• 92\textsuperscript{nd} 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.
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 Ategbole, MD, MPH
Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button
Monkeypox Update

Sapna Bamrah Morris, MD, MBA, FIDSA
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
Case Count: 56,026 September 7, 2022

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>COUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>21,274</td>
</tr>
<tr>
<td>Spain</td>
<td>6,749</td>
</tr>
<tr>
<td>Brazil</td>
<td>5,525</td>
</tr>
<tr>
<td>France</td>
<td>3,646</td>
</tr>
<tr>
<td>Germany</td>
<td>3,511</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>3,484</td>
</tr>
<tr>
<td>Peru</td>
<td>1,724</td>
</tr>
<tr>
<td>Canada</td>
<td>1,289</td>
</tr>
</tbody>
</table>

Source: 2022 Monkeypox Outbreak Global Map | Monkeypox | Poxvirus | CDC
Worldwide Trend in Cases

Source: Monkeypox - Our World in Data

Data produced by the 'GlobalHealth' team — available at github.com/globalhealth/monkeypox
Case Count: 21,274 September 7, 2022

<table>
<thead>
<tr>
<th>STATE</th>
<th>COUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>4,140</td>
</tr>
<tr>
<td>New York</td>
<td>3,542</td>
</tr>
<tr>
<td>Florida</td>
<td>2,148</td>
</tr>
<tr>
<td>Texas</td>
<td>1,871</td>
</tr>
<tr>
<td>Georgia</td>
<td>1,522</td>
</tr>
<tr>
<td>Illinois</td>
<td>1,128</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>618</td>
</tr>
</tbody>
</table>

Source: 2022 U.S. Map & Case Count | Monkeypox | Poxvirus | CDC
U.S. Monkeypox Case Trends Reported to CDC

Source: U.S. Monkeypox Case Trends Reported to CDC | Monkeypox | Poxvirus | CDC
Select Demographic and Clinical Characteristics

Monkypox cases reported to CDC: Race/Ethnicity by Week

Race / Ethnicity
- American
- Indian/Alaska Native
- Asian
- Black or African American
- Hispanic or Latino
- Multiple Races
- Native Hawaiian or Other Pacific Islander
- White

Source: Monkypox Cases by Age and Gender, Race/Ethnicity, and Symptoms | Monkypox | Poxvirus | CDC
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

Source: Non-Variola Orthopoxvirus and Monkeypox Virus Laboratory Testing Data | Monkeypox | Poxvirus | CDC
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**
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
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
**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

- 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)

Source: JYNNEOS Vaccine | Monkeypox | Poxvirus | CDC
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
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

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

Morbidity and Mortality Weekly Report

Jesse O’Shea, MD1,*; Thomas D. Filardo, MD1,2,*; Sapna Bamrah Morris, MD1; John Weiser, MD1; Brett Petersen, MD1; John T. Brooks, MD1

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

Follow here for updates:
https://www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html

Source: https://www.cdc.gov/mmwr/volumes/71/wr/mm7132e4.htm and 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

Source: https://www.cdc.gov/mmwr/volumes/71/wr/mm7132e4.htm and https://www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html
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
Community Resources

CDC Monkepox 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

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
  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

CDC and FDA Update: Interim Clinical Considerations for Monkeypox Vaccination:
  Website: https://emergency.cdc.gov/coca/calls/2022/callinfo_081122.asp
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 (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
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

https://covid.cdc.gov/covid-data-tracker/#variant-proportions
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
Modelers predicting next peak in late November

Potential evolution of COVID-19

- Increased indoor activity
- Waning immunity in the population
- Increased risk of a major COVID-19 outbreak
- Potential for emergence of novel variants

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
---|---|---
GMT | 4150 | 9870 | 5869
436 | 5869 | 2075
1131 | 2075 | 2075
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 4th (2nd booster) dose

<table>
<thead>
<tr>
<th>Neutralization Input Virus</th>
<th>mRNA 1273 GMT (95% CI)</th>
<th>mRNA 1273.214 GMT (95% CI)</th>
<th>GMT Ratio (95% CI) mRNA-1273.214/mRNA-1273</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omicron/BA.1</td>
<td>1473 (1271, 1708)</td>
<td>2372 (2071, 2718)</td>
<td>1.75 (1.49, 2.04)</td>
</tr>
<tr>
<td>Ancestral (D614G)</td>
<td>5649 (5057, 6311)</td>
<td>5977 (5322, 6713)</td>
<td>1.22 (1.08, 1.37)</td>
</tr>
</tbody>
</table>
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 4th (2nd booster) dose

<table>
<thead>
<tr>
<th>Neutralization Input Virus</th>
<th>BNT162b2 GMT (95% CI) N=141</th>
<th>BNT162b2 OMI GMT (95% CI) N=132</th>
<th>GMT Ratio (95% CI) BNT162b2 OMI/ BNT162b2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omicron/BA.1</td>
<td>1100 (932, 1297)</td>
<td>1929 (1632, 2281)</td>
<td>1.75 (1.39, 2.22)</td>
</tr>
<tr>
<td>Ancestral (D614G)</td>
<td>12009 (10744, 13425)</td>
<td>11997 (10554, 13638)</td>
<td>Not Evaluated</td>
</tr>
</tbody>
</table>
BA.4 triggers increased breadth compared to BA.1, and is more comparable to Beta

Simone Richardson, slide courtesy of Penny Moore

www.fda.gov
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

Since April, hospitalization rates in older age groups increased relative to other age groups.

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

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
### 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)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Population</th>
<th>Unvaccinated/Incomplete Primary Series</th>
<th>10 Months</th>
<th>11 Months</th>
<th>7 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 to 11 years</td>
<td>25,665,565</td>
<td>69%</td>
<td>22%</td>
<td>2%</td>
<td>7%</td>
</tr>
<tr>
<td>12 to 17 years</td>
<td>22,598,723</td>
<td>42%</td>
<td>24%</td>
<td>7%</td>
<td>3%</td>
</tr>
<tr>
<td>18 to 49 years</td>
<td>126,877,863</td>
<td>31%</td>
<td>29%</td>
<td>3%</td>
<td>2%</td>
</tr>
<tr>
<td>50 to 64 years</td>
<td>58,683,902</td>
<td>19%</td>
<td>27%</td>
<td>7%</td>
<td>10%</td>
</tr>
<tr>
<td>65+ years</td>
<td>51,057,797</td>
<td>4%</td>
<td>24%</td>
<td>38%</td>
<td>17%</td>
</tr>
</tbody>
</table>

*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) | Total | CLI cases | Days since most recent dose, median (IQR) | Adjusted VE % (95% CI) |
---|---|---|---|---|
**BA.2/BA.2.12.1 period**
Unvaccinated | 27,907 | 3,501 | Ref.
2 doses (14-149) | 1,774 | 110 | 104 (71, 128) | 51 (38 - 60)
2 doses (≥150) | 20,883 | 2,584 | 352 (278, 398) | 12 (7 - 17)
3 doses (7-119) | 9,142 | 441 | 94 (72, 108) | 56 (51 - 61)
3 doses (≥120) | 26,654 | 3,186 | 166 (145, 190) | 26 (21 - 30)
4 doses (7-59)* | 4,092 | 355 | 28 (17-42) | 66 (60 - 71)
**BA.4/BA.5 period**
Unvaccinated | 22,867 | 6,717 | Ref.
2 doses (14-149) | 540 | 82 | 106 (70, 133) | 44 (28 - 56)
2 doses (≥150) | 15,614 | 3,686 | 420 (321, 465) | 26 (22 - 30)
3 doses (7-119) | 1,280 | 154 | 77 (45, 100) | 59 (50 - 66)
3 doses (≥120) | 18,803 | 4,063 | 223 (193, 252) | 33 (29 - 37)
4 doses (7-59)* | 2,169 | 259 | 39 (24, 49) | 62 (54 - 68)
4 doses (60-119)* | 3,741 | 617 | 85 (74, 91) | 49 (41 - 56)

* 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](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.
## 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

### BA.2/BA.2.12.1 period

<table>
<thead>
<tr>
<th>Vaccination status (days since most recent dose)</th>
<th>Total</th>
<th>CLI cases</th>
<th>Days since most recent dose, median (IQR)</th>
<th>Adjusted VE % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated</td>
<td>6,682</td>
<td>494</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 doses (14-149)</td>
<td>*</td>
<td>*</td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>2 doses (≥150)</td>
<td>5,118</td>
<td>393</td>
<td>371 (308, 413)</td>
<td>24 (12 - 35)</td>
</tr>
<tr>
<td>3 doses (7-119)</td>
<td>2,350</td>
<td>72</td>
<td>94 (74, 108)</td>
<td>69 (58 - 76)</td>
</tr>
<tr>
<td>3 doses (≥120)</td>
<td>7,686</td>
<td>519</td>
<td>168 (146, 191)</td>
<td>52 (44 - 59)</td>
</tr>
<tr>
<td>4 doses (7-59)**</td>
<td>1,204</td>
<td>74</td>
<td>27 (17, 41)</td>
<td>80 (71 - 85)</td>
</tr>
</tbody>
</table>

### BA.4/BA.5 period

<table>
<thead>
<tr>
<th>Vaccination status (days since most recent dose)</th>
<th>Total</th>
<th>CLI cases</th>
<th>Days since most recent dose, median (IQR)</th>
<th>Adjusted VE % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated</td>
<td>4,578</td>
<td>913</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 doses (14-149)</td>
<td>*</td>
<td>*</td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>2 doses (≥150)</td>
<td>3,592</td>
<td>619</td>
<td>445 (369, 484)</td>
<td>25 (15 - 33)</td>
</tr>
<tr>
<td>3 doses (7-119)</td>
<td>335</td>
<td>32</td>
<td>76 (46, 100)</td>
<td>49 (20 - 68)</td>
</tr>
<tr>
<td>3 doses (≥120)</td>
<td>5,030</td>
<td>869</td>
<td>229 (199, 256)</td>
<td>34 (25 - 42)</td>
</tr>
<tr>
<td>4 doses (7-59)**</td>
<td>717</td>
<td>81</td>
<td>38 (23, 49)</td>
<td>60 (42 - 73)</td>
</tr>
</tbody>
</table>

* 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
- 3rd dose provides significant additional protection against infection and severe disease in all ages studied
  - VE post 3rd dose appears to wane more slowly compared with 2 doses alone during Omicron
  - Similar patterns across age groups
- Coverage with 4th 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

<table>
<thead>
<tr>
<th>Vaccination history</th>
<th>Next dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary series</td>
<td>At least 2 months</td>
</tr>
<tr>
<td>Primary series + 1 booster</td>
<td>At least 2 months</td>
</tr>
<tr>
<td>Primary series + 2 booster</td>
<td>At least 2 months</td>
</tr>
</tbody>
</table>
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

Source: Data pulled from CDC COVID Data Tracker as of 08/17/22 1200
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)
  - ≥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
Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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.
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.

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

Enroll yourself or your dependent after any dose!

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**CISA**

Clinical Immunization Safety Assessment (CISA) Project

- 7 participating medical research centers with vaccine safety experts
- clinical consult services*
- clinical research

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

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


\(^1\) 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\textsuperscript{nd} booster dose of Pfizer-BioNTech or Moderna vaccine administered during March 28–August 18, 2022.

\(^\d\) Sex was not reported in approximately 2% of reports.
**Most frequent MedDRA Preferred Terms* in reports to VAERS following 1st booster dose mRNA COVID-19 vaccinations, ages 5–11 years† (as of August 21, 2022)**

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

**N=727, all reports**

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

**N=727, clinical outcomes only shown‡**

---

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

† 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

‡ Determined by subject matter expert review
Most frequent MedDRA Preferred Terms* in reports to VAERS following 2nd booster dose mRNA COVID-19 vaccinations, ages ≥50 years† (as of August 21, 2022)

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

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

### N=724, serious reports (clinical outcomes)

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

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

† Among persons receiving Pfizer-BioNTech or Moderna dose 4 during March 29–August 21, 2022
<table>
<thead>
<tr>
<th>Age group</th>
<th>Dose 2 (primary series)</th>
<th>1st booster dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>5–11 years</td>
<td>2.5</td>
<td>0.7</td>
</tr>
<tr>
<td>12–15 years</td>
<td>47.1</td>
<td>4.2</td>
</tr>
<tr>
<td>16–17 years</td>
<td>78.7</td>
<td>7.4</td>
</tr>
<tr>
<td>18–24 years</td>
<td>39.3</td>
<td>3.9</td>
</tr>
<tr>
<td>25–29 years</td>
<td>15.3</td>
<td>3.5</td>
</tr>
<tr>
<td>30–39 years</td>
<td>7.8</td>
<td>1.0</td>
</tr>
<tr>
<td>40–49 years</td>
<td>3.3</td>
<td>1.6</td>
</tr>
<tr>
<td>50–64 years</td>
<td>0.7</td>
<td>0.5</td>
</tr>
<tr>
<td>65+ years</td>
<td>0.3</td>
<td>0.5</td>
</tr>
</tbody>
</table>

* 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 2.7 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
Reactions and health impact events reported by v-safe participants aged ≥18 years at least once in days 0-7 after homologous vaccination, by dose

**Modern**

N = 316,097

<table>
<thead>
<tr>
<th>Reaction Type</th>
<th>Dose 1</th>
<th>Dose 2</th>
<th>Booster</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any injection site reaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any systemic reaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any health impact</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Pfizer-BioNTech**

N = 341,951

<table>
<thead>
<tr>
<th>Reaction Type</th>
<th>Dose 1</th>
<th>Dose 2</th>
<th>Booster</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any injection site reaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any systemic reaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any health impact</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Includes participants who completed at least one survey in the first week after each dose, data collected during Sept 22, 2021–Aug 21, 2022
Reactions and health impact events reported by v-safe participants aged ≥50 years at least once in days 0-7 after homologous vaccination, by dose

Modern
N = 131,730

Pfizer-BioNTech
N = 128,197

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**
  - Total Doses to Date
    - Pfizer-BioNTech Booster Dose 1: 94,791

- **12-17 years old**
  - Total Doses to Date
    - Pfizer-BioNTech Booster Dose 1: 265,098

- **≥ 18 years old**
  - Total Doses to Date
    - Moderna Booster Dose 1: 2,287,427
    - Pfizer-BioNTech Booster Dose 1: 2,813,749

* Data through Aug 13, 2022

---

Slides Presented at ACIP September 1, 2022
## 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 1st booster

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose 2 primary series Pfizer-BioNTech</th>
<th>1st booster dose Pfizer-BioNTech</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cases</td>
<td>Dose 2 admin</td>
</tr>
<tr>
<td>5-11 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>3</td>
<td>207,958</td>
</tr>
<tr>
<td>Females</td>
<td>0</td>
<td>202,596</td>
</tr>
<tr>
<td>12-15 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>31</td>
<td>205,955</td>
</tr>
<tr>
<td>Females</td>
<td>5</td>
<td>204,074</td>
</tr>
<tr>
<td>16-17 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>14</td>
<td>102,091</td>
</tr>
<tr>
<td>Females</td>
<td>1</td>
<td>107,173</td>
</tr>
<tr>
<td>18-29 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>27</td>
<td>331,889</td>
</tr>
<tr>
<td>Females</td>
<td>2</td>
<td>400,321</td>
</tr>
<tr>
<td>30-39 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>5</td>
<td>341,527</td>
</tr>
<tr>
<td>Females</td>
<td>3</td>
<td>410,713</td>
</tr>
</tbody>
</table>

*Primary series surveillance for people ages ≥18 years ended May 21, 2022, all other data through August 20, 2022.
<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose 2 primary series</th>
<th>1st booster dose</th>
<th>Cases</th>
<th>Incidence rate/million doses (95% CI)</th>
<th>Cases</th>
<th>Incidence rate/million doses (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Moderna</td>
<td>Moderna</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dose 2</td>
<td>Incidence rate</td>
<td>1st booster</td>
<td>Incidence rate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-11 years**</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Males</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-15 years**</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Males</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16-17 years**</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Males</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-29 years</td>
<td>19</td>
<td>195,809</td>
<td>97.0 (58.4 – 151.5)</td>
<td>7</td>
<td>109,337</td>
<td>64.0 (25.7 – 131.9)</td>
</tr>
<tr>
<td>Males</td>
<td>19</td>
<td>195,809</td>
<td>97.0 (58.4 – 151.5)</td>
<td>7</td>
<td>109,337</td>
<td>64.0 (25.7 – 131.9)</td>
</tr>
<tr>
<td>Females</td>
<td>0</td>
<td>243,560</td>
<td>0.0 (0.0 – 12.3)</td>
<td>1</td>
<td>156,707</td>
<td>6.4 (0.2 – 35.6)</td>
</tr>
<tr>
<td>30-39 years</td>
<td>8</td>
<td>216,583</td>
<td>36.9 (15.9 – 72.8)</td>
<td>1</td>
<td>149,468</td>
<td>6.7 (0.2 – 37.3)</td>
</tr>
<tr>
<td>Males</td>
<td>8</td>
<td>216,583</td>
<td>36.9 (15.9 – 72.8)</td>
<td>1</td>
<td>149,468</td>
<td>6.7 (0.2 – 37.3)</td>
</tr>
<tr>
<td>Females</td>
<td>1</td>
<td>259,780</td>
<td>3.9 (0.1 – 21.4)</td>
<td>2</td>
<td>191,765</td>
<td>10.4 (1.3 – 37.7)</td>
</tr>
</tbody>
</table>

*Primary series surveillance for people ages 218 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 subroun.
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 1st 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 ≥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 1st booster
- In VAERS data, reporting rates of myocarditis are lower following 1st 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 1st 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

**Monkepox Update: Dr. Bamrah Morris**
- [https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html](https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html)
- [https://ourworldindata.org/monkeypox](https://ourworldindata.org/monkeypox)
- [https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html](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/mpx-trends.html)
- [https://www.cdc.gov/poxvirus/monkeypox/response/2022/demographics.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/response/2022/2022-lab-test.html)
- [https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.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/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html)
- [https://www.cdc.gov/std/treatment-guidelines/default.htm](https://www.cdc.gov/std/treatment-guidelines/default.htm)
- [https://www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html](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)
- [Safer Sex, Social Gatherings, and Monkeypox](https://www.cdc.gov/poxvirus/monkeypox/prevention/sexual-health.html)
- [CDC Health Equity Guiding Principles for Inclusive Communication](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)
Bivalent Booster Authorization Update: Dr. Marks

- https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Updated Booster Vaccine: Dr. Patel


Program Links:

- This webinar is being recorded and can be found with the slides online at https://www.idsociety.org/cliniciancalls
- Vaccine FAQ: https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines-information--faq/
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
@RealTimeCOVID19
#RealTimeCOVID19
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 and click on Contact Form
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.id society.org/cliniciancalls
-- library of all past calls available --

Contact Us:
Dana Wollins (dwollins@idsociety.org)
Deirdre Lewis (dlewis@idsociety.org)