

Vaccine Update

COWPOX TO
MONKEYPOX: 1796-
2022

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Disclosures

I have no financial disclosures related to this presentation

My eligible grandkids (ages 1, 2, and 3 years) have received COVID vaccine

What's new?

Recent recommendations

PCV15 and PCV20 for adults

PCV15 for children

Preferential influenza vaccine product recommendations for adults 65 years and older

Universal Hep B vaccine for adults under 60 years

Tickborne encephalitis vaccine for travelers

Dengue vaccine for children living in endemic areas

Cholera vaccine for children in outbreak settings

New MMR vaccine

Future recommendations and vaccines

PCV20 for children

PCV 21, 25?

One-dose HPV vaccine?

RSV vaccine for seniors and during pregnancy ?

????????????

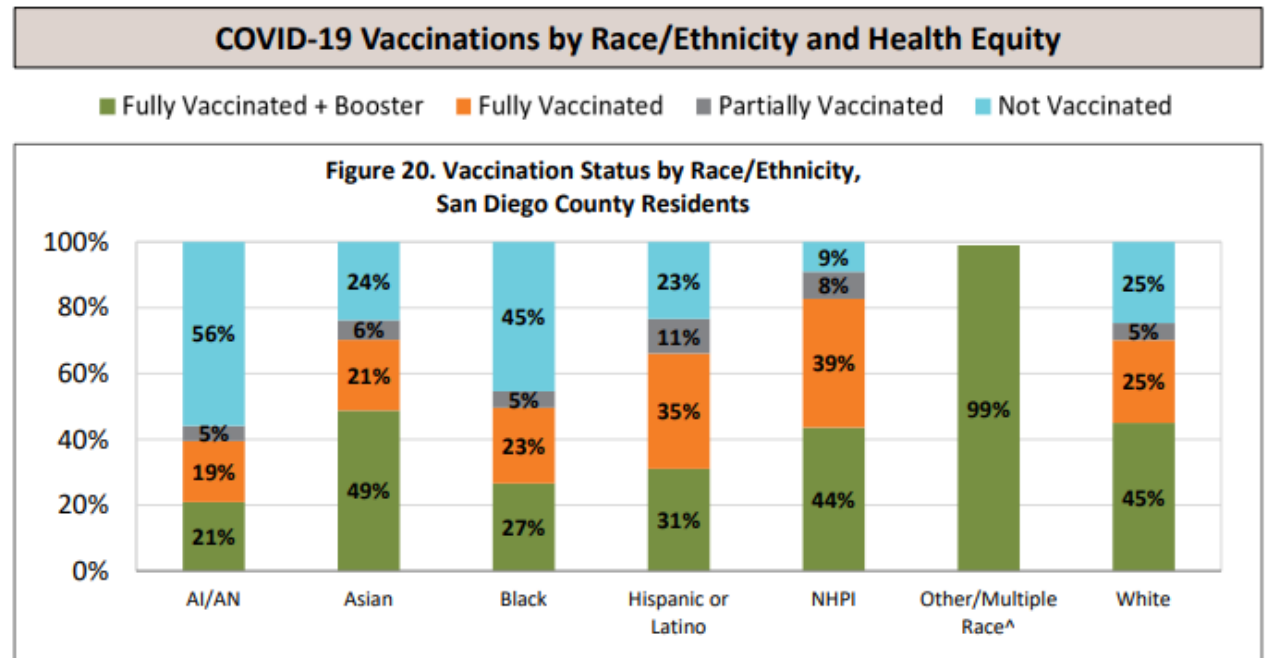
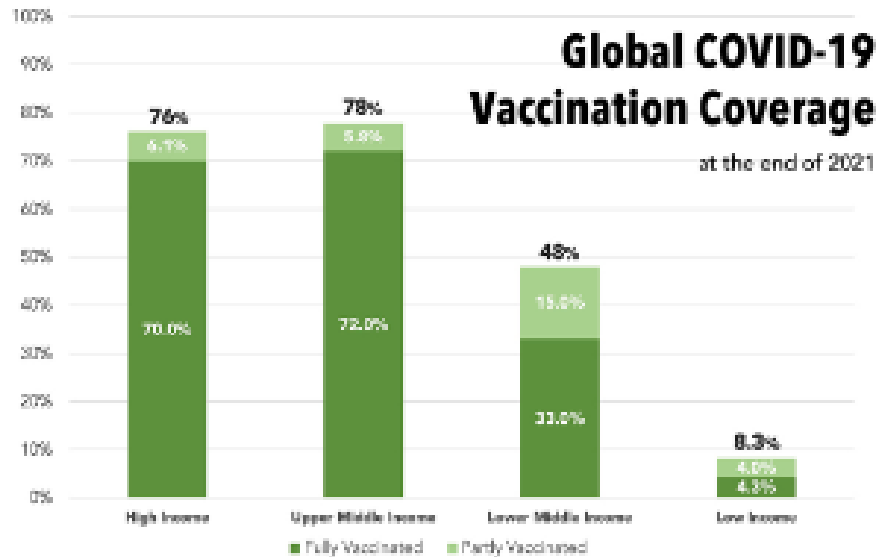
Objectives

- Quantify the racial, ethnic, and country disparities in COVID vaccine coverage so that you can take steps to address it
- Describe how to use COVID vaccines in children
- Describe how PCV15 and PCV20 might be incorporated into your practice
- List 3 other new vaccines or vaccine recommendations

COVID vaccines for children

Vaccine disparities

Figure 1

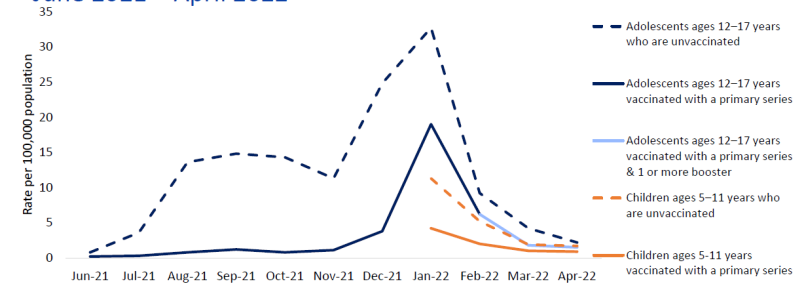


HHS COVID Watch 8/11/2022

It is simple: All kids 6 months of age and older should be immunized with available Sars-CoV-2 vaccines now

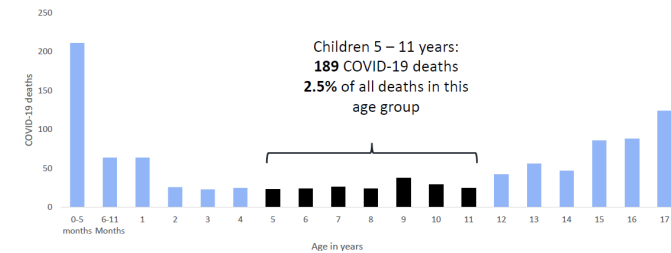
Rates of monthly COVID-19-associated hospitalizations by vaccination status among children and adolescents 5–17 years, COVID-NET

June 2021 – April 2022



COVID-19 deaths in children and adolescents by age based on death certificate data, National Center for Health Statistics

January 1, 2020–May 11, 2022



*Long
COVID
in Children*

Well actually,
It is not simple!

Dose differences/vial differences/injection
volume differences

Age differences

Dose interval differences

Reactogenicity/Myocarditis differences

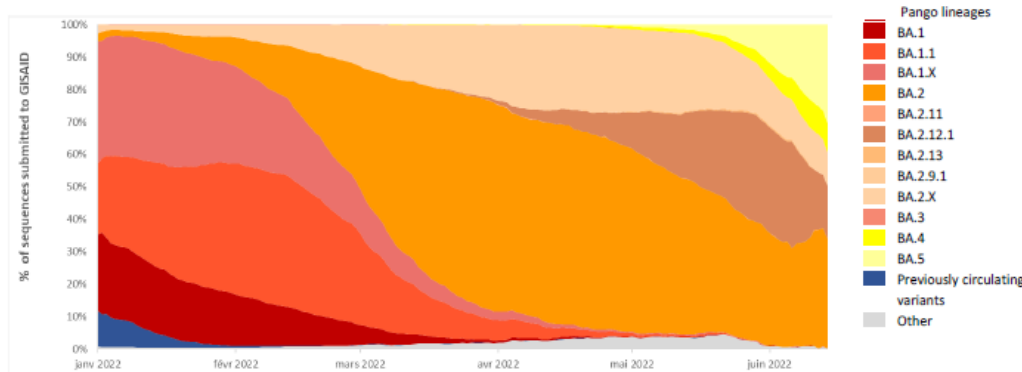
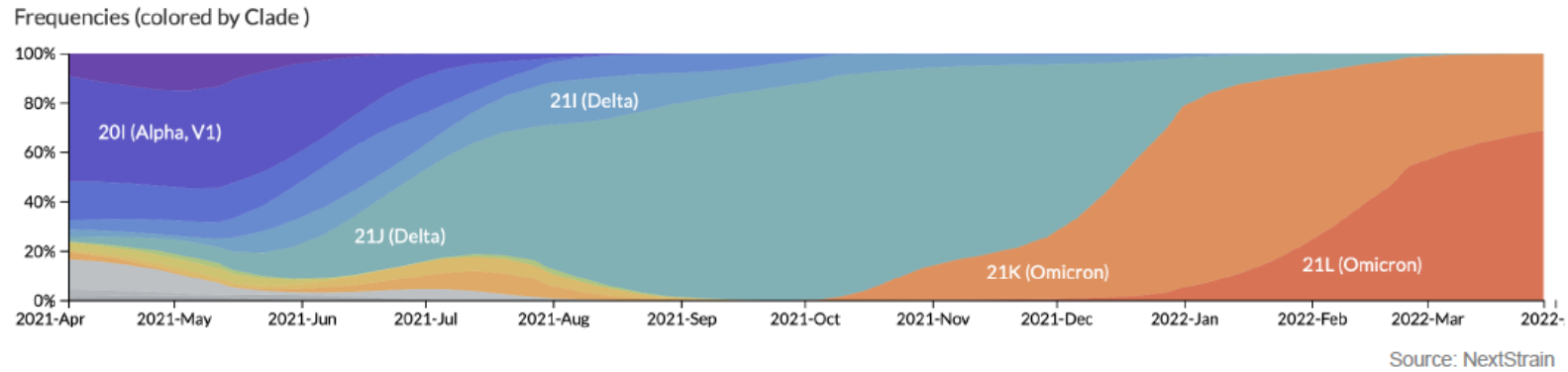
Parental reluctance

Reduced network of immunizers for young
children

1. Evolution and spread: Omicron



Since the classification of Omicron as a VOC, there has been rapid and relatively synchronous displacement of other circulating variants by Omicron in all six WHO regions.



Proportion of sequences submitted to GISAID by Omicron descendent lineage and by epidemiological week

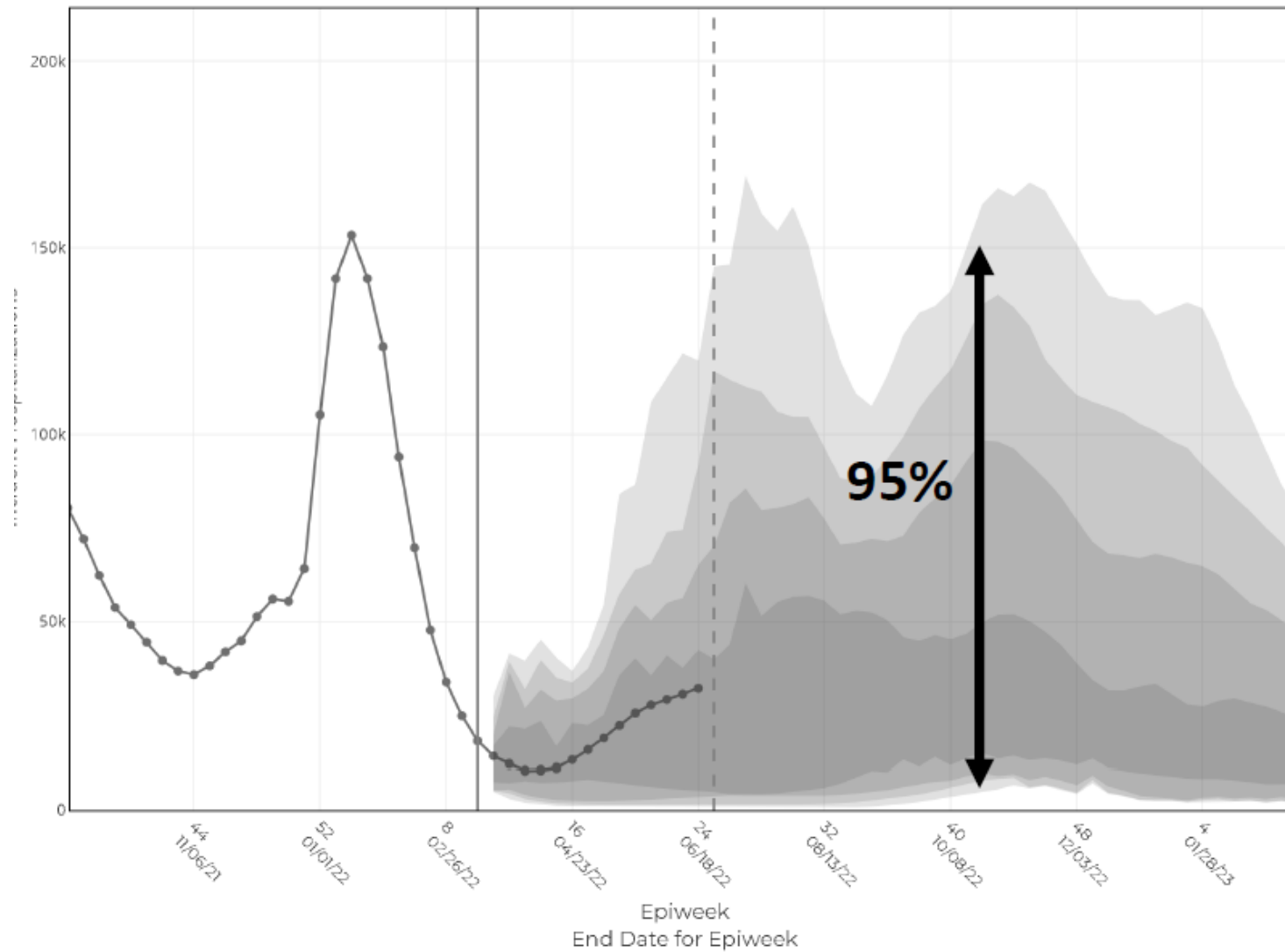
BA.2 remains the predominant Omicron descendent lineage globally.

BA.4 and BA.5 have the same spike and are increasing in proportion

Projected Incident Hospitalizations by Epidemiological Week and by Scenario for Round 13 - US

(- Projection Epiweek; -- Current Week)

Scenario D ; Pessimistic waning, New immune escape variant



Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Early Release / Vol. 71

June 28, 2022

**Interim Recommendations of the Advisory Committee on
Immunization Practices for Use of Moderna and Pfizer-BioNTech COVID-19
Vaccines in Children Aged 6 Months–5 Years — United States, June 2022**

Katherine E. Fleming-Dutra, MD¹; Megan Wallace, DrPH¹; Danielle L. Moulia, MPH¹; Evelyn Twentyman, MD¹; Lauren E. Roper, MPH¹; Elisha Hall, PhD¹; Ruth Link-Gelles, PhD¹; Monica Godfrey, MPH¹; Kate R. Woodworth, MD¹; Tara C. Anderson, DVM, PhD¹; Amy B. Rubis, MPH¹; Edwin Shanley III, MPH¹; Jefferson M. Jones, MD¹; Rebecca L. Morgan, PhD²; Oliver Brooks, MD³; H. Keipp Talbot, MD⁴; Grace M. Lee, MD⁵; Beth P. Bell, MD⁶; Matthew Daley, MD⁷; Sarah Meyer, MD¹; Sara E. Oliver, MD¹

COVID vaccines in children

- Recommended for all children 6 months of age and older
- Product, dose, and interval varies by age and underlying health condition
- Local adverse events (fever, erythema or pain at the injection site, decreased energy) are common
- Myocarditis is the only significant serious adverse event. It is rare in 12-18 year olds and even more rare in younger age groups
- All adverse events more common after dose #2. Less common after boosters
- Immunity wanes over time
- Bivalent boosters for children 5-11 years now available

VAERS reporting rates of myocarditis (per 1 million doses administered) after mRNA COVID-19 vaccination, days 0–7 and 8–21 post-vaccination^{*,†}

Age (yrs)	0–7 days			8–21 days			0–7 days			8–21 days			
	Males			Males			Females			Females			
	Dose 1	Dose 2	Booster	Dose 1	Dose 2	Booster	Dose 1	Dose 2	Booster	Dose 1	Dose 2	Booster	
Pfizer-BioNTech	5–11	0.2	2.6	0.0	0.6	0.0	0.0	0.2	0.7	0.0	0.2	0.0	0.0
	12–15	5.3	46.4	15.3	1.2	1.2	0.9	0.7	4.1	0.0	0.4	0.2	0.9
	16–17	7.2	75.9	24.1	1.7	3.2	1.3	0.0	7.5	0.0	0.7	0.4	0.0
Pfizer-BioNTech and Moderna	18–24	4.2	38.9	9.9	1.1	2.2	0.4	0.6	4.0	0.6	0.2	0.7	0.0
	25–29	1.8	15.2	4.8	0.4	1.1	0.5	0.4	3.5	2.0	0.2	0.0	0.8
	30–39	1.9	7.5	1.8	0.4	0.8	0.2	0.6	0.9	0.6	0.3	0.2	0.0
	40–49	0.5	3.3	0.4	0.2	0.5	0.0	0.4	1.6	0.6	0.2	0.2	0.0
	50–64	0.5	0.7	0.4	0.2	0.3	0.1	0.6	0.5	0.1	0.2	0.5	0.1
	65+	0.2	0.3	0.6	0.3	0.2	0.1	0.1	0.5	0.1	0.1	0.2	0.1



* As of May 26, 2022; reports verified to meet case definition by provider interview or medical record review; primary series and 1st booster doses only

† An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for days 0–7 and 8–21 risk intervals, this estimated background is 0.2 to 2.2 per 1 million person-day 0–7 risk interval and 0.4 to 3.8 per 1 million person-day 8–21 risk interval (peach shaded cells indicate that reporting rate exceeded estimated background incidence for the period)

VAERS reporting rates of verified myocarditis per 1 million mRNA COVID-19 vaccinations (Pfizer-BioNTech and Moderna combined), days 0–7 post-vaccination^{*,†}

Age group	Dose 2 (primary series)		1 st booster dose	
	Male	Female	Male	Female
5–11 years	2.5	0.7	0.0	0.0
12–15 years	47.1	4.2	12.9	0.7
16–17 years	78.7	7.4	21.6	0.0
18–24 years	39.3	3.9	13.1	0.6
25–29 years	15.3	3.5	4.4	2.2
30–39 years	7.8	1.0	1.9	0.9
40–49 years	3.3	1.6	0.2	0.6
50–64 years	0.7	0.5	0.4	0.1
65+ years	0.3	0.5	0.7	0.2

From previous slide



^{*} As of August 18, 2022. Reports verified to meet case definition by provider interview or medical record review.

[†] An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for days 0–7 risk interval, this estimated background is 0.2 to 2.2 per 1 million person-day 0–7 risk interval (peach shaded cells indicate that reporting rate exceeded estimated background incidence for the period)

FAQ-answers

Vaccine products are NOT interchangeable for the primary series

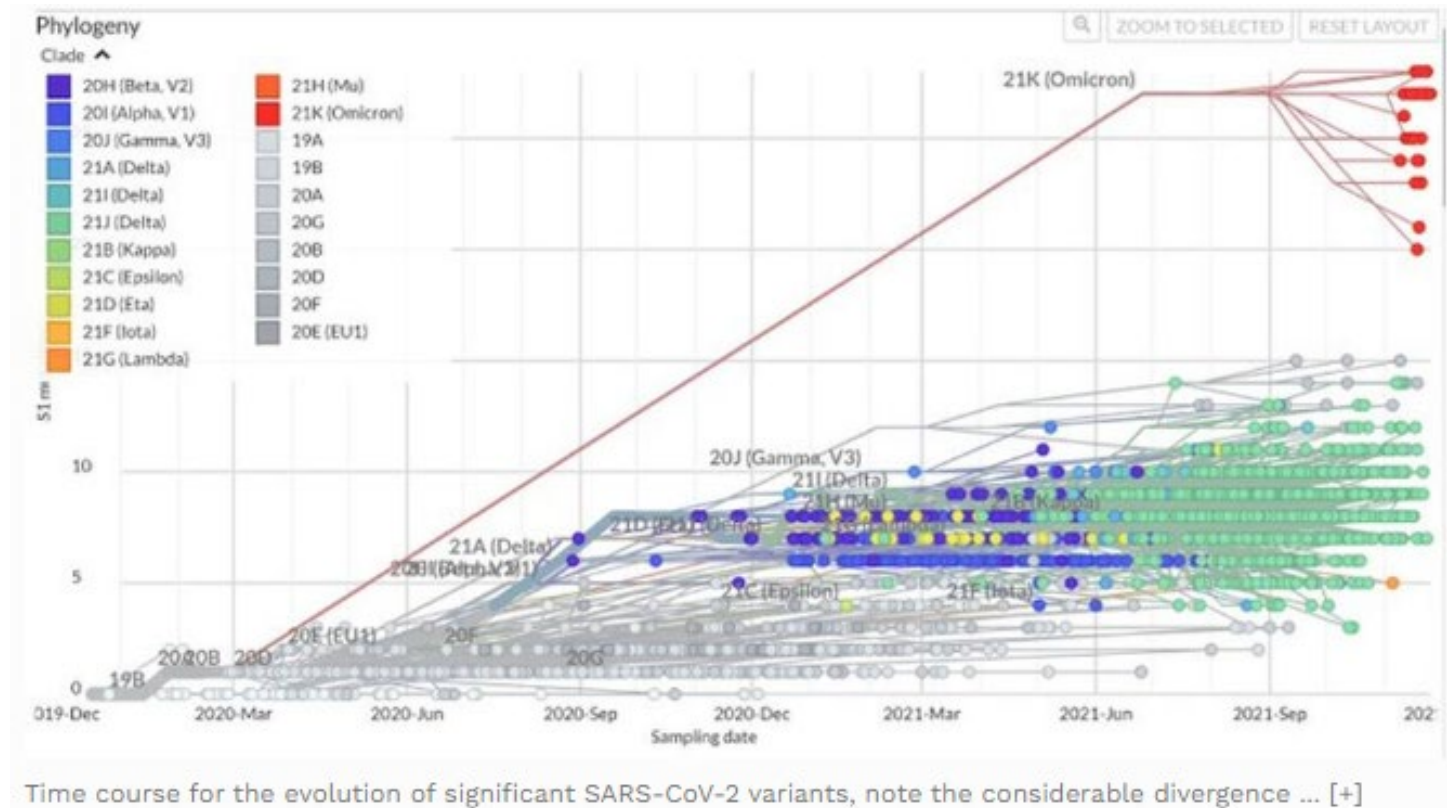
Either mRNA bivalent vaccine can be used for booster doses for 5 years and older

No minimum interval to vaccinate following natural infection but can wait up to 90 days

Coadministration with other vaccines is allowed and even recommended

AAP/CDC recommend giving the dose appropriate for age on the day of vaccination

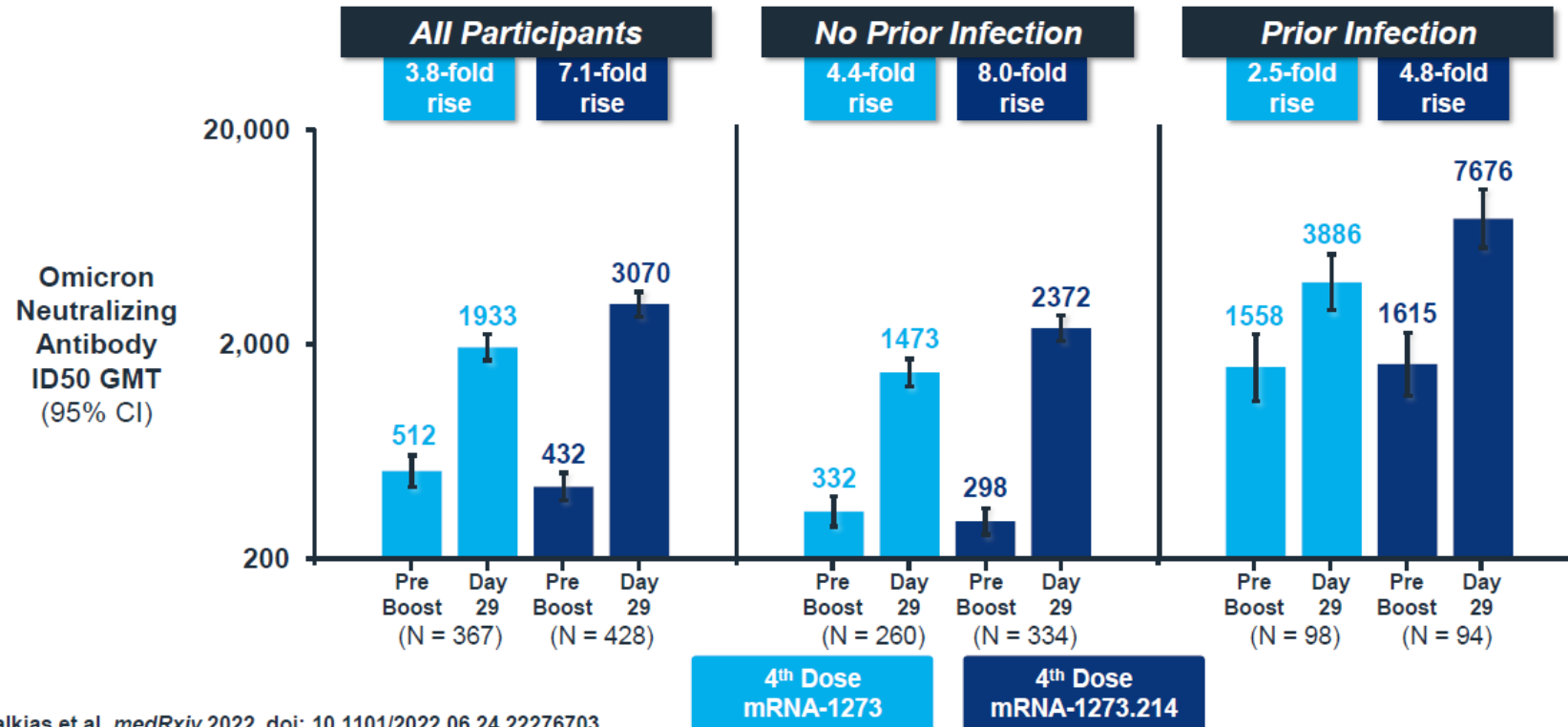
Omicron is an odd duck



<https://www.forbes.com/sites/williamhaseltine/2022/01/26/birth-of-the-omicron-family-ba1-ba2-ba3-each-as-different-as-alpha-is-from-delta/?sh=2abc3d6b3da9>

Omicron Neutralizing Titers After 4th Dose Significantly Higher with mRNA-1273.214 than mRNA-1273

Study 205, Per-Protocol Immunogenicity Set

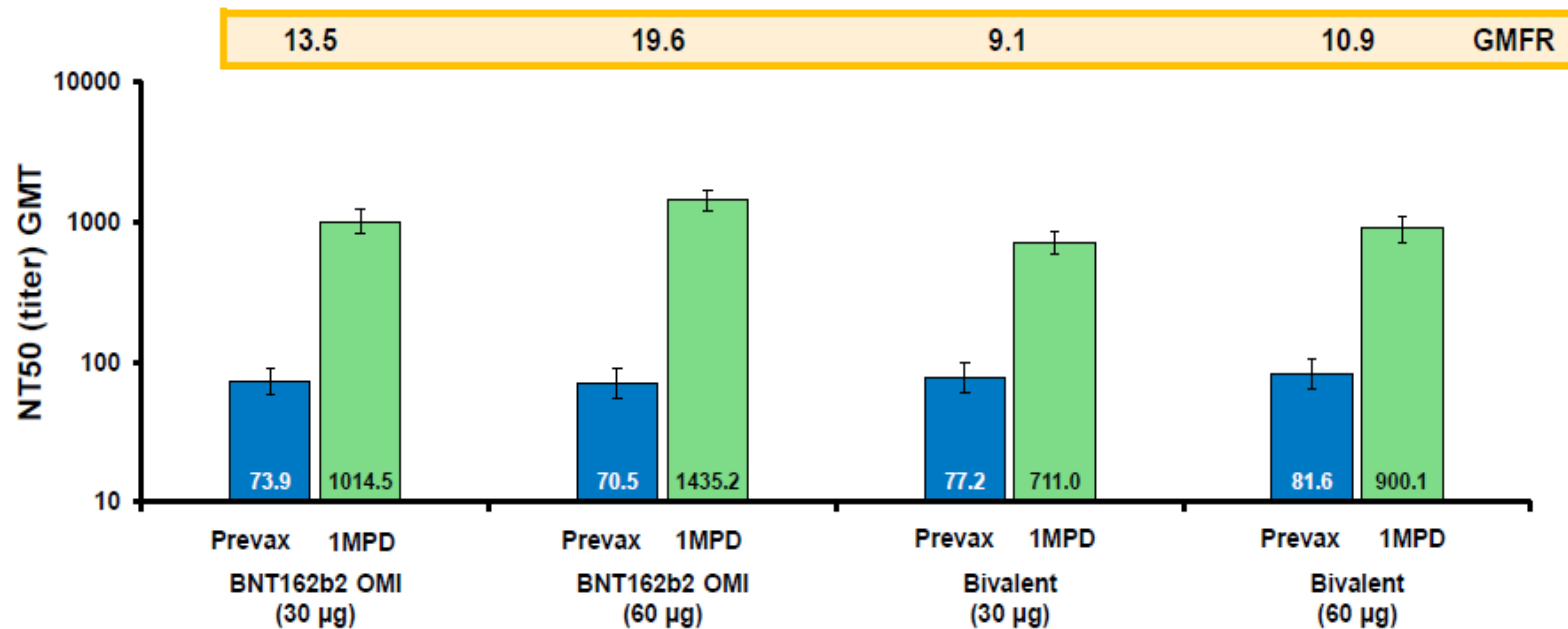


Chalkias et al. medRxiv 2022. doi: 10.1101/2022.06.24.22276703

Moderna presentation, VRBPAC –28-2022
<https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/2022-meeting-materials-vaccines-and-related-biological-products-advisory-committee>

Omicron BA.1 Neutralization Activity Substantially Increased with Omicron-Modified Vaccines as 4th Dose Booster

>55 Year Olds Without Evidence of Prior Infection
 Median Time from Dose 3 to Study Vaccination: 6.3 Months (4.7, 12.9)



Omicron BA.1 NT50 measured using validated 384-well assay

CC-15

Pfizer presentation, VRBPAC 6-28-2022

<https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/2022-meeting-materials-vaccines-and-related-biological-products-advisory-committee>

Pediatric COVID-19 Vaccine Dosing Quick Reference Guide

Pfizer-BioNTech COVID-19 Vaccine Products

Monovalent Product

- Maroon cap: 3 mcg/0.2 ml (dilute before use)
- Orange cap: 10 mcg/0.2 ml (dilute before use)
- Gray cap: 30 mcg/0.3 ml

Bivalent Product

- Bivalent gray cap: 30 mcg/0.3 ml

Moderna COVID-19 Vaccine Products

Monovalent Product

- Blue cap/magenta label: 25 mcg/0.25 ml
- Blue cap/purple label: 50 mcg/0.5 ml
- Red cap/blue label: 100 mcg/0.5 ml

Bivalent Product

- Blue cap/gray label: 50 mcg/0.5 ml

Novavax COVID-19 Vaccine Product

Monovalent Product

- Dark blue cap: 5 mcg/0.5 ml

Age at First Dose	Pfizer-BioNTech COVID-19 Vaccine			Moderna COVID-19 Vaccine		Novavax COVID-19 Vaccine
6 months–4 years	Dose 1 Maroon cap	Dose 2 3-8 weeks after dose 1 Maroon cap	Dose 3 at least 8 weeks after dose 2 Maroon cap	Dose 1 Blue cap/magenta label	Dose 2 4-8 weeks after dose 1 Blue cap/magenta label	
5 years	Dose 1 Orange cap	Dose 2 3-8 weeks after dose 1 Orange cap	Dose 3 at least 5 months after dose 2 Orange cap	Dose 1 Blue cap/magenta label	Dose 2 4-8 weeks after dose 1 Blue cap/magenta label	
6–11 years	Dose 1 Orange cap	Dose 2 3-8 weeks after dose 1 Orange cap	Dose 3 at least 5 months after dose 2 Orange cap	Dose 1 Blue cap/purple label	Dose 2 4-8 weeks after dose 1 Blue cap/purple label	

Pediatric COVID-19 Vaccine Dosing Quick Reference Guide



Pfizer-BioNTech COVID-19 Vaccine Products

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- Maroon cap: 3 mcg/0.2 ml (dilute before use)
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Bivalent Product

- Blue cap/gray label: 50 mcg/0.5 ml

Novavax COVID-19 Vaccine Product

Monovalent Product

- Dark blue cap: 5 mcg/0.5 ml

Age at First Dose

Pfizer-BioNTech COVID-19 Vaccine

Moderna COVID-19 Vaccine

Novavax COVID-19 Vaccine

Age at First Dose	Pfizer-BioNTech COVID-19 Vaccine			Moderna COVID-19 Vaccine			Novavax COVID-19 Vaccine		
12–17 years	Dose 1 Gray cap	Dose 2 3-8 weeks after dose 1 Gray cap	Bivalent dose at least 2 months after last dose [†] Bivalent gray cap	Dose 1 Red cap/blue label	Dose 2 4-8 weeks after dose 1 Red cap/blue label	Bivalent dose at least 2 months after dose 2 Pfizer's Bivalent gray cap	Dose 1 Dark blue cap	Dose 2 3-8 weeks after dose 1 Dark blue cap	Bivalent dose at least 2 months after dose 2 Pfizer's Bivalent gray cap
18 years and older	Dose 1 Gray cap	Dose 2 3-8 weeks after dose 1 Gray cap	Bivalent dose at least 2 months after last dose [†] Bivalent gray cap OR Moderna's Blue cap/gray label	Dose 1 Red cap/blue label	Dose 2 4-8 weeks after dose 1 Red cap/blue label	Bivalent dose at least 2 months after last dose [†] Blue cap/gray label OR Pfizer's Bivalent gray cap	Dose 1 Dark blue cap	Dose 2 3-8 weeks after dose 1 Dark blue cap	Bivalent dose at least 2 months after dose 2 Pfizer's Bivalent gray cap OR Moderna's Blue cap/gray label

[†]At least 2 months after completion of monovalent primary series or last monovalent booster dose.

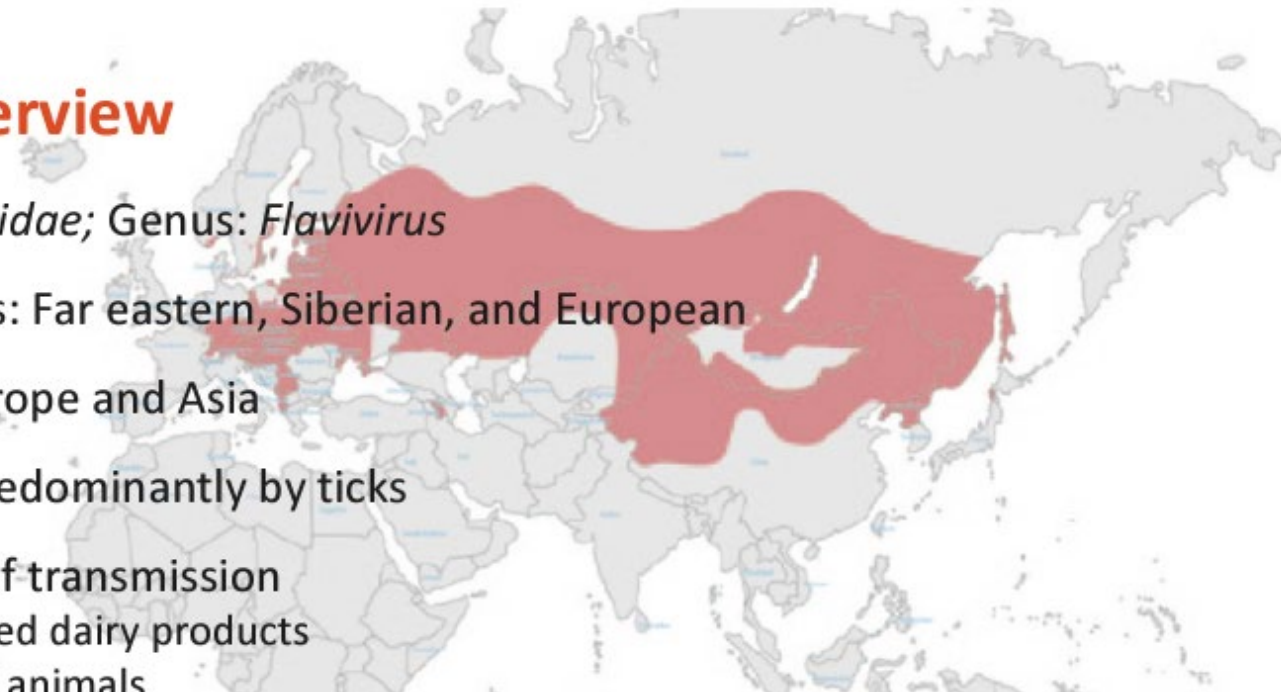
View online at aap.org/CovidVaccineGuide



What is tick-borne encephalitis (TBE)?

TBE virus overview

- Family: *Flaviviridae*; Genus: *Flavivirus*
- Three subtypes: Far eastern, Siberian, and European
- Endemic to Europe and Asia
- Transmitted predominantly by ticks
- Other modes of transmission
 - Unpasteurized dairy products
 - Slaughter of animals
 - Transfusion or transplantation
 - Breastfeeding
 - Laboratory exposure



TBE vaccine

Licensed in Europe since the 1970's; new formulations in use since 2001

Approved by FDA on August 13, 2021

Brand name is Ticovac

Inactivated, whole virus vaccine.
Alum adjuvant.



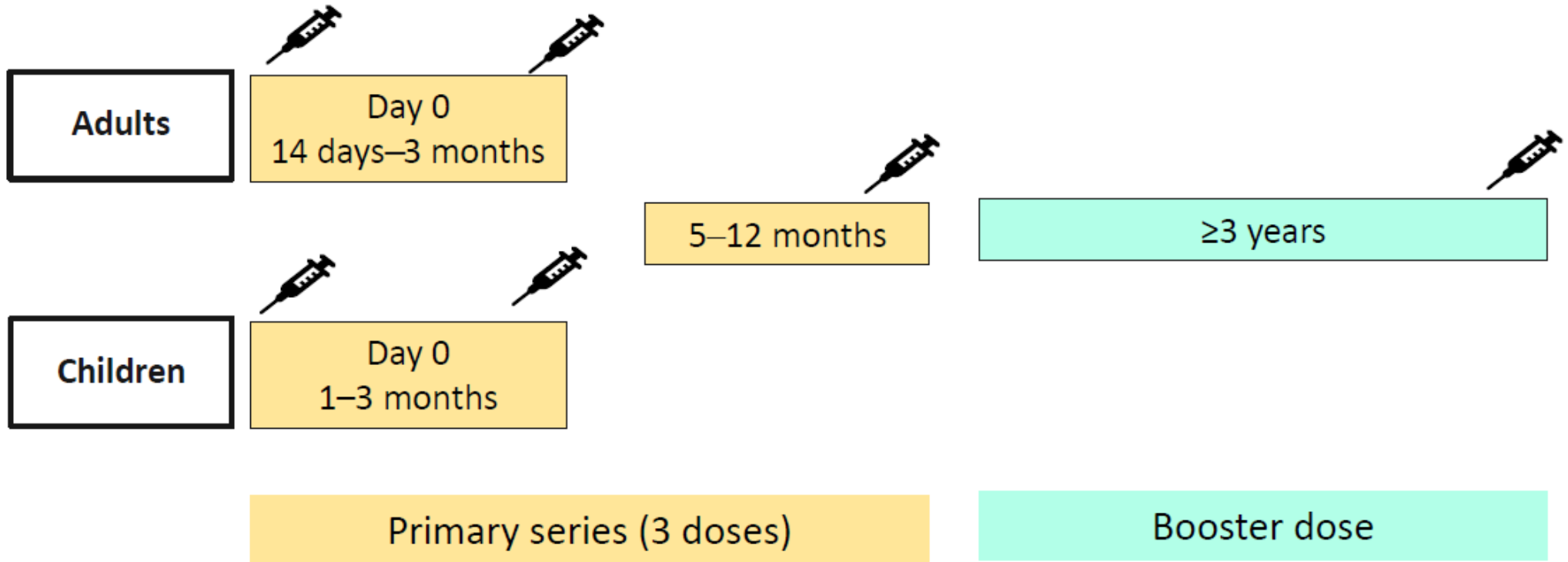
TBE vaccine administration

Dose	Adult dose: ≥16 years (0.5mL) Pediatric dose: 1–15 years (0.25mL)
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Presentation	Prefilled syringe
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Route	Intramuscular
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TBE vaccination schedule*



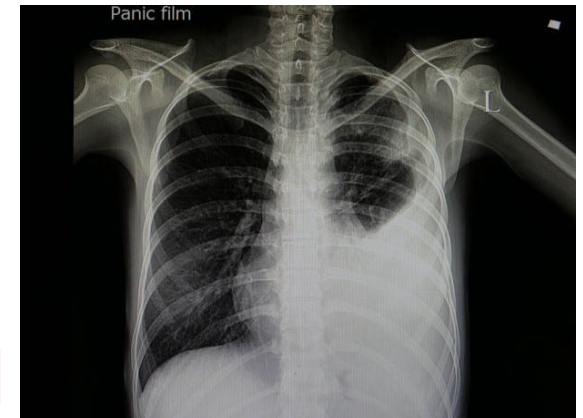
*All intervals are following previous dose

TBE vaccine recommended for children 1 year of age and older moving or traveling to a TBE-endemic area and will have extensive exposure to ticks

PCV shakeup!

Serotypes Contained in Current and New Pneumococcal Vaccines

	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F	22F	33F	8	10A	11A	12F	15B	2	9N	17F	20	
PCV13	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow												
PCV15	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Green	Green										
PCV20	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Green	Green	Blue	Blue	Blue	Blue	Blue	Blue				
PPSV23	Yellow	Yellow	Yellow	Yellow	White	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Green	Green	Blue	Blue	Blue	Blue	Blue	Blue	Orange	Orange	Orange	Orange



- **PCV15 non-PCV13:** includes serotypes **22F** and **33F**
- **PCV20 non-PCV13:** includes serotypes **22F**, **33F**, **8**, **10A**, **11A**, **12F**, and **15B**
- **PPSV23 non-PCV20:** includes serotypes **2**, **9N**, **17F**, and **20**

New Pneumococcal Vaccine Recommendations- Considerations

- Simple is better
- Cost effectiveness
- Health equity
- Compliance with a 2-vaccine recommendation
- Waning immunity over time

Current and Proposed Options for an **Age-based Recommendation**

	Current Policy	Proposed Policy Option
None of the conditions listed below	PCV13* based on shared clinical decision making, PPSV23 for all	<div style="border: 2px solid red; padding: 10px; text-align: center;"> PCV20 OR PCV15 and PPSV23 </div>
Chronic medical conditions† (CMC)		
Cochlear implant, CSF leak	Both PCV13* and PPSV23	
Immunocompromising conditions		

PCV13: 13-valent pneumococcal conjugate vaccine, PCV15: 15-valent pneumococcal conjugate vaccine, PCV20: 20-valent pneumococcal conjugate vaccine, PPSV23: 23-valent pneumococcal polysaccharide vaccine

Current and Proposed Options for a Risk-Based Recommendation

	Current policy	Proposed Policy Option
None of the conditions listed below	No recommendation	No recommendation
Chronic medical conditions [†] (CMC)	PPSV23	PCV20 OR PCV15 and PPSV23
Cochlear implant, CSF leak	Both PCV13* and PPSV23	
Immunocompromising conditions	Both PCV13* and PPSV23, repeat PPSV23 after 5 years	

PCV13: 13-valent pneumococcal conjugate vaccine
 PPSV23: 23-valent pneumococcal polysaccharide vaccine

*If not previously given; †Examples include alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking
<https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf>

New PCV15 guidelines for children

- **Either PCV13 or PCV15** is recommended as a 4-dose series at ages 2, 4, 6, and 12–15 months.
- **PCV13 and PCV15 can be used interchangeably.**
- Interruption of the vaccination schedule does not require reinstatement of the entire series or the addition of extra doses.


Complete PCV13 Vaccination

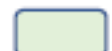
- **A supplemental dose of PCV15 is not indicated for children who have received 4 doses of PCV13 or another age-appropriate, complete PCV13 schedule.**


Influenza Vaccines by Age Indication, United States, 2021–22 Influenza Season

Vaccine type		0 through 6 months	6 through 23 months	2 through 17 years	18 through 49 years	50 through 64 years	≥65 years	
IIV4s	Standard-dose, unadjuvanted inactivated (IIV4)	Not approved for age group	Eggbased				Afluria Quadrivalent Fluarix Quadrivalent FluLaval Quadrivalent Fluzone Quadrivalent	
	Cell culture-based inactivated (ccIIV4)		Not eggbased					Flucelvax Quadrivalent
	Adjuvanted inactivated (aIIV4)	Not approved for age group					Fluad Quadrivalent	
	High-dose inactivated (HD-IIV4)	Not approved for age group					Fluzone High-Dose Quadrivalent	
RIV4	Recombinant (RIV4)	Not approved for age group			Not eggbased			Flublok Quadrivalent
LAIV4	Live attenuated (LAIV4)	Not approved for age group		Eggbased		Not approved for age group		

IIV4=quadrivalent inactivated influenza vaccine RIV4=quadrivalent recombinant influenza vaccine LAIV4=quadrivalent live attenuated influenza vaccine

 Not approved for age group

 Eggbased

 Not eggbased

All vaccines expected for 2021–22 are quadrivalent (i.e., contain hemagglutinin derived from four viruses: one influenza A(H1N1), one influenza A(H3N2), one influenza B/Victoria and one influenza B/Yamagata).

Rabies pre-exposure prophylaxis: ACIP recommendation

- ACIP recommends a 2-dose [0, 7 days] intramuscular rabies vaccine series in immunocompetent persons <18 years of age for whom rabies vaccine pre-exposure prophylaxis (PrEP) is indicated
- ACIP recommends an intramuscular booster dose of rabies vaccine, as an alternative to a titer check, for immunocompetent persons < 18 years of age who have sustained and elevated risk for only recognized rabies exposures (i.e., those in risk category #3 of rabies PrEP recommendations table J). The booster dose should be administered no sooner than day 21 but no later than 3 years after the 2-dose PrEP series

Another MMR vaccine

GSK MMR Vaccine Development for the US



GSK's MMR vaccine (*PRIORIX*)

- First licensed in Germany in 1997; approved in > 100 countries outside US and over 400 million doses distributed worldwide

The goal of GSK's MMR development program is to bring a vaccine to the US market that:

1. fulfills the ACIP recommendations for measles, mumps and rubella vaccination [CDC, 2013]
2. demonstrates immunologic non-inferiority and comparable safety to the currently licensed US vaccine, *M-M-R II* (Merck & Co., Inc)
3. can be administered interchangeably to individuals who received a previous vaccination with *M-M-R II* or *ProQUAD*

Presentation by GSK to the ACIP meeting Feb 23, 2022.
Trademarks are property of their respective owners.

MMR Vaccine Components

	M-M-R II ¹	Priorix ²	Component Similarity
Measles	Enders' Edmonston strain	Schwarz strain	100% identical on a nucleotide level
Mumps	Jeryl Lynn™ (B level))	RIT4385	100% identical on a protein level ³
Rubella	Wistar RA 27/3 strain	Wistar RA 27/3 strain	100% identical on a nucleotide level

- **Inactive ingredients: Priorix does not contain gelatin**

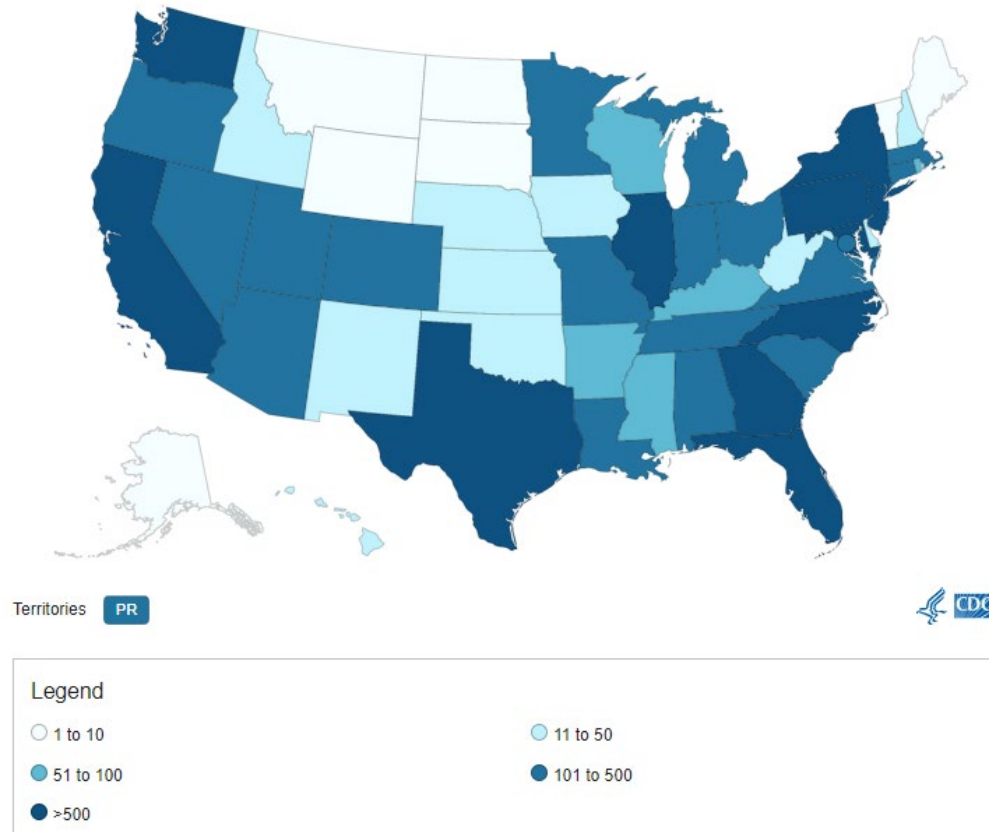
¹ M-M-R II PI: http://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf

² Priorix PI: <https://www.fda.gov/media/158941/download>

³ GSK's RIT4385 (JL1 clone) and Merck's JL1 component of the Jeryl Lynn strain

Monkeypox-U.S. June 2022

As of September 30,
2022:
U.S. 25,851 cases
CA 5,010 cases



The rash of monkeypox

RASH DESCRIPTION: Well circumscribed, umbilicated lesions

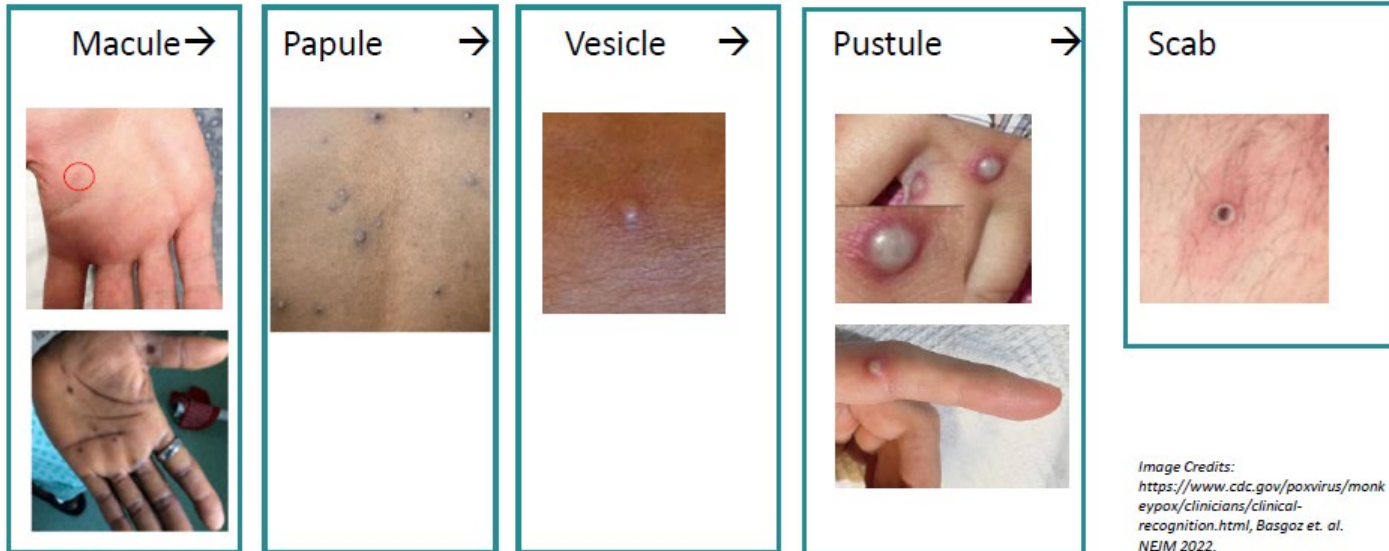


Image Credits:
<https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html>, Basgoz et. al. NEJM 2022.

Monkeypox-Transmission

Direct contact

- Contact with body fluids or lesion materials

Indirect contact

- Contact with fomites

Exposure to respiratory secretions

- During prolonged, face-to-face contact
- Less common

Sexual Transmission

- Not an STI in the traditional sense, but sex involves close and intimate personal contact and hence can result in transmission

Vaccine

Vaccine options in the [Strategic National Stockpile](#) for prevention of smallpox and monkeypox:

- ACAM 2000 (Live attenuated, replicating)

Not Available

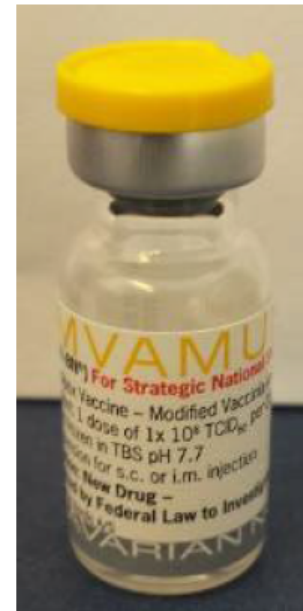
- JYNNEOS (Live attenuated, non-replicating)

IMVAMUNE, IMVANEX, MVA

Licensed by FDA in September 2019

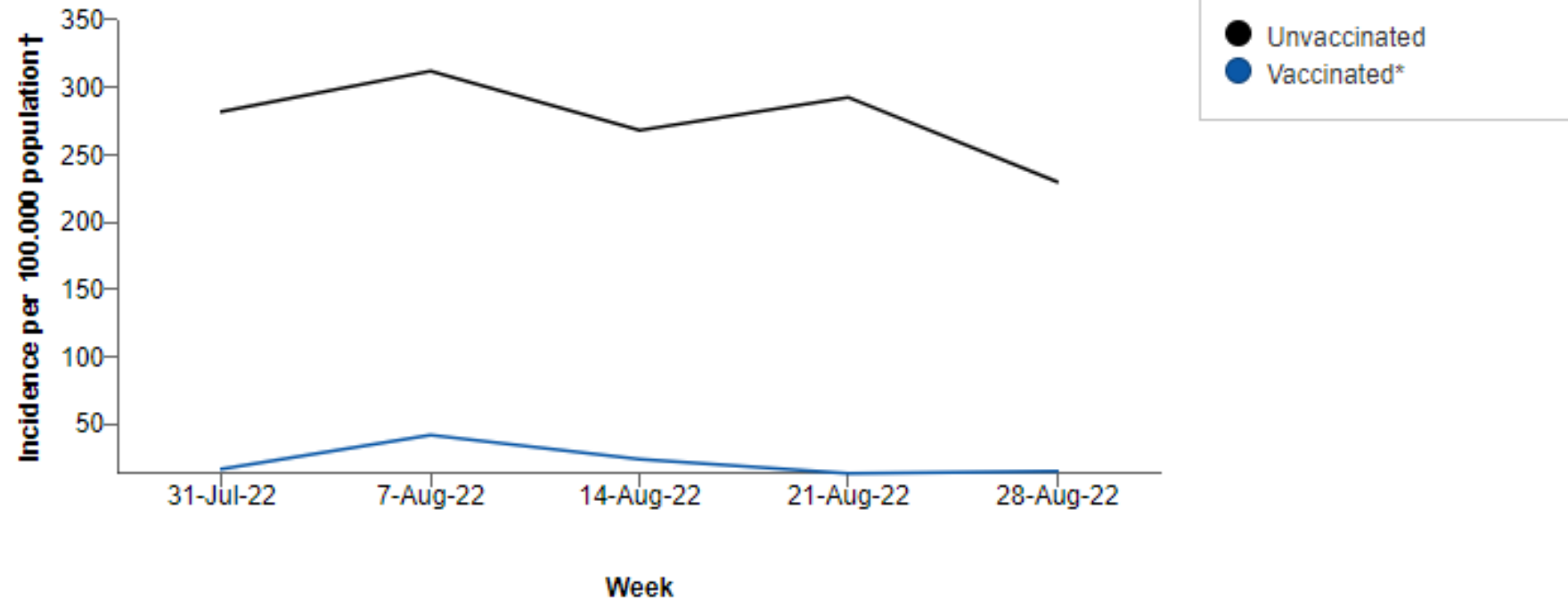
Two-doses separated by 28 days

<https://www.cdc.gov/poxvirus/monkeypox/clinicians/smallpox-vaccine.html>

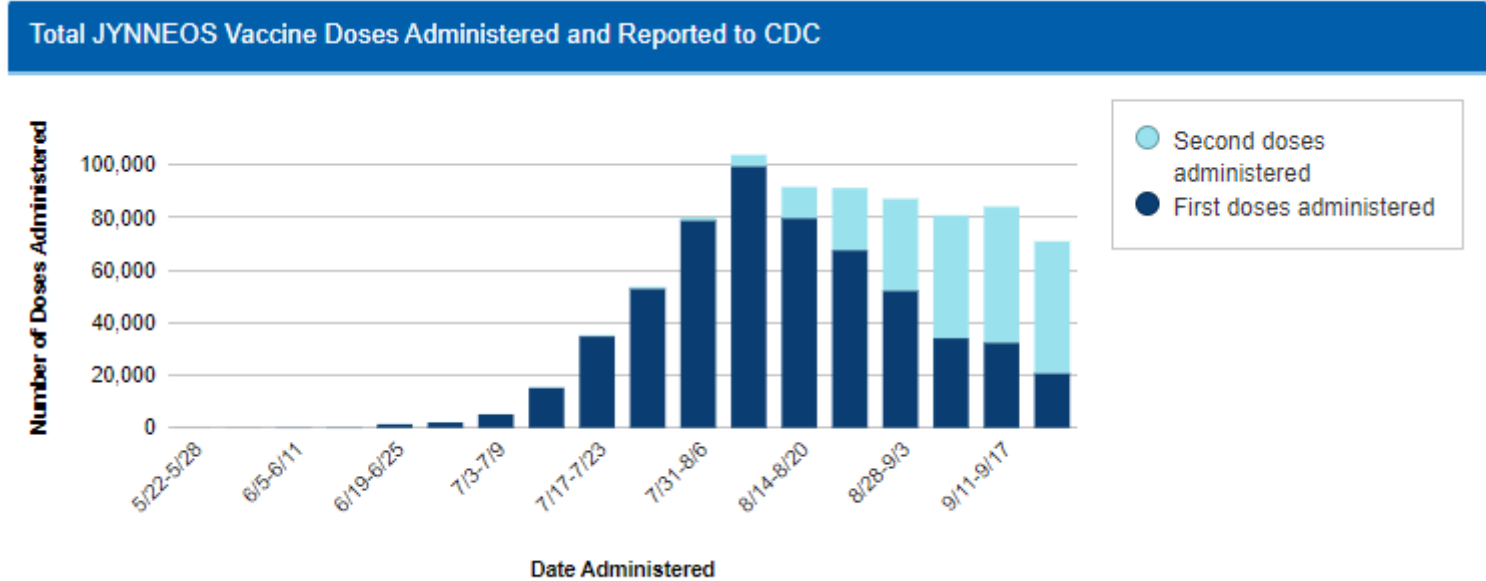


Rates of Monkeypox Cases by 1st Dose Vaccination Status

July 31, 2022 – September 3, 2022 (32 U.S. jurisdictions)



Monkeypox vaccine uptake-U.S.y



The rest of the news...

Dengue vaccine now recommended children 9 through 16 years of age

Zoster vaccine for immunocompromised individuals 19 years and older

Japanese Encephalitis booster dose-now recommended for children 1 year after primary series

Cholera vaccine-live attenuated vaccine. Only recommended for individuals traveling to areas with active cholera. Children may be included in the near future

Hepatitis B vaccine for all adults

Summary

We are behind on routine childhood immunizations due to the COVID pandemic

Kids need to get COVID vaccines

There are several new travel associated vaccines to keep in mind: Tick-borne encephalitis vaccine, Dengue vaccine, 2-dose rabies vaccine

Big shakeup with pneumococcal vaccines coming