccines at no cost for all children (under age 19) via CVP Program, and all under- and uninsured adults (age 19+) via the AVP (Bridge) Programs.
Mobile Services	• Mobile vaccination services (including DOH's Care-A-Van) • Mass vaccination pop-up sites across US	• DOH's Care-A-Van is still operational. • Mass Vaccination sites have ended.

New 2023-24 COVID-19 Vaccines

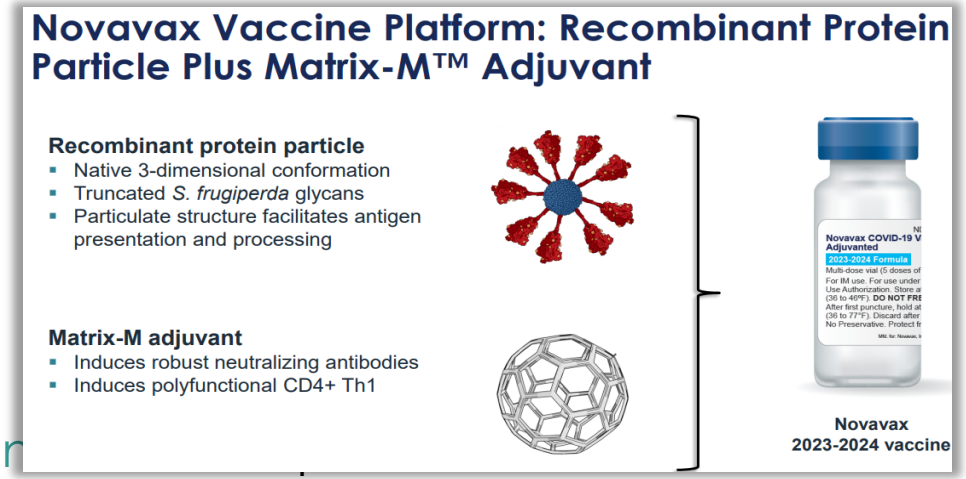
- Updated Moderna and Pfizer 2023-24 COVID-19 vaccines were approved 9/12. An updated 2023-24 COVID-19 vaccine from Novavax was approved 10/3.
- Formulated to more closely target currently circulating variants, and to provide better protection against serious consequences of COVID-19, including hospitalization and death.
- Everyone ages 6 months+ are eligible for the updated COVID-19 vaccines.
- “Up to Date” vaccination status means getting all recommended doses considering patient age and health history, with at least 1 dose of the 2023-24 COVID-19 vaccines.
- Updated CDC vaccination resources:
  - Interim COVID-19 Immunization Schedule (Updated 9/22/2023)
  - COVID-19 Vaccination Recommendations Infographic (Updated 9/20/2023)
  - COVID-19 Vaccination Recommendations Infographic (Immunocompromised) (Updated 9/20/2023)
  - COVID-19 Vaccine Product Information (Updated 9/25/2023)

Novavax, Adjuvanted 2023-24 COVID-19 Vaccine

Authorized for use in individuals 12 years of age and older

- Previously vaccinated:
  - One dose of updated Novavax at least two months after the last dose of COVID-19 vaccine.
- Not previously vaccinated:
  - Two doses of updated Novavax, administered three weeks apart.
- Immunocompromised individuals:
  - Additional doses of updated Novavax may be administered at least 2 months following the last dose of a 2023-24 COVID-19 vaccine, at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances. The timing of the additional doses may be based on the individual's clinical circumstances.

- Fact sheets can be found here:
  - Novavax Fact Sheet for Healthcare Providers
  - Novavax Fact Sheet for Recipients and Caregivers



Simultaneous Administration of COVID-19 and other vaccines

Providers may simultaneously administer COVID-19, influenza, and respiratory syncytial virus (RSV) vaccines to eligible patients.

- the Health Alert Network (HAN) published on September 5, 2023 may be consulted for additional information about simultaneous administration of these vaccines.
- There are additional considerations if administering an orthopoxvirus vaccine and COVID-19 vaccine.
- In accordance with General Best Practice Guidelines for Immunization, 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.

Vaccine Delays

- Limited vaccine availability from manufacturers and supply chain constraints are causing significant delays during 2023-24 COVID-19 vaccine rollout.
- **As a result, ordering for COVID-19 vaccine products in the WA IIS may only be intermittently available over the next few weeks.**
- What this means:
  - Submitted vaccine order requests are subject to reduction or denial until adequate supply is available. This includes orders showing as "Pending State Approval", "Pending Local Approval", "In State Manual Review", and "In Manual Review" in the IIS.
  - We recommend providers to place smaller orders rather than larger ones.
- **We anticipate these delays will be over in the next few weeks and greatly appreciate your patience while manufacturers and delivery systems ramp up to full capacity.**
- We will continue to share updates about supply in the coming weeks to support our partners and providers.

COVID-19 Vaccine Cost

- **Most people will not have out-of-pocket costs for COVID-19 vaccines due to their insurance coverage.**
  - **Following past vaccine approvals, insurance coverage could take months. However, with COVID-19 vaccines this is NOT the case.**
  - "Per CARES Act Section 3203 insurance companies are required to provide coverage of COVID-19 vaccines. However, some insurance plans require cost sharing or co-pays. In those cases, the Bridge Access Program covers the cost of COVID-19 vaccination."
  - July 2023, HHS issued guidance to payors to cover COVID-19 vaccination with the onset of commercialization.
- **Children**: All recommended vaccines are available at no cost for children through age 18 via the Childhood Vaccine Program of Washington.
- **Uninsured Adult COVID-19 vaccines**: Adult Vaccine Program Providers and pharmacies in the Federal Bridge Access Program will provide vaccines at no cost to uninsured and underinsured adults.

How Can the Public Find the Vaccines?

1. **Health care providers:** Most Primary Care Providers and pharmacists can administer all respiratory disease vaccines.

2. **CVS & Walgreens pharmacies.**

3. **CDC website**: Find flu and COVID-19 vaccines on https://www.vaccines.gov/ or text ZIP code to GETVAX (438829).

4. **Federally Qualified Health Centers**

5. Newly updated **Provider Map** to find a clinic enrolled in the Childhood Vaccine Program and/or the Adult Vaccine program.

6. **Care-A-Van Mobile Vaccine Clinic Locations**

Updated COVID-19 Vaccine Resources

Newly Updated General Public Resources:

- Getting Vaccinated to Protect Against COVID-19 Illness
- Pediatric COVID-19 Vaccines What Parents/Guardians Should Know


Washington State Department of HEALTH

Scan this QR code for more information on COVID-19 vaccines:

Getting Vaccinated to Protect Against COVID-19 Illness

Updated 2023-2024 COVID-19 vaccines are safe and recommended to everyone 6 months and up.

Most people ages 5 years and older just need one updated 2023-2024 dose to be up to date.

- **Unvaccinated against COVID-19:** you just need one updated 2023-2024 dose to be up to date with COVID-19 vaccination.
- **Previously vaccinated against COVID-19:** you just need one updated 2023-2024 dose at least 2 months after your last dose to be up to date with COVID-19 vaccination.

Children 6 months-4 years may need more than one dose of an updated 2023-2024 COVID-19 vaccine in order to be up to date with COVID-19 vaccination.

People 6 months and older who are moderately to severely immunocompromised should complete a 3-dose series and may receive additional doses of the updated 2023-2024 at least 2 months after their last dose.

Which COVID-19 vaccines are currently available?

Pfizer-BioNTech/Comirnaty
2023-2024 formula, 6 months and older*

Moderna/Spikevax
2023-2024 formula, 6 months and older*

Novavax
Original formula, 12 years and older**

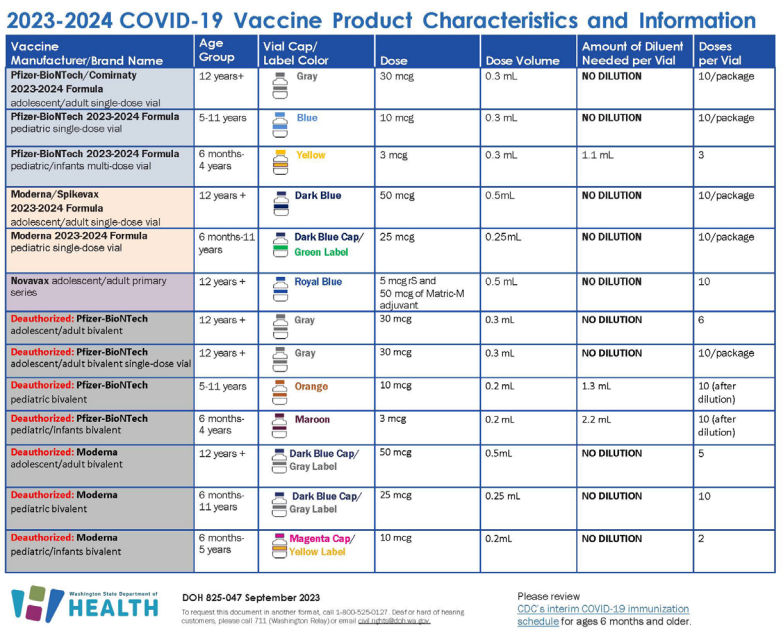
*Comirnaty and Spikevax are brand names of the mRNA vaccines currently approved for ages 12 and older. Pfizer and Moderna mRNA vaccines are authorized for ages 6 months and older.

** If you are unable or choose not to get a recommended 2023-2024 mRNA COVID-19 vaccine, you may choose to receive Novavax. You will be up to date if you get the Novavax COVID-19 vaccine doses approved for your age group.

SEPTEMBER 2023 DOH 348-782

Newly Updated Resources for Providers:

- Health Care Provider Discussion Guide: Novavax
- COVID-19 Vaccines: Pediatric Vaccine Toolkit for Providers
- Provider Discussion Guide
- Discussion Guide for People Experiencing Homelessness
- Discussion Guide for Immigrants and Refugees
- Pregnancy and COVID-19 Vaccine Toolkit
- 2023-2024 COVID-19 Vaccine Product Chart
- COVID-19 Vaccines: Toolkit for Schools


2023-2024 COVID-19 Vaccine Product Characteristics and Information

Vaccine Manufacturer/Brand Name	Age Group	Vial Cap/ Label Color	Dose	Dose Volume	Amount of Diluent Needed per Vial	Doses per Vial
Pfizer-BioNTech/Comirnaty 2023-2024 Formula adolescent/adult single-dose vial	12 years+	Gray	30 mcg	0.3 mL	**NO DILUTION**	10/package
Pfizer-BioNTech 2023-2024 Formula pediatric single-dose vial	5-11 years	Blue	10 mcg	0.3 mL	**NO DILUTION**	10/package
Pfizer-BioNTech 2023-2024 Formula pediatric/infants multi-dose vial	6 months-4 years	Yellow	3 mcg	0.3 mL	1.1 mL	3
Moderna/Spikevax 2023-2024 Formula adolescent/adult single-dose vial	12 years +	Dark Blue	50 mcg	0.5mL	**NO DILUTION**	10/package
Moderna 2023-2024 Formula pediatric single-dose vial	6 months-11 years	Dark Blue Cap/ Green Label	25 mcg	0.25mL	**NO DILUTION**	10/package
Novavax adolescent/adult primary series	12 years +	Royal Blue	5 mcg rS and 50 mcg of Matric-M adjuvant	0.5 mL	**NO DILUTION**	10
Deauthorized: Pfizer-BioNTech adolescent/adult bivalent	12 years +	Gray	30 mcg	0.3 mL	**NO DILUTION**	6
Deauthorized: Pfizer-BioNTech adolescent/adult bivalent single-dose vial	12 years +	Gray	30 mcg	0.3 mL	**NO DILUTION**	10/package
Deauthorized: Pfizer-BioNTech pediatric bivalent	5-11 years	Orange	10 mcg	0.2 mL	1.3 mL	10 (after dilution)
Deauthorized: Pfizer-BioNTech pediatric/infants bivalent	6 months-4 years	Maroon	3 mcg	0.2 mL	2.2 mL	10 (after dilution)
Deauthorized: Moderna adolescent/adult bivalent	12 years +	Dark Blue Cap/ Gray Label	50 mcg	0.5mL	**NO DILUTION**	5
Deauthorized: Moderna pediatric bivalent	6 months-11 years	Dark Blue Cap/ Gray Label	25 mcg	0.25 mL	**NO DILUTION**	10
Deauthorized: Moderna pediatric/infants bivalent	6 months-5 years	Magenta Cap/ Yellow Label	10 mcg	0.2mL	**NO DILUTION**	2

Washington State Department of HEALTH

DOH 825-047 September 2023

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Please review CDC's interim COVID-19 immunization schedule for ages 6 months and older.

Send additional questions and requests for information to:

COVID.Vaccine@doh.wa.gov

Additional Resources

Conference Outreach

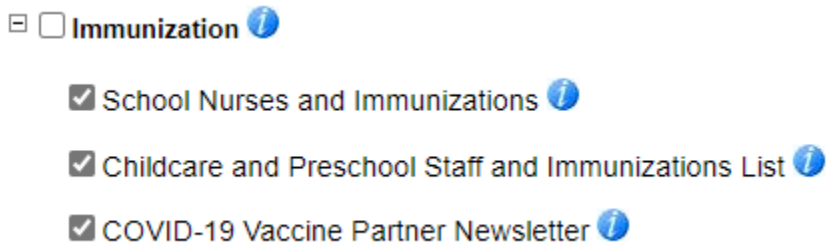
Visit POP's table at these upcoming events-

- American Physical Therapy Association
  - October 13 – 15
- School Nurse Organization of WA
  - October 13 – 14
- WA State Board of Nursing
  - October 19 – 20
- ARNP's United
  - October 20 – 21
- WA State Pharmacy Association
  - November 3 – 4

COVID-19 Vaccine Newsletter

- The COVID-19 Vaccine Newsletter is a topic people can subscribe to on GovDelivery.
- People can manage their subscriptions by going to the following link.
  - From there, click on 'add subscriptions' at the bottom of the page.

  - On the next page, expand the 'Immunizations' tab and check the box for "COVID-19 Vaccine Partner Newsletter."

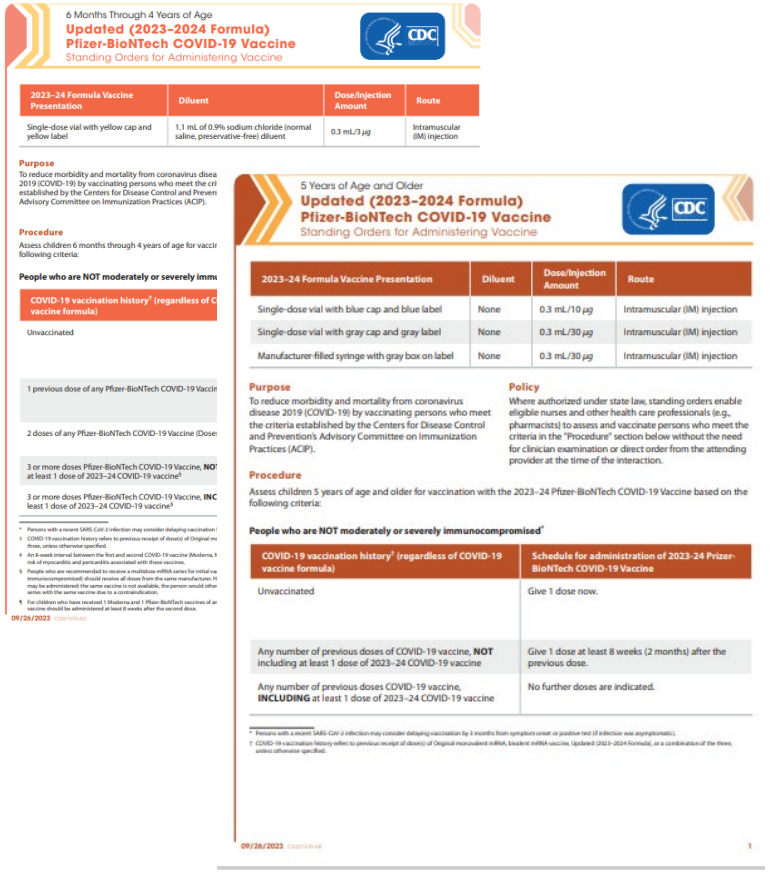


Minimum Order Quantities

Vaccine	Doses/Vial	Doses/Package	Minimum Order Quantities
Moderna 6m–11y	SDV	10	**10**
Moderna 12y+	SDV	10	**10**
Pfizer 6m–4y	3 Doses / Vial	30	**30**
Pfizer 5y–11y	SDV	10	**10**
Pfizer 12y+	SDV	10	**10**

- Moderna vaccines ship within a week of when the order is approved
- Pfizer vaccines arrive within 15 business days of when the order is approved

Standing Order Templates



6 Months Through 4 Years of Age
Updated (2023–2024 Formula)
Pfizer-BioNTech COVID-19 Vaccine
Standing Orders for Administering Vaccine

2023–24 Formula Vaccine Presentation	Diluent	Dose/Injection Amount	Route
Single-dose vial with yellow cap and yellow label	1.1 mL of 0.9% sodium chloride (normal saline, preservative-free) diluent	0.3 mL/3 µg	Intramuscular (IM) injection

Purpose
To reduce morbidity and mortality from coronavirus disea
2019 (COVID-19) by vaccinating persons who meet the cri
established by the Centers for Disease Control and Preven
Advisory Committee on Immunization Practices (ACIP).

Procedure
Assess children 6 months through 4 years of age for vaccir
following criteria:

People who are NOT moderately or severely imm

COVID-19 vaccination history† (regardless of C vaccine formula)
Unvaccinated
1 previous dose of any Pfizer-BioNTech COVID-19 Vacci
2 doses of any Pfizer-BioNTech COVID-19 Vaccine (Dose
3 or more doses Pfizer-BioNTech COVID-19 Vaccine, NO at least 1 dose of 2023–24 COVID-19 vaccine§
3 or more doses Pfizer-BioNTech COVID-19 Vaccine, INC least 1 dose of 2023–24 COVID-19 vaccine§

09/26/2023

5 Years of Age and Older
Updated (2023–2024 Formula)
Pfizer-BioNTech COVID-19 Vaccine
Standing Orders for Administering Vaccine

2023–24 Formula Vaccine Presentation	Diluent	Dose/Injection Amount	Route
Single-dose vial with blue cap and blue label	None	0.3 mL/10 µg	Intramuscular (IM) injection
Single-dose vial with gray cap and gray label	None	0.3 mL/30 µg	Intramuscular (IM) injection
Manufacturer-filled syringe with gray box on label	None	0.3 mL/30 µg	Intramuscular (IM) injection

Purpose
To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy
Where authorized under state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure
Assess children 5 years of age and older for vaccination with the 2023–24 Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:

People who are NOT moderately or severely immunocompromised*

COVID-19 vaccination history† (regardless of COVID-19 vaccine formula)	Schedule for administration of 2023-24 Prizer-BioNTech COVID-19 Vaccine
Unvaccinated	Give 1 dose now.
Any number of previous doses of COVID-19 vaccine, **NOT** including at least 1 dose of 2023–24 COVID-19 vaccine	Give 1 dose at least 8 weeks (2 months) after the previous dose.
Any number of previous doses COVID-19 vaccine, **INCLUDING** at least 1 dose of 2023–24 COVID-19 vaccine	No further doses are indicated.

* Persons with a recent SARS-CoV-2 infection may consider delaying vaccination by 3 months from symptom onset or positive test (if infection was asymptomatic).
† COVID-19 vaccination history refers to previous receipt of dose(s) of Original monovalent mRNA, bivalent mRNA vaccine, Updated (2023–2024 Formula), or a combination of the three, unless otherwise specified.

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6 Months Through 4 Years of Age
Updated (2023–2024 Formula)
Moderna COVID-19 Vaccine
Standing Orders for Administering Vaccine

2023–24 Formula Vaccine Presentation	Dose/Injection Amount	Route
		Intramuscular (IM) injection

5 Years of Age and Older
Updated (2023–2024 Formula)
Moderna COVID-19 Vaccine
Standing Orders for Administering Vaccine

2023–24 Formula Vaccine Presentation	Dose/Injection Amount	Route
Single-dose vial with dark blue cap and green label	0.25 mL/25 µg	Intramuscular (IM) injection
Single-dose vial with dark blue cap and blue label	0.50 mL/50 µg	Intramuscular (IM) injection
Manufacturer-filled syringe with dark blue box on label	0.50 mL/50 µg	Intramuscular (IM) injection

Purpose
To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

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Procedure
Assess children 5 years of age and older for vaccination with the 2023–24 Moderna COVID-19 Vaccine based on the following criteria:

People who are NOT moderately or severely immunocompromised*

COVID-19 vaccination history† (regardless of COVID-19 vaccine formula)	Schedule for administration of 2023-24 Moderna COVID-19 Vaccine
Unvaccinated	Give 1 dose now.
Any number of previous doses of COVID-19 vaccine, **NOT** including at least 1 dose of 2023–24 COVID-19 vaccine	Give 1 dose at least 8 weeks (2 months) after the previous dose.
Any number of previous doses COVID-19 vaccine, **INCLUDING** at least 1 dose of 2023–24 COVID-19 vaccine	No further doses are indicated.

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† COVID-19 vaccination history refers to previous receipt of dose(s) of Original monovalent mRNA, bivalent mRNA vaccine, Updated (2023–2024 Formula), or a combination of the three, unless otherwise specified.

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

Thank you!

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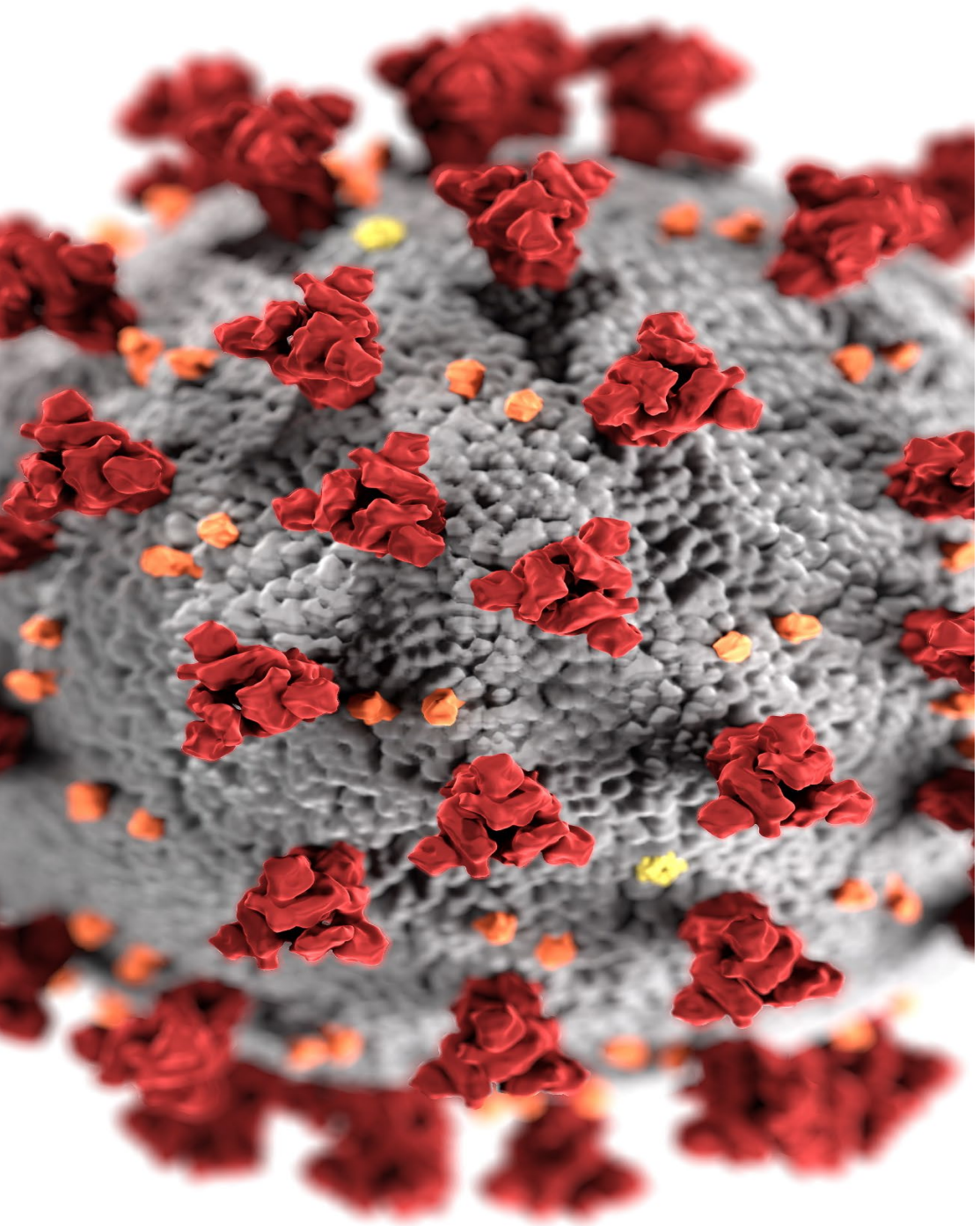
Washington State Department of Health

COVID-19 VACCINATION AND EXCESS DEATH, 2020-2021

Office of Health and Science
Center for Disease Control and Health Statistics

Excess Death Report Team

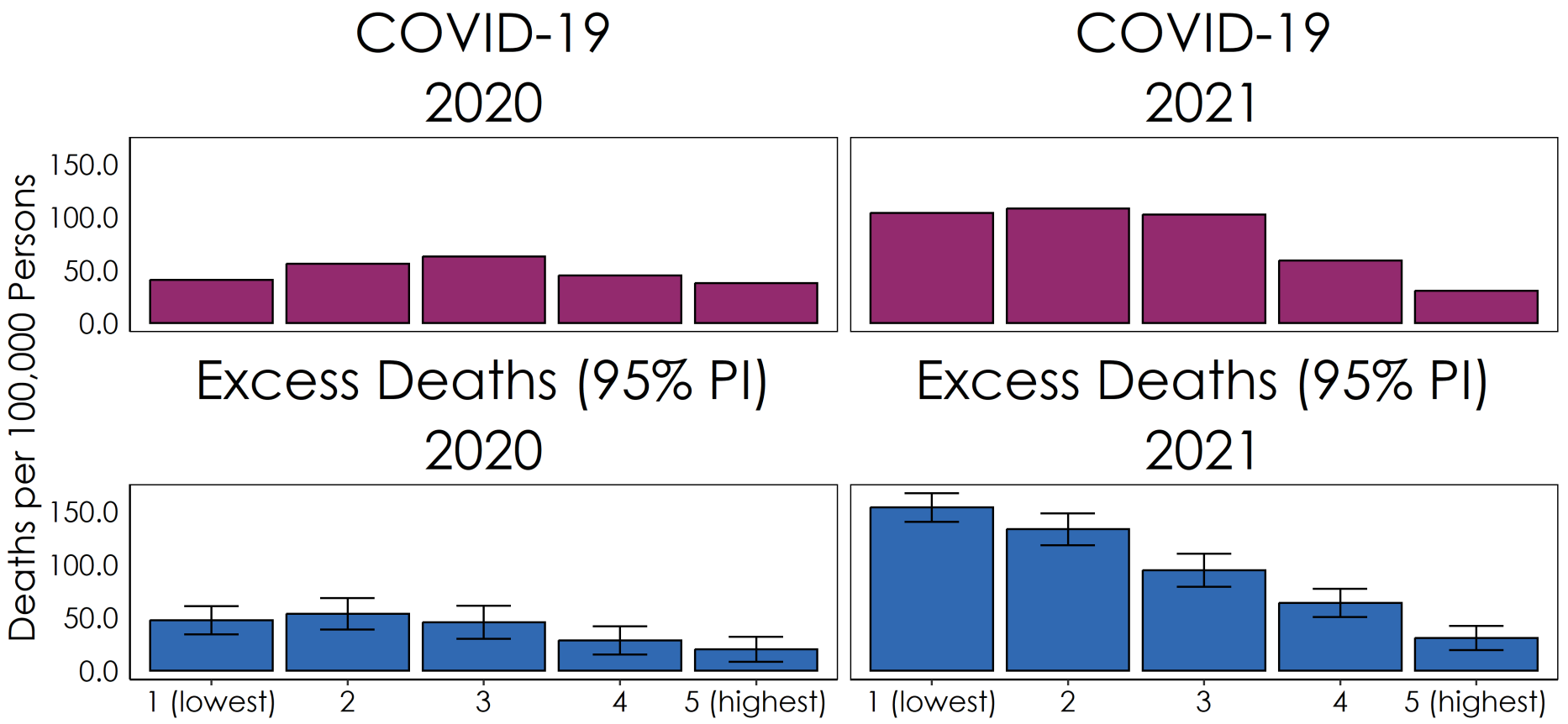
- Jon Downs (Presenting)
- Katie Hutchinson
- Ian Painter
- Sean Coffinger



Vaccination Protects the Whole Community

- We split the state into 5 groups according to the area's vaccination rate as of 12/31/2021 and compared death rates
- In 2020, before vaccines, we find small variations in death rates by eventual community vaccination
- In 2021, the **least-vaccinated areas had a COVID-19 death rate three times higher** than the most-vaccinated areas
- Based on historical trends, deaths from any cause in the **least vaccinated areas** were **21% higher than expected** in 2021
- Deaths in the **most vaccinated areas** were **6% higher than expected** in 2021

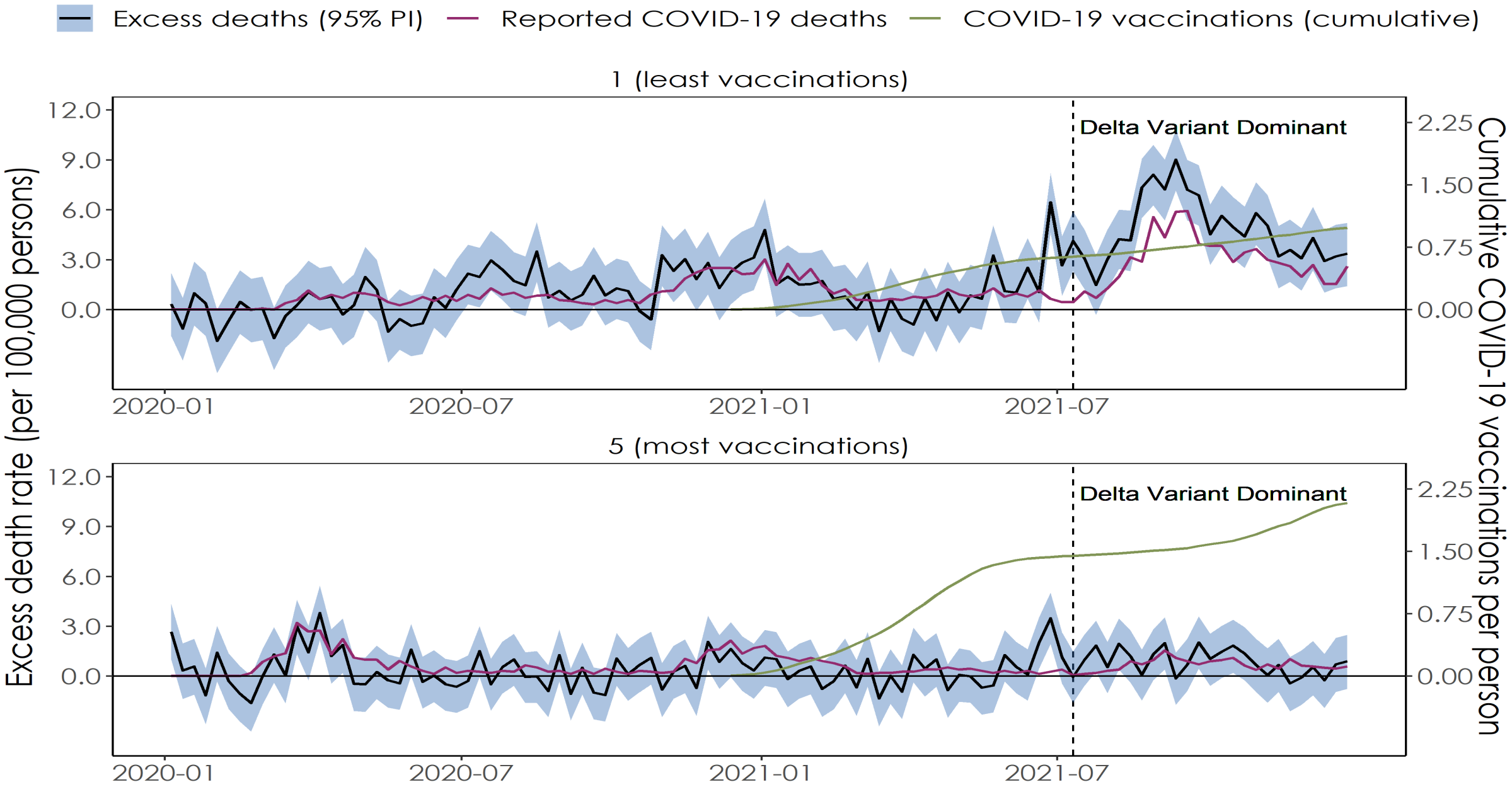
Reported COVID-19 and Excess Death Rates by Community Vaccination Rate*, 2020-2021



* Quintiles of vaccine doses per person by census tract. Weighted by population.

- Vaccines were not available until December 2020, and we see little variation in death rates during this time
- After vaccines were available, the most-vaccinated areas had the lowest COVID-19 and excess death rates

Less Vaccinated Areas were Most Impacted by the Delta Wave



COVID-19 vs. Excess Deaths: What's the Difference?

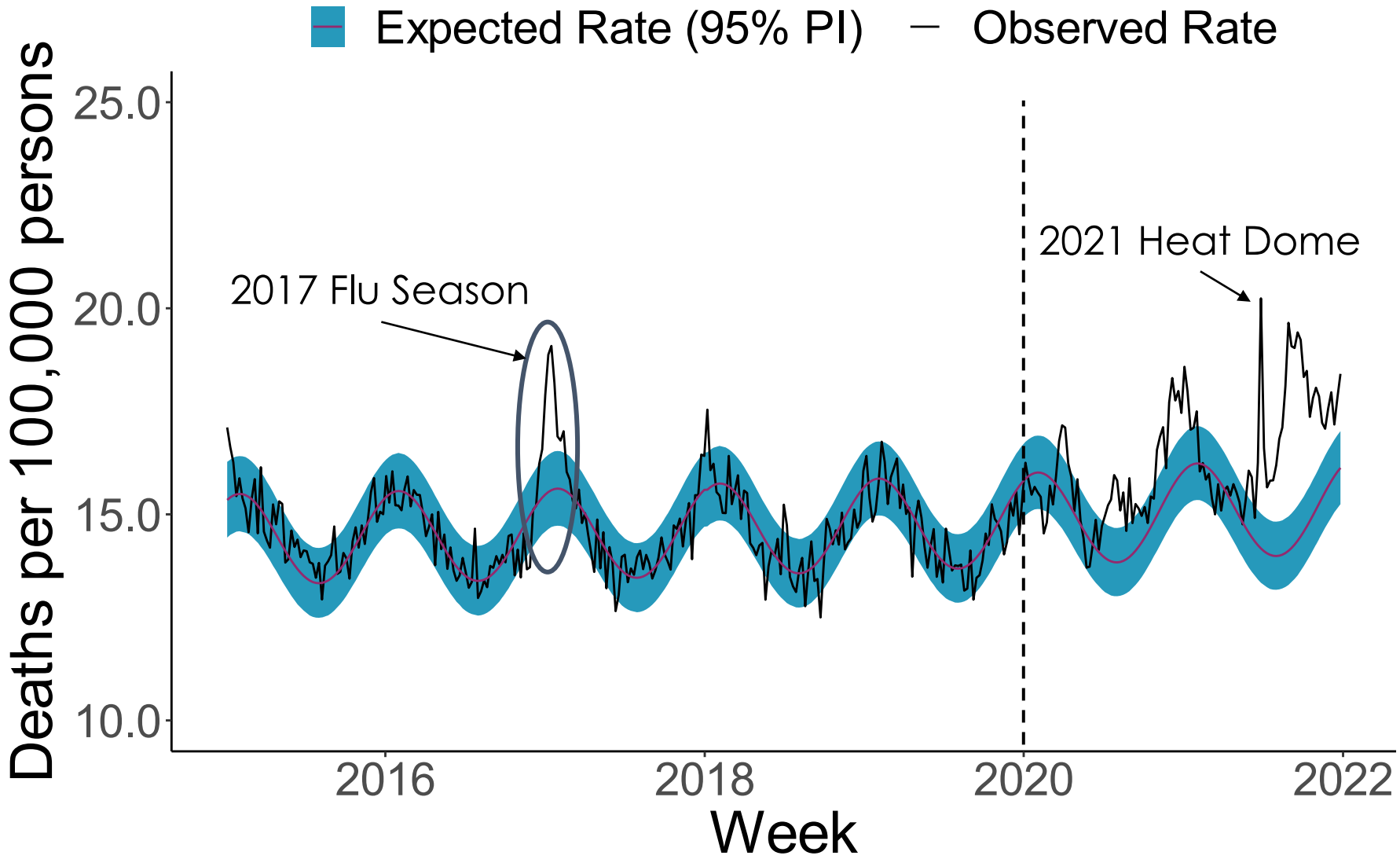
Reported COVID-19 Deaths

- Reported COVID-19 deaths must meet a **case definition**, such as a recent positive test
- COVID-19 could have indirectly increased or decreased deaths from other causes
- Undiagnosed COVID-19 infections ↑
- COVID-19 infections increased the risk of death from diabetes, kidney disease, or other pre-existing conditions ↑
- Masking and social distancing reduced deaths from flu and pneumonia ↓
- Some COVID-19 deaths would have happened later due to another cause ↓

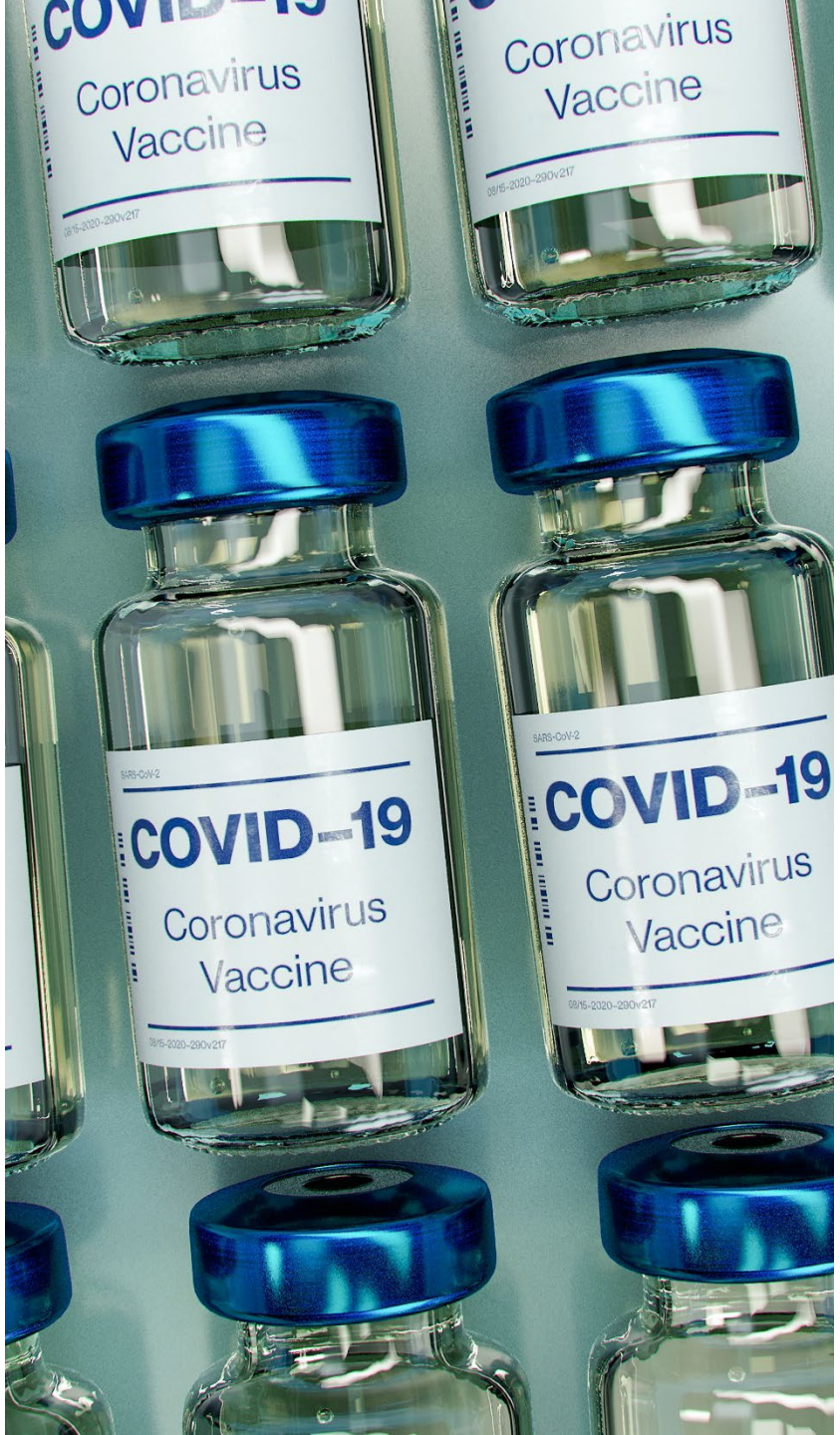
Excess Deaths

- We performed an **excess death analysis** to determine the net impact of COVID-19
- Before the pandemic, death rates were quite stable
- We used historical data (2011-2019) to determine the **expected number of deaths** had prior trends continued
- Deaths above the expected amount are **excess deaths**
- Excess deaths are evaluated at the population label. We cannot say whether any individual death was ‘excess’.

Statewide Observed vs. Expected Deaths (2011-2021)

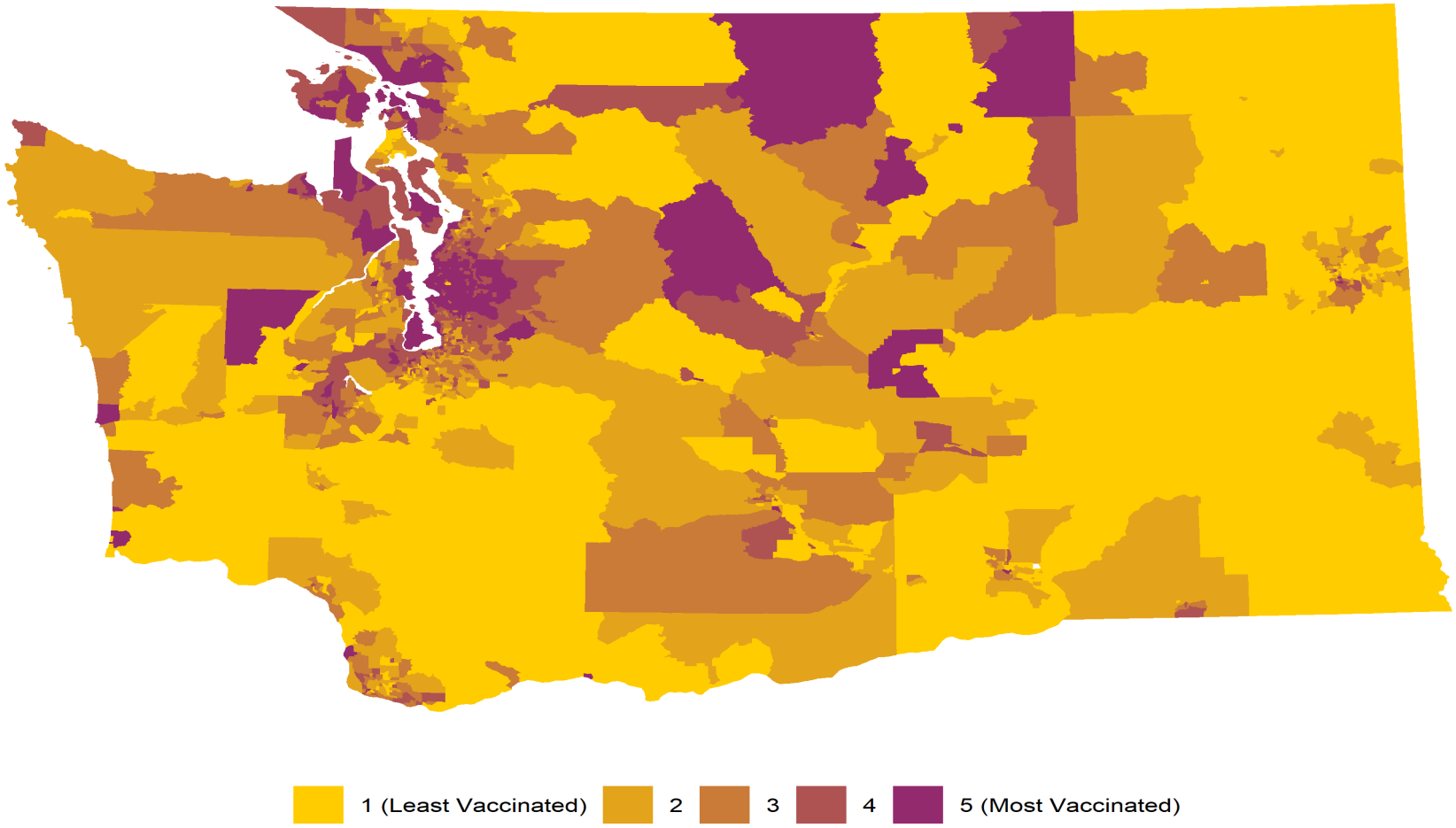


Determining Community Vaccination Rates



Vaccination Data

- Of 11,877,070 vaccinations delivered between 12/15/2020 and 12/31/2021, 98.9% provided a home address. We used this to determine a **Census tract** for each dose
- We calculated the **vaccination rate** (doses/total population) for each Census tract as of 12/31/2021
- Next, we split all Census tracts in the state into 5 groups based on the vaccination rate (highest to lowest)
- Most vaccinations were delivered in 2021, and vaccines take time to work
- We expected that the difference in excess deaths between the most and least vaccinated areas would be **relatively small in 2020** then **grow larger in 2021**



Washington Census Tracts by Assigned Vaccination Quintile

Summary and Closing Thoughts

Conclusions

- The least vaccinated areas had the highest rates of excess death
- The most vaccinated areas had the lowest rates of excess death
- Death rates were most different after vaccines became available
- Our results are consistent with other studies of COVID-19 vaccination
- Our full report, available here, covers this and other findings

Special Thanks

- WA DOH Immunization team for giving us access to this great data!
- The other co-authors (Katie Hutchinson, Sean Coffinger, Ian Painter)
- All the LHJ's and workers who distributed vaccinations, collected the data, and cleaned it
- Daniel Casey and PHSKC for developing the population dataset we used in our study
- Draft reviews by many, including Samantha Rolland, Steven Erly, Danielle Legeai, Cathy Wasserman, and the project team
- Brianna Pergola, Francesca Brina-Francis, and Samantha Rolland advised on variable coding and death data quality
- Craig Erickson maintains GIS tools used to geocode vaccinations/deaths

My Questions for You

- What are the community-level barriers to vaccination?
- What research would you like to see on vaccines and death rates?
- What do we know about boosters and death from COVID-19?
- Do you have any questions about our study?

Today's Agenda

Time	Agenda Item	Facilitator
12:25 – 12:55	**X. Respiratory Syncytial Virus**	**Elyse Bevers** **Janel Jorgenson** **Trang Kuss**
12:55 – 1:00	XI. Future Agenda Items XII. 2024 VAC Meeting Dates: Jan 11th, April 11th (hybrid), July 11th, Oct 10th XI. Adjourn	Tao Sheng Kwan-Gett

EPIDEMIOLOGY OF RESPIRATORY SYNCYTIAL VIRUS

Elyse Bevers, MPH
Office of Communicable Disease Epidemiology
Washington State Department of Health

GOALS

- Explain Respiratory Syncytial Virus (RSV) data limitations
- Provide an overview of national RSV data from three systems:
  - NVSN, RSV-Net and NRVSS
- Discuss what is known about RSV in Washington State

RSV Surveillance

RSV is not a notifiable condition in most states including Washington

- National Surveillance Systems:
  - New Vaccine Surveillance Network (NVSN)
  - Respiratory Syncytial Virus Hospitalization Surveillance Network (RSV-Net)
  - National Respiratory and Enteric Virus Surveillance System (NREVSS)

- WA Disease Surveillance Resources:
  - Rapid Information Health Network (RHINO) – Syndromic Surveillance System
  - Washington Health and Life Event System (WHALES) – Vital Record Information

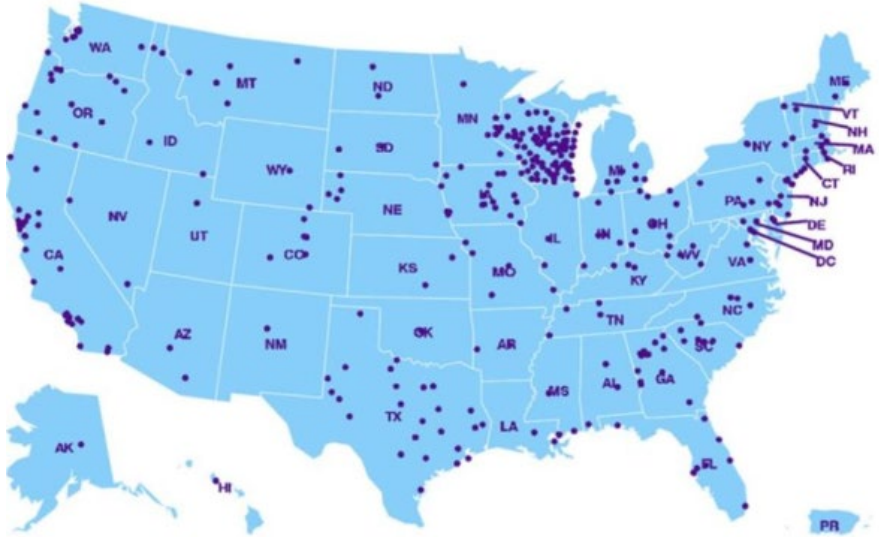
National Surveillance

National Surveillance Systems

RSV Associated Hospitalization Surveillance Network (RSV-NET)

New Vaccine Surveillance Network (NVSN)

National Respiratory and Enteric Virus Surveillance System (NREVSS)



RSV Burden Estimates – Nationwide

Each year in the United States, RSV leads to approximately:

Among children under 5 under years old:

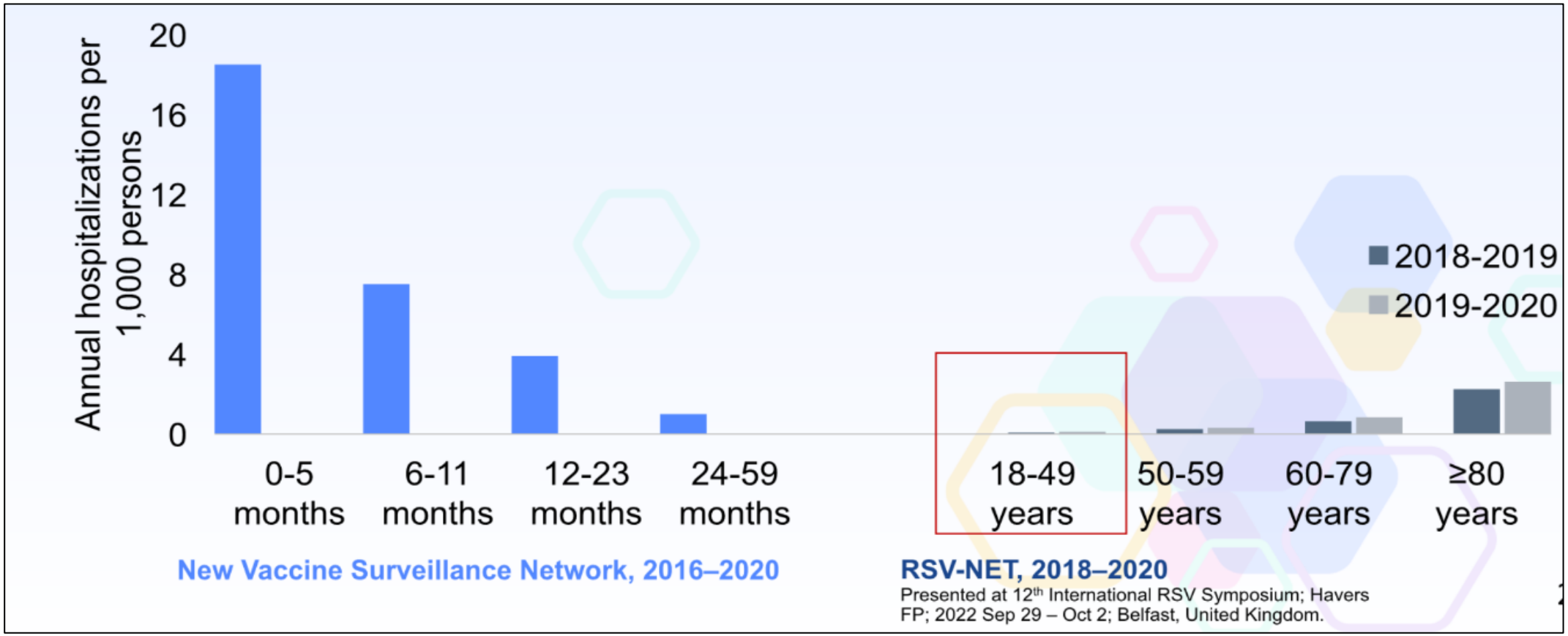
- 2.1 million outpatient visits (non-hospitalization)
- 58,000-80,000 hospitalizations
- 100–300 deaths

Among adults 65 years and older:

- 60,000-160,000 hospitalizations
- 6,000-10,000 deaths among adults 65 years and older

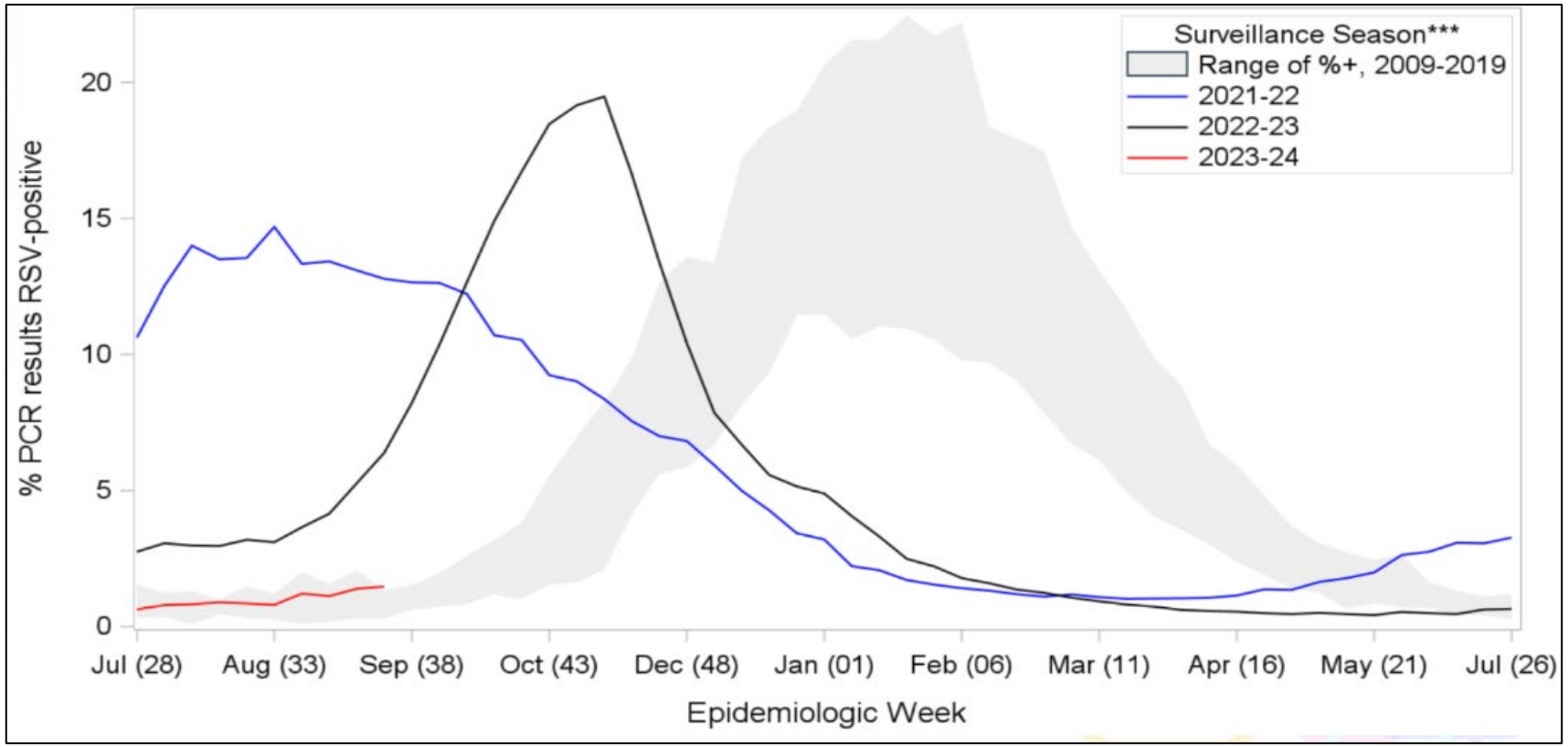
www.cdc.gov/rsv/research/index.html

Annual Rate of RSV Hospitalizations by Age Category, US



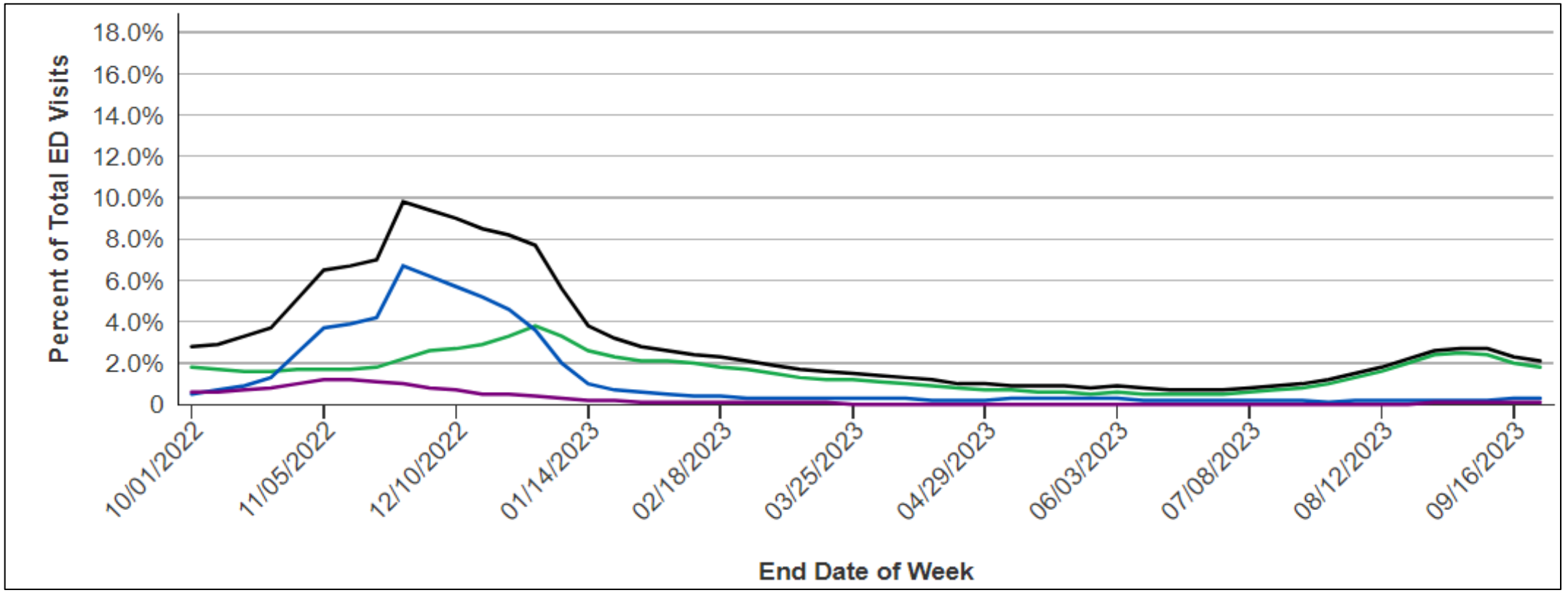
RSV-NET and NVSN

Timing of Seasonal RSV Epidemics



NREVESS

Respiratory Illness Activity Nationwide 2022-2023 Season



www.cdc.gov/wcms/vizdata/live/Respitory_Viruses/EmergencyDepartmentVisitCombined.json

Take-away Messages From National Surveillance

Experts say that **RSV** is likely to return to normal seasonal patterns following the severe 2022-2023 season

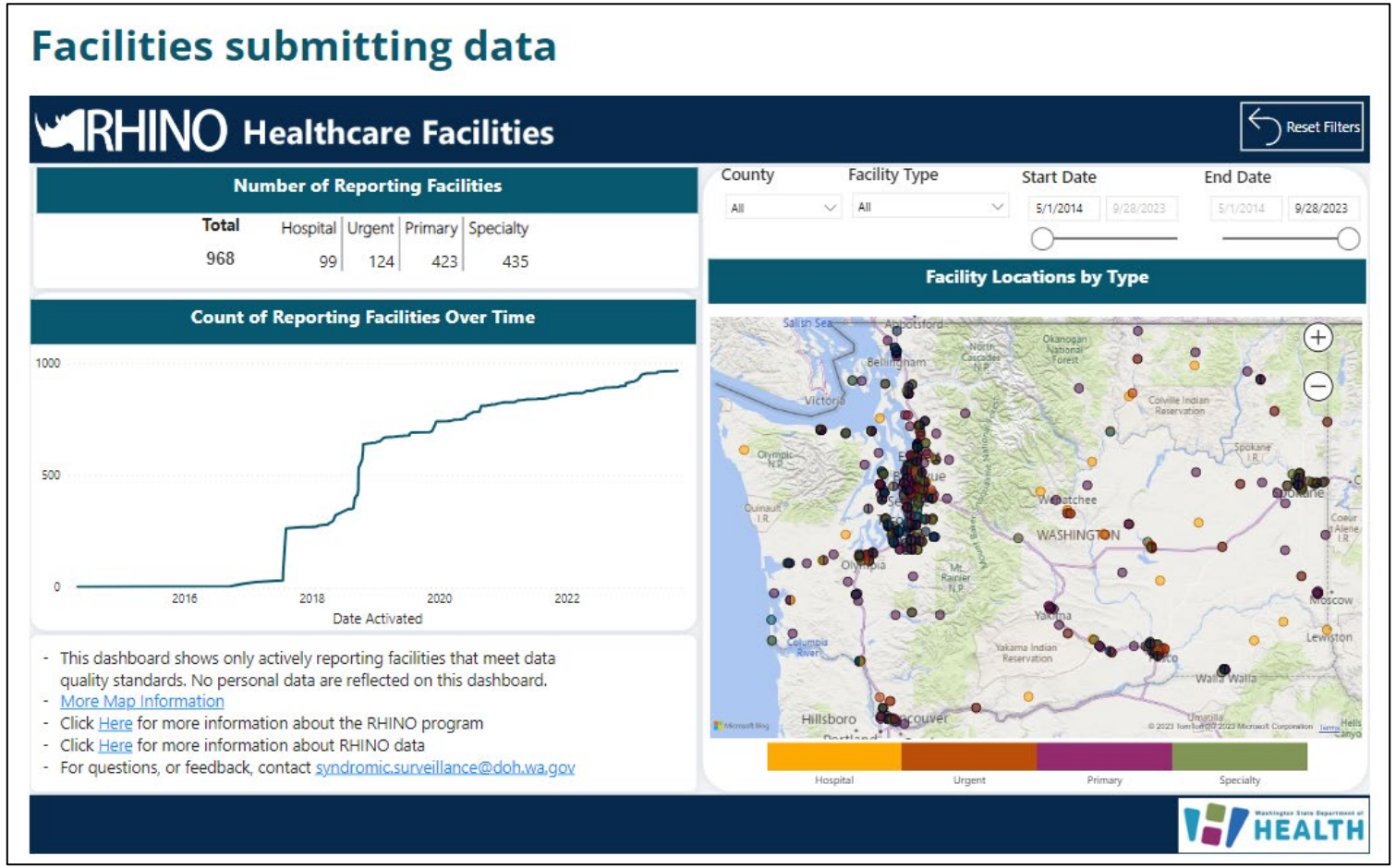
- Population immunity had been lowered by reduced RSV circulation during the early COVID-19 pandemic (2020-2021 & 2021-2022 seasons)
- The more severe 2022-2023 season likely elevated population immunity to typical levels
- The use of these new prevention products could potentially decrease hospital burden

For RSV, we have less precise estimates for the burden of illnesses and hospitalizations data on past seasons to inform expectations for this fall/winter

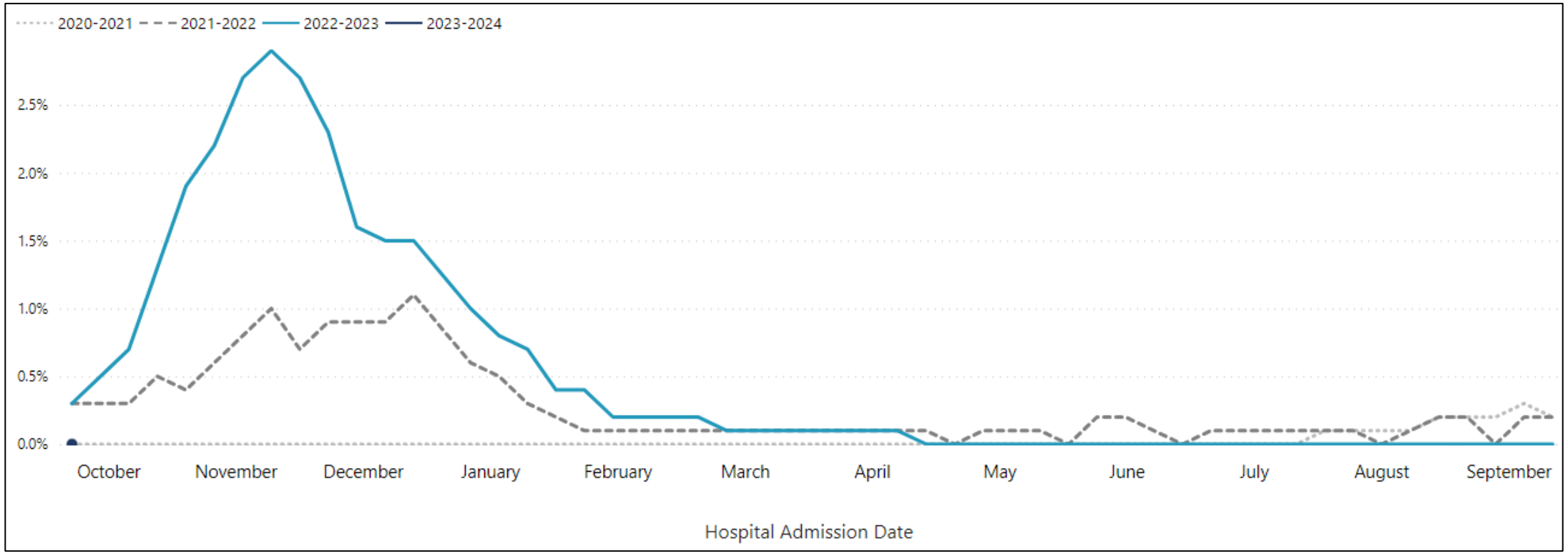
www.cdc.gov/forecast-outbreak-analytics/about/season-outlook.html

Washington State Surveillance

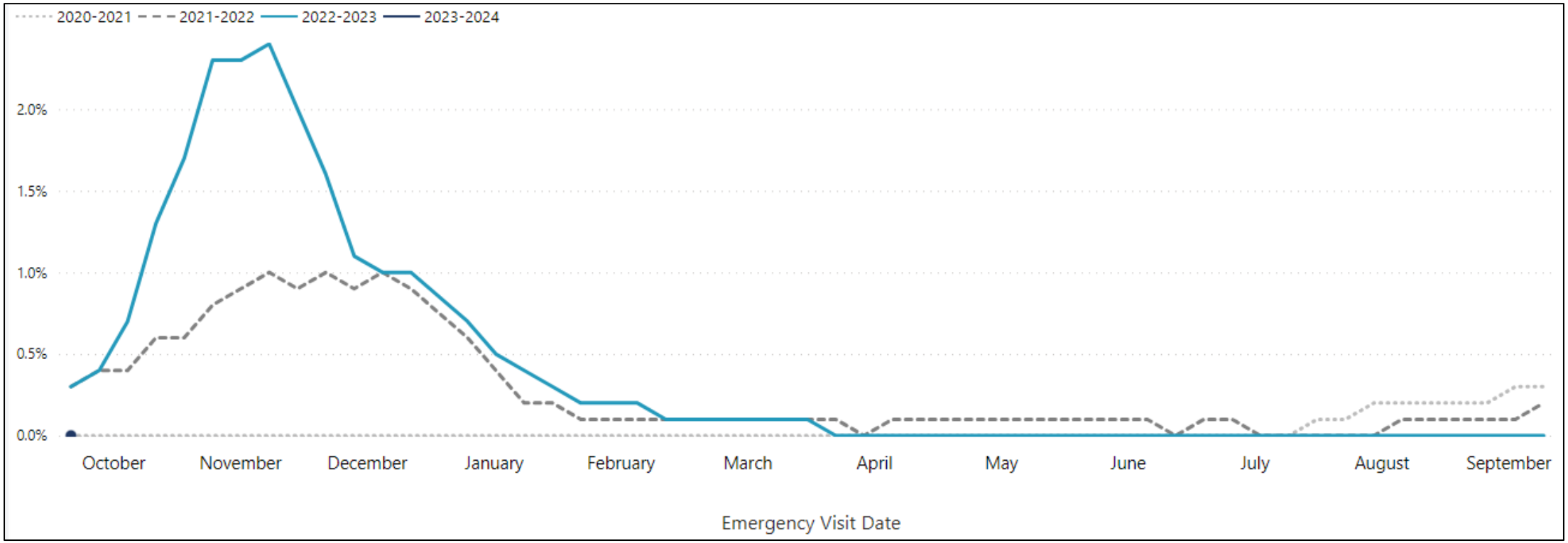
Rapid Information Health Network (RHINO)



Percent of Hospitalizations Associated with RSV, WA



Percent of Emergency Department Visits Associated with RSV, WA

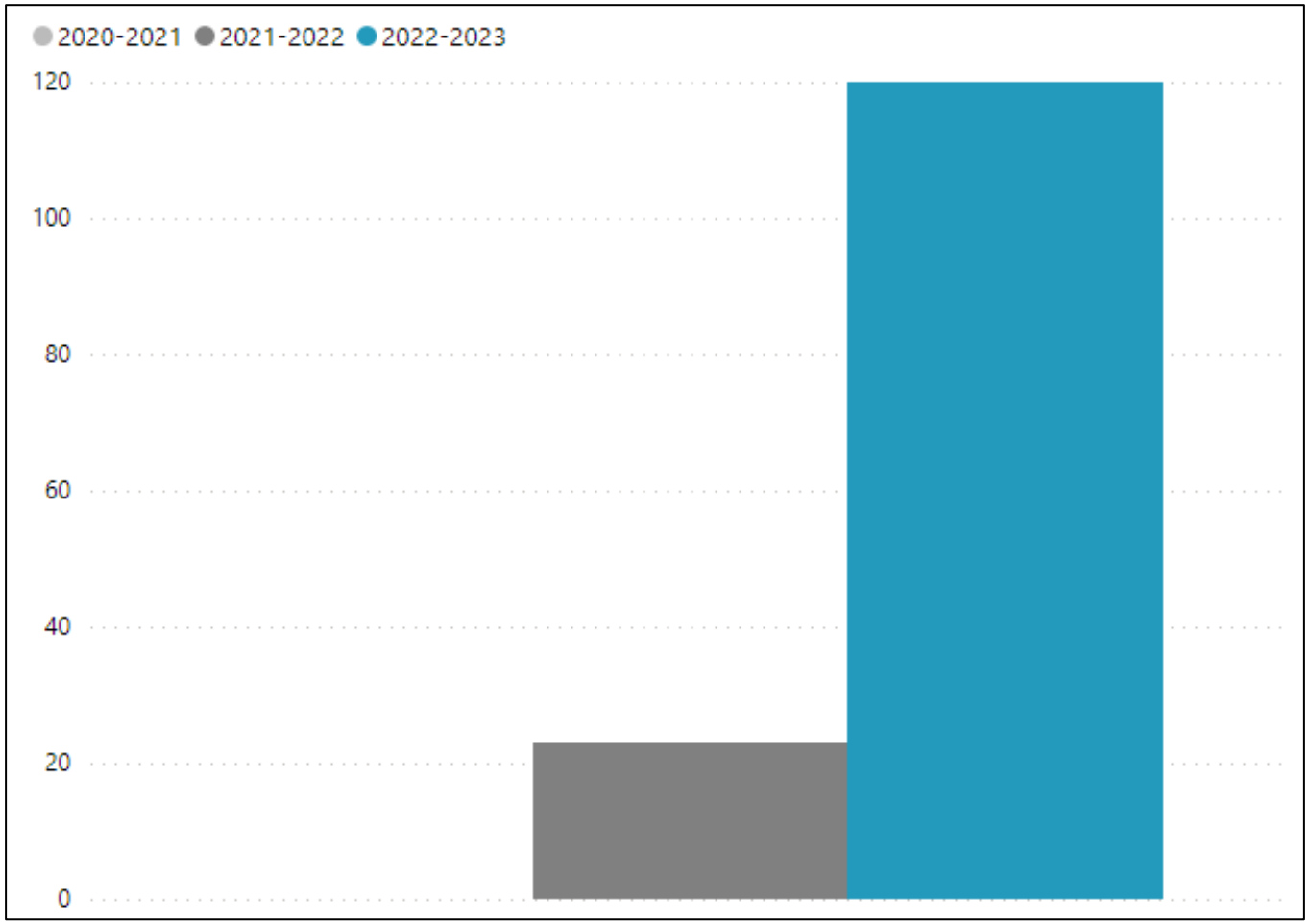


Washington Health and Life Event System (WHALES)

- The data for RSV deaths are obtained from the registered death certificates for WA residents, which are housed in WHALES.

- RSV death reporting and surveillance relies only on information in the cause of death fields on the death certificate.

RSV-Associated Deaths by Season, WA

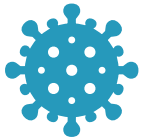


Thank you!

Explore the

WA DOH Respiratory Illness Data Dashboard

Nirsevimab Availability
Brand Name: Beyfortus



Availability & Ordering

- The Washington Vaccine Associate has agreed to fund nirsevimab as part of the Childhood Vaccine Program (CVP)
- Nirsevimab is **now available** for all CVP providers to order
- Ordering is competed in the Immunization Information System (IIS) in the same manner as childhood vaccines
- RSV will show in the IIS under the brand name Beyfortus
- Presentations:
  - 5 pack of 50 mg (or 0.5mL) prefilled syringe
  - 5 pack of 100 mg (or 1.0mL) prefilled syringe

Ordering Cont.

- CDC contract price is $395 per dose
- Providers are encouraged to order as needed
  - Smaller orders more frequently
  - Be mindful of storage space
- It will ship with routine vaccines coming from McKesson
- Product should arrive in provider offices one to two weeks after placing an order
- ACIP has recommended nirsevimab as a routine immunization. Therefore, it is an expectation CVP providers have it available for patients

Storage and Handling

- Storage and handling is similar to routine vaccines for children
- Store in refrigerator at 36-46°F (2-8°C)
- May be kept at room temperature 68-77 °F (20-25°C) for a maximum of 8 hours
- After removal from the refrigerator, must be used within 8 hours or discarded
- Store in original carton to protect from light until time of use.
- Do not freeze. Do not shake. not expose to heat.

Adult and Maternal RSV Vaccine Availability

Availability & Ordering

- Two products available
  - GSK/ Arexvy – 60+
  - Pfizer/Abrysvo – 60+ and pregnant persons
- Currently not available on CDC contract
- Widely available on commercial/private market
  - Private market price approx. $300/dose
- Will not be able to add to the Adult Vaccine Program this season for uninsured individuals due to high cost and limited funding.
- ACIP voted to include the Pfizer Abrysvo product in the VFC program for pregnant persons less than 19 years.
  - Waiting on CDC contract to make it available through CVP
  - Method for ordering is TBD and dependent on package sizes included in the CDC contract.

GSK/ Arexvy: Storage and Handling

- **Before Reconstitution:**
- Store refrigerated between 36-46°F(2-8°C)
- Do Not Freeze
- Store in original package to protect from light

- **After Reconstitution:**
- Administer immediately or
- Store in refrigerator at 36-46°F(2-8°C) OR at room temperature (up to 77°F) for up to 4 hours
- Protect from light
- Do Not Freeze
- Use within **4 hours**

Pfizer/Abrysvo: Storage and Handling

- **Before Reconstitution:**
- Store refrigerated between 36-46°F(2-8°C)
- Do Not Freeze

- **After Reconstitution:**
- Administer immediately or
- Store at room temperature 59–86 °F (15-30°C)
- Use within **4 hours**
- Do Not refrigerate
- Do Not Freeze

Tools and Resources

- DOH RSV webpage
- CDC RSV landing page
- Provider Enrollment for the CVP
- Vaccine Ordering & Receiving
- Search, Add, Reconcile & Report Inventory
- RSV Codes 2023
- Beyfortus package insert
- Arexvy package insert
- Abrysvo package insert

Questions?

Childhood Vaccine Program Main Contact Information
WAChildhoodVaccines@doh.wa.gov
Phone: (360)236-2829
Fax: (360)236-3811

RSV VACCINE RECOMMENDATIONS
OLDER ADULTS, PREGNANT PERSONS, AND NIRSEVIMAB

Trang Kuss, MN, MPH, RN

[CDC webinar New RSV Vaccines for Adults: General Information and Clinical Guidance]

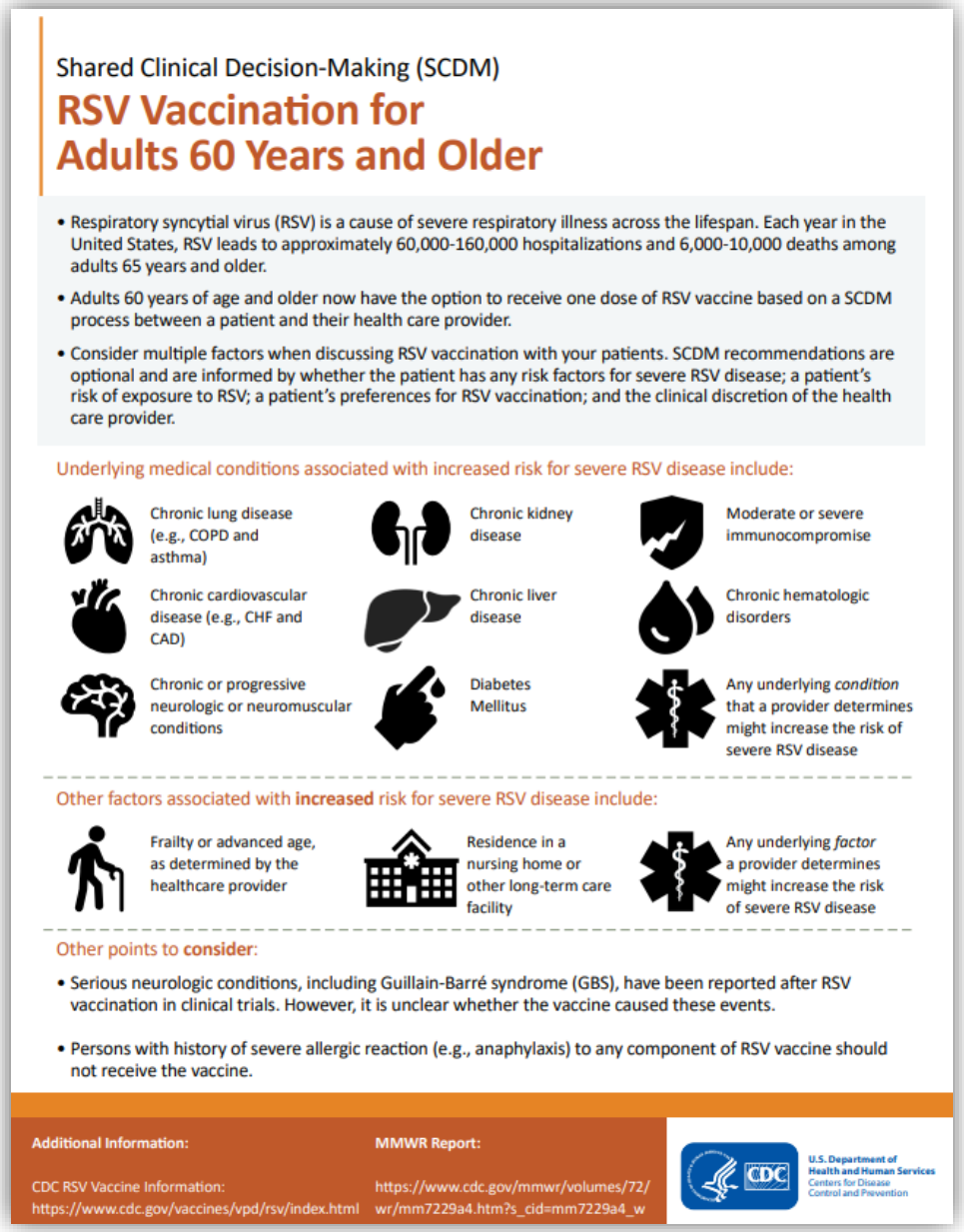
RSV Vaccines for Adults Ages 60 Years and Older

RSVPreF3 (Arexvy, GSK)

RSVpreF (Abrysvo, Pfizer, Inc.)

There is no preferential recommendation; give whichever vaccine is available.

https://www.fda.gov/media/167805/download
https://www.fda.gov/media/168889/download
Photo source: GSK and Pfizer, Inc.



Shared Clinical Decision-Making (SCDM)

RSV Vaccination for Adults 60 Years and Older

- Respiratory syncytial virus (RSV) is a cause of severe respiratory illness across the lifespan. Each year in the United States, RSV leads to approximately 60,000-160,000 hospitalizations and 6,000-10,000 deaths among adults 65 years and older.
- Adults 60 years of age and older now have the option to receive one dose of RSV vaccine based on a SCDM process between a patient and their health care provider.
- Consider multiple factors when discussing RSV vaccination with your patients. SCDM recommendations are optional and are informed by whether the patient has any risk factors for severe RSV disease; a patient's risk of exposure to RSV; a patient's preferences for RSV vaccination; and the clinical discretion of the health care provider.

Underlying medical conditions associated with increased risk for severe RSV disease include:

- Chronic lung disease (e.g., COPD and asthma)
- Chronic kidney disease
- Moderate or severe immunocompromise
- Chronic cardiovascular disease (e.g., CHF and CAD)
- Chronic liver disease
- Chronic hematologic disorders
- Chronic or progressive neurologic or neuromuscular conditions
- Diabetes Mellitus
- Any underlying *condition* that a provider determines might increase the risk of severe RSV disease

Other factors associated with **increased** risk for severe RSV disease include:

- Frailty or advanced age, as determined by the healthcare provider
- Residence in a nursing home or other long-term care facility
- Any underlying *factor* a provider determines might increase the risk of severe RSV disease

Other points to **consider**:

- Serious neurologic conditions, including Guillain-Barré syndrome (GBS), have been reported after RSV vaccination in clinical trials. However, it is unclear whether the vaccine caused these events.
- Persons with history of severe allergic reaction (e.g., anaphylaxis) to any component of RSV vaccine should not receive the vaccine.

Additional Information:

CDC RSV Vaccine Information:
https://www.cdc.gov/vaccines/vpd/rsv/index.html

MMWR Report:

https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm?s_cid=mm7229a4_w

CDC

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

[RSV Vaccination for Adults 60 Years and Older (cdc.gov)]

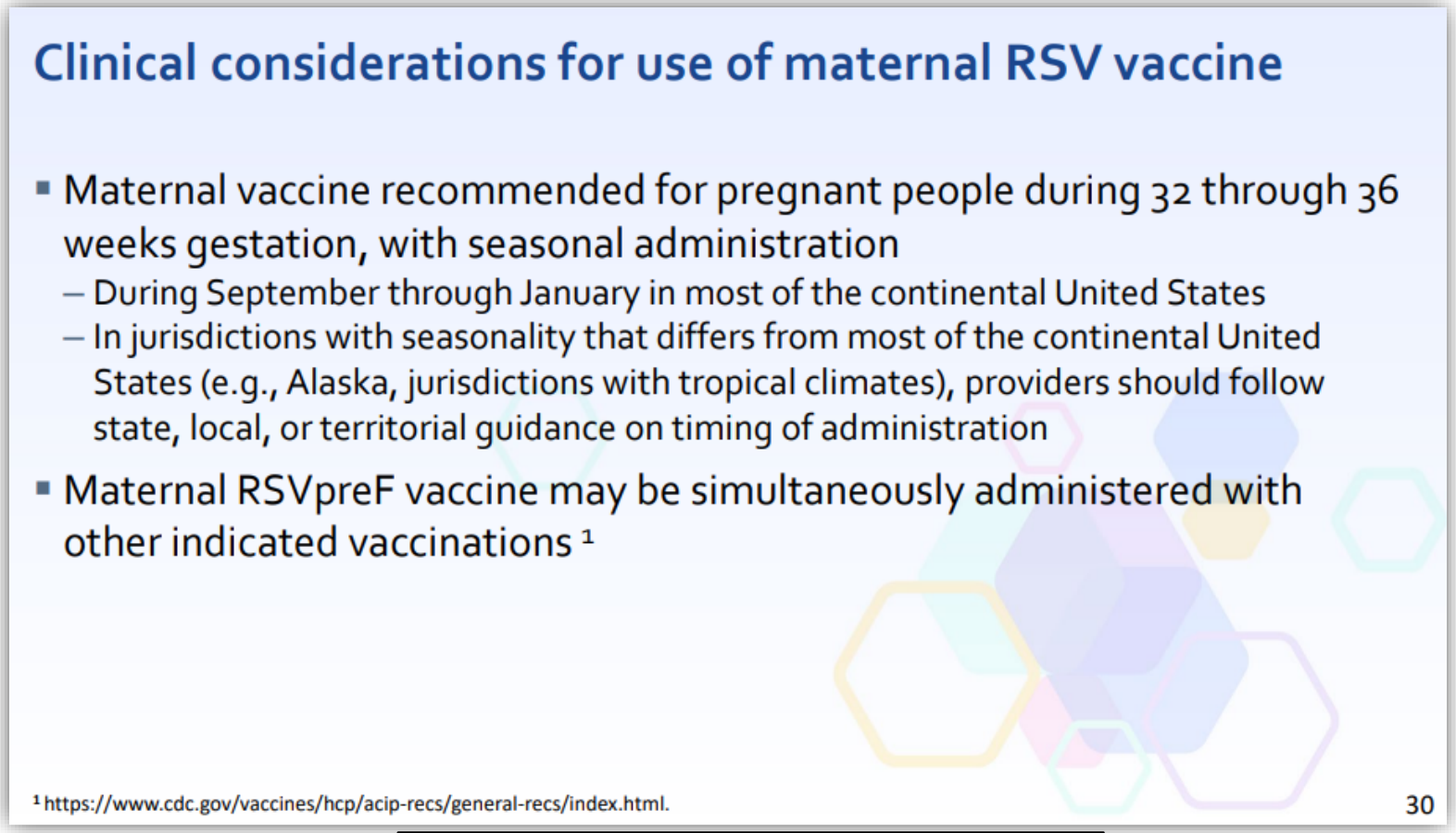
V-safe

- New version of V-safe developed starting Summer 2023
  - Leverages existing CDC IT infrastructure
  - Includes email and text messaging options
  - First use for RSV vaccines received by persons aged 60 and older
  - Use for maternal RSV vaccines planned for later this fall

- **V-safe objectives:**
  1. Characterize local and systemic reactogenicity during days 0-7 after vaccination
  2. Characterize health impacts during a 6-week post-vaccination follow-up period
  3. Identify participants who report medically attended events after vaccination and encourage completion of a VAERS report

CDC webinar Clinical Considerations for Maternal RSVPreF Vaccine and Nirsevimab

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 (cdc.gov)



RSVpreF vaccine=Abrysvo (Pfizer)

ACIP meeting 092223 slides Evidence to Recommendations Framework Updates

Work Group members found the following data reassuring regarding preterm birth imbalance

- When using the full trial dosing interval (24–36 weeks gestation), most preterm births (60%) were >30 days after vaccination, and no known biologic mechanism for vaccines to cause preterm birth, particularly >30 days after vaccination
- When assessed among those vaccinated during the approved interval (32–36 weeks gestation), data on preterm birth were reassuring to the Work Group
  - Imbalance in preterm birth was still present but lessened
  - Most infants born preterm in the vaccine group (72%, 49/68) were born at 36 weeks
  - In the United States (largest contributing country in the trial), imbalance in preterm births reversed:
    - Trial dosing interval: 5.7% in vaccine vs. 5.3% in placebo recipients
    - Approved dosing interval: 4.0% in vaccine vs. 4.4% in placebo recipients
- Majority of the Work Group felt the approved dosing interval (32–36 weeks gestation) reduces the potential risk of preterm birth and the potential for complications from preterm birth, which is their major safety concern

Nirsevimab is a passive immunization

- Active immunity results from infection or vaccination, which triggers an immune response
- Passive immunity is when a person receives antibodies from an external source
  - From mother to baby through transplacental or breastmilk transfer
  - Direct administration of antibodies, such as IVIG or monoclonal antibodies

Nirsevimab (brand name Beyfortus), a long-acting monoclonal antibody, is given by injection. The antibody boosts the immune system, adding an extra layer of defense against severe illness from respiratory syncytial virus

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 (cdc.gov)

Timing of nirsevimab for infants born shortly before or during RSV season

- Nirsevimab should be administered within 1 week of birth.
  - Administration can be during the birth hospitalization or in the outpatient setting
- Infants with prolonged birth hospitalizations due to prematurity or other causes should receive nirsevimab shortly before or promptly after discharge

ACIP Meeting Nirsevimab

CDC webinar Clinical Considerations for Maternal RSVPreF Vaccine and Nirsevimab

Timing of nirsevimab

- Providers should target administration[1]:
  - In the first week of life for infants born shortly before and during the season
  - Shortly before the start of the RSV season for infants aged <8 months
  - Shortly before the start of the RSV season for children aged 8–19 months who are at increased risk of severe RSV disease
- Based on pre-pandemic patterns, this means nirsevimab could be administered in most of the continental United States from October through the end of March
- Because timing of the onset, peak, and decline of RSV activity may vary, providers can adjust administration schedules based on local epidemiology

[1] While optimal timing for nirsevimab administration is shortly before the season, nirsevimab may be given at any time during the RSV season for age-eligible infants and children who have not yet received a dose

[CDC webinar Clinical Considerations for Maternal RSVPreF Vaccine and Nirsevimab]

Children aged 8–19 months recommended to receive nirsevimab when entering their second RSV season because of increased risk of severe disease

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season
- Children with severe immunocompromise
- Children with cystic fibrosis who have manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or weight-for-length <10th percentile
- American Indian and Alaska Native children

Nirsevimab Dosing

- All infants aged <8 months born during or entering their first RSV season
  - 50 mg for infants weighing <5 kg [<11 lb]
  - 100 mg for infants weighing ≥5 kg [≥11 lb])
- Children aged 8–19 months who are at increased risk for severe RSV disease and entering their second RSV season
  - 200 mg, administered as two 100 mg injections given at the same time at different injection sites
- Can be co-administered with other routine vaccines

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 (cdc.gov)

CDC webinar Clinical Considerations for Maternal RSVPreF Vaccine and Nirsevimab

Recommendations for use of nirsevimab in setting of an available maternal RSV vaccine

- Nirsevimab is recommended for infants aged <8 months born during or entering their first RSV season if
  - Mother did not receive RSV vaccine or unknown if mother received RSV vaccine
  - Mother vaccinated but infant born <14 days after vaccination
- Nirsevimab is not needed for most infants born ≥14 days after maternal vaccination

CDC webinar Clinical Considerations for Maternal RSVPreF Vaccine and Nirsevimab

Circumstances for which nirsevimab can be considered when mother has received RSV vaccine ≥14 days prior to birth

- Nirsevimab can be considered in rare circumstances when, per the clinical judgment of the healthcare provider, the potential incremental benefit of administration is warranted
  - Infants born to pregnant people who may not mount an adequate immune response to vaccination (e.g., people with immunocompromising conditions) or have conditions associated with reduced transplacental antibody transfer (e.g., people living with HIV infection)[1]
  - Infants with cardiopulmonary bypass, leading to loss of maternal antibodies
  - Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission and requiring oxygen at discharge)

[1] Palmerira Clin Dev Immunol 2012.

Nirsevimab Administration by MAs

- The statutes and rules that govern the MA's scope of practice would not prohibit them from administering nirsevimab or biologic medications (WAC 246-827-0240).
- Delegation laws
  - MAs cannot be delegated anything requiring the exercise of clinical judgement, complex observation, or that presents the risk of immediate or serious harm to the patient. Whether or not the task is delegable to the MA is a decision for the healthcare organization/supervising healthcare practitioner.
- A healthcare organization can implement policies that go above and beyond the state statute and rule restrictions if determined necessary.

References:
http://app.leg.wa.gov/RCW/default.aspx?cite=18.360.060
http://app.leg.wa.gov/WAC/default.aspx?cite=246-827-0110

Resources

- Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over | CDC
- ACIP Shared Clinical Decision-Making Recommendations | CDC
- Respiratory Syncytial Virus | Washington State Department of Health
- CDC webinar RSV Vaccination in Adults 60 years and Older
- CDC Webinar Clinical Guidance for Use of Products to Prevent RSV Disease in Infants
- ACIP September 22, 2023 Presentation Slides | Immunization Practices | CDC
- ACIP Vaccine Recommendations and Schedules | CDC
- Update on RSV and New Vaccine Recommendation | CDC
- 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 (cdc.gov)
- Healthcare Providers: RSV Immunization for Children 19 Months and Younger | CDC

Today's Agenda

Time	Agenda Item	Facilitator
12:55 – 1:00	**xi. Future Agenda Items** **xii. 2024 VAC Meeting Dates:** **Jan 11th, April 11th (hybrid), July 11th, Oct 10th** **xi. Adjourn**	**Tao Sheng Kwan-Gett**

Washington State Department of HEALTH

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