IZB Clinical Updates

Priyanka Saxena, DO, MPH

Reminder: J&J/Janssen COVID-19 Vaccine EUA Revoked

- May 2023: All doses of J&J/Janssen COVID-19 vaccine expired
- June 1, 2023: FDA revoked the Emergency Use Authorization (EUA) for the J&J/Janssen COVID-19 vaccine
- Recommendations:
  - Dispose of any remaining doses.
  - If expired vaccine was administered, report to VAERS and revaccinate with an authorized COVID-19 vaccine.

FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting – June 15, 2023

Voting Question

Vaccine composition: For the 2023-2024 Formula of COVID-19 vaccines in the U.S., does the committee recommend a periodic update of the current vaccine composition to a monovalent XBB-lineage?

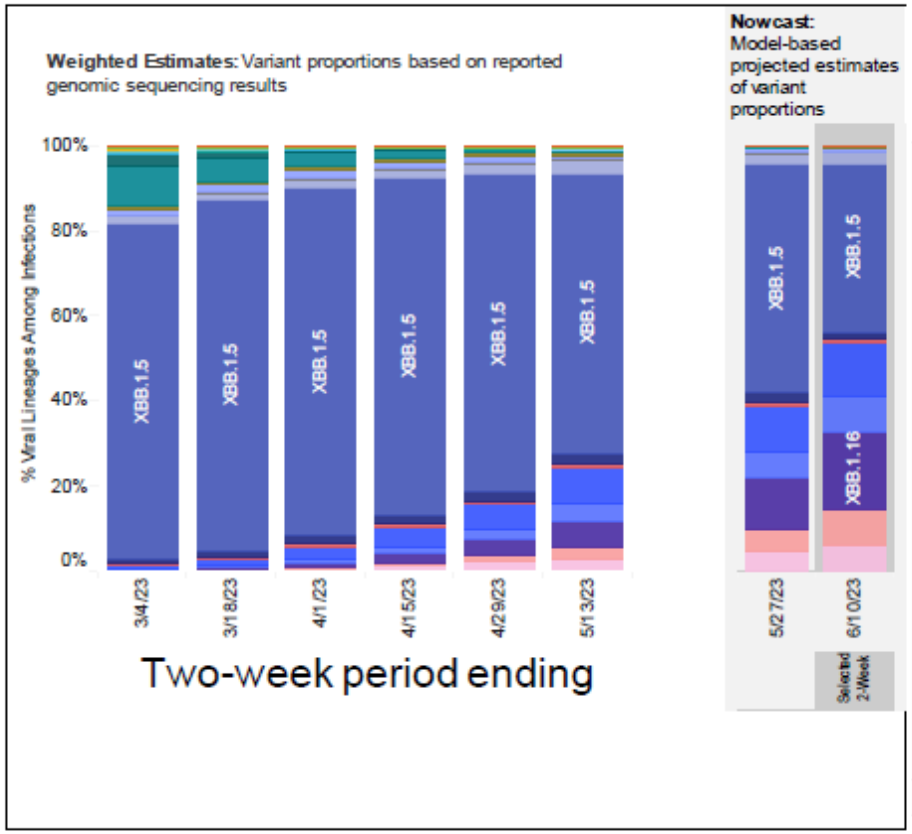
Committee vote on 6/15/23: Unanimous Yes (21/21 panel members)

VRBPAC voted to recommend an update of the COVID-19 vaccine to a monovalent XBB.1.5-lineage composition for the 2023-2024 formulation.

Moving to an XBB-lineage composition for vaccine would improve protection against currently circulating strains.

Trends in Weighted Variant Proportion Estimates & Nowcast United States, February 19-June 10, 2023

Weighted and Nowcast Estimates in United States for 2-Week Periods in 2/19/2023 – 6/10/2023



Nowcast Estimates in United States for 5/28/2023 – 6/10/2023

USA

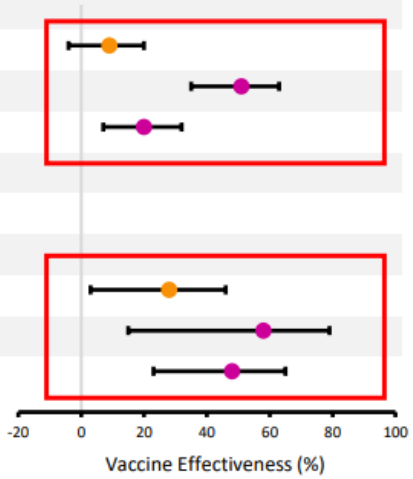
WHO label	Lineage #	US Class	%Total	95%PI
Omicron	XBB.1.5	VOC	39.9%	36.7-43.2%
	XBB.1.16	VOC	18.2%	15.5-21.2%
	XBB.1.9.1	VOC	12.5%	11.0-14.3%
	XBB.1.16.1	VOC	8.4%	6.1-11.5%
	XBB.1.9.2	VOC	8.4%	6.3-11.1%
	XBB.2.3	VOC	6.0%	4.4-8.1%
	XBB	VOC	3.0%	2.0-4.7%
	XBB.1.5.1	VOC	1.6%	1.2-2.1%
	FD.2	VOC	0.9%	0.3-2.1%
	XBB.1.5.10	VOC	0.8%	0.5-1.3%
	CH.1.1	VOC	0.2%	0.1-0.2%
	BQ.1.1	VOC	0.1%	0.0-0.1%
	BQ.1	VOC	0.0%	0.0-0.0%
	BA.2	VOC	0.0%	0.0-0.0%
	BA.5	VOC	0.0%	0.0-0.0%
	BA.2.75	VOC	0.0%	0.0-0.0%
	BN.1	VOC	0.0%	0.0-0.0%
	BF.7	VOC	0.0%	0.0-0.0%
Other	Other*		0.0%	0.0-0.0%

PI=Prediction Interval, VOC=Variants of Concern, VBM=Variants Being Monitored. https://covid.cdc.gov/covid-data-tracker/#variant-proportions Accessed June 9, 2023

Bivalent Vaccines Protect Against Severe Illness

VISION: *Absolute* VE of *monovalent* and *bivalent* booster doses against *hospitalization* and *critical illness* among immuno*competent* adults aged ≥18 years, during *XBB* predominance – January – May 2023

mRNA Dosage Pattern	Total tests	SARS-CoV-2-test-positive, N (%)	Median interval since last dose, days (IQR)	Adjusted VE (95% CI)
Hospitalization				
Unvaccinated (ref)	4,979	409 (8)	--	Ref
Monovalent doses only	11,279	980 (9)	469 (375-605)	9 (-4 to 20)
Bivalent booster, 7-89 days earlier	1,045	60 (6)	65 (43-79)	**51 (35 to 63)**
Bivalent booster, 90-179 days earlier	4,654	419 (9)	139 (119-157)	**20 (7 to 32)**
Critical illness				
Unvaccinated (ref)	4,652	82 (2)	--	Ref
Monovalent doses only	10,439	140 (1)	469 (375-602)	**28 (3 to 46)**
Bivalent booster, 7-89 days earlier	994	9 (1)	65 (43-78)	**58 (15 to 79)***
Bivalent booster, 90-179 days earlier	4282	47 (1)	139 (119-157)	**48 (23 to 65)**



CDC unpublished data. VE estimates adjusted for age, sex, race and ethnicity, geographic region, and calendar time.

* These interim estimates are imprecise, which might be because of a relatively small number of persons in each level of vaccination or case status. This imprecision indicates the actual VE may be substantially different from the point estimate shown, and estimates should therefore be interpreted with caution. Additional data accrual should increase precision and allow appropriate interpretation.

Variant predominance based on regional circulation: https://covid.cdc.gov/covid-data-tracker/#variant-proportions

45

Policy Considerations for Fall 2023-2024 COVID-19 Vaccine Composition Change

- Policy on COVID-19 vaccine composition change will be coordinated with FDA for regulatory action and CDC for recommendations for use

Next Steps

- No changes to FDA or CDC guidance have been made at this time

- **Continue to recommend bivalent mRNA COVID-19 vaccines**
  - Bivalent mRNA COVID-19 vaccines protect against severe COVID-19 from currently circulating XBB lineage variants.
  - People who receive a bivalent mRNA vaccine now will most likely be eligible for the Fall 2023 composition (with appropriate interval between doses).

- Reminder:
  - National recommendations, primarily from the FDA and CDC, will suffice as the basis for proceeding in California.
  - Western States Scientific Safety Review Workgroup (WSSSRW) has disbanded.

CDC Advisory Committee on Immunization Practices (ACIP) Meeting, June 21-23, 2023

- Topics covered:
  - COVID-19 vaccines
  - RSV vaccines for adults (vote)
  - Influenza vaccines (vote)
  - Pneumococcal vaccine in children (vote)
  - Polio vaccine for adults (vote)
  - RSV vaccines for children/pregnant people
  - Mpox vaccine
  - Meningococcal vaccines
  - Dengue & chikungunya vaccines
- ACIP Meeting Materials

COVID-19 Vaccine Updates

- Topics covered:
  - COVID-19 epidemiology and vaccine effectiveness
  - Infection-induced and hybrid immunity
- No votes on updated recommendations for COVID-19 vaccines

RSV Product Timeline

May 2023

- FDA approves AREXVY® (GSK) and ABRYSVO® (Pfizer) RSV vaccines for adults ages ≥60 years

June 2023

- CDC ACIP recommends AREXVY® and ABRYSVO® RSV vaccines for adults ages ≥60 years under shared clinical decision-making

July-Sept 2023

- *Anticipated:* FDA approval for ABRYSVO® RSV vaccine for maternal vaccination
- *Anticipated:* FDA approval for nirsevimab (RSV monoclonal antibody)

October 2023

- *Anticipated:* ACIP recommendation for maternal RSV vaccine
- *Anticipated:* Recommendation for nirsevimab

RSV Vaccine (Adult)

- **Voting Questions**

Vote #1 (amended): Adults 65 years of age and older may receive a single dose of RSV vaccine, using shared clinical decision-making.

Committee vote #1, 6/21/23: Yes (9), No (5)

Vote #2: Individual adults aged 60-64 years may receive a single dose of RSV vaccine, using shared clinical decision-making

Committee vote #2, 6/21/23: Yes (13), Abstain (1)

Influenza Vaccines

- **Voting Questions**

Vote #1: All persons ages >= 6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipient's age and health status can be used.

Vote #2: Affirm the updated MMWR Recommendations and Reports, "Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices – United States, 2023-2024 Influenza Season"

Committee vote #1 & #2, 6/21/23: Unanimous Yes (14/14 panel members)