



# CDC/IDSA Clinician Call

Sept. 10, 2022

## Welcome & Introductions



**Dana Wollins, DrPH, MGC**  
Vice President  
Clinical Affairs & Guidelines  
Infectious Diseases Society of America

- 92<sup>nd</sup> in a series of calls, initiated in 2020 as a forum for information sharing among frontline clinicians caring for patients with COVID-19.
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at [www.idsociety.org/cliniciancalls](http://www.idsociety.org/cliniciancalls).

## 1. Monkeypox Update



**Sapna Bamrah Morris, MD, MBA, FIDSA**  
Clinical Disease and Health Systems Team Lead  
Health Systems and Worker Safety Task Force  
CAPT, U.S. Public Health Service  
U.S. Centers for Disease Control & Prevention

## 2. Bivalent COVID-19 Boosters



**Bivalent Booster Authorization Update**  
**Peter Marks, MD, PhD**  
Director  
Center for Biologics Evaluation and Research  
U.S. Food and Drug Administration



**CDC/ACIP Update & Recommendations**  
**Priti Patel, MD, MPH**  
COVID-19 Vaccination Fall Strategy Lead  
Detailed to Immunization Services Division, National  
Center for Immunization and Respiratory Diseases  
U.S. Centers for Disease Control & Prevention

# CDC/IDSA Clinician Call

Sept. 10, 2022



**Safety of Booster Doses of COVID 19 Vaccines**  
**Kathryn M. Edwards, MD**  
Sarah H. Sell and Cornelius Vanderbilt Professor  
Division of Infectious Diseases  
Department of Pediatrics  
Vanderbilt University Medical Center

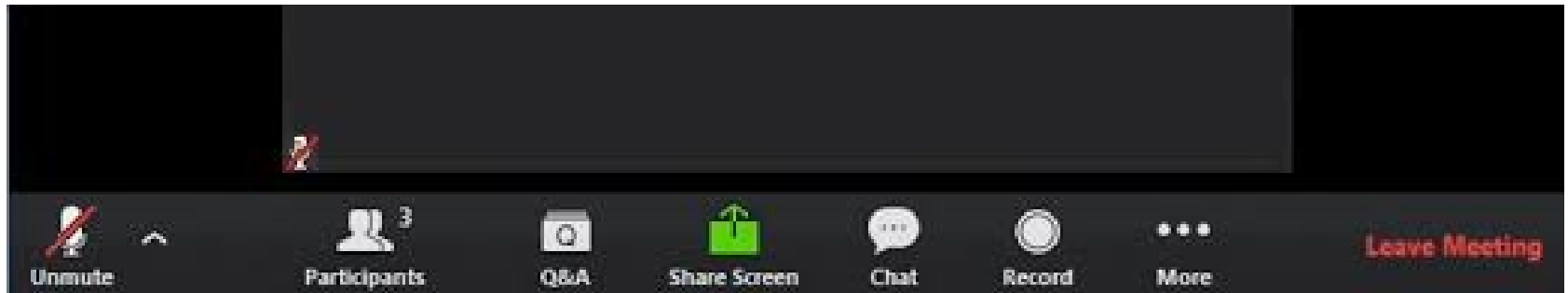
## Q&A/Discussion

*With additional Q&A assistance from  
CDC COVID-19 Clinical Team members:*  
**Mark A Swancutt, MD, PhD, DTM&H**  
**Muyiwa Ategbale, MD, MPH**

Question?  
Use the “Q&A” Button



Comment?  
Use the “Chat” Button



# Monkeypox Update



**Sapna Bamrah Morris, MD, MBA, FIDSA**

# MONKEYPOX

## Monkeypox Update: What ID Clinicians Need to Know

Sapna Bamrah Morris MD, MBA

CDC/IDSA Clinician Call

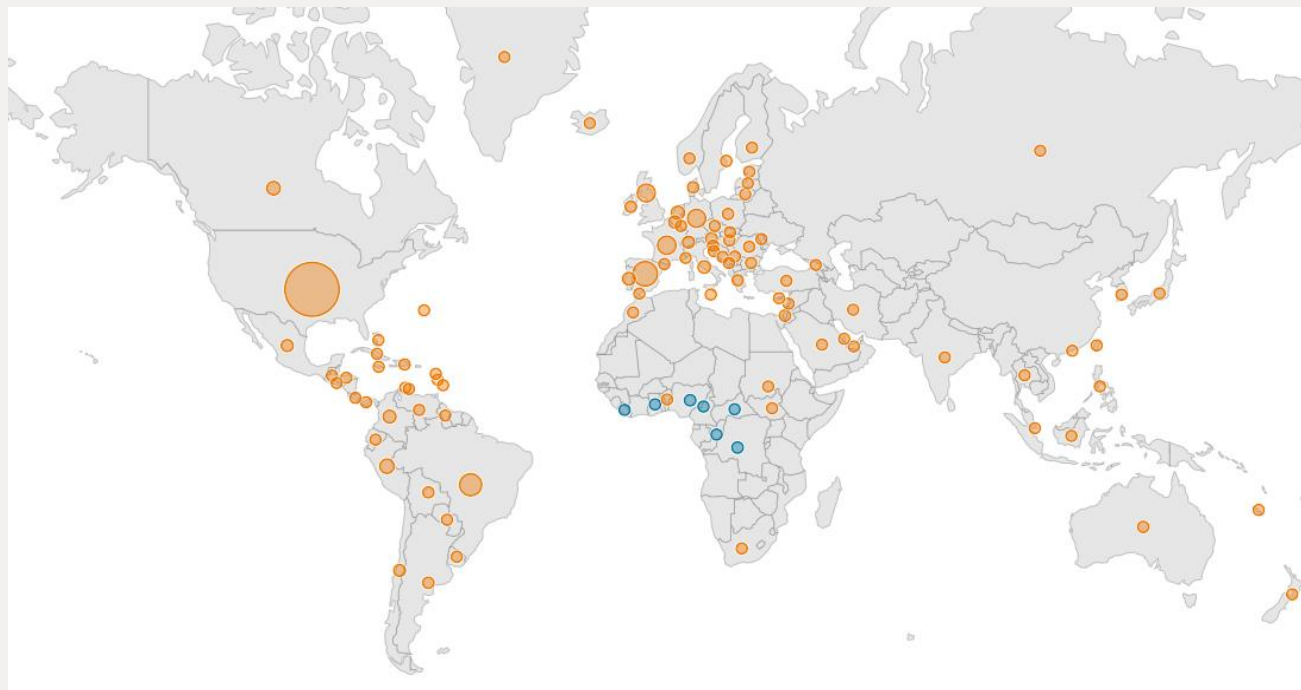
Saturday, September 10, 2022

Multinational Monkeypox Outbreak Response



# MONKEYPOX

## Case Count: 56,026 September 7, 2022

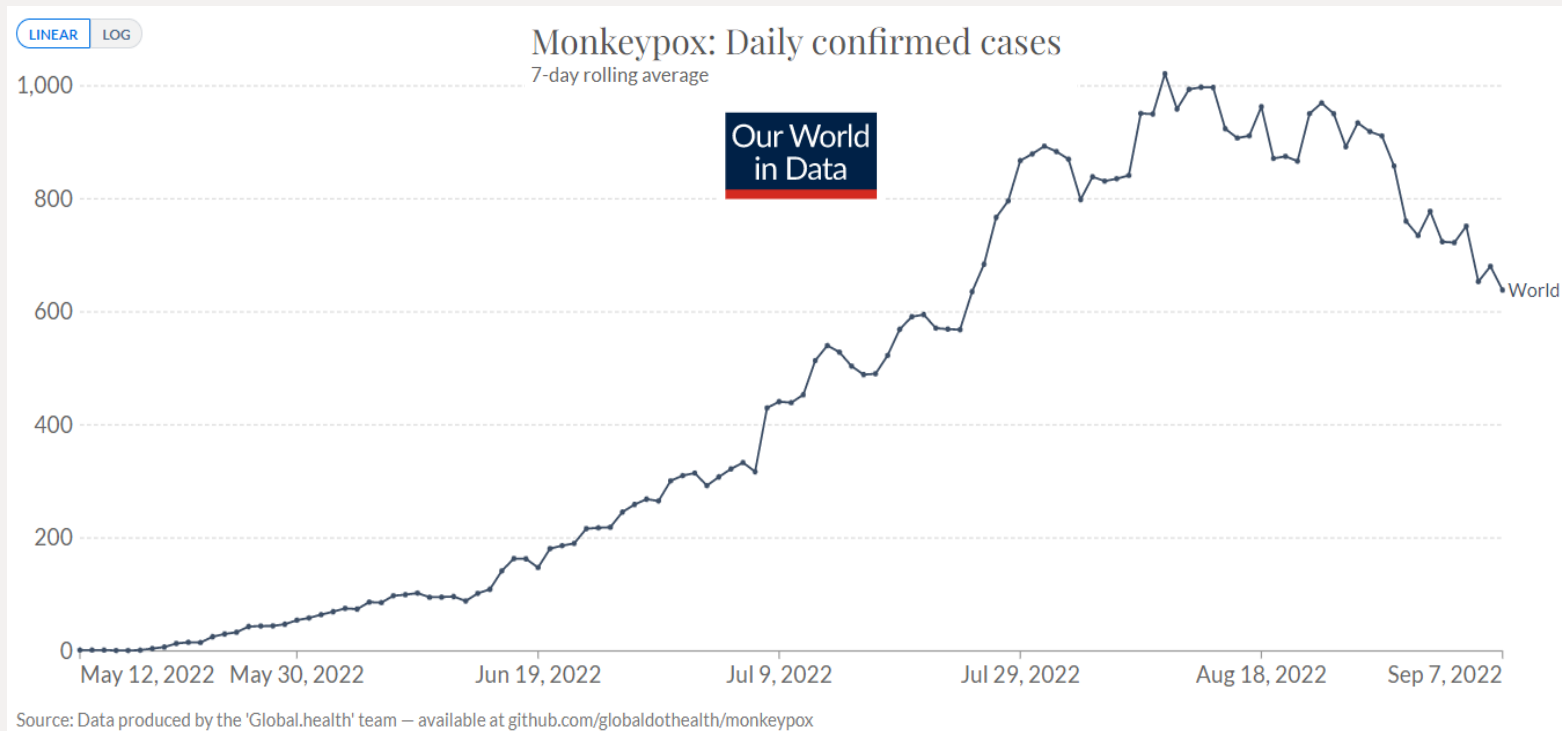


COUNTRY	COUNT
United States	21,274
Spain	6,749
Brazil	5,525
France	3,646
Germany	3,511
United Kingdom	3,484
Peru	1,724
Canada	1,289

- Has not historically reported monkeypox
- Has historically reported monkeypox

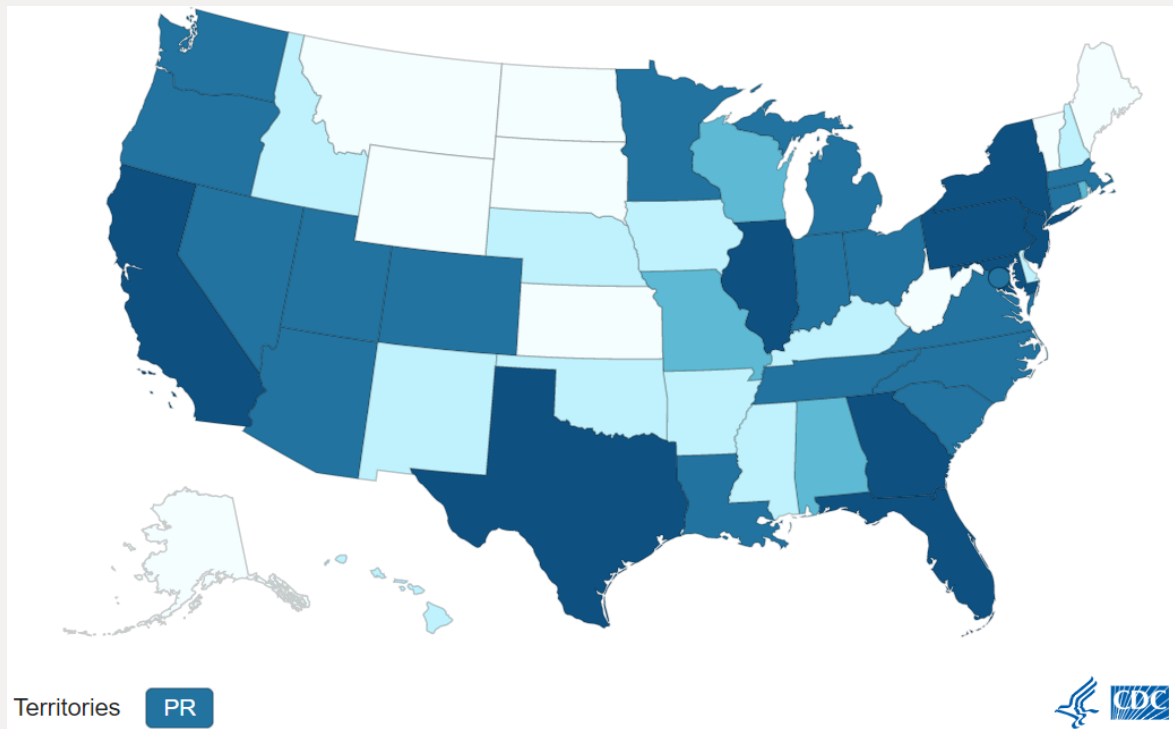
# MONKEYPOX

## Worldwide Trend in Cases



# MONKEYPOX

## Case Count: 21,274 September 7, 2022



STATE	COUNT
California	4,140
New York	3,542
Florida	2,148
Texas	1,871
Georgia	1,522
Illinois	1,128
Pennsylvania	618

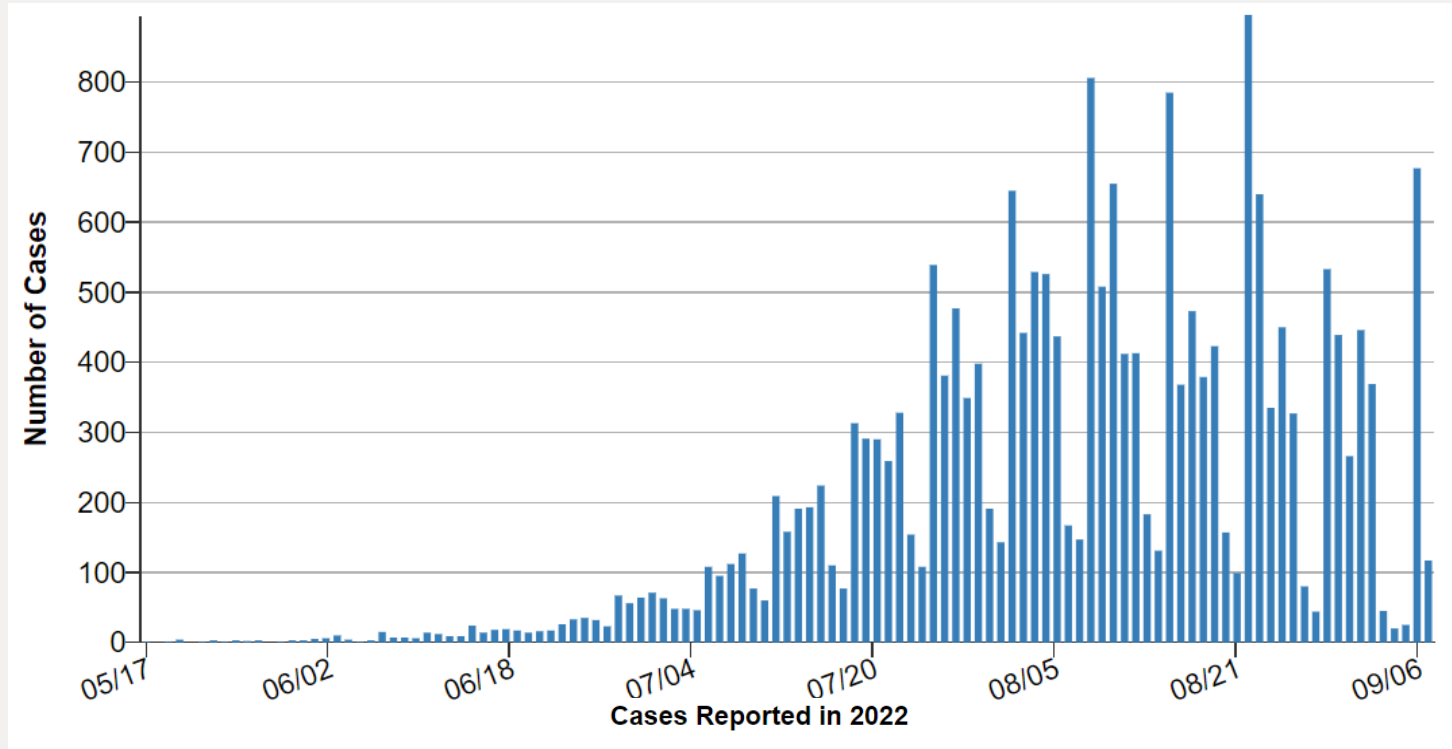
Case Range





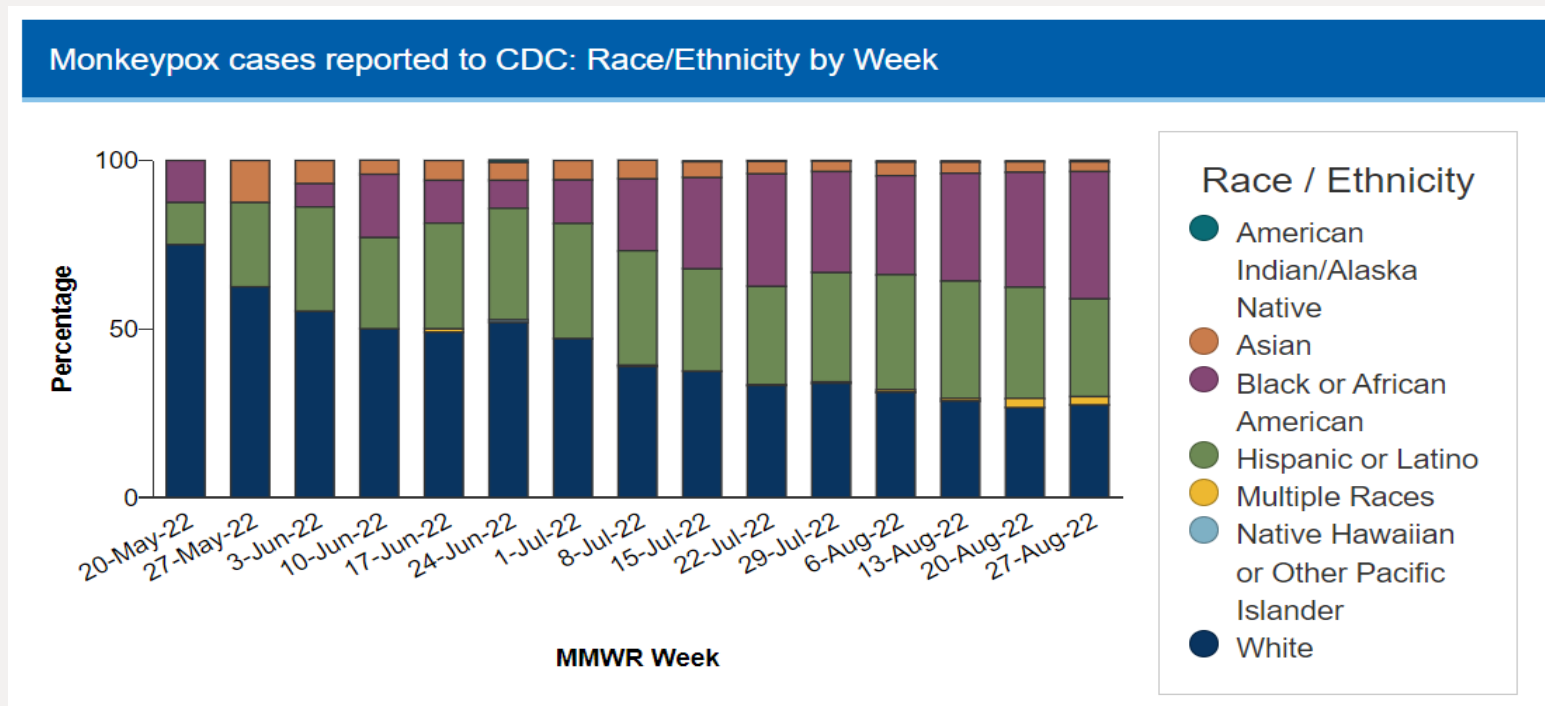
# MONKEYPOX

## U.S. Monkeypox Case Trends Reported to CDC



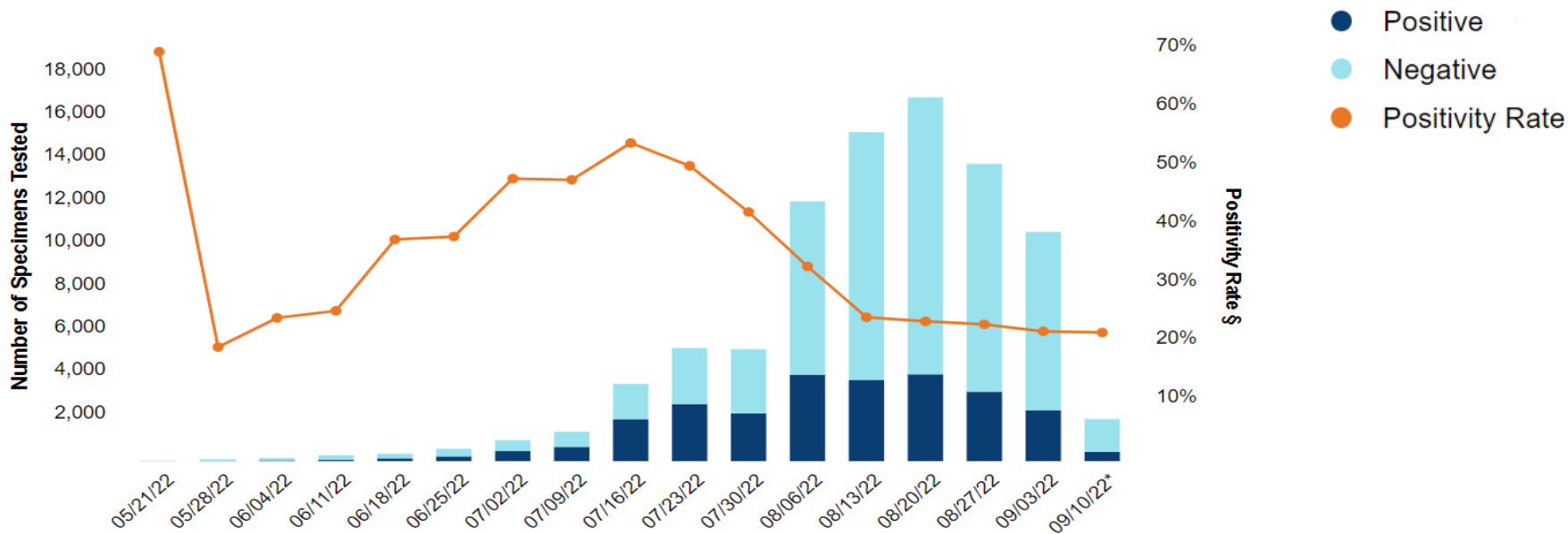
# MONKEYPOX

## Select Demographic and Clinical Characteristics



# MONKEYPOX

## Non-variola orthopox/Monkeypox testing from public health and select commercial laboratories †



† Data from Laboratory Response Network laboratories and 4 commercial laboratories using the CDC non-variola orthopox assay, and one commercial laboratory using a non-variola orthopox and monkeypox multiplex assay.

§ Positivity rate based on specimens tested, not patients. Most patients have multiple specimens tested. Positivity rate is calculated as (number of positive specimens)/(number of positive + negative specimens) per week. Results that are equivocal or inconclusive are not included.

¶ Total testing capacity, as described in press releases: May 26 – 6840; June 21 – 8,000; June 28 – 10,000; July 6 – 20,000; July 11 – 30,000; July 13 – 60,000; July 14 – 70,000; July 18 – 80,000<sup>1</sup>

# MONKEYPOX

## *Clinical Illness: ‘Classic’*

- **Incubation period:** 5–13 days on average (range 4–17 days)
- **Prodrome:** fever, malaise, headache, weakness, and lymphadenopathy that may be generalized or localized to several areas (e.g., neck and armpit)
- **Rash: appears shortly *after* prodrome starts**
  - Typically lesions develop simultaneously and evolve together on any given part of the body
  - Four stages – macular, papular, vesicular, to pustular – before scabbing over and resolving
  - Well-circumscribed, deep seated with umbilication, painful
  - When disseminated tend to be centrifugal: more on arms, legs, hands, feet
  - Can involve palms and soles
- **Illness duration is typically 2–4 weeks**

# MONKEYPOX

## *Clinical Illness: ‘2022 Lesions’*

- Pattern: **scattered or localized** to a body site rather than diffuse
- **Rash often starts in mucosal areas** (e.g., genital, perianal, oral mucosa) and may not develop simultaneously in all body areas
  - **Balanitis/urethritis:** complicated by phimosis
  - **Proctitis:** anorectal pain (lancinating), tenesmus, and rectal bleeding; associated with visible perianal vesicular, pustular, or ulcerative skin lesions and proctitis
  - **Oropharyngitis:** complicated by tonsillar swelling, abscess, dysphagia
- “Prodromal” symptoms can be absent or follow rash onset

# MONKEYPOX

## *Transmission*

- **Spread person-to-person through:**
  - **Direct contact** with the infectious rash, scabs, or body fluids
  - **Respiratory secretions** during prolonged, face-to-face contact, or during intimate physical contact, such as kissing, cuddling, or sex
  - **Touching items (such as clothing or linens)** that previously touched the infectious rash or body fluids
  - **Through placenta** in an infected pregnant person to their fetus
- **Patients are infectious once symptoms begin (whether prodromal or rash symptoms) and remain infectious until lesions form scabs, scabs fall off, and a fresh layer of skin forms**

# MONKEYPOX

## *JYNNEOS Vaccine*



**Total number of vaccine doses shipped (9/7/22) 775,033**

<https://aspr.hhs.gov/SNS/Pages/JYNNEOS-Distribution.aspx>

**Total number of vaccine doses administered (9/7/22) 461,049**

[https://www.cdc.gov/poxvirus/monkeypox/response/2022/vaccines\\_data.html](https://www.cdc.gov/poxvirus/monkeypox/response/2022/vaccines_data.html)

- **Primary prevention -- PreP**
- **Post-exposure prophylaxis with vaccine**
  - Available for people with known or presumed exposure to monkeypox
- **JYNNEOS vaccine considered safe for people with HIV**
  - Live but **non-replicating** virus vaccine (modified vaccinia Ankara, or MVA)

## *Examination and Diagnosis*

- **Collect a complete sexual and travel history for past 21 days**
  - Consider possibility of foreign or domestic animal or animal product contact
- **Perform a thorough skin and mucosal examination** (e.g., genital, anal, oral) in a room with *good lighting*
- **If rash present, consider a broad differential** (e.g., syphilis, varicella zoster, herpes simplex, molluscum contagiosum), especially if the person has epidemiologic risk factors for monkeypox infection in the current outbreak
- **Evaluate for STIs per the 2021 CDC STI Treatment Guidelines**
  - Persons with monkeypox have had STIs including acute HIV



# MONKEYPOX

## *Managing Monkeypox*

- **Most patients with intact immune systems, supportive care and pain control may be enough**
  - Point mutation leading to resistance, consider need for antiviral therapy
  - Anticipate guidance from FDA and CDC next week
- **Antiviral treatments are available for people who are at higher risk of severe illness**
  - Severe immunocompromise due to conditions such as advanced or poorly controlled human immunodeficiency virus (HIV), leukemia, lymphoma, generalized malignancy, solid organ transplantation, etc.
  - Pregnant or breastfeeding people
  - Pediatric populations, particularly patients younger than 8 years of age
  - People with a condition affecting skin integrity
- **For those who need treatment– particularly people living with HIV:**
  - No major interactions with antiretroviral medications if already taking ART
  - Delay starting long-acting cabotegravir/rilpivirine for two weeks after completing tecovirimat treatment

## *Managing Monkeypox in People with HIV*

Morbidity and Mortality Weekly Report

### **Interim Guidance for Prevention and Treatment of Monkeypox in Persons with HIV Infection — United States, August 2022**

Jesse O'Shea, MD<sup>1,\*</sup>; Thomas D. Filardo, MD<sup>1,2,\*</sup>; Sapna Bamrah Morris, MD<sup>1</sup>; John Weiser, MD<sup>1</sup>; Brett Petersen, MD<sup>1</sup>; John T. Brooks, MD<sup>1</sup>

US Department of Health and Human Services/Centers for Disease Control and Prevention

MMWR / August 12, 2022 / Vol. 71 / No. 32

1023

Follow here for updates:

<https://www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html>

## *Managing Monkeypox in People with HIV*

- **People with advanced HIV or who are not virologically suppressed**
  - New HIV infection being diagnosed simultaneously with monkeypox
  - Increased risk of severe disease related to monkeypox virus infection
    - Diffuse and coalescing lesions; Nodular disease
    - Lymphadenopathy
    - Hemodynamic instability (consider % of body surface area affected)
    - Encephalitis, myocarditis
  - Fatalities have been reported in patients who are not virologically suppressed
  - Increased risk of transmission
    - Household members of PLWH have been infected

# MONKEYPOX

## STOMP Trial

- **ACTG Trial** [*ClinicalTrials.gov Identifier: NCT05534984* ]      September 12th
- A Randomized, Placebo-Controlled, Double-Blinded Trial of the Safety and Efficacy of Tecovirimat for the Treatment of Human Monkeypox Virus Disease
- **Inclusion criteria**
  - 530 participants; all ages, confirmed MPX less than 14 days
  - Will include those at risk for severe illness (higher dosing), peds, pregnant patients with open label use of tecovirimat
- **Primary Outcome:** Time to clinical resolution

# MONKEYPOX

## *Community Resources*

CDC Monkeypox Website: <https://www.cdc.gov/monkeypox>

Reducing Stigma in Monkeypox Communication and Community Engagement

Website: <https://www.cdc.gov/poxvirus/monkeypox/reducing-stigma.html>

Fact Sheet: [https://www.cdc.gov/poxvirus/monkeypox/pdf/Monkeypox\\_Stigma\\_508.pdf](https://www.cdc.gov/poxvirus/monkeypox/pdf/Monkeypox_Stigma_508.pdf)

Safer Sex, Social Gatherings, and Monkeypox

Website: <https://www.cdc.gov/poxvirus/monkeypox/sexualhealth>

Fact Sheet: [https://www.cdc.gov/poxvirus/monkeypox/pdf/MonkeyPox-SaferSex-InfoSheet-508\\_1.pdf](https://www.cdc.gov/poxvirus/monkeypox/pdf/MonkeyPox-SaferSex-InfoSheet-508_1.pdf)

Also available in Arabic, French, Korean, Spanish, Simplified Chinese, Tagalog, and Vietnamese.

CDC Health Equity Guiding Principles for Inclusive Communication:

Website: [https://www.cdc.gov/healthcommunication/Health\\_Equity.html](https://www.cdc.gov/healthcommunication/Health_Equity.html)

CDC and FDA Update: Interim Clinical Considerations for Monkeypox Vaccination:

Website: [https://emergency.cdc.gov/coca/calls/2022/callinfo\\_081122.asp](https://emergency.cdc.gov/coca/calls/2022/callinfo_081122.asp)

# MONKEYPOX

## *Community Resources*

### **If You Are Sick with Monkeypox**

- **Website:** <https://www.cdc.gov/poxvirus/monkeypox/if-you-are-sick.html>

### **5 Things to Know About Monkeypox**

- **Video:** <https://youtu.be/9GziSwQTo4A> (Spanish version in development)

### **Monkeypox - 5 Things Sexually Active People Need to Know**

- **Video:** [https://youtu.be/xf2x62i1\\_c8](https://youtu.be/xf2x62i1_c8) (Spanish version in development)

### **Clinical Considerations for Treatment and Prophylaxis of Monkeypox Virus Infection in People with HIV**

- **Website:** <https://www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html>
- **MPX and HIV FAQs:** <https://www.cdc.gov/poxvirus/monkeypox/faq.html#Monkeypox-and-HIV>



**For more information, contact CDC**

1-800-CDC-INFO (232-4636)

TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions of this report represent the opinion of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention



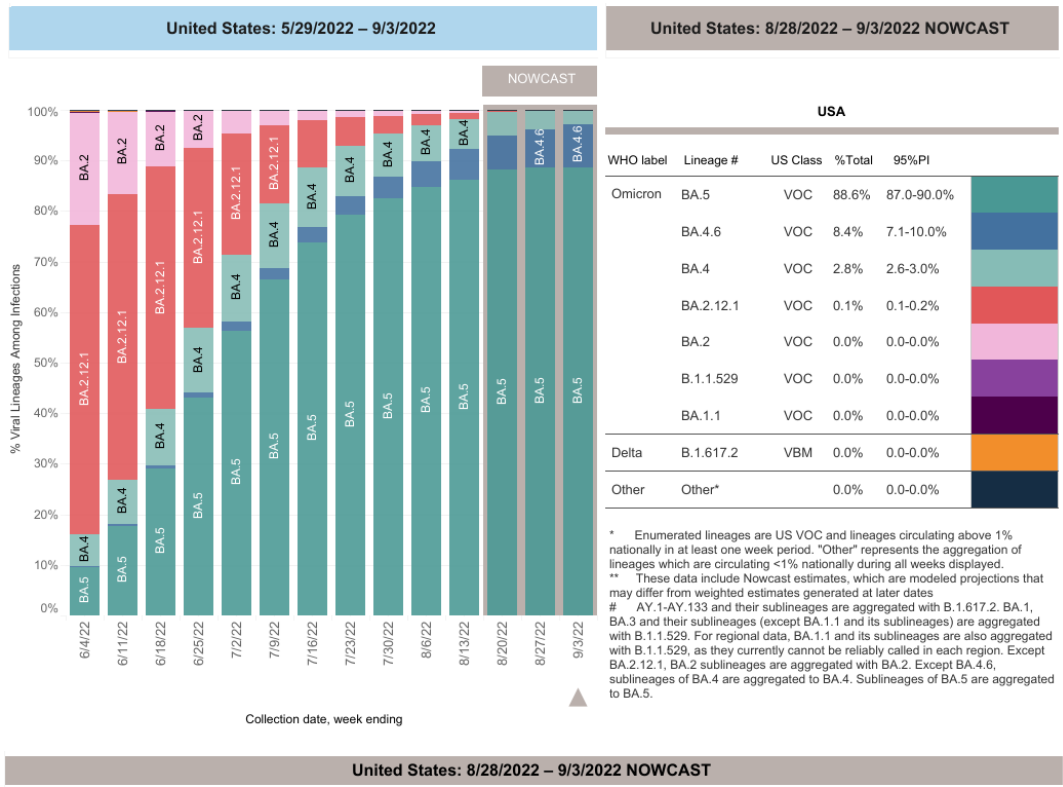
**Peter Marks, MD, PhD**



# Bivalent Booster Authorization Update

Peter Marks, M.D., Ph.D  
CDC/IDSA Clinician Call  
September 10, 2022

# Recent Evolution of SARS-CoV-2



# Neutralizing Antibody Titers Against Omicron Sub-Variants following Vaccination and BA.1 or BA.2 Infection



- BA.1 or BA.2 infection after vaccination increases antibody titers against Omicron variants
- Titers against BA.2.12.1 and BA.4/BA.5 lower than titers against BA.1 or BA.2

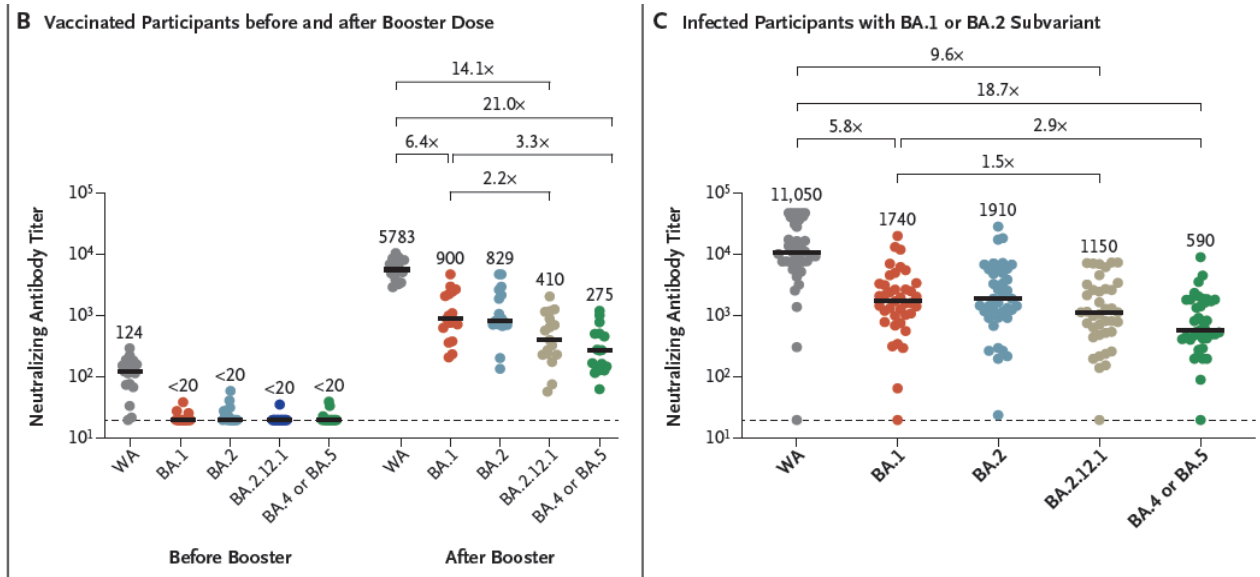
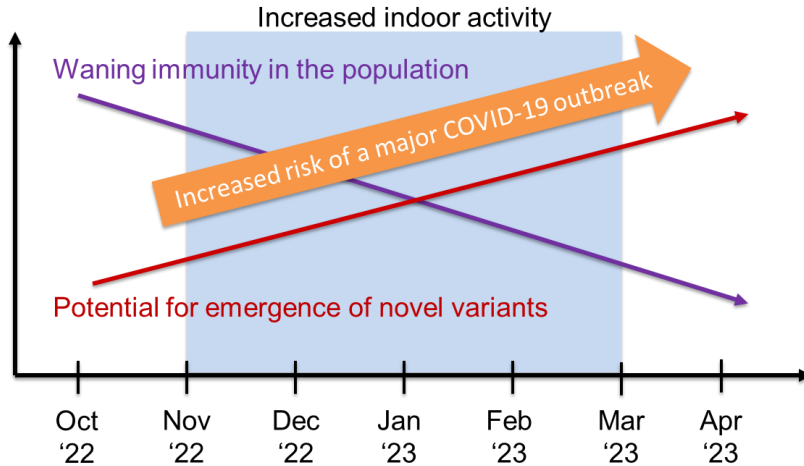


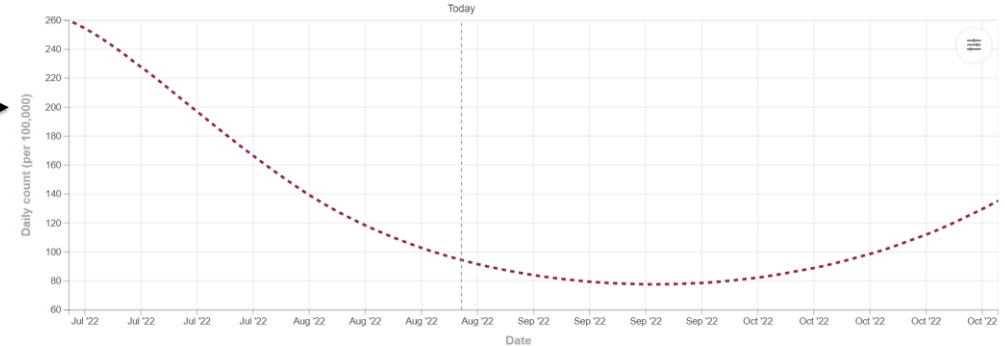
Figure 1B & 1C – from Hachmann NP et al 2022 N Engl J Med DOI: 10.1056/NEJMc2206576

# Fall 2022 Predictive Modeling

## Potential evolution of COVID-19



## Modelers predicting next peak in late November

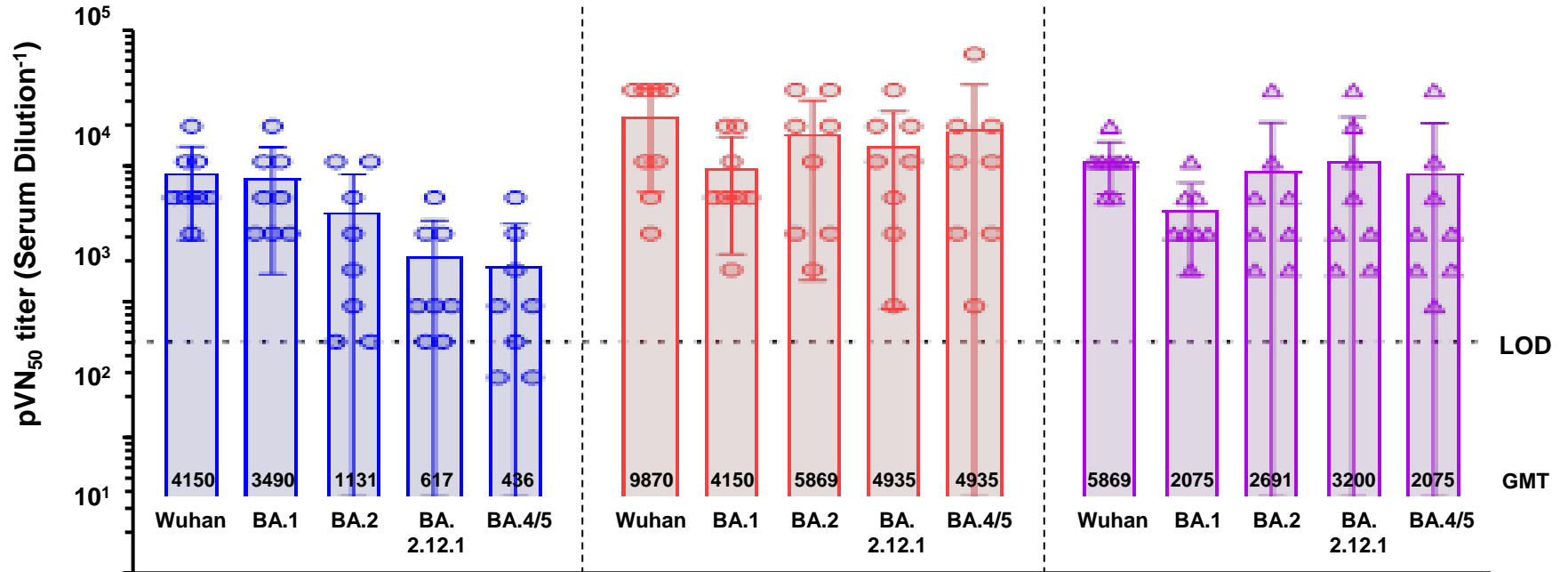


<https://covid19.healthdata.org/united-states-of-america?view=infections-testing&tab=trend&test=infections>

# Use of Totality of the Evidence

- Extensive knowledge of the safety and efficacy of the mRNA platforms was used for booster decision-making, given hundreds of millions who have received the prototype component contained in the booster
- As for the BA.4/5 component of the booster, a combination of nonclinical data and safety and immunogenicity data obtained in clinical studies with three variant vaccines, including omicron BA.1 were used

# Experimental Data from Mice with BA.1 and BA.4/5 Boosters



N=8 mice Balb/c mice. Mice preimmunized with 2 doses of BNT162b2; boosters given at day 104  
Pseudovirus neutralization assay; LOD, Limit of Detection

OMI BA.1

OMI BA.4/5

BNT162b2 + OMI BA.4/5

# Moderna COVID-19 Vaccine

- Analysis population: previously uninfected adults 18 years of age and older
- Vaccines evaluated:
  - mRNA-1273: monovalent, 50 µg mRNA encoding prototype S protein
  - mRNA-1273.214: bivalent, 25 µg each of mRNA encoding prototype or Omicron/BA.1 S protein

**Neutralizing antibody GMT at 4 weeks after a 4<sup>th</sup> (2<sup>nd</sup> booster) dose**

Neutralization Input Virus	mRNA 1273 GMT (95% CI) N=260	mRNA 1273.214 GMT (95% CI) N=334	GMT Ratio (95% CI) mRNA-1273.214/ mRNA-1273
Omicron/BA.1	1473 (1271, 1708)	2372 (2071, 2718)	1.75 (1.49, 2.04)
Ancestral (D614G)	5649 (5057, 6311)	5977 (5322, 6713)	1.22 (1.08, 1.37)

# Pfizer-BioNTech COVID-19 Vaccine



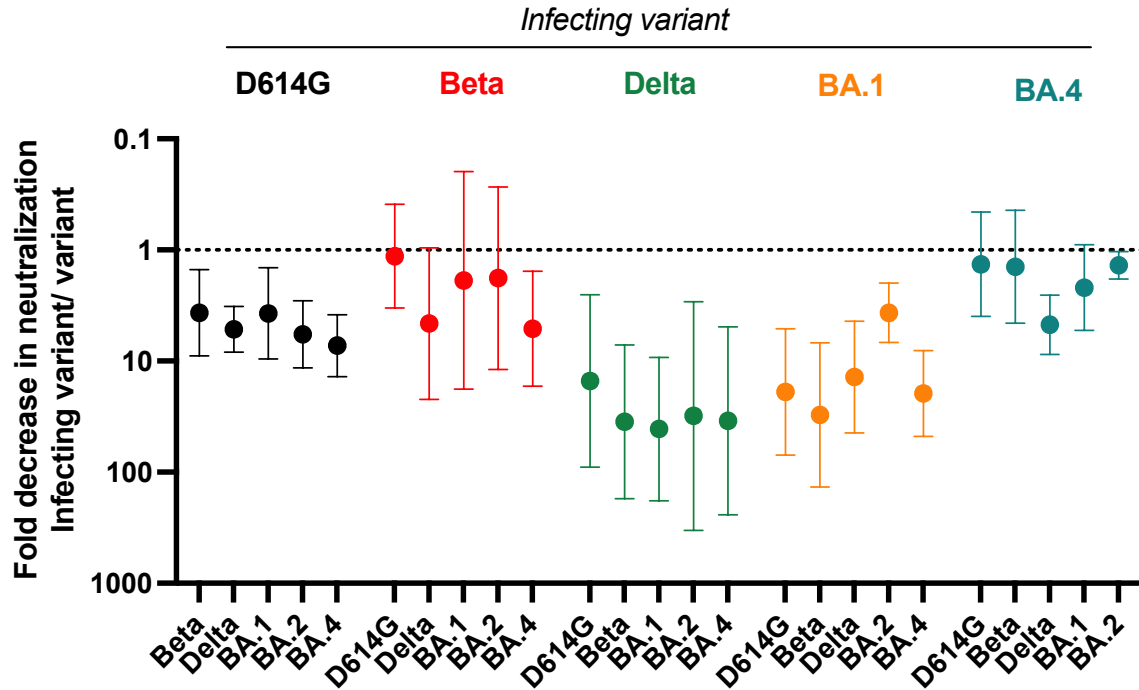
- Analysis previously uninfected adults 18-55 years of age
- Vaccines evaluated:
  - BNT162b2: monovalent, 30 µg mRNA encoding prototype S protein
  - BNT162b2 OMI: monovalent, 30 µg mRNA encoding Omicron/BA.1 S protein

## Neutralizing antibody GMT at 1 month after a 4<sup>th</sup> (2<sup>nd</sup> booster) dose

Neutralization Input Virus	BNT162b2 GMT (95% CI) N=141	BNT162b2 OMI GMT (95% CI) N=132	GMT Ratio (95% CI) BNT162b2 OMI/ BNT162b2
Omicron/BA.1	1100 (932, 1297)	1929 (1632, 2281)	1.75 (1.39, 2.22)
Ancestral (D614G)	12009 (10744, 13425)	11997 (10554, 13638)	Not Evaluated



# BA.4 triggers increased breadth compared to BA.1, and is more comparable to Beta



# Studies of Bivalent Boosters

- Ongoing human studies with the BA.4/BA.5 boosters will provide important insight into the protection that these new boosters provide in comparison to previous variants
- These studies will also provide the basis for determining the efficacy of BA.4/BA.5 boosters against future variants
- These studies may also be relevant for consideration of the appropriate composition of the vaccine primary series

# Summary of Actions – Aug 31, 2022

- Moderna Bivalent COVID-19 Vaccine (Original + BA.4/BA.5) authorized for individuals ages 18 and older
- Pfizer-BioNTech Bivalent COVID-19 Vaccine (Original + BA.4/BA.5) authorized for individuals ages 12 and older
- Primary series doses continue with monovalent Moderna and Pfizer-BioNTech COVID-19 vaccine
- Authorizations for monovalent Moderna and Pfizer-BioNTech COVID-19 vaccine boosters revoked

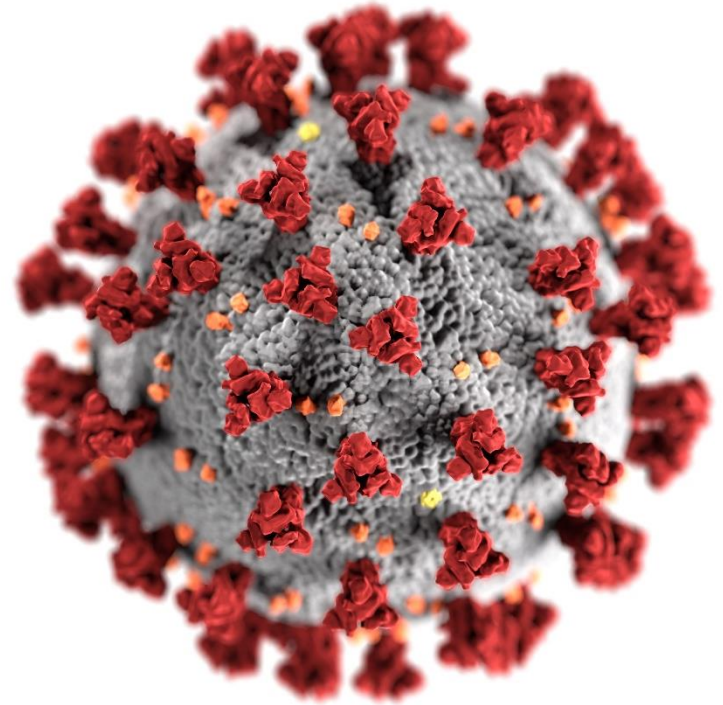


**Priti Patel, MD, MPH**

# COVID-19 Updated Booster Vaccine

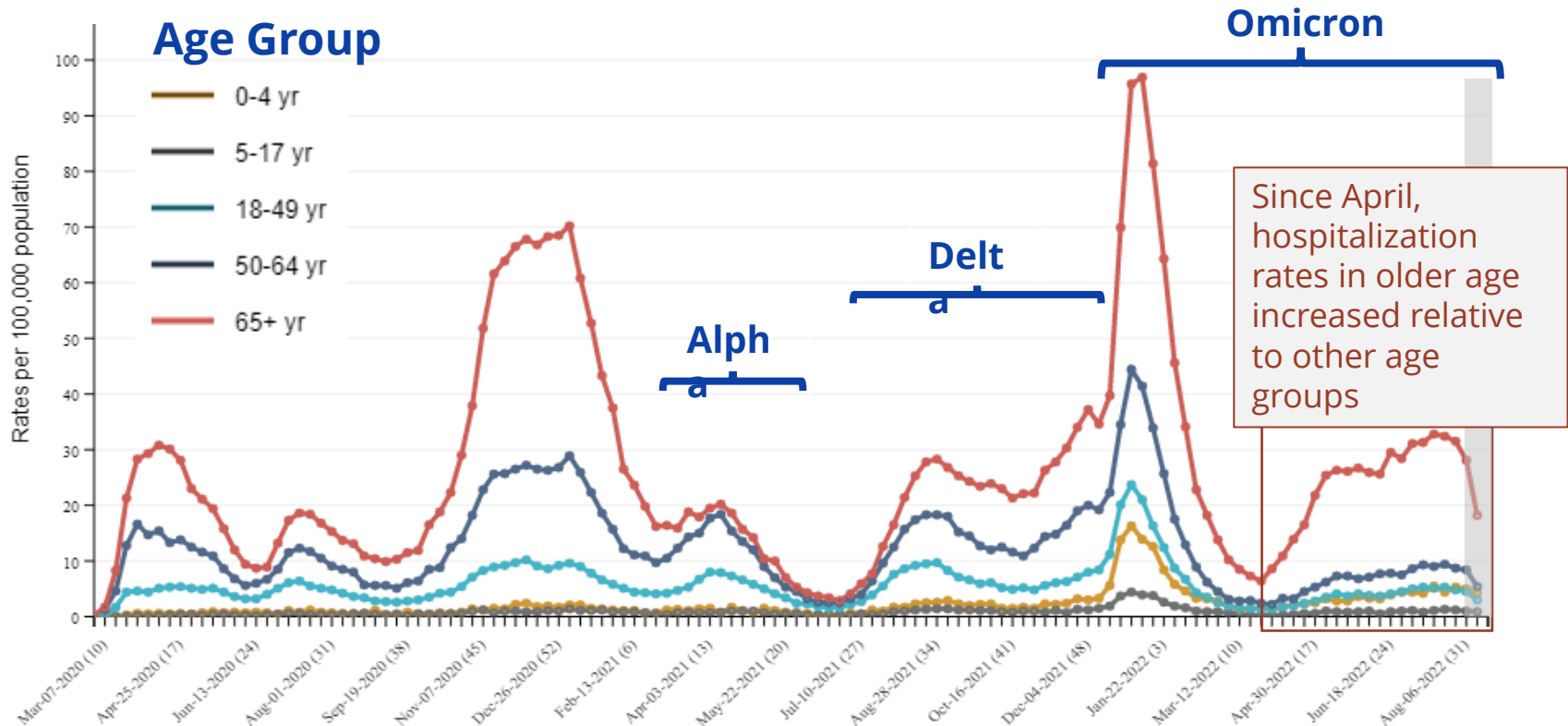
**Priti Patel MD, MPH**

September 10, 2022



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

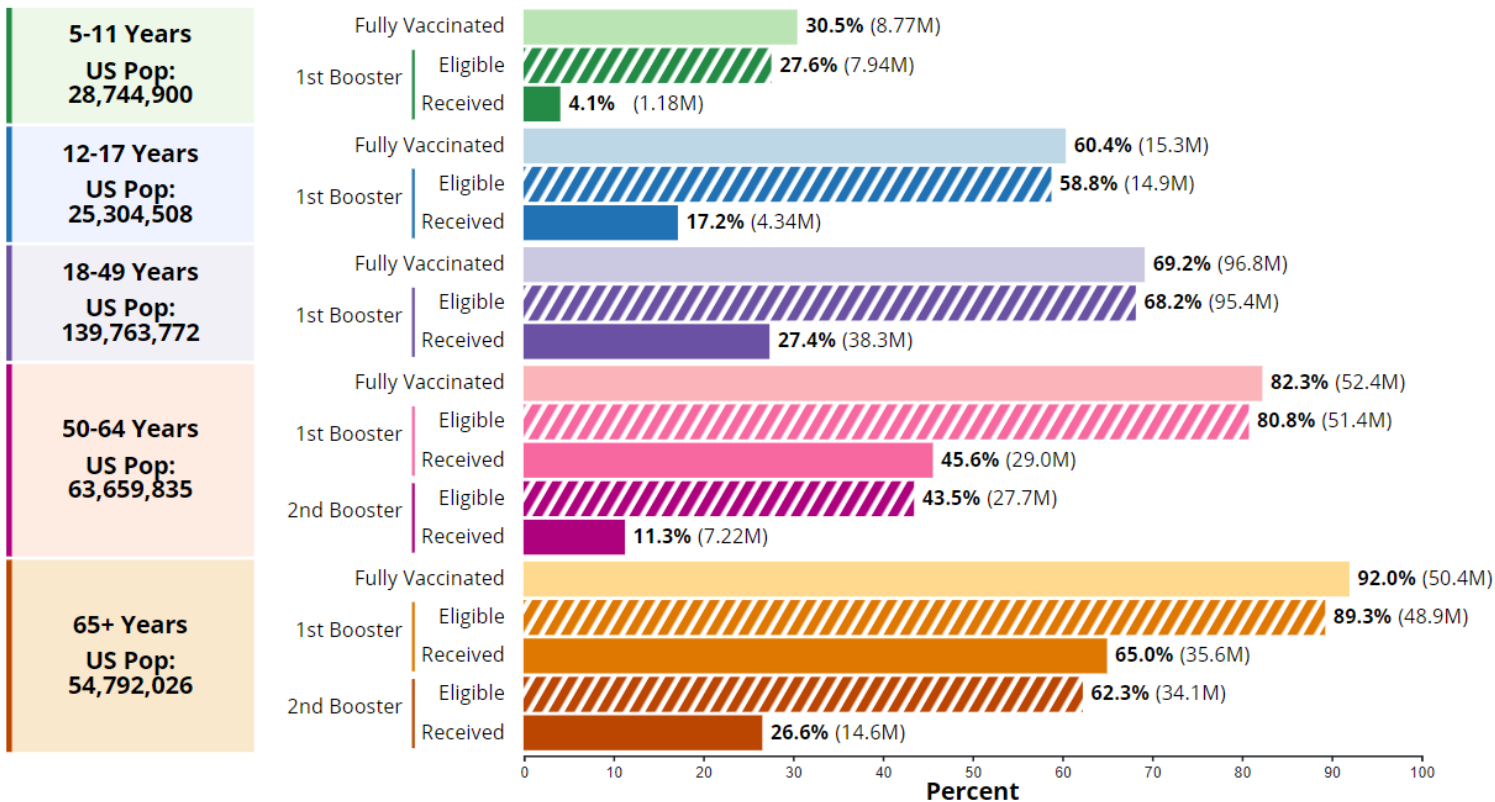
# Weekly Trends in COVID-19-Associated Hospitalization Rates by Age Group — COVID-NET, March 2020 – August 20, 2022



Grey shaded area denotes the most recent 2 weeks where reporting is <95% complete.

Source: COVID-NET; [https://gis.cdc.gov/grasp/COVIDNet/COVID19\\_3.html](https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html) Accessed August 26, 2022

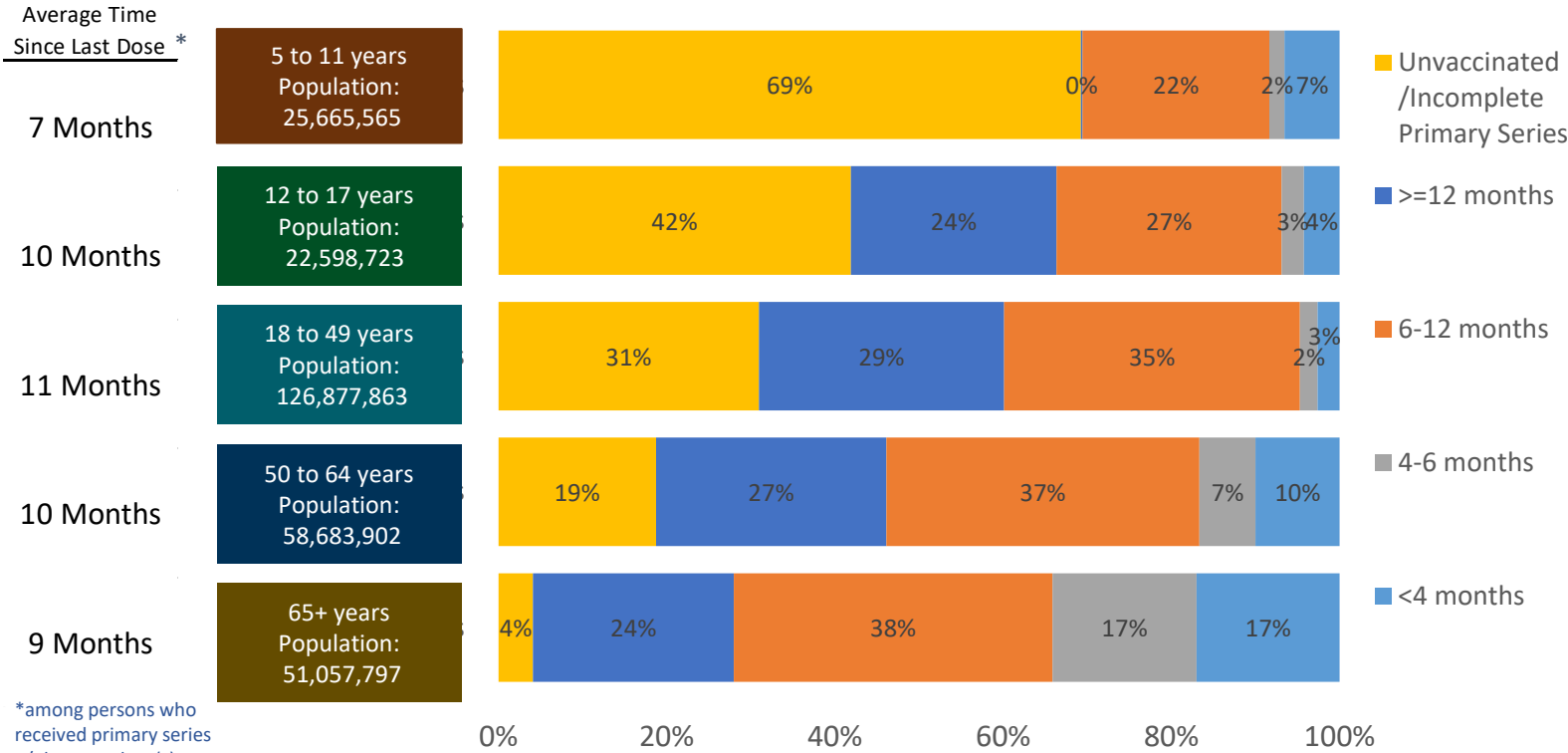
# Primary Series Completion, Booster Dose Eligibility, and Booster Dose Receipt by Age, United States (as of August 25, 2022)



Fully vaccinated defined as having completed the primary vaccine series

[https://covid.cdc.gov/covid-data-tracker/#vaccinations\\_vacc-people-additional-dose-totalpop](https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-additional-dose-totalpop)

# Percentage of US Population by Age Group that Received their Most Recent COVID-19 Vaccine Dose (Primary Series or Booster) within a Given Time Period (as of Sept 7, 2022)



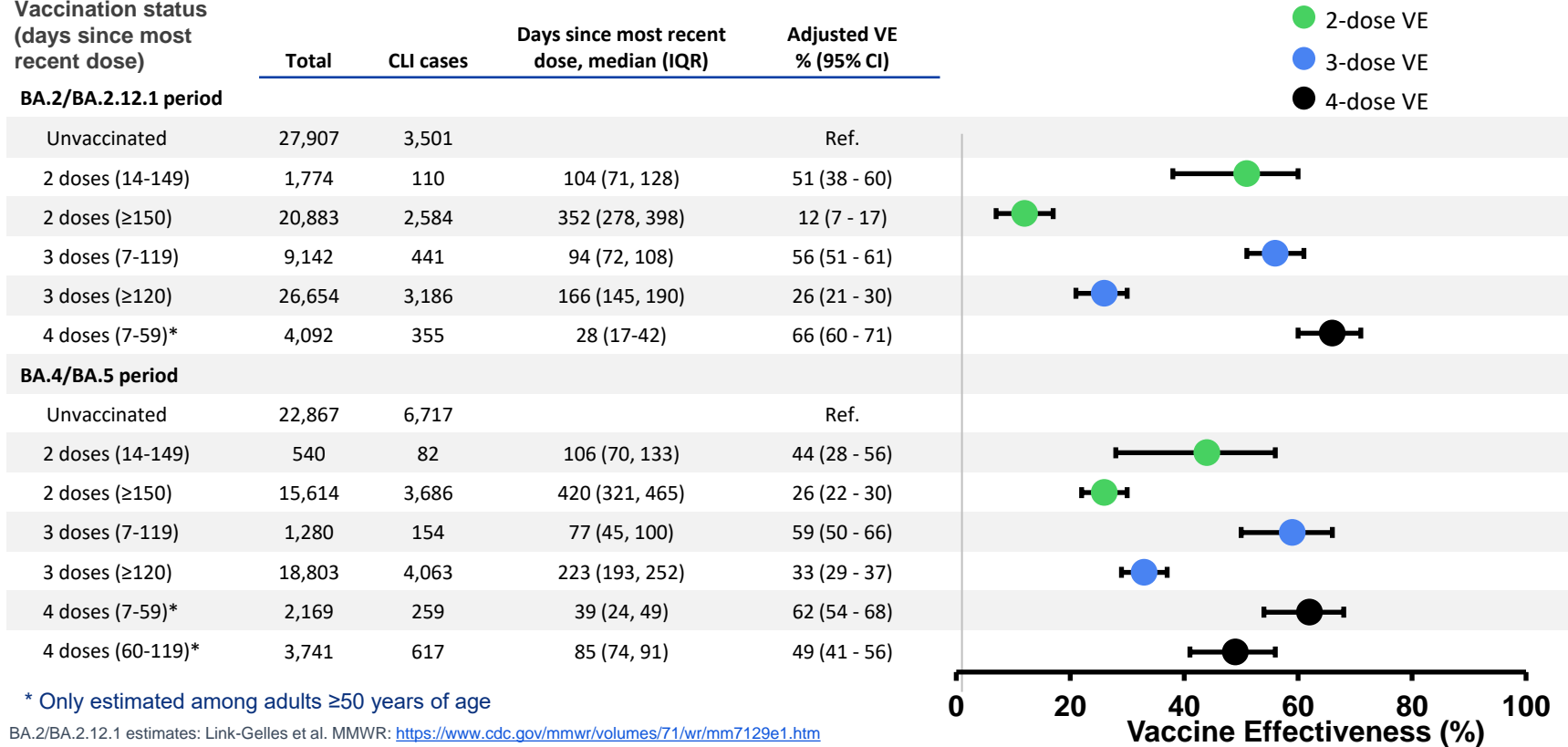
\*among persons who received primary series +/- booster dose(s)

Linking administrations to individuals is inexact and inflates the number of unique individuals receiving doses. This results in the underestimation of Unvaccinated/Incomplete Primary Series counts. Excludes vaccine administrations for residents of Texas (all records) and Idaho (records for persons ages <18 years only) because data on the primary series cannot be linked to data on booster doses in the aggregate data format submitted by these jurisdictions. Source: Immunization Data Lake. Data as of 6 AM ET Wednesday Sept 7, 2022.



# VISION: mRNA VE for ED/UC visits among immunocompetent adults ≥18 years by number of doses and time since last dose receipt, late-Mar–late-Jul 2022

Vaccination status  
(days since most recent dose)



\* Only estimated among adults ≥50 years of age

BA.2/BA.2.12.1 estimates: Link-Gelles et al. MMWR: <https://www.cdc.gov/mmwr/volumes/71/wr/mm7129e1.htm>

BA.4/BA.5 estimates: CDC, preliminary unpublished data. Individuals with prior infections excluded. Adjusted for calendar time, geographic region, age, sex, race, ethnicity, local virus circulation, respiratory, non-respiratory underlying medical conditions, and propensity to be vaccinated.

# VISION: mRNA VE for hospitalizations among immunocompetent adults ≥18 years by number of doses and time since last dose receipt, late-Mar–late-Jul 2022

## Vaccination status (days since most recent dose)

### BA.2/BA.2.12.1 period

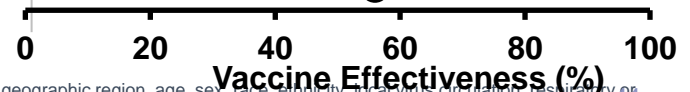
	Total	CLI cases	Days since most recent dose, median (IQR)	Adjusted VE % (95% CI)	
Unvaccinated	6,682	494		Ref.	
2 doses (14-149)	*	*	*	*	
2 doses (≥150)	5,118	393	371 (308, 413)	24 (12 - 35)	● 2-dose VE
3 doses (7-119)	2,350	72	94 (74, 108)	69 (58 - 76)	● 3-dose VE
3 doses (≥120)	7,686	519	168 (146, 191)	52 (44 - 59)	● 4-dose VE
4 doses (7-59)**	1,204	74	27 (17, 41)	80 (71 - 85)	
<b>BA.4/BA.5 period</b>					
Unvaccinated	4,578	913		Ref.	
2 doses (14-149)	*	*	*	*	
2 doses (≥150)	3,592	619	445 (369, 484)	25 (15 - 33)	● 2-dose VE
3 doses (7-119)	335	32	76 (46, 100)	49 (20 - 68)	● 3-dose VE
3 doses (≥120)	5,030	869	229 (199, 256)	34 (25 - 42)	● 4-dose VE
4 doses (7-59)**	717	81	38 (23, 49)	60 (42 - 73)	
4 doses (60-119)**	1,146	157	84 (73, 97)	56 (41 - 67)	

\* Estimates with confidence intervals >50 percentage points are not shown.

\*\* Only estimated among adults ≥50 years of age

BA.2/BA.2.12.1 estimates: Link-Gelles et al. MMWR: <https://www.cdc.gov/mmwr/volumes/71/wr/mm7129e1.htm>

BA.4/BA.5 estimates: CDC, preliminary unpublished data. Individuals with prior infections excluded. Adjusted for calendar time, geographic region, age, sex, race, ethnicity, local virus circulation, respiratory or non-respiratory underlying medical conditions, and propensity to be vaccinated.



# Vaccine effectiveness during Omicron

- Effectiveness against severe disease continues to be higher and more sustained over time than effectiveness against infection
- VE during BA.4/BA.5 predominance was generally comparable to VE during BA.2 predominance
- 3<sup>rd</sup> dose provides significant additional protection against infection and severe disease in all ages studied
  - VE post 3<sup>rd</sup> dose appears to wane more slowly compared with 2 doses alone during Omicron
  - Similar patterns across age groups
- Coverage with 4<sup>th</sup> dose too low to draw conclusions but additional benefits demonstrated for infection, ED/UC, and hospitalization

# Bivalent COVID-19 vaccines:

## What we know

- COVID-19 vaccines have a **high degree** of safety
  - Rare events of myocarditis seen after mRNA COVID-19 vaccines in post-authorization studies
- COVID-19 vaccines provide **high levels** of protection against **severe disease**
  - Initially, COVID-19 vaccines also provided high levels of protection against infection and transmission
  - As the virus evolved, noted rapid waning of protection against asymptomatic or mild disease
- COVID-19 booster doses **further increase** protection against **severe disease**
- Bivalent COVID-19 vaccines **expand immune response** after vaccination
  - Vaccines that contain Omicron will improve antibody response to Omicron
  - Bivalent vaccines appear to provide more diverse response overall, likely improving response to future variants

# CDC/ACIP Recommendations & Staying Up To Date

- A single dose of bivalent Pfizer-BioNTech COVID-19 vaccine is recommended for individuals **ages 12 years and older** at least **2 months** after receipt of a primary series or prior monovalent booster dose, under the EUA issued by FDA.
- A single dose of bivalent Moderna COVID-19 vaccine is recommended for individuals **ages 18 years and older** at least **2 months** after receipt of a primary series or prior monovalent booster dose, under the EUA issued by FDA.
- ✓ CDC encourages people to “Stay up to date with your COVID-19 vaccines”
- ✓ You are up to date if you have completed a primary series and received the most recent booster dose recommended for you by CDC

# Fall Booster “Reset”

- Recommendations are simplified
- Change from dose counting to 1 bivalent booster for everyone eligible

Vaccination history	→	Next dose
Primary series	At least 2 months →	1 bivalent booster dose
Primary series + 1 booster	At least 2 months →	1 bivalent booster dose
Primary series + 2 booster	At least 2 months →	1 bivalent booster dose

# Infrastructure Exists to Reach Key Populations: U.S. COVID-19 Vaccine Program Milestones (August 2022)



**Over 800 million doses delivered in 88 weeks**



**Over 606 million doses administered in 87 weeks**



**About 90% of 18+ population have received at least 1 dose**



**About 92% of 65+ population are fully vaccinated with 71% boosted**



**Over 223 million people fully vaccinated**

# Jurisdictional Planning and Implementation Considerations

- The U.S. Government has purchased 171 million bivalent mRNA COVID-19 vaccine booster doses for the fall and beyond
- Initial authorizations for Pfizer BioNTech (ages 12+ years) and Moderna (ages 18+ years) bivalent COVID-19 booster vaccines
  - Authorizations for younger age groups expected to follow
- Current eligibility
  - Completion of the primary vaccine series (nearly 200 M adults)
  - $\geq 2$  months since last primary series or booster vaccine dose
- Monovalent mRNA vaccine still used to complete primary series
- Jurisdictions and pharmacies asked to consider strategies to ensure high-risk populations have access
  - e.g., long-term care, older adults, homebound persons, disproportionately affected communities, rural areas





# Influenza and COVID-19 Vaccine Co-Administration is Safe and Effective

- Providers should offer all vaccines for which a person is eligible at the same visit
- Coadministration may be an essential strategy in some populations or areas
- Consider benefits to timely completion of recommended immunizations and discuss concerns



# Vaccines.gov Update

- Flu vaccines returned to the Vaccines.gov search experience August 26
- Updated COVID-19 booster search fields added September 6
- One site with search for both COVID-19 and flu vaccines

**WE CAN DO THIS** | Vaccines.gov ☰ Menu

Need help finding a COVID-19 vaccine in the U.S.?  
Call [1-800-232-0233](tel:1-800-232-0233) (TTY [1-888-720-7489](tel:1-888-720-7489))

**Find a COVID-19 vaccine near you**

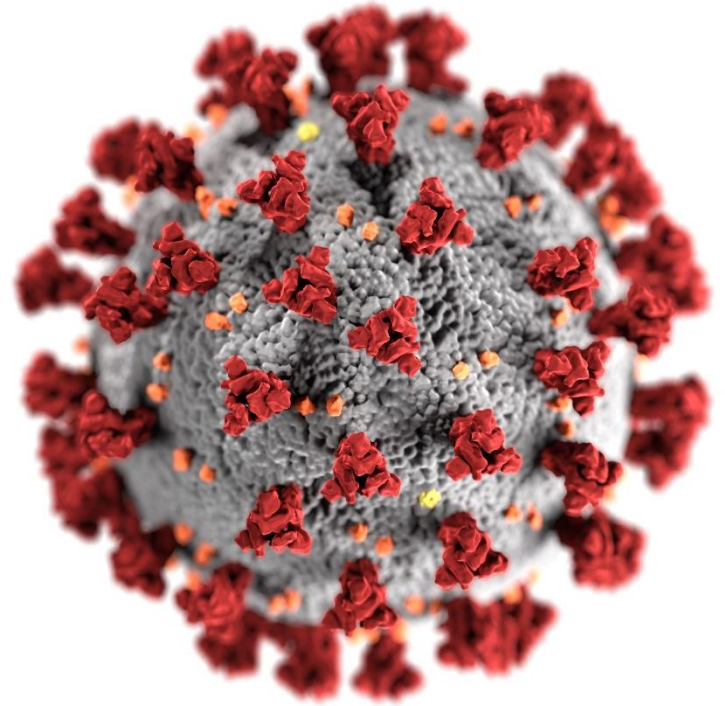
Use Vaccines.gov to find a location near you, then call or visit their website to make an appointment.

[Find COVID-19 Vaccines & Boosters](#)

[I'm looking for flu vaccines →](#)

Powered by **VaccineFinder**

# Thank you!



For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.





Kathryn M. Edwards, MD

### Disclosures:

Dr. Edwards has disclosed the following financial relationships. Any real or apparent conflicts of interest related to the content of this presentation have been resolved.

<b>Affiliation / Financial Interest</b>	<b>Organization</b>
Grant Recipient	CDC (Vaccine Safety with COVID vaccines)
Grant Recipient	NIH (Mentoring young investigators in vaccine sciences)
Consultant	BioNet (pertussis vaccines)
Consultant	IBM (vaccine safety networks)
Consultant	Data Safety and Monitoring Boards: Sanofi, X-4 Pharma, Seqirus, Moderna, Pfizer, Merck, GSK, Roche

# Safety of Booster Doses of COVID 19 Vaccines

**Kathryn M. Edwards, MD**

Sarah H. Sell and Cornelius Vanderbilt Professor  
Division of Infectious Diseases  
Department of Pediatrics  
Vanderbilt University Medical Center

# VAERS

VAERS accepts reports from everyone (healthcare professionals, patients, parents, caregivers, manufacturers, etc.) regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event

## Key strengths

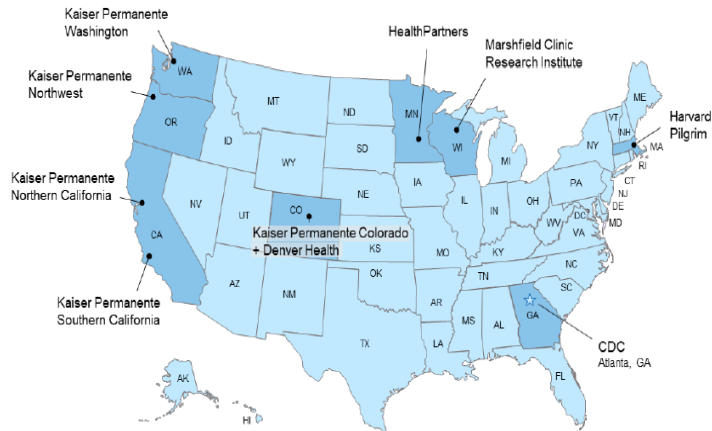
- Rapidly detects potential safety problems
- Can detect rare adverse events

## Key limitations

- Passive surveillance system
- Inconsistent quality and completeness of information
- Reporting biases
- Generally, cannot determine cause and effect



# Vaccine Safety Datalink (VSD)



- Established in 1990

# CDC Safety Networks

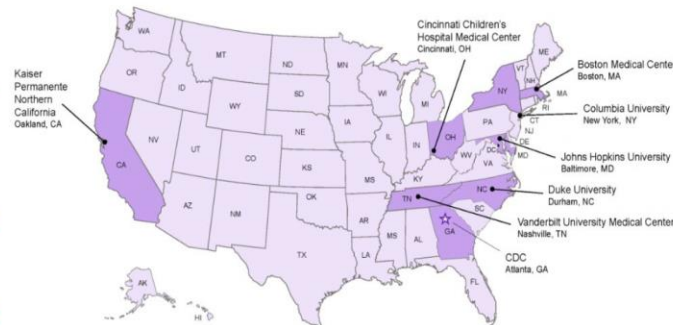
Smartphone-based active safety monitoring



<https://vsafe.cdc.gov>



**CISA**  
Clinical Immunization Safety Assessment (CISA) Project



7 participating medical research centers with vaccine safety experts

- clinical consult services<sup>†</sup>
- clinical research

<sup>†</sup>More information about clinical consults available at <http://www.cdc.gov/vaccinesafety/Activities/CISA.html>

# U.S. reports to VAERS following 1<sup>st</sup> and 2<sup>nd</sup> mRNA COVID-19 booster vaccinations\* (as of August 21, 2022)

Booster dose	Doses admin <sup>†</sup>	Total reports	Median age	Male <sup>‡</sup> n (%)	Female <sup>‡</sup> n (%)	Non-serious n (%)	Serious n (%)
<b>1<sup>st</sup> booster</b> (5–11 years)	1,153,611	727	9 years	369 (51)	348 (48)	723 (99)	4 (1)
<b>1<sup>st</sup> booster</b> (≥12 years)	102,063,616	64,265	53 years	21,841 (34)	41,234 (64)	57,048 (89)	7,217 (11)
<b>2<sup>nd</sup> booster</b> (≥50 years)	20,145,400	12,619	68 years	4,556 (36)	7,973 (63)	11,895 (94)	724 (6)

\* Among persons receiving Pfizer-BioNTech dose 3: children ages 5–11 years vaccinated during May 17–August 21, 2022; children and adolescents ages 12–15 years vaccinated during January 3–August 21, 2022, and ages 16–17 years vaccinated during December 9, 2021–August 21, 2022; adults ages ≥18 years vaccinated during September 22, 2021–August 21, 2022. Among persons receiving Moderna dose 3: adults ages ≥18 years vaccinated during October 20, 2021–August 21, 2022. Among persons ages ≥50 years: dose 4 Pfizer-BioNTech or Moderna vaccine received during March 29–August 21, 2022.

<sup>†</sup> Doses of Pfizer-BioNTech dose 3 administered among children ages 5–11 years during June 16–August 18, 2022; children and adolescents ages 12–15 years during January 6–August 18, 2022; adolescents ages 16–17 years during December 9, 2021–August 18, 2022; adults ages ≥18 years during September 22, 2021–August 18, 2022. Doses of Moderna dose 3 administered among adults ages ≥18 years during October 28, 2021–August 18, 2022. Among adults ages ≥50 years, 2<sup>nd</sup> booster dose of Pfizer-BioNTech or Moderna vaccine administered during March 28–August 18, 2022.

<sup>‡</sup> Sex was not reported in approximately 2% of reports.



# Most frequent MedDRA Preferred Terms\* in reports to VAERS following 1<sup>st</sup> booster dose mRNA COVID-19 vaccinations, ages 5–11 years<sup>†</sup> (as of August 21, 2022)

N=727, all reports

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	Product Preparation Issue	197 (27)
2	Incorrect Dose Administered	164 (23)
3	No Adverse Event	139 (19)
4	Product Preparation Error	69 (9)
5	Product Administered To Patient Of Inappropriate Age	67 (9)
6	Expired Product Administered	53 (7)
7	Pyrexia/Fever	51 (7)
8	Pain In Extremity	40 (6)
9	Fatigue	37 (5)
10	Vomiting	27 (4)

N=727, clinical outcomes only shown<sup>‡</sup>

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	Pyrexia/Fever	51 (7)
2	Pain In Extremity	40 (6)
3	Fatigue	37 (5)
4	Vomiting	27 (4)
5	Dizziness	24 (3)
6	Headache	23 (3)
7	Injection Site Pain	23 (3)
8	Pain	21 (3)
9	Chills	18 (2)
10	Lymphadenopathy	18 (2)



VAERS

\* Medical Dictionary for Regulatory Activities Preferred Terms (<https://www.meddra.org/how-to-use/basics/hierarchy>)

<sup>†</sup> Among children ages 5–11 years receiving Pfizer-BioNTech dose 3 during May 17–August 21, 2022; reports received and processed as of August 23, 2022

<sup>‡</sup> Determined by subject matter expert review



## Most frequent MedDRA Preferred Terms\* in reports to VAERS following 2<sup>nd</sup> booster dose mRNA COVID-19 vaccinations, ages ≥50 years<sup>†</sup> (as of August 21, 2022)

N=11,895, non-serious reports (clinical outcomes)

Rank	Adverse event (not mutually exclusive)	n (%)
1	COVID-19	3,951 (33)
2	SARS-CoV-2 Test Positive	2,757 (23)
3	Fatigue	2,057 (17)
4	Cough	1,724 (14)
5	Headache	1,645 (14)
6	Pyrexia/Fever	1,622 (14)
7	Pain	1,247 (10)
8	Oropharyngeal Pain	1,235 (10)
9	Rhinorrhoea	838 (7)
10	Malaise	811 (7)

N=724, serious reports (clinical outcomes)

Rank	Adverse event (not mutually exclusive)	n (%)
1	COVID-19	218 (30)
2	SARS-CoV-2 Test Positive	165 (23)
3	Dyspnoea	91 (13)
4	Asthenia	76 (11)
5	Fatigue	76 (11)
6	Death	66 (9)
7	Vaccine Breakthrough Infection	65 (9)
8	Headache	64 (9)
9	Cough	60 (8)
10	Pyrexia/Fever	60 (8)



VAERS

\* Medical Dictionary for Regulatory Activities Preferred Terms (<https://www.meddra.org/how-to-use/basics/hierarchy>)

<sup>†</sup> Among persons receiving Pfizer-BioNTech or Moderna dose 4 during March 29–August 21, 2022

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## VAERS reporting rates of verified myocarditis per 1 million mRNA COVID-19 vaccinations (Pfizer-BioNTech and Moderna combined), days 0–7 post-vaccination<sup>\*,†</sup>

Age group	Dose 2 (primary series)		1 <sup>st</sup> 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  
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slide

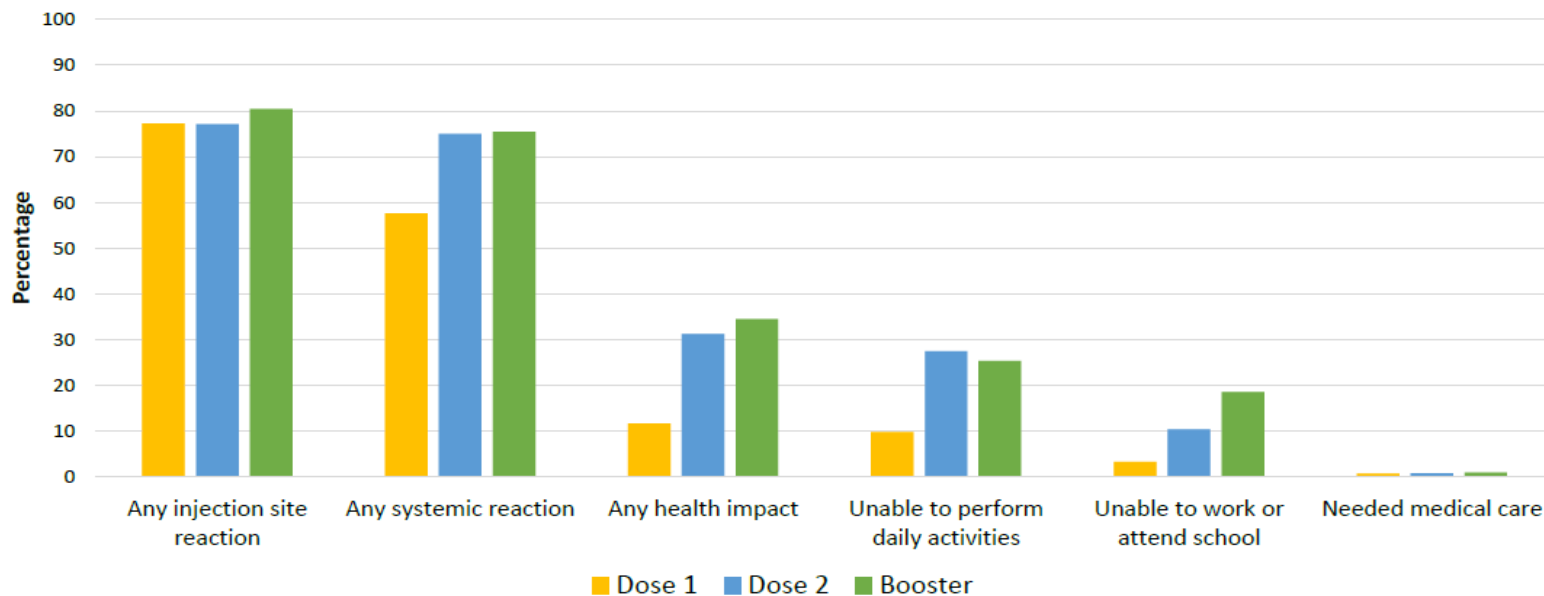


VAERS

\* 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)

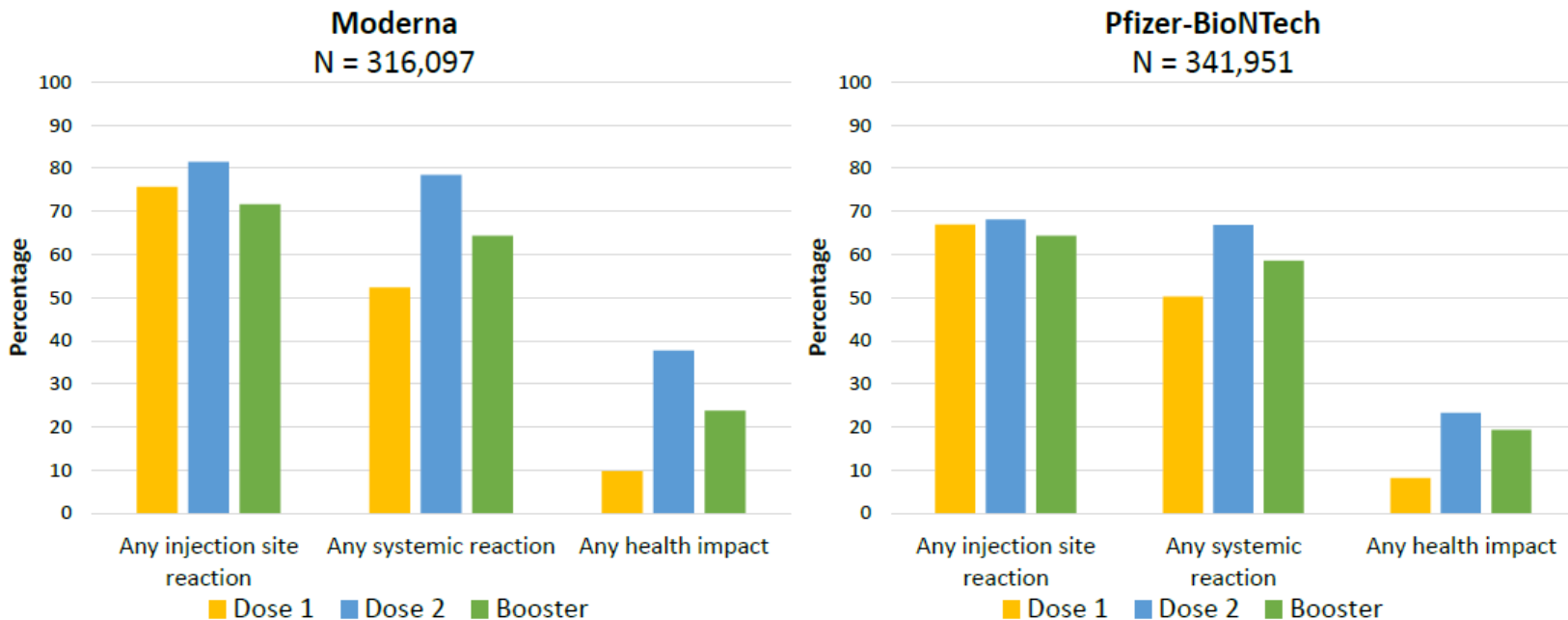
## Reactions and health impact events reported by v-safe participants aged 12-17 years at least once in days 0-7 after homologous Pfizer-BioNTech vaccination, by dose



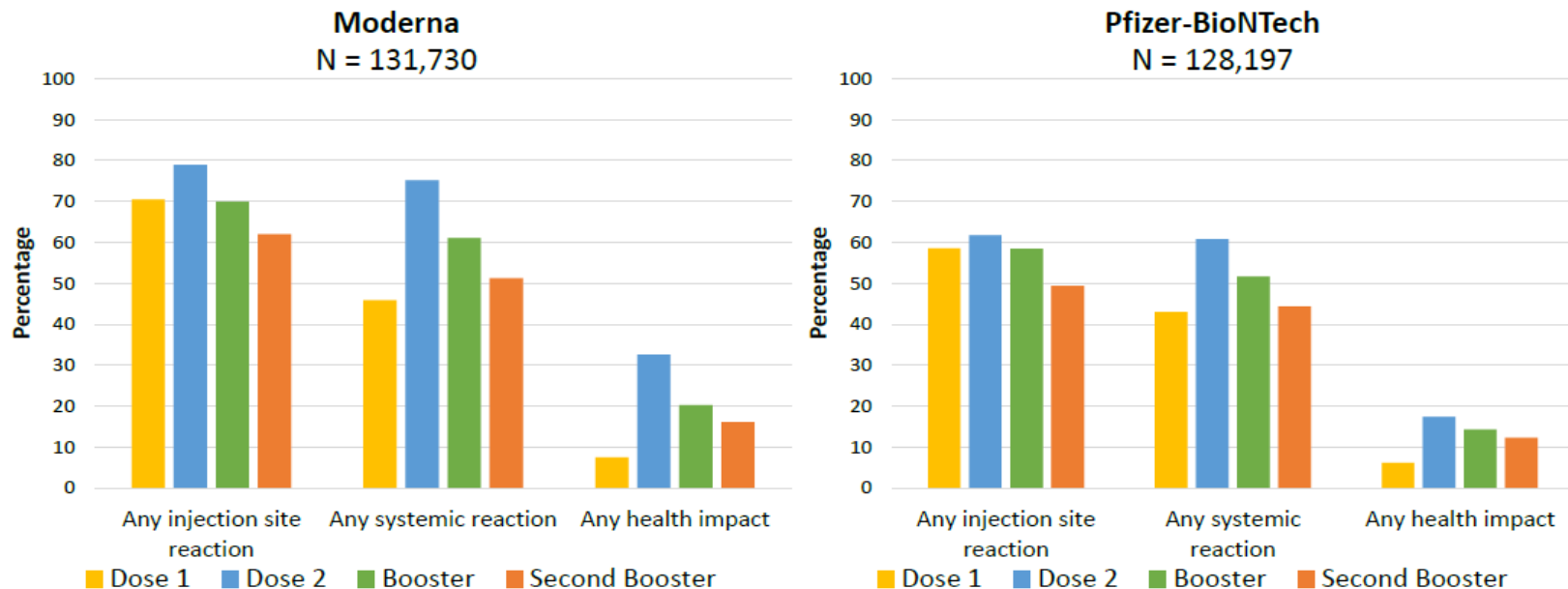
Includes 4,369 participants who completed at least one survey in the first week after each dose, data collected during Dec 9, 2021–Aug 21, 2022

Slides Presented at ACIP September 1, 2022

## Reactions and health impact events reported by v-safe participants aged $\geq 18$ years at least once in days 0-7 after homologous vaccination, by dose



## Reactions and health impact events reported by v-safe participants aged $\geq 50$ years at least once in days 0-7 after homologous vaccination, by dose



Includes participants who completed at least one survey in the first week after each dose, data collected during Mar 29–Aug 21, 2022

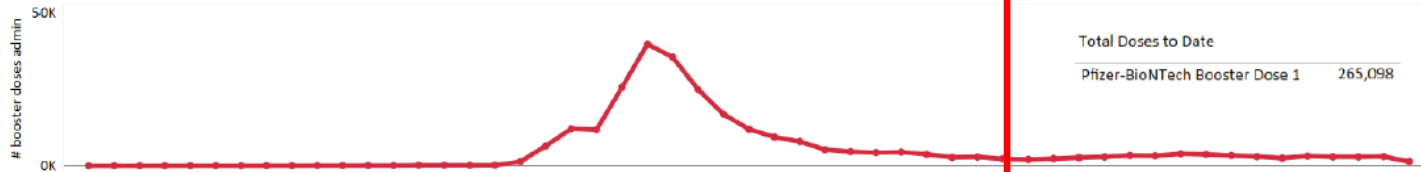
Slides Presented at ACIP September 1, 2022

# mRNA COVID-19 booster vaccine doses administered in VSD in people ages 5–11, 12–17, and ≥18 years, over time\*

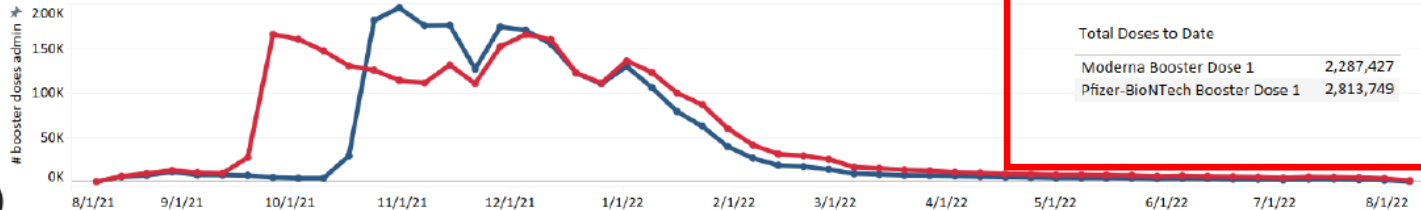
## 5-11 years old



## 12-17 years old



## ≥ 18 years old



**VSD**

vaccine safety datalink

\* Data through Aug 13, 2022

■ Moderna Booster Dose 1

■ Pfizer-BioNTech Booster Dose 1

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## VSD incidence rates of verified myocarditis/pericarditis in the 0–7 days after Pfizer-BioNTech vaccination in people ages 5–39 years, dose 2 and 1<sup>st</sup> booster\*

	Dose 2 primary series Pfizer-BioNTech			1 <sup>st</sup> booster dose Pfizer-BioNTech		
	Cases	Dose 2 admin	Incidence rate/ million doses (95% CI)	Cases	1 <sup>st</sup> boosters admin	Incidence rate/ million doses (95% CI)
<b>5-11 years</b>						
Males	3	207,958	14.4 (3.0 – 42.2)	0	50,415	0.0 (0.0 – 59.4)
Females	0	202,596	0.0 (0.0 – 14.8)	0	49,261	0.0 (0.0 – 60.8)
<b>12–15 years</b>						
Males	31	205,955	150.5 (102.3 – 213.6)	5	81,613	61.3 (19.9 – 143.0)
Females	5	204,074	24.5 (8.0 – 57.2)	0	84,114	0.0 (0.0 – 35.6)
<b>16–17 years</b>						
Males	14	102,091	137.1 (75.0 – 230.1)	9	47,874	188.0 (86.0 – 356.9)
Females	1	107,173	9.3 (0.2 – 52.0)	2	55,004	36.4 (4.4 – 131.3)
<b>18–29 years</b>						
Males	27	331,889	81.4 (53.6 – 118.4)	7	166,973	41.9 (16.9 – 86.4)
Females	2	400,321	5.0 (0.6 – 18.0)	1	240,226	4.2 (0.1 – 23.2)
<b>30–39 years</b>						
Males	5	341,527	14.6 (4.8 – 34.2)	3	197,554	15.2 (3.1 – 44.4)
Females	3	410,713	7.3 (1.5 – 21.3)	1	268,412	3.7 (0.1 – 20.8)

**VSD**

vaccine safety datalink

\*Primary series surveillance for people ages ≥18 years ended May 21, 2022, all other data through August 20, 2022.

Slides Presented at ACIP September 1, 2022

## VSD incidence rates of verified myocarditis/pericarditis in the 0–7 days after Moderna vaccination in people ages 5–39 years, dose 2 and 1<sup>st</sup> booster\*

	Dose 2 primary series Moderna			1 <sup>st</sup> booster dose Moderna		
	Cases	Dose 2 admin	Incidence rate/ million doses (95% CI)	Cases	1 <sup>st</sup> boosters admin	Incidence rate/ million doses (95% CI)
<b>5-11 years**</b>						
<b>Males</b>	N/A	N/A	N/A	N/A	N/A	N/A
<b>Females</b>	N/A	N/A	N/A	N/A	N/A	N/A
<b>12–15 years**</b>						
<b>Males</b>	N/A	N/A	N/A	N/A	N/A	N/A
<b>Females</b>	N/A	N/A	N/A	N/A	N/A	N/A
<b>16–17 years**</b>						
<b>Males</b>	N/A	N/A	N/A	N/A	N/A	N/A
<b>Females</b>	N/A	N/A	N/A	N/A	N/A	N/A
<b>18–29 years</b>						
<b>Males</b>	19	195,809	97.0 (58.4 – 151.5)	7	109,337	64.0 (25.7 – 131.9)
<b>Females</b>	0	243,560	0.0 (0.0 – 12.3)	1	156,707	6.4 (0.2 – 35.6)
<b>30–39 years</b>						
<b>Males</b>	8	216,583	36.9 (15.9 – 72.8)	1	149,468	6.7 (0.2 – 37.3)
<b>Females</b>	1	259,780	3.9 (0.1 – 21.4)	2	191,765	10.4 (1.3 – 37.7)

**VSD**

vaccine safety datalink

\*Primary series surveillance for people ages ≥18 years ended May 21, 2022, all other data through August 20, 2022.

\*\*Monitoring ongoing. no data provided if less than 2,500 doses given in a subgroup.



## Summary: mRNA COVID-19 vaccine safety of booster doses in people ages 5 years and older

- Safety findings are generally consistent with those observed for primary series vaccination
- Evidence suggests an increased risk for myocarditis following 1<sup>st</sup> booster dose
  - Myocarditis is a rare event following mRNA COVID-19 booster vaccination
    - CDC has verified 131 myocarditis case reports to VAERS in people ages  $\geq 5$  years after 123,362,627 million mRNA COVID-19 booster vaccinations
  - Risk primarily observed in adolescent and young adult males
  - No statistical signal for myocarditis to date in children ages 5–11 years following 1<sup>st</sup> booster
- In VAERS data, reporting rates of myocarditis are lower following 1<sup>st</sup> booster dose vs. dose 2 of primary series (and lower following dose 1 vs. dose 2 of primary series)
- In VSD analyses, myocarditis/pericarditis incidence following 1<sup>st</sup> booster dose and dose 2 of the primary series are similar, though case counts are small and confidence intervals around point estimates are wide



# **Q&A/ Discussion**

## Selected Resources

### **Monkeypox Update: Dr. Bamrah Morris**

- <https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html>
- <https://ourworldindata.org/monkeypox>
- <https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html>
- <https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpx-trends.html>
- <https://www.cdc.gov/poxvirus/monkeypox/response/2022/demographics.html>
- <https://www.cdc.gov/poxvirus/monkeypox/response/2022/2022-lab-test.html>
- <https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html>
- <https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html>
- <https://www.cdc.gov/std/treatment-guidelines/default.htm>
- <https://www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html>

### **Community Resources:**

- **CDC Monkeypox Website** <https://www.cdc.gov/poxvirus/monkeypox/index.html>
- **Reducing Stigma in Monkeypox Communication and Community Engagement**  
<https://www.cdc.gov/poxvirus/monkeypox/resources/reducing-stigma.html>  
[https://www.cdc.gov/poxvirus/monkeypox/pdf/Monkeypox\\_Stigma\\_508.pdf](https://www.cdc.gov/poxvirus/monkeypox/pdf/Monkeypox_Stigma_508.pdf)
- **Safer Sex, Social Gatherings, and Monkeypox**  
<https://www.cdc.gov/poxvirus/monkeypox/prevention/sexual-health.html>  
<https://www.cdc.gov/poxvirus/monkeypox/pdf/MonkeyPox-SaferSex-InfoSheet-508.pdf>
- **CDC Health Equity Guiding Principles for Inclusive Communication**  
[https://www.cdc.gov/healthcommunication/Health\\_Equity.html](https://www.cdc.gov/healthcommunication/Health_Equity.html)
- **CDC and FDA Update: Interim Clinical Considerations for Monkeypox Vaccination**  
[https://emergency.cdc.gov/coca/calls/2022/callinfo\\_081122.asp](https://emergency.cdc.gov/coca/calls/2022/callinfo_081122.asp)

## Selected Resources

### Bivalent Booster Authorization Update: Dr. Marks

- <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>
- <https://covid19.healthdata.org/united-states-of-america?view=infections-testing&tab=trend&test=infections>

### Updated Booster Vaccine: Dr. Patel

- [https://gis.cdc.gov/grasp/COVIDNet/COVID19\\_3.html](https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html)
- [https://covid.cdc.gov/covid-data-tracker/#vaccinations\\_vacc-people-additional-dose-totalpop](https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-additional-dose-totalpop)
- <https://www.cdc.gov/vaccines/covid-19/downloads/CDC-Fall-Vaccination-Operational-Planning-Guide.pdf>

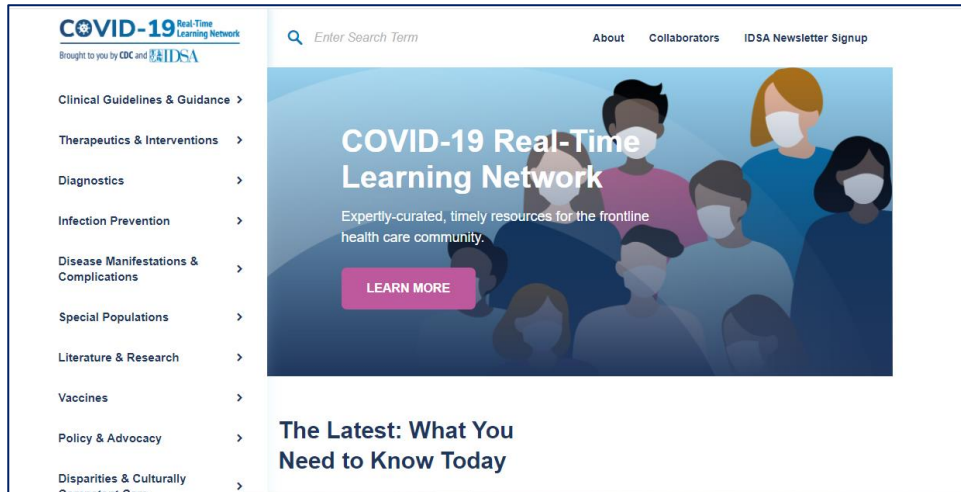
### Program Links:

- This webinar is being recorded and can be found with the slides online at <https://www.idsociety.org/cliniciancalls>
- COVID-19 Real-Time Learning Network: <https://www.idsociety.org/covid-19-real-time-learning-network/>
- Vaccine FAQ: <https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines-information--faq/>

# COVID-19 Real-Time Learning Network

Brought to you by CDC and IDSA

*An online community bringing together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.*



## Specialty Society Collaborators

American Academy of Family Physicians  
American Academy of Pediatrics  
American College of Emergency Physicians  
American College of Obstetricians & Gynecologists  
American College of Physicians  
American Geriatrics Society  
American Thoracic Society  
Pediatric Infectious Diseases Society  
Society for Critical Care Medicine  
Society for Healthcare Epidemiology of America  
Society of Hospital Medicine  
Society of Infectious Diseases Pharmacists

[www.COVID19LearningNetwork.org](http://www.COVID19LearningNetwork.org)

@RealTimeCOVID19

#RealTimeCOVID19

# CDC-IDSA Partnership: Clinical Management Call Support

## FOR WHOM?

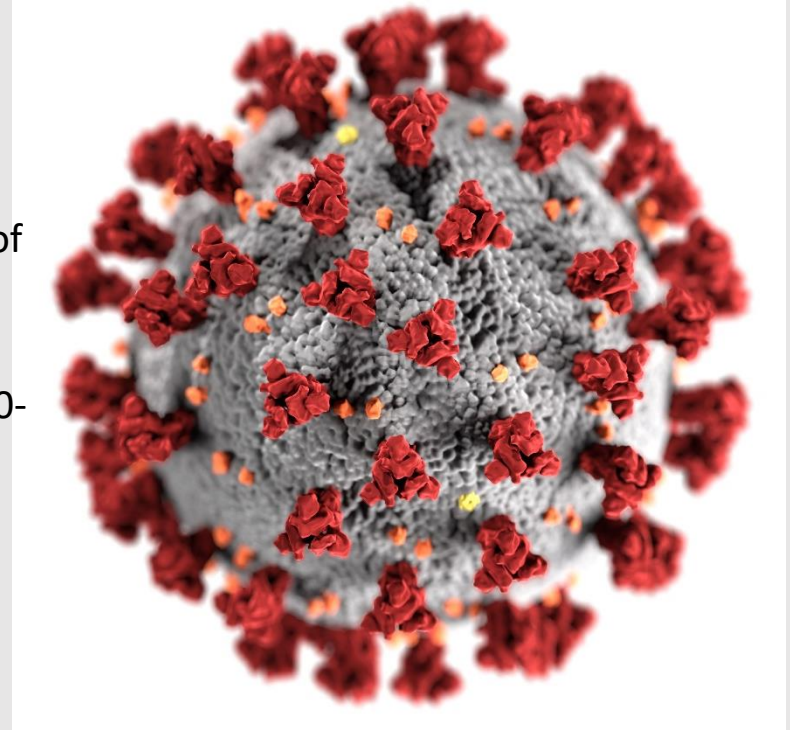
- Clinicians who have questions about the clinical management of COVID-19

## WHAT?

- Calls from clinicians will be triaged by CDC to a group of IDSA volunteer clinicians for peer-to-peer support

## HOW?

- Clinicians may call the main CDC information line at 800-CDC-INFO (800-232-4636)
- To submit your question in writing, go to [www.cdc.gov/cdc-info](http://www.cdc.gov/cdc-info) and click on Contact Form



**IDSA**  
Infectious Diseases Society of America

[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

# THANK YOU

We want to hear from you!

Please complete the post-call survey.

A recording of this call, slides and the answered Q&A will be posted at

[www.idsociety.org/cliniciancalls](http://www.idsociety.org/cliniciancalls)

*-- library of all past calls available --*

## Contact Us:

Dana Wollins ([dwillins@idsociety.org](mailto:dwillins@idsociety.org))

Deirdre Lewis ([dlewis@idsociety.org](mailto:dlewis@idsociety.org))