Vaccine Update: COVID-19 and RSV

Shireesha Dhanireddy, MD
University of Washington

Last Updated 12 October 2023

Disclosures

No conflicts of interest to disclose

Disclaimer

Funding for this presentation was made possible by U1OHA29296 from the Human Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. *Any trade/brand names for products mentioned during this presentation are for training and identification purposes only.*

AETC AIDS Education & Training Center Program Mountain West

COVID-19 Vaccines

Currently Available FDA-Approved COVID-19 Vaccines

- mRNA Vaccines
  - Moderna COVID-19 Vaccine (2023-2024 formula) and SPIKEVAX.
    - SPIKEVAX is the product licensed for people ages ≥ 12 years
  - Pfizer-BioNTech COVID-19 Vaccine (2023-2024 formula) and COMIRNATY.
    COMIRNATY is the product licensed for people ages ≥ 12 years

- Protein subunit vaccine
  - Novavax COVID-19 Vaccine, Adjuvanted authorized for people ages ≥ 12 years

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02

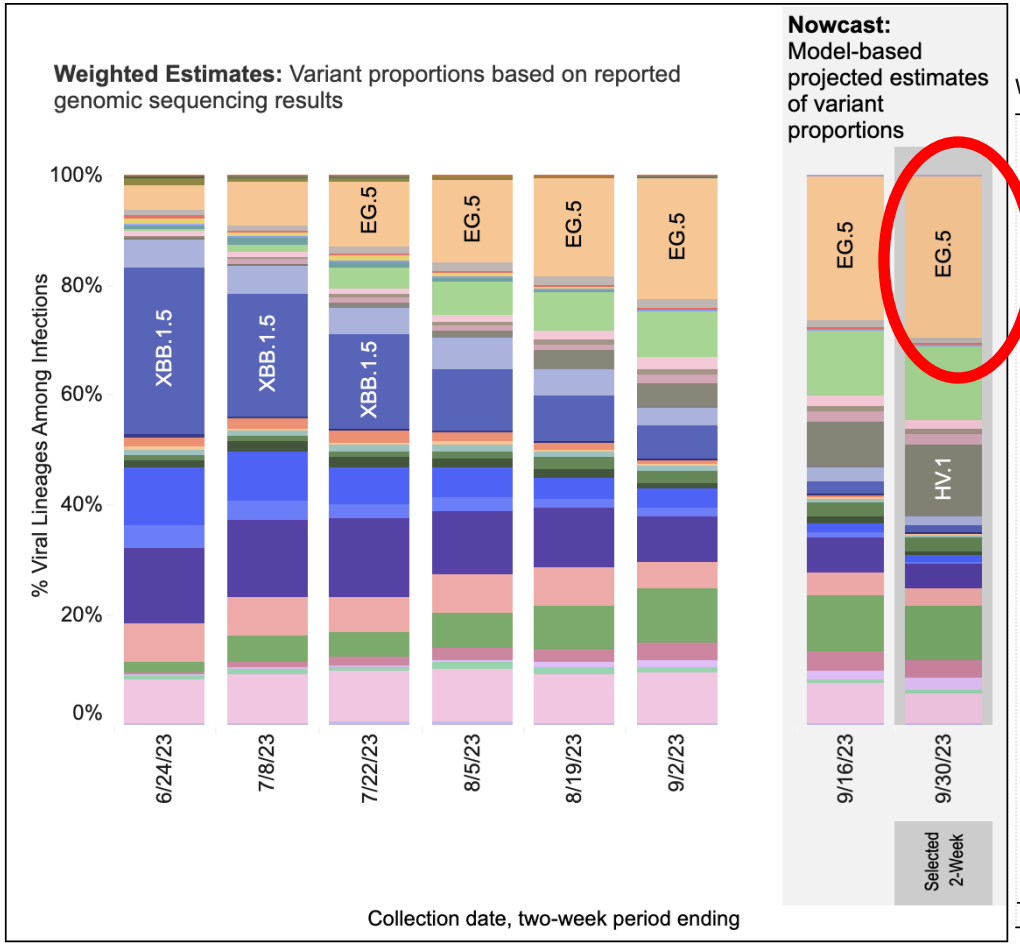
MWAETC

Updated COVID-19 Vaccines

- Now monovalent vaccines again
- Targeted toward Omicron XBB.1.5 sublineage of SARS-CoV-2
  - The original and bivalent vaccines targets the wild-type strain and Omicron BA.4/BA.5

Weighted and Nowcast Estimates in United States for 2-Week Periods in 6/11/2023 – 9/30/2023

Hover over (or tap in mobile) any lineage of interest to see the amount of uncertainty in that lineage's estimate.



Nowcast Estimates in United States for 9/17/2023 – 9/30/2023

USA

WHO label	Lineage #	%Total	95%PI
Omicron	EG.5	29.4%	26.4-32.6%
	FL.1.5.1	13.7%	10.8-17.1%
	HV.1	12.9%	10.5-15.6%
	XBB.1.16.6	10.1%	8.6-11.7%
	XBB.2.3	5.6%	4.7-6.5%
	XBB.1.16	4.3%	3.8-4.9%
	XBB.1.16.11	3.2%	2.6-3.9%
	XBB.1.16.1	3.0%	2.4-3.8%
	XBB.1.5.70	2.5%	1.9-3.4%
	XBB.1.16.15	2.0%	1.4-3.0%
	HF.1	1.8%	1.1-2.9%
	XBB	1.8%	1.5-2.1%
	GE.1	1.7%	1.3-2.2%
	XBB.1.5	1.1%	1.0-1.3%
	XBB.1.9.1	1.1%	0.9-1.3%
	EG.6.1	1.0%	0.7-1.4%
	GK.2	0.9%	0.7-1.3%
	XBB.1.5.72	0.8%	0.6-1.0%
	XBB.1.42.2	0.7%	0.4-1.1%
	XBB.1.9.2	0.5%	0.4-0.7%
	XBB.1.5.68	0.5%	0.3-0.8%
	XBB.1.5.10	0.4%	0.3-0.6%
	XBB.2.3.8	0.3%	0.2-0.4%
	CH.1.1	0.2%	0.1-0.3%
	XBB.1.5.59	0.2%	0.1-0.3%
	FD.1.1	0.2%	0.1-0.2%
	FE.1.1	0.1%	0.1-0.2%
	BA.2	0.1%	0.0-0.2%
	EU.1.1	0.0%	0.0-0.1%
	XBB.1.5.1	0.0%	0.0-0.0%
	BQ.1	0.0%	0.0-0.0%
	FD.2	0.0%	0.0-0.0%
	BA.5	0.0%	0.0-0.0%
Other	Other*	0.1%	0.0-0.1%

How well do the new COVID-19 vaccines work?

- EG.5 now the most prevalent
- Descendent of XBB strain and genetically similar so vaccine is predicted to work
- Not going to prevent all symptomatic infection
- No head-to-head studies of mRNA vs protein subunit vaccine
- Goal is to still prevent hospitalizations and deaths
- CDC estimates that with universal COVID-19 vaccine recommendation, 400,000 hospitalizations and 40,000 deaths could be prevented over the next 2 years

- Should I mix and match?

  Some data suggest that Novavax booster after primary mRNA vaccine suggest similar to superior responses to mRNA boosters

MWAETC

2023-2024 CDC ACIP COVID-19 Vaccine Recommendations

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine*	Updated (2023–2024 Formula) vaccine	Number of updated (2023–2024 Formula) doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors§	Interval between doses
Unvaccinated	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	—
	OR				
	Novavax	2	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	Dose 1 and Dose 2: 3–8 weeks†
	OR				
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	—
1 or more doses any mRNA; 1 or more doses Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine doses	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose
	OR				
	Novavax	1	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	At least 8 weeks after last dose
	OR				
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-01

MWAETC

2023-2024 CDC ACIP COVID-19 Vaccine Recommendations for Moderate to Severely Immunocompromised Persons

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine†	Updated (2023–2024 Formula) vaccine	Number of updated (2023–2024 Formula) doses indicated‡	Dosage (mL/ug)	Vaccine vial cap and label colors§	Interval between doses
Unvaccinated	Moderna	3	0.5 mL/50 ug	Dark blue cap; blue label	Dose 1 and Dose 2: 4 weeks Dose 2 and Dose 3: At least 4 weeks
	OR				
	Novavax	2	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	Dose 1 and Dose 2: 3 weeks
	OR				
	Pfizer-BioNTech	3	0.3 mL/30 ug	Gray cap; gray label	Dose 1 and Dose 2: 3 weeks Dose 2 and Dose 3: At least 4 weeks

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02

MWAETC

RSV Vaccines

Respiratory Syncytial Virus (RSV)

- One of the most common causes of illness
- Most common cause of hospitalization in infants
- Adults typically have mild or no symptoms but people 60+ at higher risk for lower respiratory disease
- RSV season starts in the fall and peaks in the winter typically

MWAETC

RSV: Risk Factors for Severe Disease

Chronic underlying medical conditions associated with increased risk

- Lung disease (such as chronic obstructive pulmonary disease and asthma)
- Cardiovascular diseases (such as congestive heart failure and coronary artery disease)
- Moderate or severe immune compromise*
- Diabetes mellitus
- Neurologic or neuromuscular conditions
- Kidney disorders
- Liver disorders
- Hematologic disorders
- Other underlying conditions that a health care provider determines might increase the risk for severe respiratory disease

Other factors associated with increased risk

- Frailty†
- Advanced age§
- Residence in a nursing home or other long-term care facility
- Other underlying factors that a health care provider determines might increase the risk for severe respiratory disease

MWAETC

RSV Vaccines

Morbidity and Mortality Weekly Report (*MMWR*)

Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023

Weekly / July 21, 2023 / 72(29);793–801

- 2 FDA approved vaccines
  - RSVPreF3 (Arexvy, GSK)
  - RSVPreF (Abrysvo, Pfizer)

RSV Vaccines

TABLE 1. Efficacy of 1 dose of GSK respiratory syncytial virus RSVpreF3 vaccine against respiratory syncytial virus–associated disease among adults aged ≥60 years — multiple countries, 2021–2023

Return

Efficacy evaluation period	Vaccine efficacy against outcome*	
	RSV-associated LRTD†	RSV-associated medically attended LRTD§
Season 1¶	82.6 (57.9–94.1)**	87.5 (58.9–97.6)††
Season 2§§	56.1 (28.2–74.4)††	—¶¶
Combined seasons 1 and 2 (interim)***	74.5 (60.0–84.5)†††	77.5 (57.9–89.0)††

TABLE 3. Efficacy of 1 dose of Pfizer respiratory syncytial virus RSVpreF vaccine against respiratory syncytial virus–associated disease among adults aged ≥60 years — multiple countries, 2021–2023

Return

Efficacy evaluation period	Vaccine efficacy against outcome, % (95% CI)*	
	RSV-associated LRTD†	RSV-associated medically attended LRTD§
Season 1¶	88.9 (53.6–98.7)	84.6 (32.0–98.3)
Season 2 (interim)**	78.6 (23.2–96.1)	—††
Combined seasons 1 and 2 (interim)§§	84.4 (59.6–95.2)	81.0 (43.5–95.2)

MWAETC

RSV Vaccines

TABLE 2. Safety* of 1 dose of GSK respiratory syncytial virus RSVPreF3 vaccine in adults aged ≥60 years — multiple countries, 2021–2023

Return

Safety event	Risk for event		
	RSVPreF3 recipients no./No. (%)†	Placebo recipients no./No. (%)§	Relative risk (95% CI)¶
Serious AE**	549/12,570 (4.4)	540/12,604 (4.3)	1.02 (0.91–1.15)
Severe reactogenicity events††	37/979 (3.8)	9/976 (0.9)	4.10 (1.99–8.45)
Inflammatory neurologic events§§	3 events in trials without placebo recipients¶¶	—¶¶	—¶¶

TABLE 4. Safety* of 1 dose of Pfizer respiratory syncytial virus RSVpreF vaccine in adults aged ≥60 years — multiple countries, 2021–2023

Return

Safety event	Risk for event		
	RSVpreF recipients no./No. (%)†	Placebo recipients no./No. (%)§	Relative risk (95% CI)¶
Serious AE**	792/18619 (4.3%)	749/18334 (4.1%)	1.04 (0.94–1.15)
Severe reactogenicity events††	36/3673 (1.0%)	24/3491 (0.7%)	1.43 (0.85–2.39)
Inflammatory neurologic events§§	3/18622 (—)¶¶	0/18335 (—)	—¶¶

MWAETC

RSV Vaccines Summary

- Two new RSV vaccines from GSK (Arexvy) Pfizer (Abrysvo) were FDA approved in May 2023 for adults ≥60
- Both vaccines were generally safe and well-tolerated in phase 3 clinical trials, and demonstrated >80% efficacy against symptomatic
- Both are protein-based (not live) vaccines
- Immunocompromised patients were not included in the trials; efficacy in this group is unknown, and further studies are needed to assess for any specific safety concerns

MWAETC

CDC ACIP RSV Vaccine Recommendations 2023-2024

- Adults age ≥ 60 years MAY receive a single dose of RSV vaccine using shared decision-making

- Abrysvo (Pfizer) is also FDA approved for pregnant individuals between 32 and 36 weeks of gestational age to confer RSV protection to young infants

- If given, vaccinate before onset of RSV season ideally
- Ok to give with other vaccines (no data however)

- Infants: New monoclonal antibody (Nirsevimab)
  - Recommended for all infants younger than 8 months born during RSV season or entering their first RSV season (except if born ≥ 14 days after maternal RSV vaccination)
  - Some children 8-19 months at increased risk for severe RSV and entering their second RSV season

Premature with chronic lung disease
Severe immunocompromise
Cystic fibrosis
American Indian and Alaska Native

MWAETC

Summary

- Don’t forget flu shots
- Recommendations for COVID-19 vaccine 2023-2024 booster for people with HIV not different from general population except:
  - CD4 count < 200 or uncontrolled HIV – then follow immunocompromised vaccine schedule guidance
- RSV vaccine is a “consider” recommendations for people 60+ through shared decision making, except for pregnant individuals for whom there is a stronger recommendation

- *On a different note – mpox is back! Don’t forget to immunize those at risk who didn’t receive or complete their vaccination series before!*

MWAETC

Acknowledgment

This Mountain West AIDS Education and Training (MWAETC) program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $3,333,289 with 0% financed with non-governmental sources.

The content in this presentation are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by, HRSA, HHS, or the U.S. Government.

AETC AIDS Education & Training Center Program Mountain West