Recommendations for Bivalent COVID-19 Booster Doses in People Ages 12 Years and Older

Clinician Outreach and Communication Activity (COCA) Call

Tuesday, September 13, 2022

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Objectives

At the conclusion of today's session, the participant will be able to accomplish the following:

1. Discuss new recommendations for bivalent COVID-19 vaccines for people ages 12 years and older, including those who are moderately or severely immunocompromised.
2. List key points for healthcare providers to use when discussing bivalent COVID-19 vaccines with patients.
3. Describe where to find online resources for clinicians about bivalent COVID-19 vaccinations.

To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov

Today's Presenters

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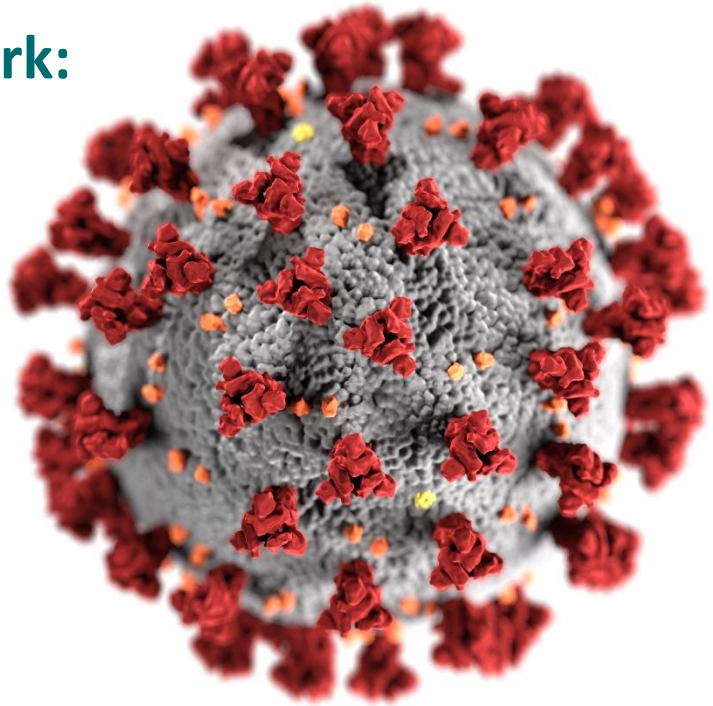
Evidence to Recommendations Framework:
Bivalent COVID-19 Vaccine Booster Doses



Sara Oliver, MD, MSPH
Lead, COVID-19 Coordinating Unit
COCA Call
September 13, 2022

cdc.gov/coronavirus

Evidence to Recommendations (EtR) Framework

EtR Domain	Question(s)	Domain Equity Question(s)
Public Health Problem	• Is the problem of public health importance?	• **Does the problem impact all populations equally?**
Benefits and Harms	• How substantial are the desirable anticipated effects? • How substantial are the undesirable anticipated effects? • Do the desirable effects outweigh the undesirable effects?	• **Are the desirable and undesirable anticipated effects demonstrated across all populations equally?**
Values	• Does the population feel the desirable effects are large relative to the undesirable effects?	• **Is there important variability in how patients or populations value the outcome?**
Acceptability	• Is the intervention acceptable to key stakeholders?	• **Is the intervention equally acceptable across all populations?**
Feasibility	• Is the intervention feasible to implement?	• **Is the intervention equally feasible to implement across all populations?**
Resource Use	• Is the intervention a reasonable and efficient allocation of resources?	• **Is the intervention a reasonable and efficient allocation of resources across all populations?**

"The intervention" = Bivalent COVID-19 vaccine booster doses

"The problem" = COVID-19

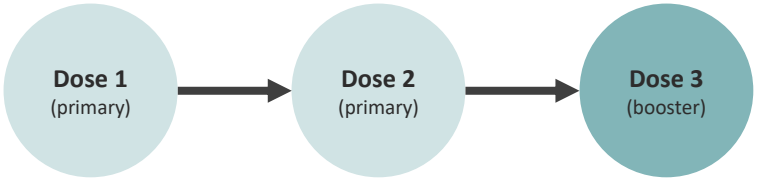
Evidence to Recommendations (EtR) Framework

Question

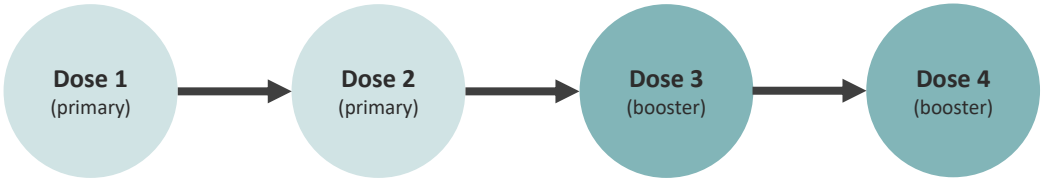
- Does ACIP support the use of updated (bivalent) COVID-19 vaccine booster doses, for those populations currently recommended to receive a COVID-19 vaccine booster?

Previous recommendations

People ages 5-49 years

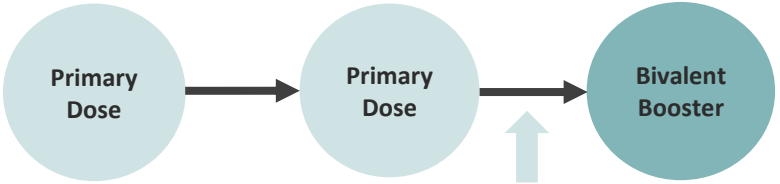


People ages 50 years and older



Updated recommendations

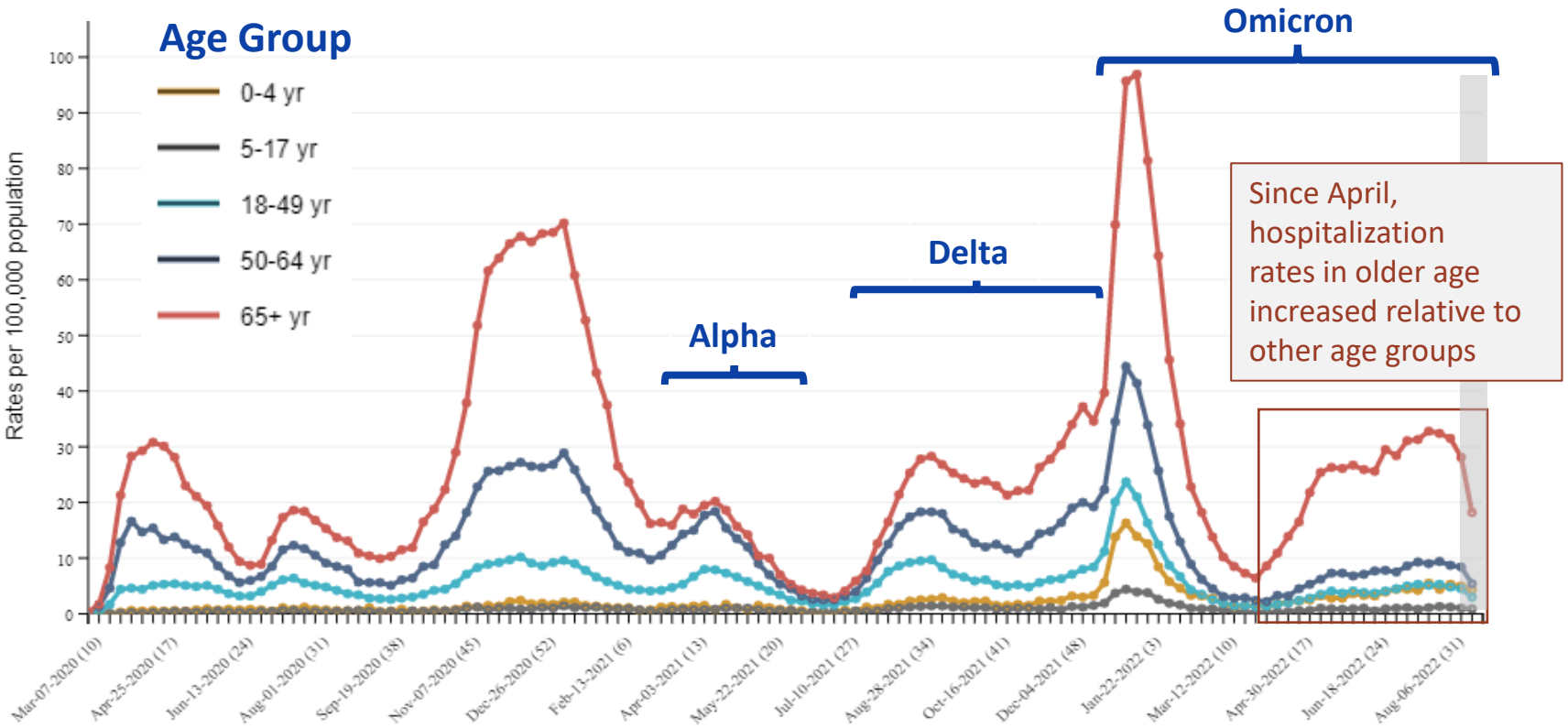
People ages 5 years and older*



Regardless of previous booster doses given

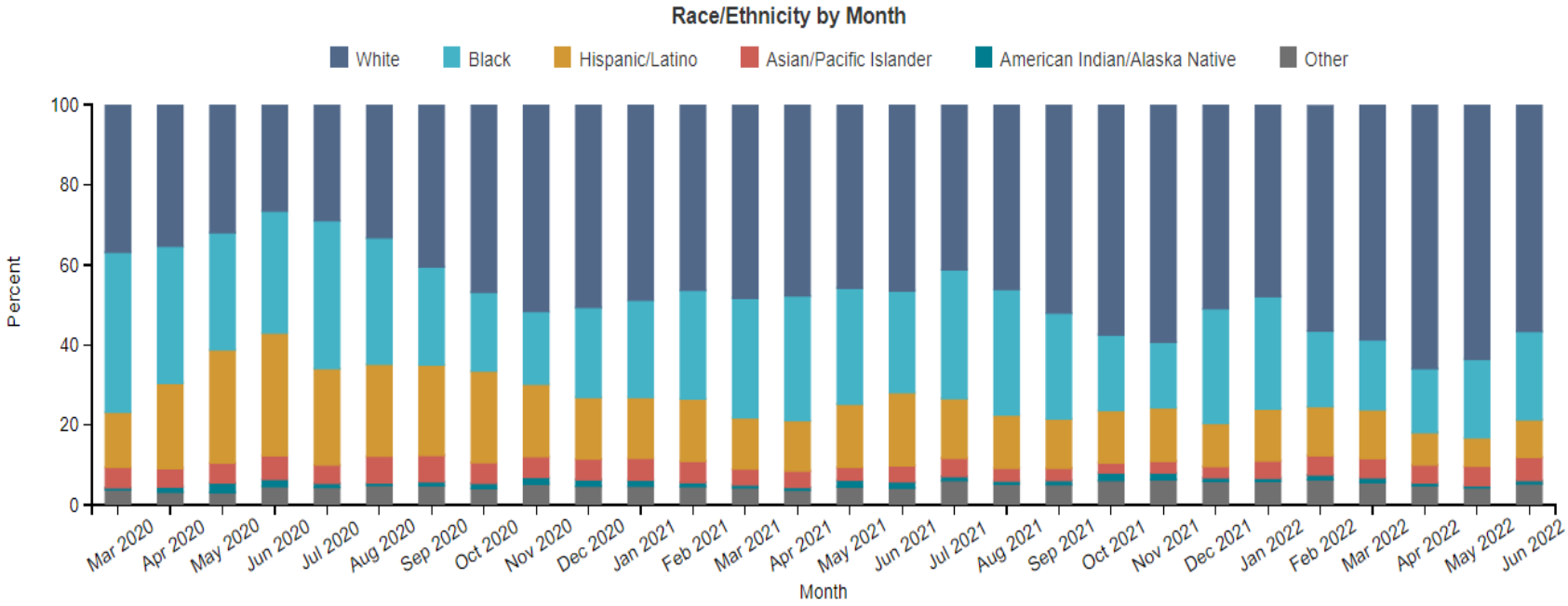
*Ages and vaccines as authorized by FDA and recommended by ACIP/CDC

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



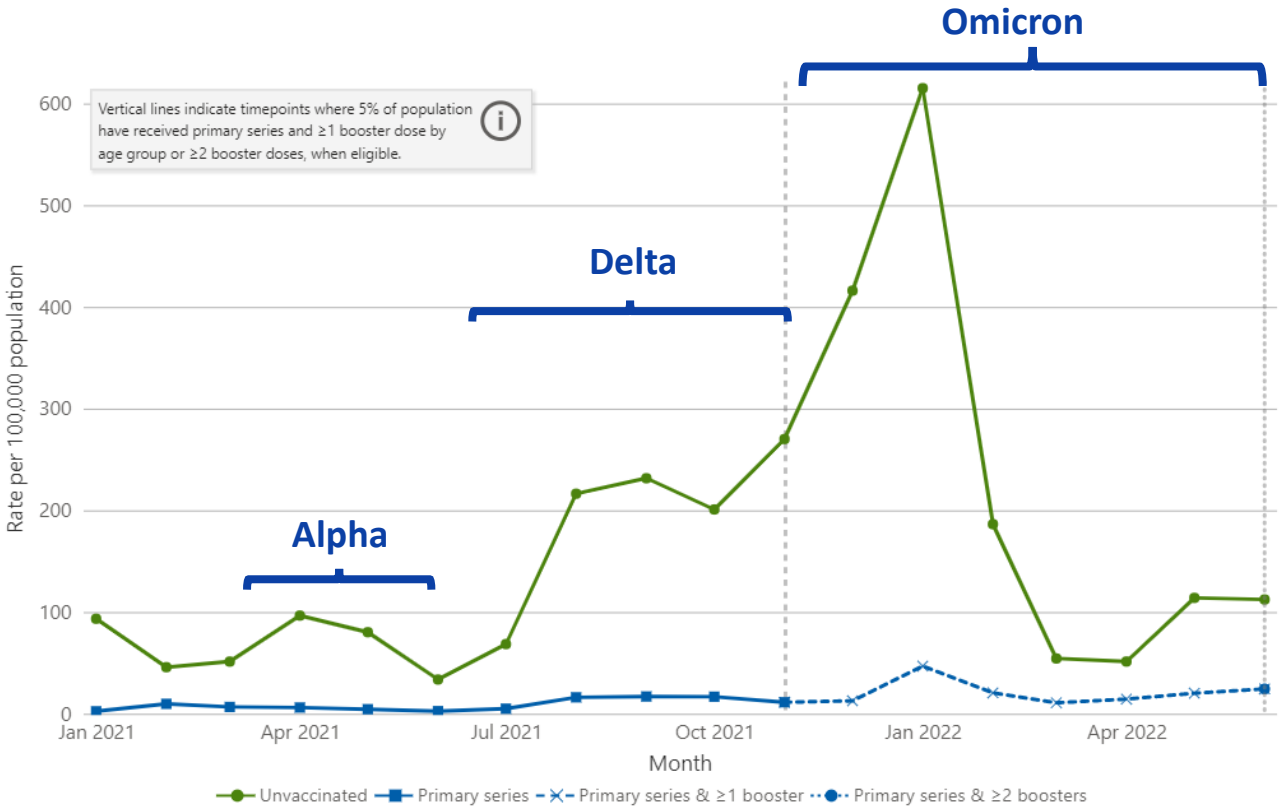
Source: COVID-NET; https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html Accessed August 26, 2022

Characteristics of COVID-19-associated hospitalizations by race and ethnicity, March 1, 2020 – June 30, 2022



CDC COVID Data Tracker. COVID-NET Laboratory-confirmed COVID-19 hospitalizations. https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network Accessed August 25, 2022

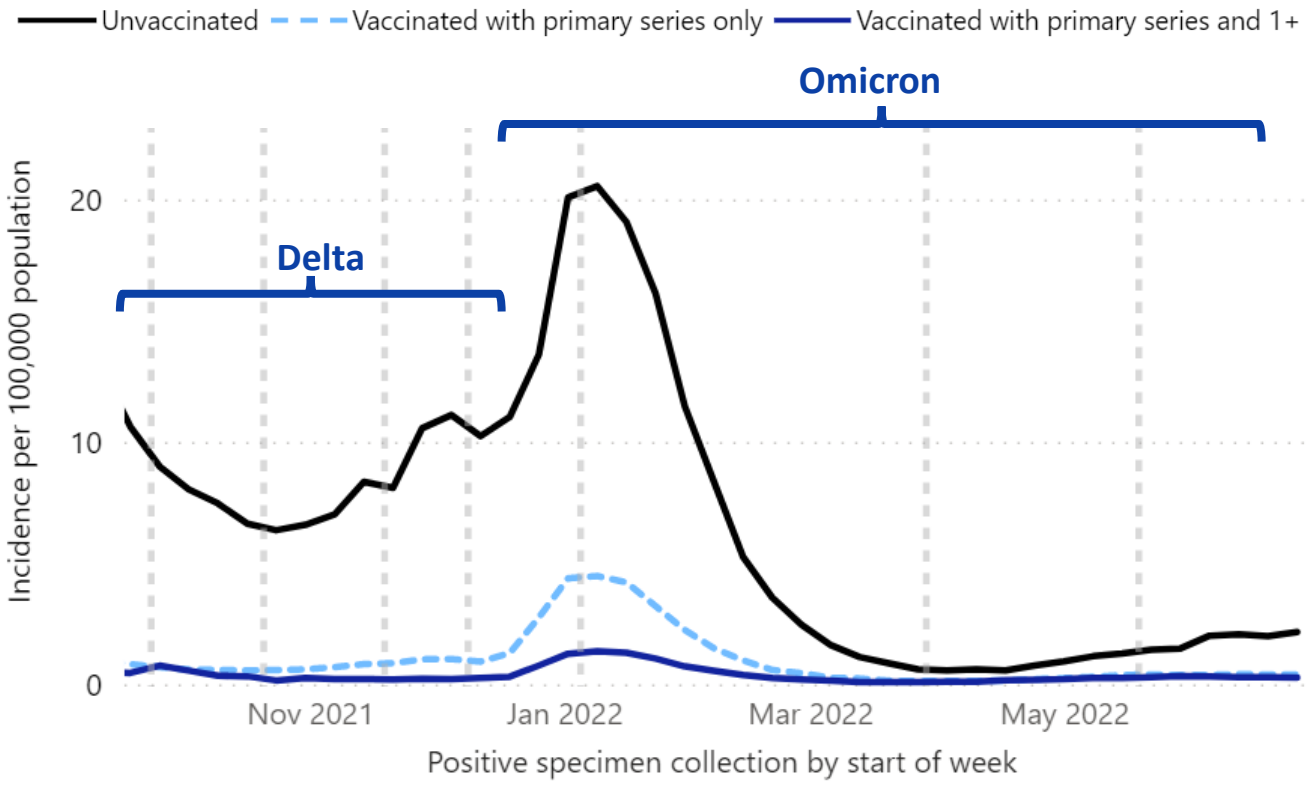
Age-Adjusted Rates of COVID-19-Associated Hospitalization by Vaccination Status and Receipt of Booster Dose in Adults Ages ≥18 Years, January 2021–June 2022



In June 2022, **unvaccinated** adults ages ≥18 years had **4.6X higher** COVID-19-associated hospitalization rates compared to those vaccinated with at least **one booster dose**

CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination Accessed August 3, 2022

Age-Adjusted Rates of COVID-19-Associated Deaths by Vaccination Status and Receipt of Booster Dose,* September 19, 2021 – July 2, 2022 (29 U.S. Jurisdictions)



In June 2022, **unvaccinated** people ages ≥5 years had **8X higher** COVID-19-associated death rates compared to those with at least **one booster dose**

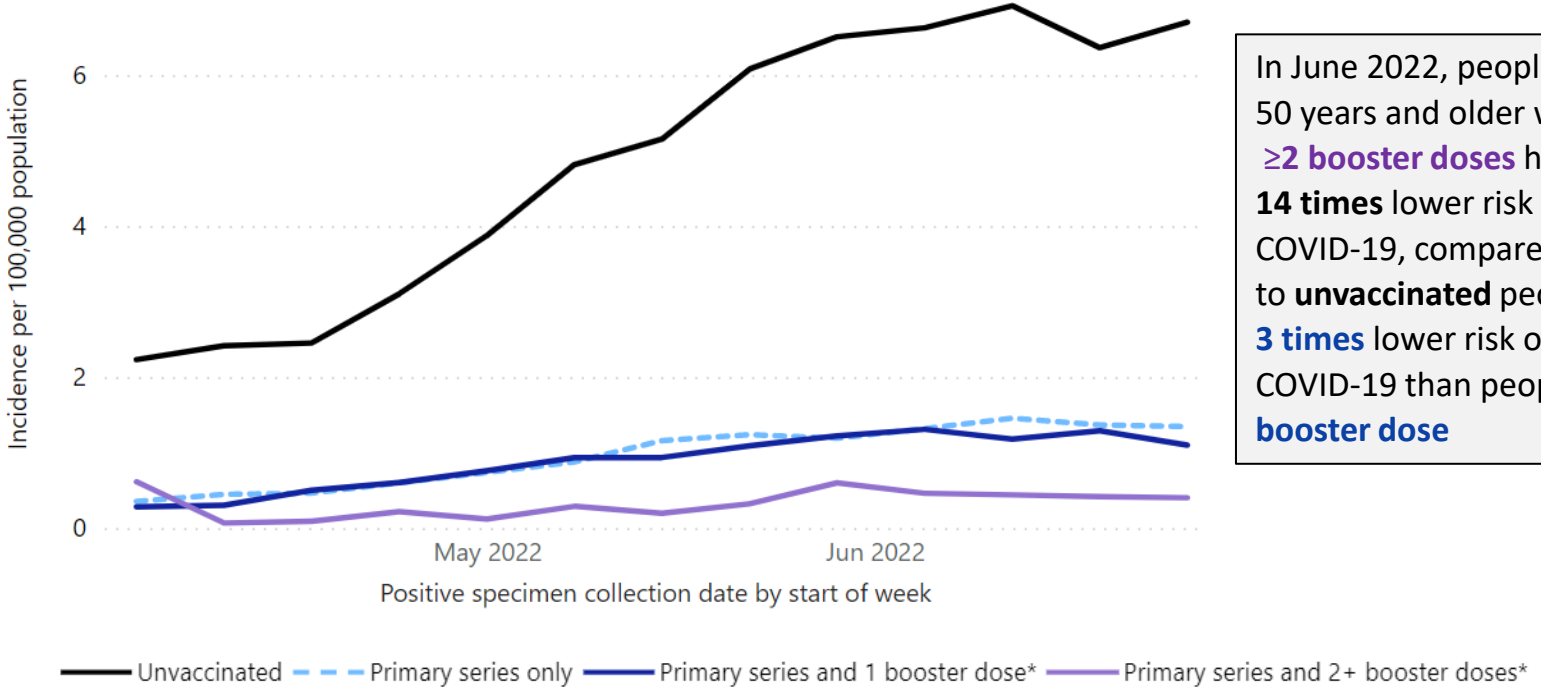
This was a decrease from **~20X** during January-March 2022

*This includes people who received booster doses and people who received additional doses. Vertical lines denote changes in booster dose recommendations.

CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status Accessed August 24, 2022

Death Rates by Vaccination Status and Receipt of 1st and 2nd Booster Doses Among People Ages 50+ Years

April 3–July 2, 2022 (25 U.S. Jurisdictions)



In June 2022, people ages 50 years and older with **≥2 booster doses** had **14 times** lower risk of dying from COVID-19, compared to **unvaccinated** people and **3 times** lower risk of dying from COVID-19 than people with **one booster dose**

*Includes either a booster or additional dose.

https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccinbooine-status. Accessed August 24, 2022

Summary

Public Health Problem

- As of August 2022, over **94 million** COVID-19 cases reported in the United States
- Since April 2022, hospitalization rates in older age groups increased relative to other age groups
  - Moreover, in June 2022, during Omicron predominance, unvaccinated adults ages 18 years and older had **4.6X** higher COVID-19-associated hospitalization rates compared to those vaccinated with at least one booster dose
- In June 2022, unvaccinated people ages ≥5 years had **8X** higher COVID-19-associated death rates compared to those with at least one booster dose
  - Additionally, people ages 50 years and older with ≥2 booster doses had **14X** lower risk of dying from COVID-19, compared to unvaccinated people and **3X** lower risk of dying from COVID-19 than people with one booster dose
- Vaccination rates are much higher among older adults relative to other age groups
- People of racial and ethnic minority groups have been disproportionately burdened by COVID-19 illness, hospitalization, and death

Summary of available data

- Clinical trial data from COVID-19 vaccine manufacturers
  - Moderna bivalent booster clinical trial
  - Pfizer-BioNTech bivalent booster clinical trial
- Other considerations
  - Myocarditis/pericarditis
  - Modeling data
  - Immune tolerance
  - Imprinting
  - Antigenic cartography
  - BA.1 and BA.4/BA.5
  - Prior SARS-CoV-2 infection
  - Non mRNA COVID-19 vaccines

Immunogenicity: Moderna bivalent booster

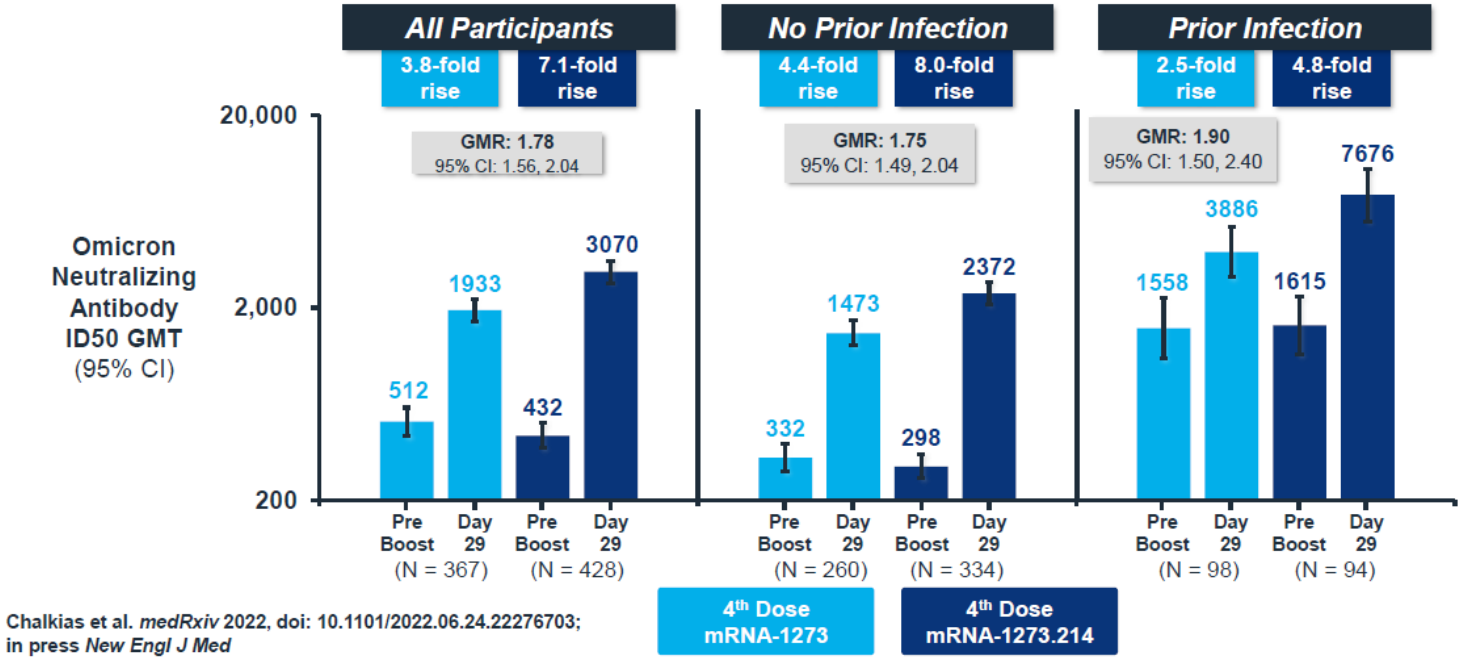
- Participants ≥18 years on **day 29** after the study vaccination
- Bivalent vaccine met superiority* criteria for both Omicron and ancestral SARS-CoV-2 antibodies

Assay	Timepoint	Bivalent mRNA-1273.214 GMT (95% CI)	mRNA-1273 GMT (95% CI)	Vaccine group/mRNA-1273 GMR
Without evidence of prior infection		N=334	N=260	
Omicron neutralizing antibody (ID_{50})	Day 29 post-dose	2372.4 (2070.6, 2718.2)	1473.5 (1270.8, 1708.4)	1.75 (1.49, 2.04)
Ancestral SARS-CoV-2 neutralizing antibody (ID_{50})		5977.3 (5321.9, 6713.3)	5649.3 (5056.8, 6311.2)	1.22 (1.08,1.37)
With or without evidence of prior infection		N=428	N=367	
Omicron neutralizing antibody (ID_{50})	Day 29 post-dose	3070.4 (2685.4, 3510.6)	1932.8 (1681.2, 2222.0)	1.78 (1.56, 2.04)
Ancestral SARS-CoV-2 neutralizing antibody (ID_{50})		6619.0 (5941.7, 7373.5)	6048.5 (5465.9, 6691.0)	1.24 (1.12, 3.36)

GMR= geometric mean ratio; GMT= geometric mean titer; ID_{50} = 50% inhibitory dilution
*Superiority criterion: the lower bound of the 95% CI for GMR is >1.0

https://www.medrxiv.org/content/10.1101/2022.06.24.22276703v1.full.pdf

Immunogenicity: Moderna bivalent booster



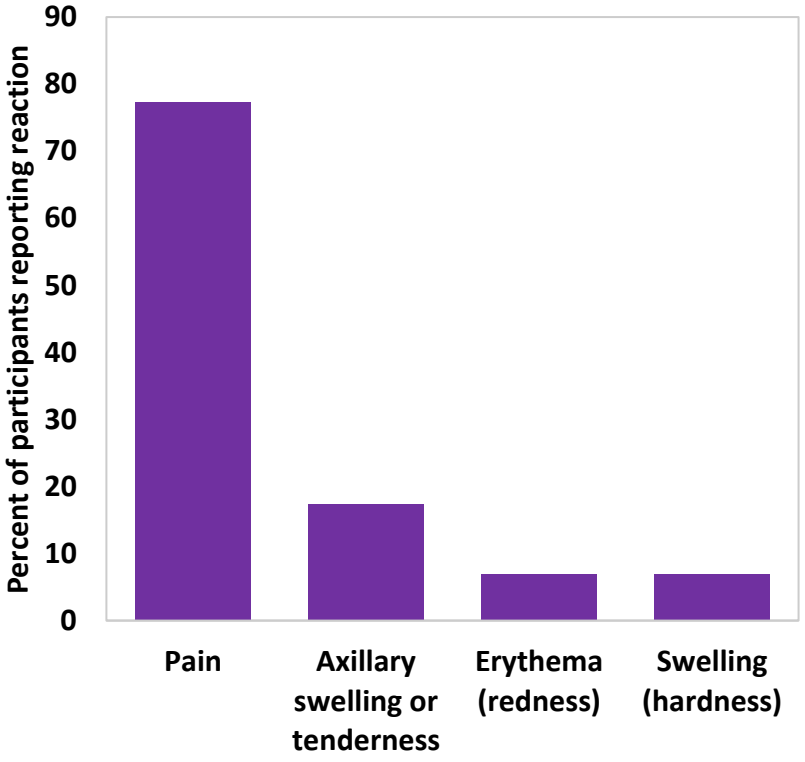
Chalkias et al. *medRxiv* 2022, doi: 10.1101/2022.06.24.22276703; in press *New Engl J Med*

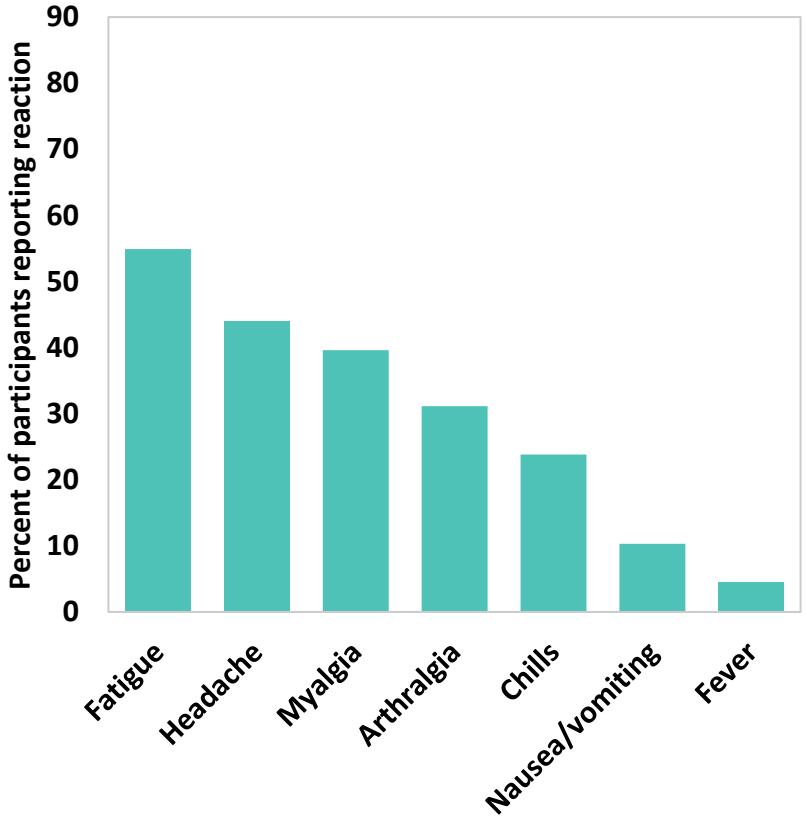
- Met superiority criteria* in participants ≥18 years <u>with or without</u> evidence of infection on day 29

https://www.medrxiv.org/content/10.1101/2022.06.24.22276703v1.full.pdf

*Superiority criterion: the lower bound of the 95% CI for GMR is >1.0

Local and systemic reactogenicity: Moderna bivalent booster





Immunogenicity: Pfizer bivalent booster, ages >55 years

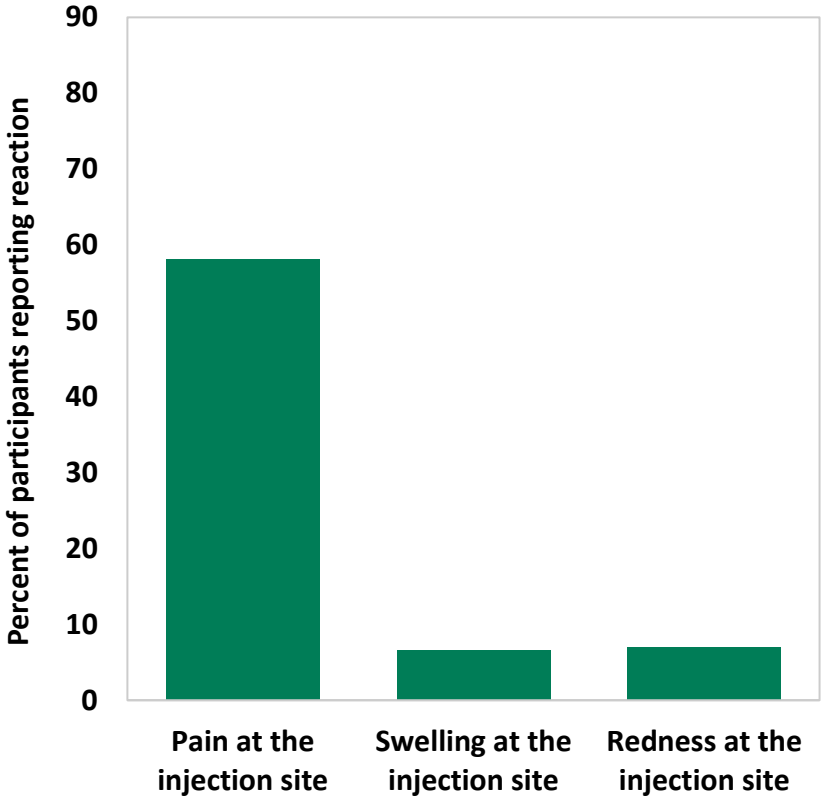
- Superiority* criterion met against Omicron BA.1 and non-inferiority criterion met against reference strain

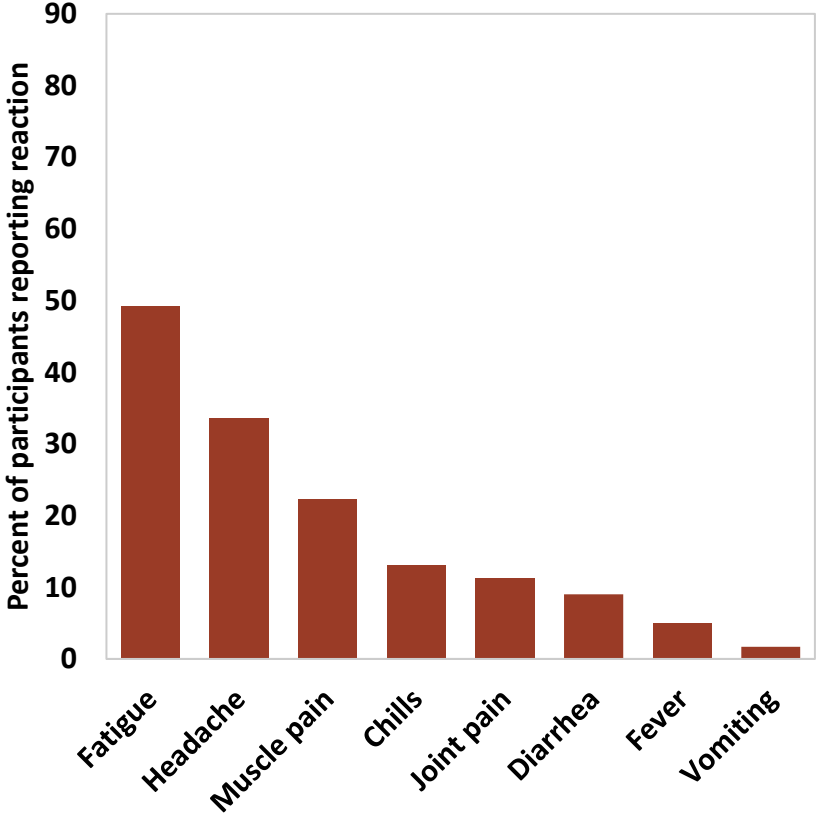
Assay	Timepoint	Bivalent Vaccine OMI 30µg GMT (95% CI)	BNT162b2 30µg GMT (95%)	Vaccine group/BNT162b2 30µg GMR (95% CI)
		N=178	N=163	
SARS-CoV-2 neutralization assay—Omicron BA.1—NT50 (titer)	1 month post-dose	711.0 (588.3, 859.2)	455.8 (365.9, 567.6)	1.56 (1.17, 2.08)
		N=186	N=182	
SARS-CoV-2 neutralization assay—Reference strain—NT50 (titer)	1 month post-dose	5933.2 (5188.2, 6785.2)	5998.1 (5223.6, 6887.4)	0.99 (0.82, 1.20)

*simple superiority criterion: the lower bound of the 95% CI for GMR is >1.0; non-inferiority criterion: the lower bound of the 95% CI for GMR is >0.67

Vaccines and Related Biological Products Advisory Committee June 28, 2022 Meeting Presentation- Pfizer/BioNTech COVID-19 Omicron-Modified Vaccine Options (fda.gov)

Local and systemic reactogenicity: Pfizer bivalent booster, ages >55 years





Summary

Clinical trial data

- Bivalent booster doses of both Moderna & Pfizer-BioNTech COVID-19 vaccines **increase immune response** in those who have completed a primary series and a previous booster
  - Compared with ancestral booster dose
    - Demonstrated superior response to Omicron
    - Demonstrated non-inferior response to ancestral strain
- Similar reactogenicity profile to primary series (and ancestral booster dose)
- Data from clinical trial limited in size, age, and bivalent booster type

Other considerations for COVID-19 vaccine boosters:
Myocarditis and pericarditis

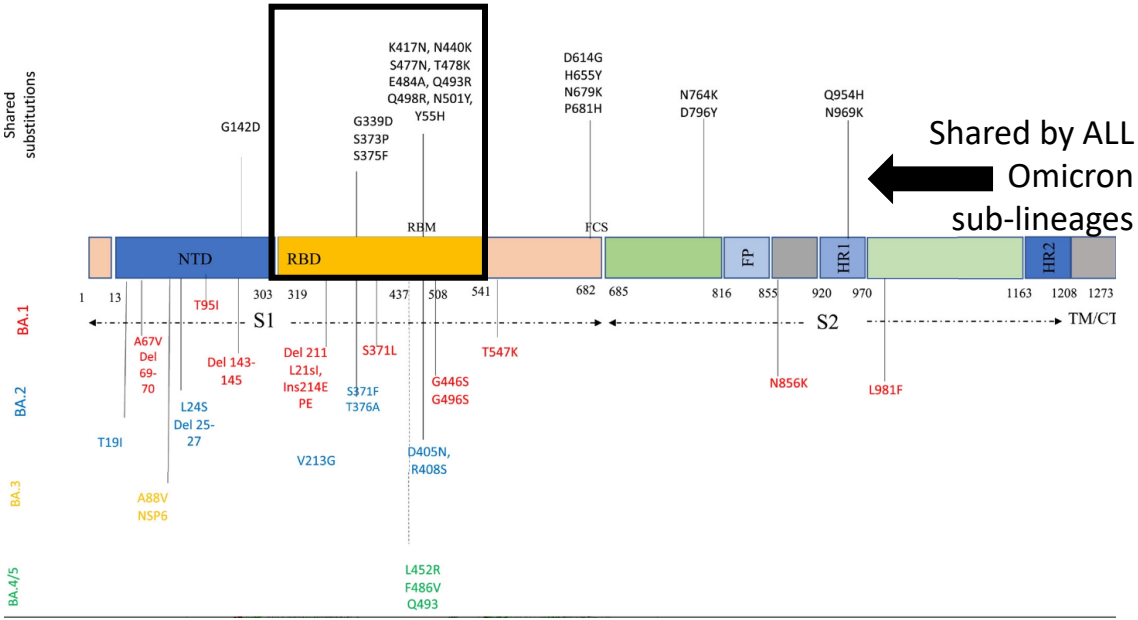
- Risk of myocarditis/pericarditis has been identified after COVID-19 vaccines
  - Risk is rare and primarily observed in adolescent and young adult males
  - Among VAERS data, reporting rates of myocarditis are **lower** after booster dose, compared to dose 2 of primary series
  - Among VSD data, incidence following dose 2 of primary series and booster dose are **similar**, but case counts are **small**
  - Among surveillance data from Canada indicate that the risk of myocarditis and/or pericarditis following a first booster dose appear **lower** than the risk following second dose of a primary series
    - Observed for both Pfizer-BioNTech and Moderna vaccine products and across all age groups[1]
- Most individuals with myocarditis/pericarditis have **fully recovered** at follow-up
- The risk of adverse cardiac outcomes were **1.8 – 5.6 times higher** after SARS-CoV-2 infection than after mRNA COVID-19 vaccination among males ages 12 – 17 years[2]
- Interval of **8 weeks** between vaccine doses may further lower myocarditis risk

1. Public Health Agency of Canada. NACI: Recommendations on the use of bivalent Omicron-containing mRNA COVID-19 vaccines. Sept 1, 2022 2. DOI: http://dx.doi.org/10.15585/mmwr.mm7114e1

Other considerations: BA.1 and BA.4/BA.5

- Clinical data from bivalent COVID-19 vaccines primarily obtained using BA.1
- Compared to the ‘ancestral’ virus, all Omicron sub-lineages have 21 ‘shared’ mutations
  - Highlighted by the black arrow

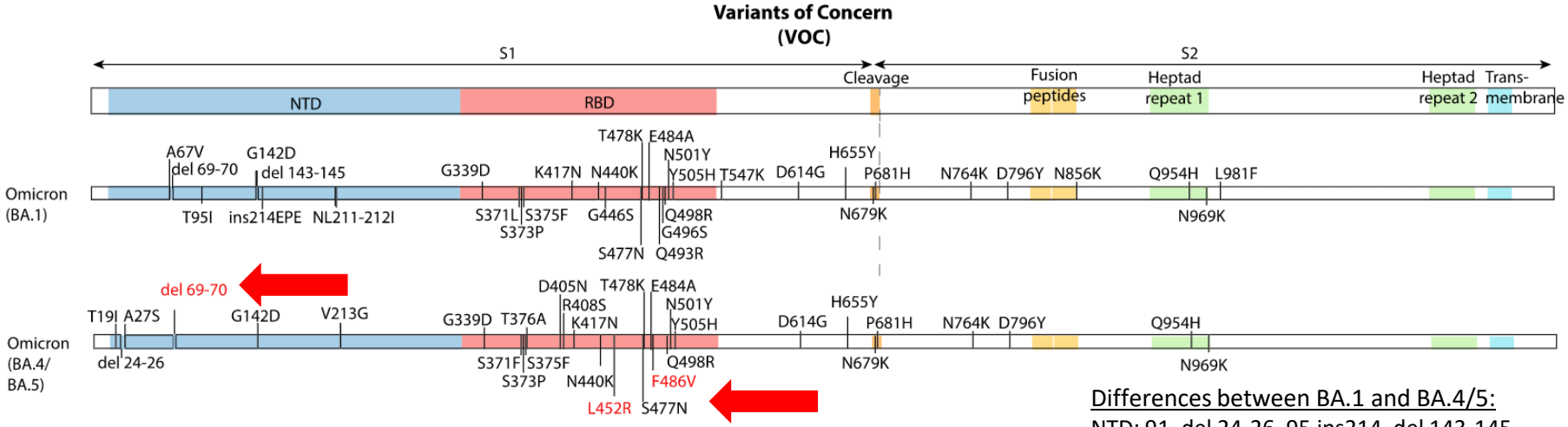
- Many mutations are in the receptor binding domain (RBD), the primary binding site for antibodies
- These mutations contribute to decreased neutralization and increased transmissibility for Omicron sub-lineages



Evolution of the SARS-CoV-2 omicron variants BA.1 to BA.5: Implications for immune escape and transmission - Shrestha - Reviews in Medical Virology - Wiley Online Library

Other considerations: BA.1 and BA.4/BA.5

- BA.4/BA.5
  - Two different Omicron sub-lineages, but Spike protein (focus of the vaccines) is identical
  - BA.4/BA.5 has additional mutations (in red), compared to previous Omicron lineages



Differences between BA.1 and BA.4/5:
NTD: 91, del 24-26, 95 ins214, del 143-145,
RBD: 376, 405, 408, 446, 452, 486, 493, 496
S1/S2 interface: 547 S2: 856, 981

SARS-CoV-2 variants ~ ViralZone (expasy.org)

Summary-balance of benefits and harms for bivalent booster doses

- Bivalent booster dose of both Moderna & Pfizer-BioNTech COVID-19 vaccines **increases immune response** in those who have completed a primary series and a previous booster
- Similar reactogenicity profile to primary series and ancestral booster dose
- Myocarditis risk following a bivalent booster dose is unknown, but anticipate similar risk to what is seen after monovalent booster doses
- Modeling projects more hospitalizations and deaths averted when booster doses are recommended for **persons ≥18 years** compared to only persons ≥50 years, and when the booster campaign begins in **September** compared to November 2022
- Benefits and harms for the U.S. population are best assessed when clinical trial and study populations are optimally representative of the U.S. population

72% of respondents "definitely" or "probably" will get an updated booster that protects against Omicron variants

'Probably' or 'Definitely' will get an updated booster

Unsure

'Probably' or 'Definitely' will not get an updated booster

CDC and University of Iowa/RAND survey, August 2022, unpublished

n=171

63% of respondents were “extremely” or “somewhat” willing get an annual flu shot and updated COVID booster at the same visit this Fall

‘Somewhat’ or ‘Extremely’ willing to get both vaccines in the same visit this Fall

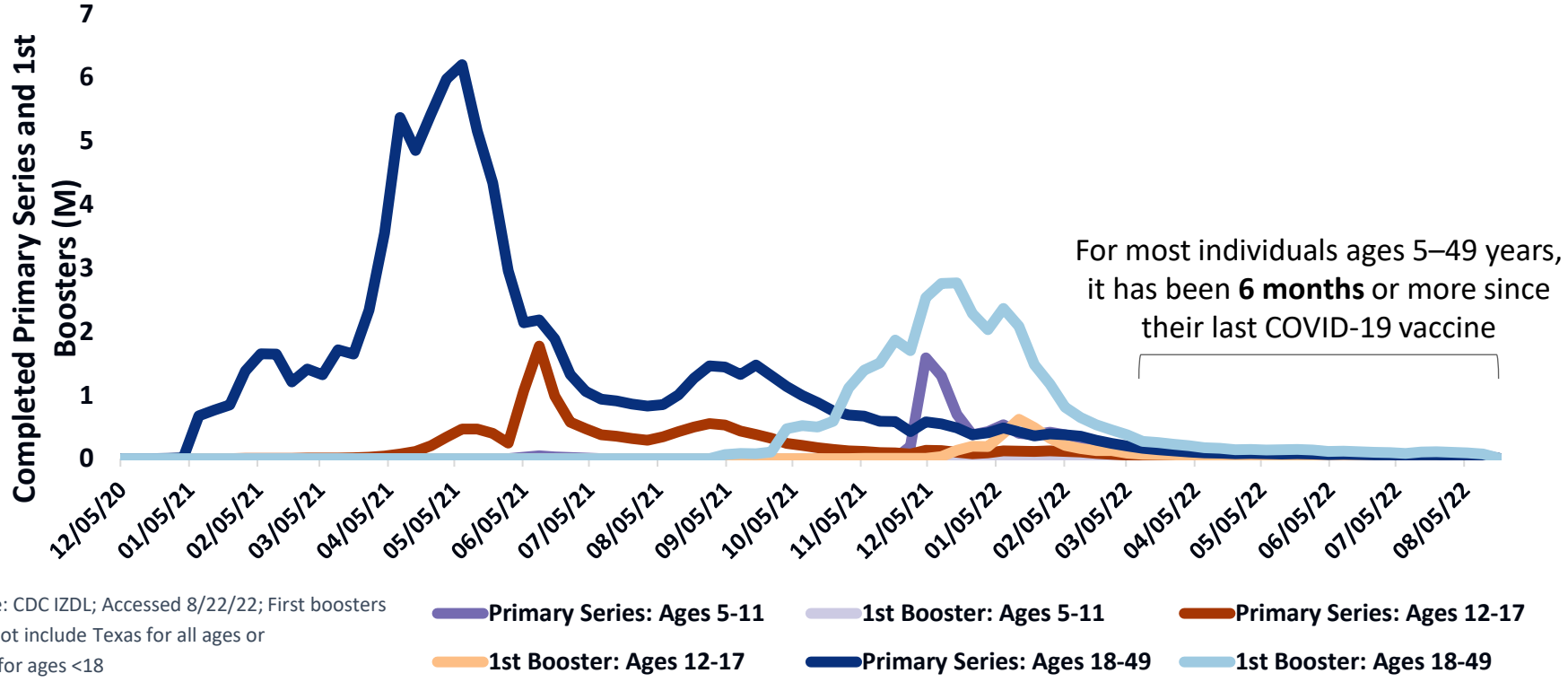
Unsure

‘A bit’ or ‘Not at all’ willing to get both vaccines in the same visit this Fall

CDC and University of Iowa/RAND survey, August 2022, unpublished

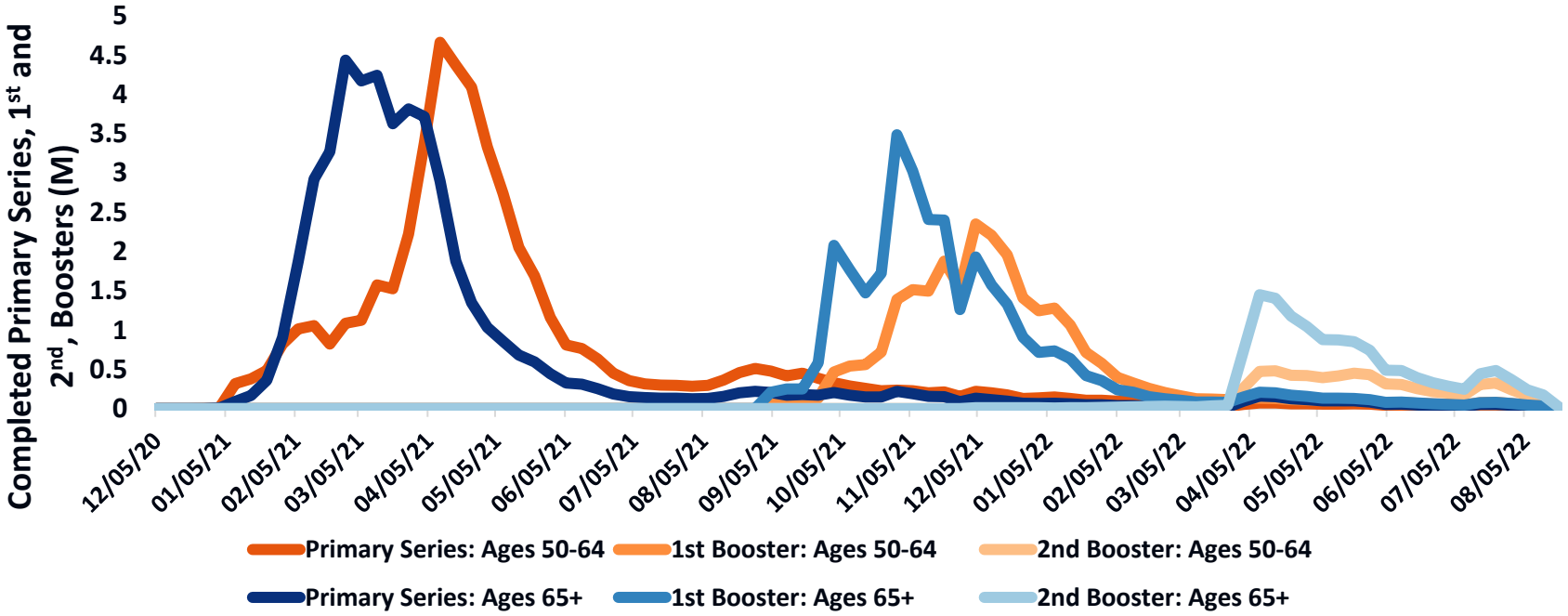
n=171

Completed primary series and 1st boosters by age group for persons ages 5-49 years, United States, December 2020 – August 2022



Source: CDC IZDL; Accessed 8/22/22; First boosters does not include Texas for all ages or Idaho for ages <18

Completed primary series, 1st boosters, and 2nd boosters by age group for persons ages ≥50 years, United States, December 2020 – August 2022



Source: CDC IZDL; Source: CDC IZDL; Accessed 8/22/22; First and second booster not include Texas for all ages or Idaho for ages <18

Persons eligible* (in millions) for a bivalent booster by age group – United States, December 2020 – August 2022

Age Group	Eligible* persons (millions)	Ineligible+ persons (millions)
12-17 years	14	0.3
18-49 years	96	0.7
50-64 years	51	1.6
≥65 years	48	2.0
Total	209	4.6

*Individuals are considered eligible if they had completed at least a primary series but had not received a vaccine dose in the prior 2 months

+Individuals are considered ineligible if they received a vaccine dose within the previous 2 months per EUA

Based on dates of 9/2/2022

Source: CDC IZDL; Source: CDC IZDL; Accessed 8/22/22; First and second booster not include Texas for all ages or Idaho for ages <18

Summary

Feasibility

- Over **200 million** people would be eligible for the bivalent COVID-19 vaccine
- While nearly **22 million** adults >50 years have received a second booster dose, most individuals ages 5 years and older are at least **6 months** out from their last COVID-19 vaccine dose
- CDC has provided an Operational Planning Guide for jurisdictions preparing for a fall vaccination campaign
- There will be a **sufficient but finite supply** of bivalent COVID-19 vaccines
- Some aspects of the bivalent COVID-19 vaccines will be easy to implement (no changes to storage/handling), but vials and labeling may need additional education
- Significant racial and ethnic disparities persist in receipt of a booster, suggesting that the intervention may not be equally feasible to implement across all populations

Bivalent COVID-19 vaccines:

Data to inform recommendations

- Experience from using COVID-19 vaccine mRNA platform for nearly 2 years and over 600 million doses in the United States alone
  - Extensive vaccine effectiveness studies as well as robust post-authorization safety data across multiple platforms
- Clinical (human) data from bivalent COVID-19 vaccines in >1700 persons
  - Includes bivalent vaccines with Beta and Omicron variants, both from manufacturers and NIH studies
  - Over 1400 individuals received bivalent vaccine with **Omicron** component specifically
  - While there are subtle differences in mutations between BA.1 and BA.4/BA.5 spike protein sequences, do not anticipate differences in safety or reactogenicity of vaccines based on these limited mutations
  - Overall composition of the vaccine as well as total antigenic load are the same as current booster doses
- Antigenic cartography and antibody studies
- Modeling data

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; cases of myocarditis attributed to the vaccine were detected in Novavax COVID-19 vaccines clinical trials
- 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

Bivalent COVID-19 vaccines:

What we do not know

- Rate of myocarditis after bivalent COVID-19 vaccines
  - Unlikely that the inclusion of Omicron would increase myocarditis rates
  - Age and sex of the individual are likely contributing factors to development of myocarditis after vaccine; interval since previous dose and total dose may be related
- Incremental increase in vaccine effectiveness
  - Antibody titers to currently circulating variants were higher after a bivalent booster than with current monovalent booster
  - Most of the data to inform recommendations from BA.1 bivalent vaccine; incremental benefits for the BA.4/BA.5 vaccine are unknown
- Duration of protection
  - Antibody titers after bivalent vaccine and prior SARS-CoV-2 infection were robust
  - This may **prolong** duration of protection and **decrease** the need for frequent boosters
  - As with all vaccines, duration of protection may vary by age and immune status

Summary

Summary

Monovalent COVID-19 vaccines

50µg  Moderna COVID-19 vaccine

50µg of spike protein from
'ancestral' ('original') SARS-CoV-2

30µg  Pfizer-BioNTech COVID-19 vaccine

30µg of spike protein from
'ancestral' ('original') SARS-CoV-2

Bivalent vaccines have the **same** total antigen amount as monovalent vaccines

Updated (Bivalent) COVID-19 vaccines

50µg  Moderna COVID-19 vaccine

25µg of spike protein from
'ancestral' ('original') SARS-CoV-2

25µg of spike protein from
Omicron (BA.4/BA.5) SARS-CoV-2

30µg  Pfizer-BioNTech COVID-19 vaccine

15µg of spike protein from
'ancestral' ('original') SARS-CoV-2

15µg of spike protein from
Omicron (BA.4/BA.5) SARS-CoV-2

Summary

- Monovalent COVID-19 vaccines have **dramatically reduced** COVID-19 hospitalizations and deaths
- As the SARS-Cov-2 virus evolved, declines in neutralizing antibodies and vaccine effectiveness as well as more rapid waning from the vaccines noted
- Inclusion of a second SARS-CoV-2 variant in the vaccine **broadens** the antibody response
- Omicron-specific bivalent COVID-19 vaccines were studied in over **1400 individuals**
- Omicron-specific bivalent COVID-19 vaccine resulted in:
  - **Higher** antibody titers for **Omicron** variants
  - **Higher** titers for **other** SARS-CoV-2 variants
  - Titers that were as high or higher for ancestral SARS-CoV-2
- Broad uptake of COVID-19 vaccine booster doses **early this fall** could prevent >100,000 hospitalizations, compared to later or more limited roll-out; in addition, **billions** of dollars of direct medical costs could be saved

Work Group Interpretation

- Work Group had broad policy discussions around use of updated (bivalent) COVID-19 vaccines for all people of age groups currently recommended for booster doses
- Based on current FDA authorizations, current recommendations would be:
  - Pfizer-BioNTech COVID-19 vaccine, bivalent for individuals ages **12 and older**
  - Moderna bivalent COVID-19 vaccine, bivalent for individuals ages **18 and older**
- Additional authorizations for other ages and vaccines may follow

Work Group Interpretation

- Current population recommended for these boosters is very **heterogenous**
  - Many in the United States had Omicron infection over the past 9 months
  - Individuals recommended for the bivalent COVID-19 booster doses may have previously received:
    - Primary series only
    - One booster dose
    - Two booster doses (for those 50 years and over)
- Balance of benefits and risks for individuals may **vary** by age, previous receipt of booster, or recent SARS-CoV-2 infection
- Uncertainties around the incremental benefits for some individuals, including those recent infection or recent vaccine receipt

Work Group Interpretation

- COVID-19 vaccines are recommended, even for those with prior infection
  - Rate of reinfections increased during the Omicron period
- Bivalent COVID-19 vaccines in the setting of prior SARS-CoV-2 infection (“hybrid immunity”) resulted in highest antibody titers
  - These high and diverse titers may result in **longer duration of protection** and decreased need for frequent COVID-19 vaccine booster doses
- Studies have shown that **increased time** between infection and vaccination may result in an improved immune response to vaccination
  - Those with recent SARS-CoV-2 infection may consider delaying a vaccine dose by **3 months** from symptom onset or positive test

Work Group Interpretation

- **Time** since most recent COVID-19 vaccine dose may be more important than cumulative number of doses
- There will be a time of transition as recommendations may move from counting dose number to optimal timing of vaccination campaigns
- Vaccine recommendations that are **simple** and **easy to communicate** are important
- If SARS-CoV-2 becomes a seasonal virus, an annual vaccine program could be an effective strategy for the future

ACIP Votes

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

ACIP repeals its previous recommendations for administration of monovalent Pfizer-BioNTech COVID-19 vaccine boosters for persons ages 12 years and older

Bivalent booster recommendations are without regard to the number of previous monovalent booster doses received

Self-knowledge Check

Under the EUAs issued by FDA, bivalent COVID-19 vaccines are recommended to be administered **at least __ month(s)** after receipt of a primary series or prior monovalent booster dose.

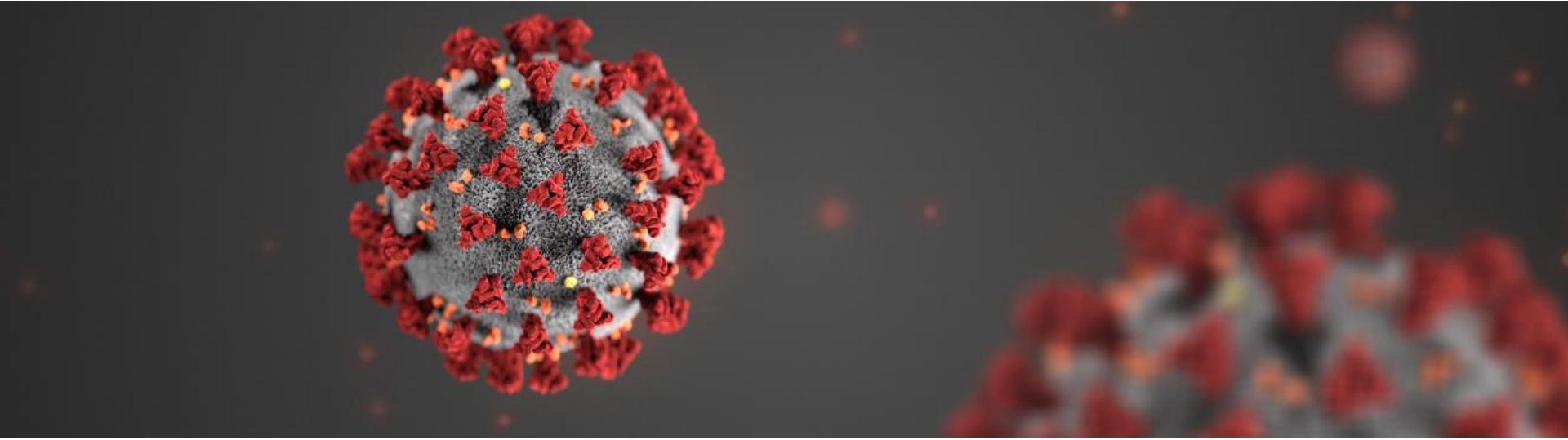
A. 1
B. 2
C. 3
D. 4
E. 5

Self-knowledge Check

The correct answer is B: 2

Under the EUAs issued by FDA:

1 dose of bivalent Pfizer-BioNTech COVID-19 vaccine is recommended for individuals ages 12 years and older AND 1 dose of bivalent Moderna COVID-19 vaccine is recommended for individuals ages 18 years and older—**both at least 2 months** after receipt of a primary series or prior monovalent booster dose.

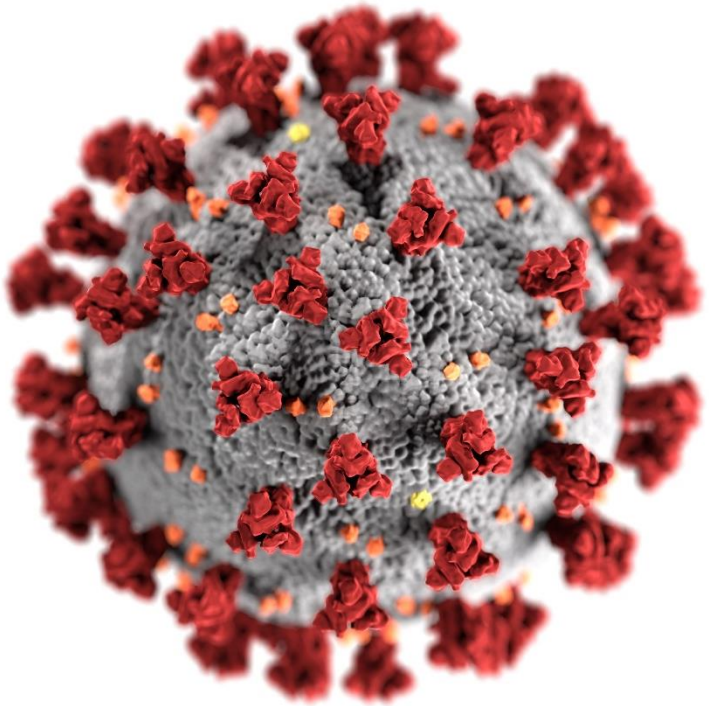


For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Thank you

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.

Interim Clinical Considerations for COVID-19 Vaccines: Bivalent Boosters



Elisha Hall, PhD
Clinical Guidelines Lead
COCA Call
September 13, 2022

cdc.gov/coronavirus

Bivalent Booster Authorized

- On August 31, 2022:
  - Moderna COVID-19 Vaccine, Bivalent authorized for use in people ages 18 years and older.
  - Pfizer-BioNTech COVID-19 Vaccine, Bivalent authorized for use in people ages 12 years and older
- Authorized as single booster dose administered at least 2 months after either:
  - Completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or
  - Receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine

Bivalent Booster Recommendations

- Everyone ages 12 years and older is recommended to receive 1 age-appropriate bivalent mRNA booster dose after completion of any FDA-approved or FDA-authorized monovalent primary series or last monovalent booster dose.
  - People cannot get a bivalent booster without first completing at least a primary series
  - Age-appropriate homologous and heterologous boosters allowed; there is no preference
- At this time, no changes to schedules for children ages 6 months through 11 years.

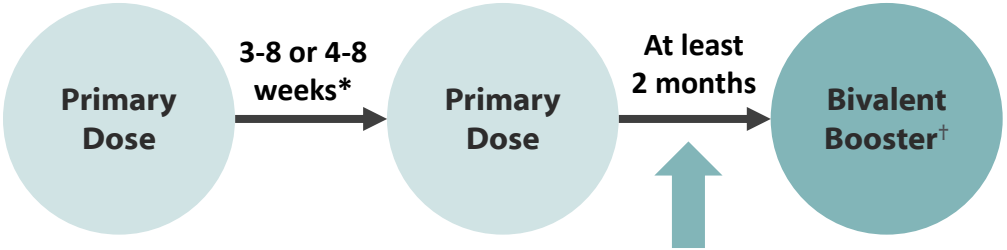
Previous Monovalent Booster Recommendations

- The bivalent booster recommendation **replaces** previous booster recommendations for people ages 12 years and older.
  - Monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses and cannot be given as booster doses to individuals ages 12 years and older.
- This means that everyone ages 5 years and older who are eligible for a booster dose will now only be eligible for ONE booster dose.
  - People ages 5 through 11 years (who received Pfizer-BioNTech primary series): 1 monovalent booster dose
  - People ages 12 years and older: 1 bivalent booster dose

COVID-19 Vaccination Schedule for People who are NOT Moderately or Severely Immunocompromised

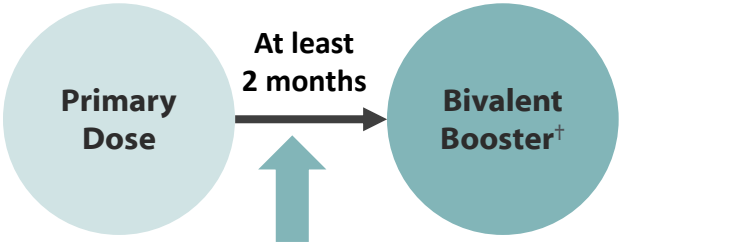
People ages 12 years and older

Moderna, Novavax, or Pfizer-BioNTech Primary Series



People ages 18 years and older

Janssen Primary Series Dose



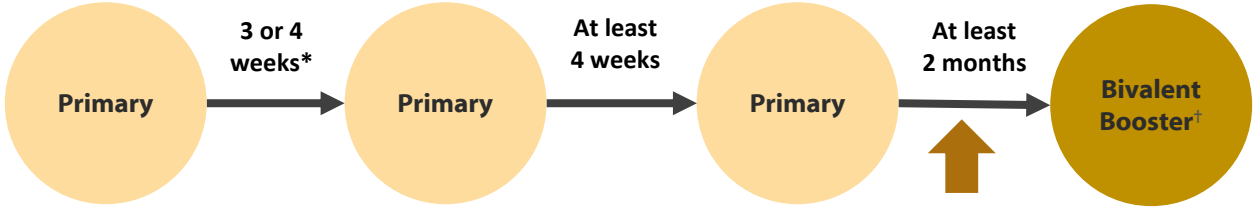
*3-8 week interval for Novavax and Pfizer-BioNTech; 4-8 week interval for Moderna

†The bivalent booster dose is administered at least 2 months after completion of the primary series. For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose. The bivalent booster should be age appropriate; Pfizer-BioNTech is authorized for people ages 12 years and older and Moderna is authorized for people ages 18 years and older.

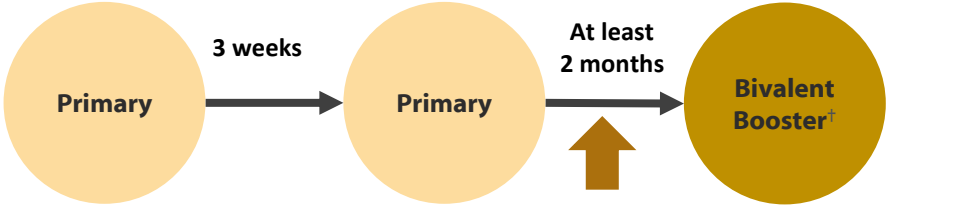
COVID-19 Vaccination Schedule for People who ARE Moderately or Severely Immunocompromised

People ages 12 years and older

Moderna or Pfizer-BioNTech Primary Series

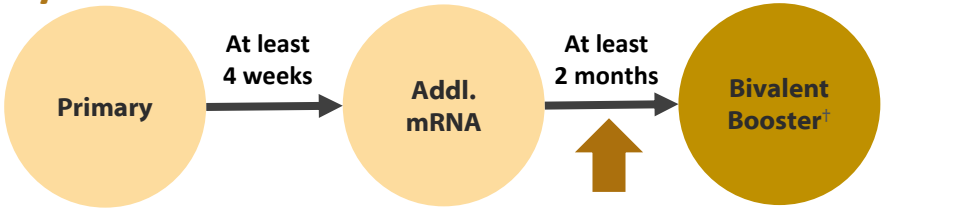


Novavax Primary Series



People ages 18 years and older who received Janssen

Janssen Primary Series Dose



*3-week interval for Pfizer-BioNTech; 4-week interval for Moderna

†The bivalent booster dose is administered at least 2 months after completion of the primary series. For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose. The bivalent booster should be age appropriate; Pfizer-BioNTech is authorized for people ages 12 years and older and Moderna is authorized for people ages 18 years and older.

Fall Booster “Reset”

- Recommendations are simplified
- Change from dose counting to 1 bivalent booster for everyone eligible
- If eligible, a bivalent should not be denied based on total number of doses

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

Timing Considerations for People with Current or Prior SARS-CoV-2 Infection

- At a minimum, defer any COVID-19 vaccination, including bivalent booster vaccination, at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.
- In addition, people who recently had SARS-CoV-2 infection may consider delaying any COVID-19 vaccination, including bivalent booster vaccination, **by 3 months** from symptom onset or positive test (if infection was asymptomatic).
- Individual factors such as risk of COVID-19 severe disease, COVID-19 community level, or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

Coadministration of COVID-19 Vaccines with Other Vaccines

- Routine administration of all age-appropriate doses of vaccines simultaneously is recommended as best practice for people for whom no specific contraindications exist at the time of the healthcare visit.
  - Exception for orthopoxvirus and COVID-19 vaccines
- Extensive experience with non-COVID 19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.
- **Providers should offer all vaccines for which a person is eligible at the same visit.**

Coadministration of Influenza and COVID-19 Vaccines

- Providers should offer influenza and COVID-19 vaccines at the same visit, if eligible.
  - This includes adjuvanted or high-dose influenza vaccines; administer in separate limbs.

- With both influenza and SARS-CoV-2 circulating, getting **both vaccines** is important for prevention of severe disease, hospitalization, and death.

- Getting both vaccines at the same visit increases the chance that a person will be up to date with their vaccinations.

Coadministration of Influenza and COVID-19 Vaccines

- Studies looking at coadministration have shown that **immunogenicity is similar** between those who received coadministered COVID-19 vaccine and seasonal influenza vaccine (SIV) and those who received these vaccines separately.[1-3]
- 9.4% (~92,000) v-safe participants reported simultaneous vaccination with an mRNA COVID-19 vaccine and SIV.[4]
- 8.7% (~454,000) of persons enrolled in the Vaccine Safety Datalink (VSD) received simultaneous vaccination with a COVID-19 booster and SIV during the 2021-2022 influenza season.
- Generally, COVID-19 vaccines administered with seasonal influenza vaccine (SIV) **showed similar or slightly higher reactogenicity**, however **no specific safety concerns were identified.**[1-4]

1. Lazarus R, Baos S, Cappel-Porter H, et al. Safety and immunogenicity of concomitant administration of COVID-19 vaccines (ChAdOx1 or BNT162b2) with seasonal influenza vaccines in adults in the UK (ComFluCOV): A multicentre, randomised, controlled, phase 4 trial. Lancet 2021, 398, 2277–2287.
2. Izikson R, Brune D, Bolduc JS, et al. Safety and immunogenicity of a high-dose quadrivalent influenza vaccine administered concomitantly with a third dose of the mRNA-1273 SARS-CoV-2 vaccine in adults aged ≥65 years: A phase 2, randomised, open-label study. Lancet Respir. Med. 2022.
3. Toback S, Galiza E, Cosgrove C, et al. Safety, immunogenicity, and efficacy of a COVID-19 vaccine (NVX-CoV2373) co-administered with seasonal influenza vaccines: An exploratory substudy of a randomised, observer-blinded, placebo-controlled, phase 3 trial. Lancet Respir. Med. 2021,10, 167–179.
4. Hause AM, Zhang B, Yue X, et al. Reactogenicity of Simultaneous COVID-19 mRNA Booster and Influenza Vaccination in the US. JAMA Netw Open. 2022;5(7):e2222241. Domnich A, Grassi R, Fallani E, Ciccone R, Bruzzone B, Panatto D, Ferrari A, Salvatore M, Cambiaggi M, Vasco A, Orsi A, Icardi G. Acceptance of COVID-19 and Influenza Vaccine Co-Administration: Insights from a Representative Italian Survey. Journal of Personalized Medicine. 2022; 12(2):139.

Best Practices for Multiple Injections

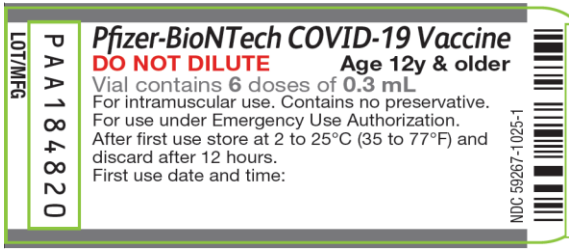
- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, initials of the preparer, and exact beyond-use time, if applicable.
- Administer each vaccine in a different injection site; separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccine and vaccines that may be more likely to cause a local reaction in different limbs, if possible.
  - Example: Adjuvanted or high-dose influenza vaccine and COVID-19 vaccine

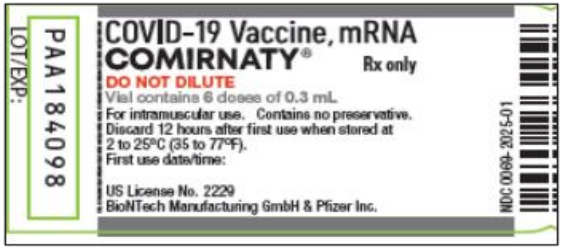
Pfizer-BioNTech COVID-19 Vaccines

	 Monovalent Product	 Bivalent Product
Authorized for ages	12 years and older	12 years and older
Authorized for doses	Primary series doses	Booster doses
Vial cap color	Gray	Gray
Dose (mRNA concentration)	30 mcg	30 mcg (15 mcg original, 15 mcg Omicron BA.4/BA.5)
Vaccine composition	Monovalent—Original	Bivalent—Original and Omicron BA.4/BA.5
Injection volume	0.3 mL	0.3 mL
Dilution required	No	No
Beyond-use date	12 hours after puncture	12 hours after puncture
Storage	Ultra-cold freezer until expiration; Refrigerator (2°C-8°C) up to 10 weeks	Ultra-cold freezer until expiration; Refrigerator (2°C-8°C) up to 10 weeks

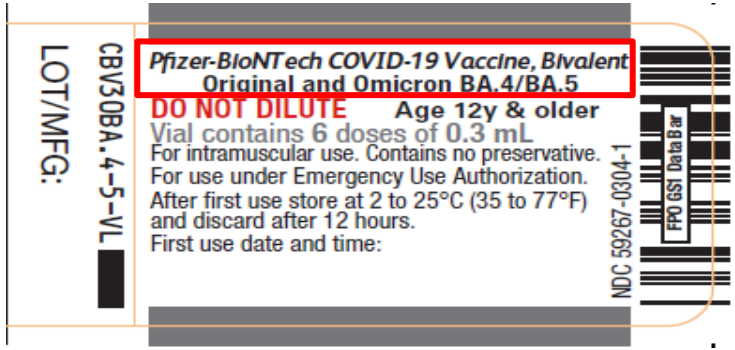
Pfizer-BioNTech Labels

Monovalent label
Primary series only
Ages 12 years and older





Bivalent label
Booster dose only
Ages 12 years and older



Moderna COVID-19 Vaccines Formulations

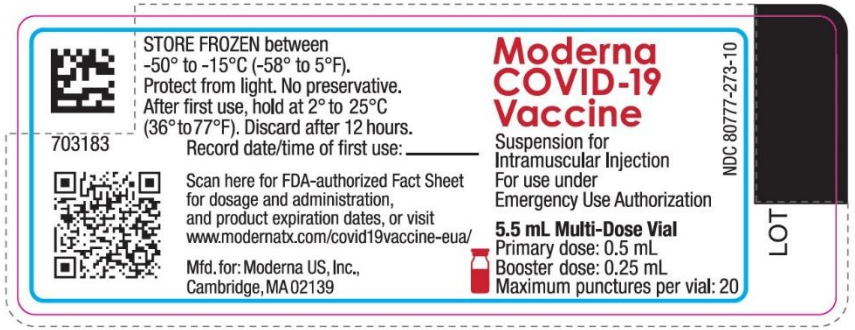
	 Monovalent Product	 Monovalent Product	 Bivalent Product
Authorized for ages	12 years and older	6–11 years	18 years and older
Vial cap color	Red	Dark blue	Dark blue
Label border color	Light blue	Purple	Gray
Dose (mRNA concentration)	100 mcg (primary dose)	50 mcg (primary dose)	50 mcg (booster dose) (25 mcg original, 25 mcg Omicron BA.4/BA.5)
Injection volume	0.5 mL	0.5 mL	0.5 mL
Dilution required	No	No	No
Beyond-use date	12 hours	12 hours	12 hours
Storage	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days

Moderna COVID-19 Vaccines Formulations

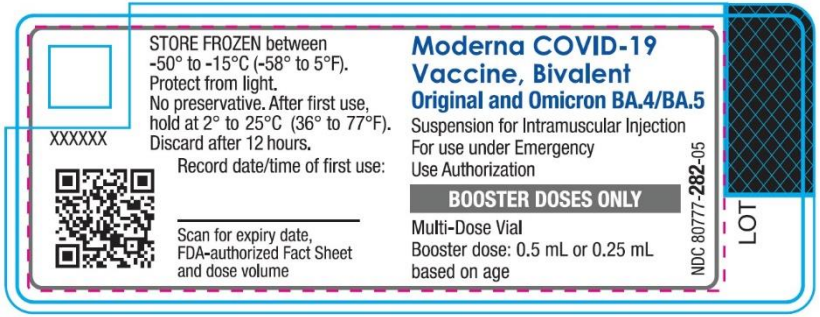
	 **Monovalent Product**	 **Bivalent Product**
Authorized for ages	12 years and older	18 years and older
Vial cap color	Red	Dark blue
Label border color	Light blue	Gray
Dose (mRNA concentration)	100 mcg (primary dose)	50 mcg (booster dose) (25 mcg original, 25 mcg Omicron BA.4/BA.5)
Injection volume	0.5 mL	0.5 mL
Dilution required	No	No
Beyond-use date	12 hours	12 hours
Storage	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days

Moderna Labels

Monovalent label
Primary series only
Ages 12 years and older



Bivalent label
Booster dose only
Ages 18 years and older

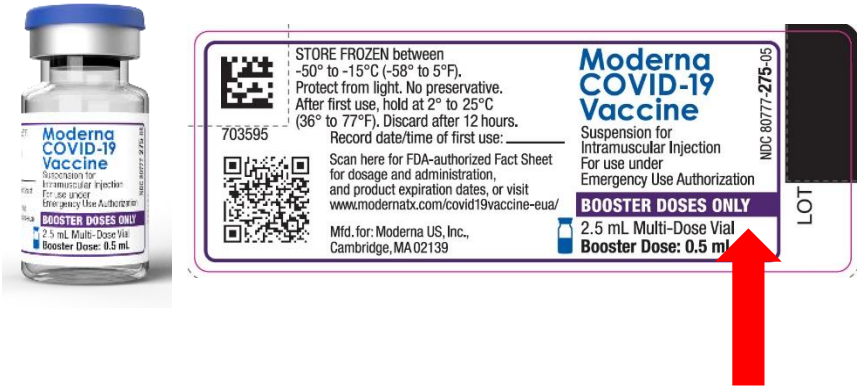


Moderna COVID-19 Vaccines Formulations

	 Monovalent Product	 Bivalent Product
Authorized for ages	6–11 years	18 years and older
Vial cap color	Dark blue	Dark blue
Label border color	Purple	Gray
Dose (mRNA concentration)	50 mcg (primary dose)	50 mcg (booster dose) (25 mcg original, 25 mcg Omicron BA.4/BA.5)
Injection volume	0.5 mL	0.5 mL
Dilution required	No	No
Beyond-use date	12 hours	12 hours
Storage	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days

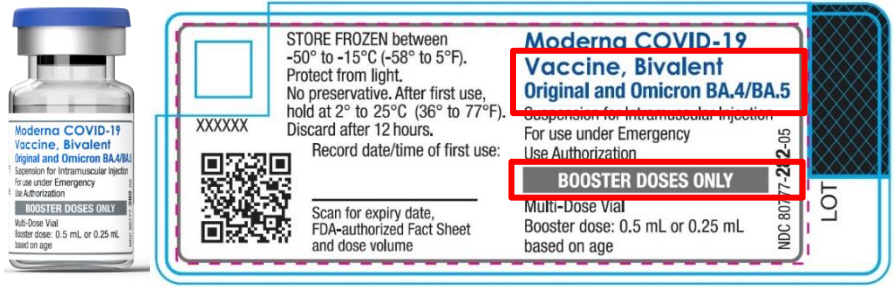
Moderna Labels

Monovalent label
Primary series only
Ages 6–11 years



Despite label, do NOT use for booster doses

Bivalent label
Booster dose only
Ages 18 years and older



Practices to Prevent Vaccine Administration Errors

Staff training

Storage

Preparation and Administration

Preventing Vaccine Administration Errors

- Staff training practices
  - Integrate vaccine administration training into orientation and other appropriate education requirements.
  - Provide education when new products are added to inventory or recommendations are updated.

Preventing Vaccine Administration Errors

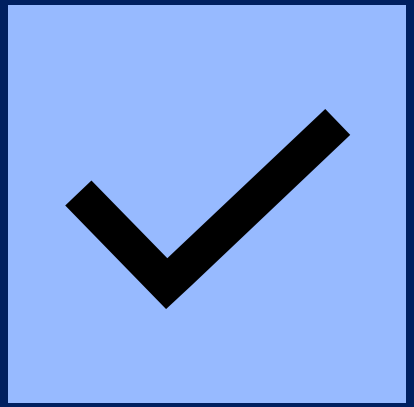
- Storage practices
  - Circle important information on the packaging to emphasize the difference between the vaccines.
  - Separate vaccines into bins or other containers according to type and formulation.
  - Use color-coded identification labels on vaccine storage containers.
  - Store look-alike vaccines in different areas of the storage unit.
  - Consider using "name alert" or "look-alike" stickers on packaging and areas where these vaccines are stored.

Preventing Vaccine Administration Errors

- Preparation and administration practices
  - Establish "Do NOT Disturb" or no-interruption areas or times when vaccines are being prepared or administered.
  - Prepare vaccine for one patient at a time. Once prepared, label the syringe with vaccine name.
  - Do not administer vaccines prepared by someone else.

Always triple-check work before administering a vaccine and ask another staff member to check.





Vaccine Administration Errors

Errors	Recommended Action
• Bivalent vaccine incorrectly administered for the primary series	• Pfizer-BioNTech bivalent vaccine: Do not repeat dose. • Moderna bivalent vaccine: Repeat 1 monovalent dose immediately (no minimum interval)* because administration of the booster dose will result in a lower-than-authorized dose.
• Monovalent vaccine incorrectly administered for a booster dose (if bivalent booster indicated)	• In general, do not repeat dose. • However, providers may administer 1 bivalent booster dose as a repeat dose based on clinical judgement and patient preference. In this case, space the repeat dose after the dose given in error by at least 2 months.

*Some experts suggest delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis and pericarditis from mRNA (i.e., Moderna or Pfizer-BioNTech) and Novavax COVID-19 vaccines, particularly in groups at increased risk for myocarditis and pericarditis (e.g., males ages 12–39 years). Individual risk for COVID-19 and the likelihood for an adverse event following vaccination should be taken into consideration when recommending a longer interval.

Vaccine Administration Errors

- For all vaccine administration errors:
  - Inform the recipient of the vaccine administration error.
  - Consult with the state immunization program and/or immunization information system (IIS).
  - Report the error to the Vaccine Adverse Event Reporting System (VAERS)
  - Determine how the error occurred and implement strategies to prevent it from happening again.
  - Follow the revaccination guidance in interim clinical considerations for COVID-19 vaccines

Staying Up To Date

- CDC encourages people to “Stay up to date with your COVID-19 vaccines”.
- Staying up to date keeps people current with COVID-19 vaccine recommendations.
- You are up to date if you have completed a primary series and received the most recent booster dose recommended for you by CDC.

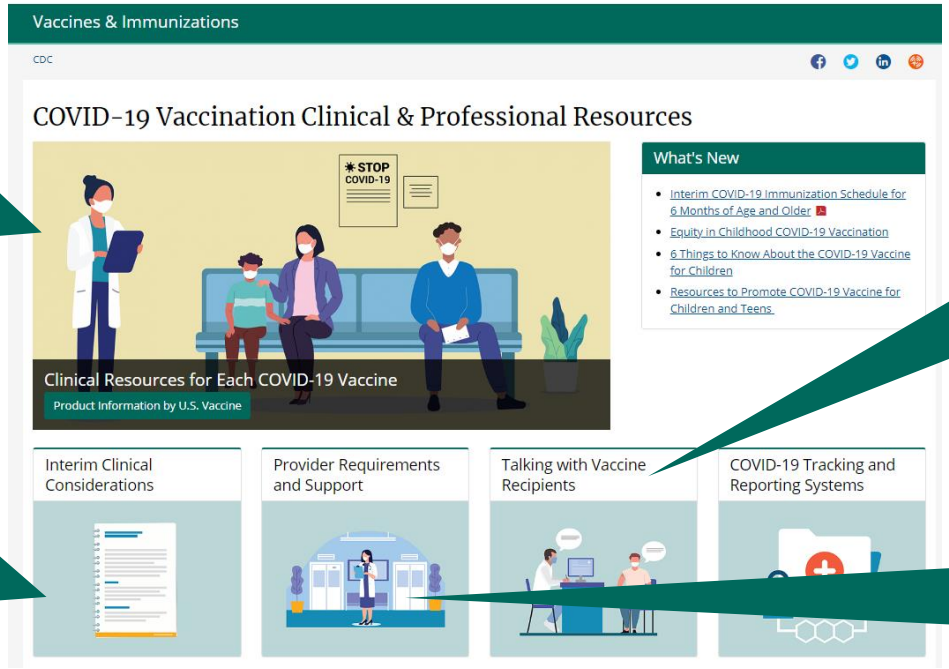
Resources


DEPARTMENT OF HEALTH & HUMAN SERVICES USA
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

COVID-19 Vaccination Clinical and Professional Resources: Your One-Stop-Shop

- https://www.cdc.gov/vaccines/covid-19/index.html

Find vaccine-specific job aids



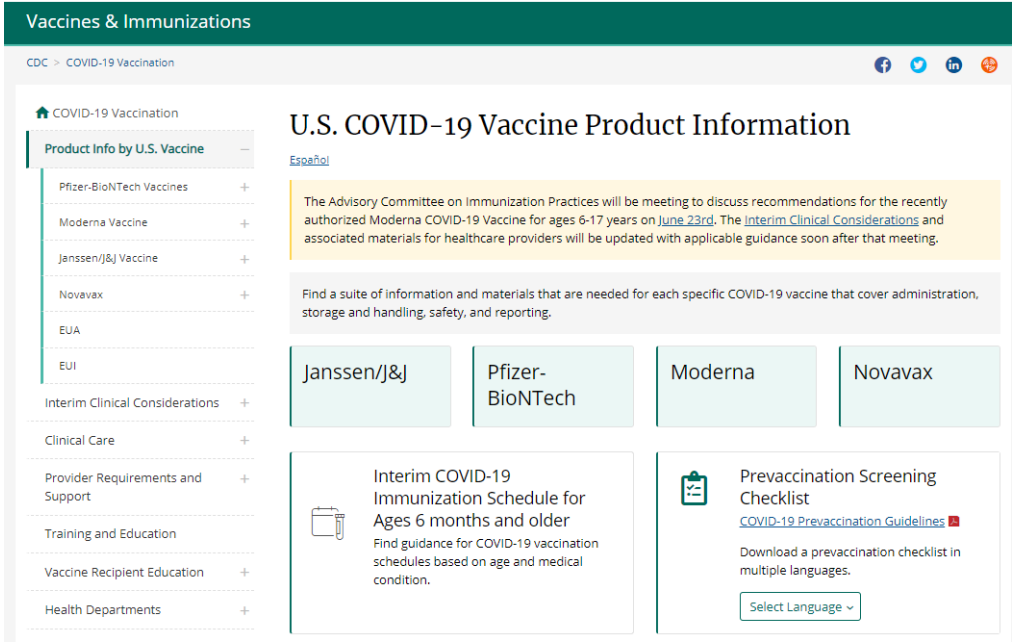
Find a variety of tools to help you educate vaccine recipients

Read the most updated clinical guidance

Stay up to date with requirements

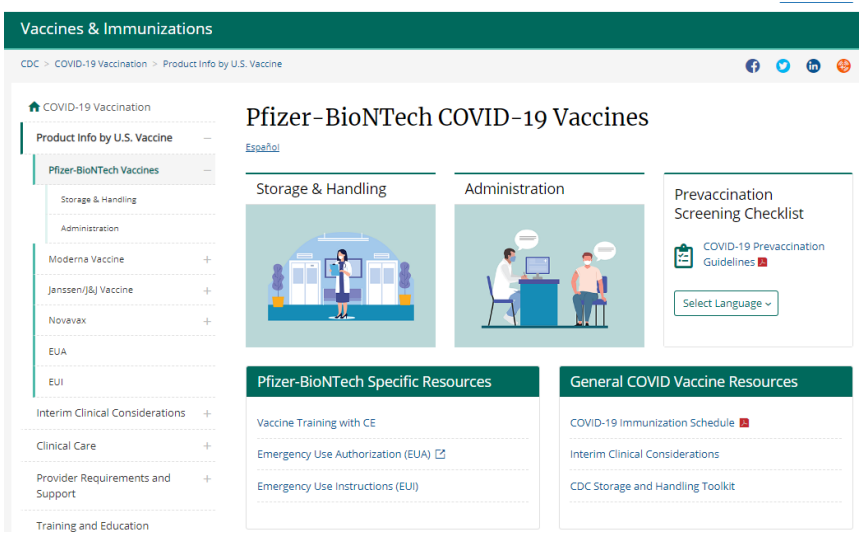
US COVID-19 Vaccine Product Information

- https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html



Example Product Page

- Tools and resources
  - Storage and handling summary
  - Storage labels
  - Beyond-use date labels
  - Temperature logs
  - Vaccine expiration tracker
  - Schedule
  - Preparation and administration summary
  - Prevaccination checklist
  - Standing orders
  - And more!



Interim Clinical Considerations for Use of COVID-19 Vaccines

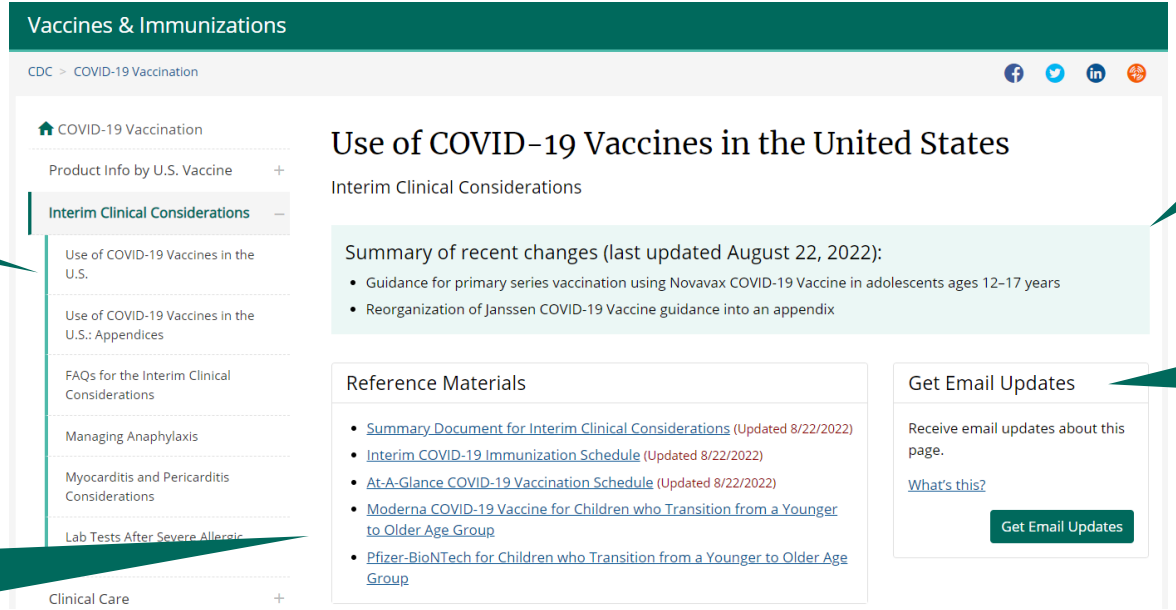
- https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Learn when guidance was last updated

Check out other resources

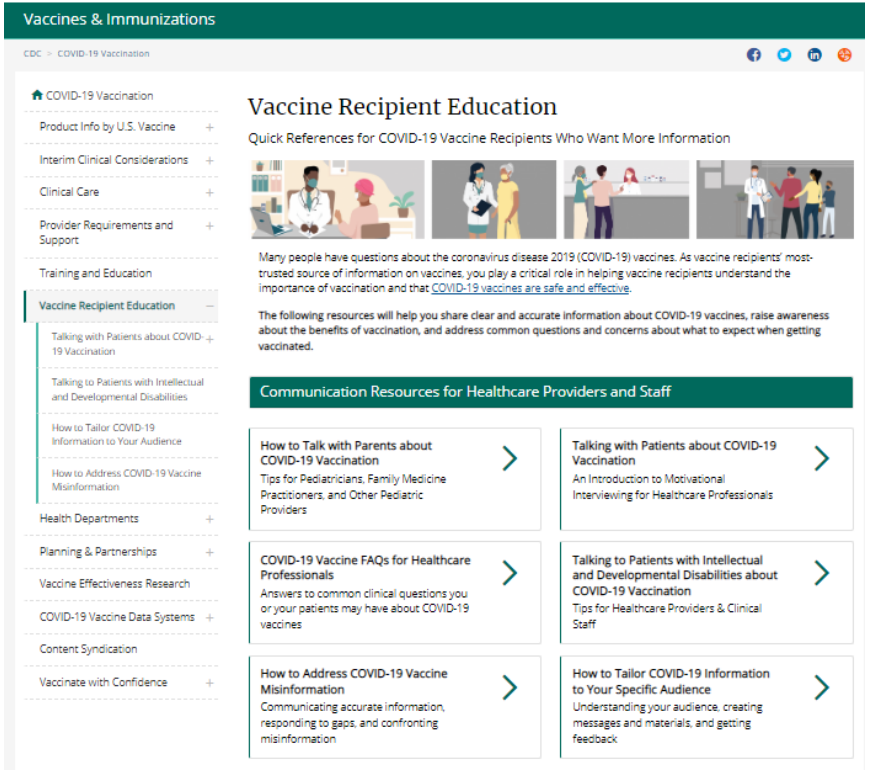
Sign up for email updates

Download job aids



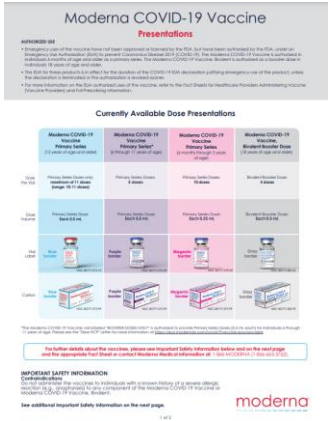
Vaccine Recipient Education

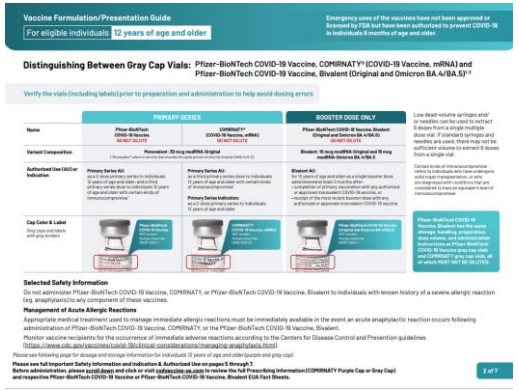
- https://www.cdc.gov/vaccines/covid-19/planning/children/resources-promote.html
- Talking to Parents and patients
- FAQs
- Addressing misinformation
- Tailoring information to your audience
- Many resources—videos, posters, social media graphics, customizable letter, and more



Manufacturer Resources

- Moderna COVID-19 Vaccine Presentations: https://eua.modernatx.com/covid19vaccine-eua/providers/MOUS0299_Moderna_EUA_Presentations_QC_v17lg.pdf
- Pfizer-BioNTech Vaccine Formulation/Presentation Guide: https://webfiles.pfizer.com/formulation-guide





Self-knowledge Check

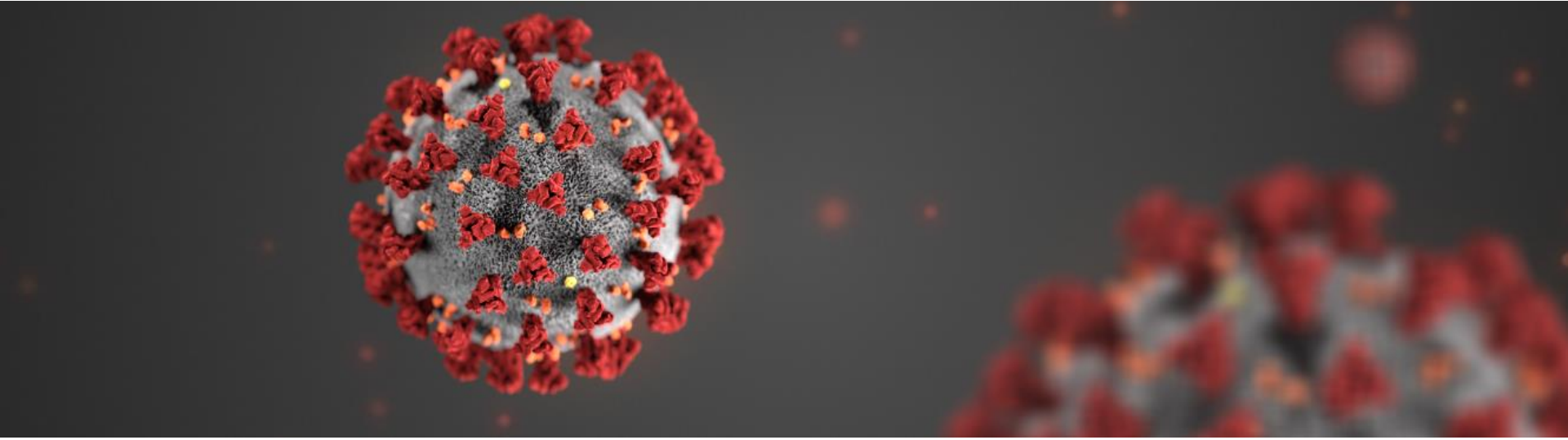
True or False: Eligibility for the bivalent booster dose depends on how many monovalent COVID-19 booster doses were previously received.

A. True
B. False

Self-knowledge Check

The correct answer is B: False

People ages 12 years and older who completed a primary series are recommended to receive a bivalent booster dose **regardless of previous monovalent booster doses received** (as long as it has been at least 2 months since their last primary series or booster dose).



For more information, contact CDC
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TTY: 1-888-232-6348 www.cdc.gov

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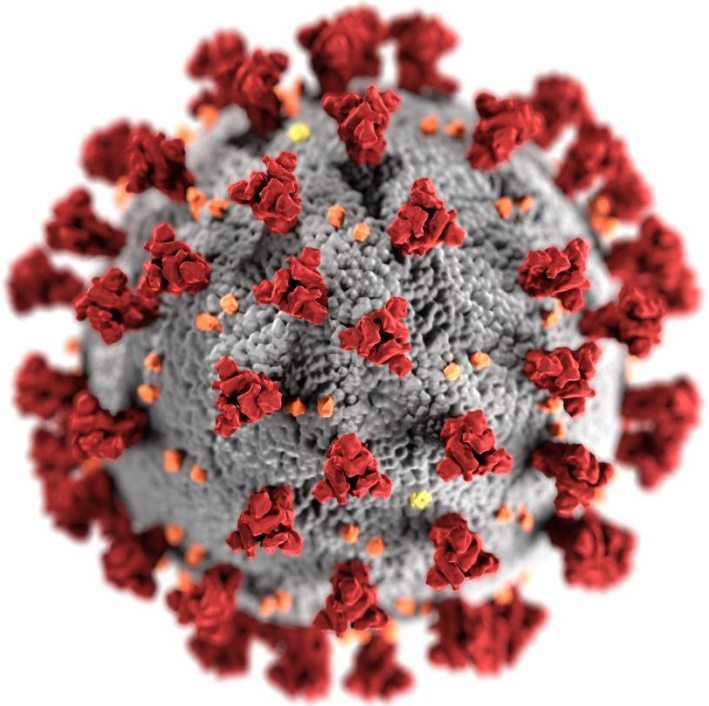
Pre-exposure prophylaxis for people with moderate or severe immunocompromise



Evelyn Twentyman, MD MPH
COVID-19 Vaccine Policy Unit Lead
COCA Call
September 13, 2022

cdc.gov/coronavirus

Who may benefit from Evusheld?

- People ages ≥12 years:
  - With moderate to severe immune compromise
  - For whom vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s)

Evusheld Healthcare Providers FS 06292022 (fda.gov)
Image: ASPR Webinar: What is Evusheld? https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Evusheld/Pages/default.aspx

Tixagevimab/Cilgavimab (EVUSHELD™)

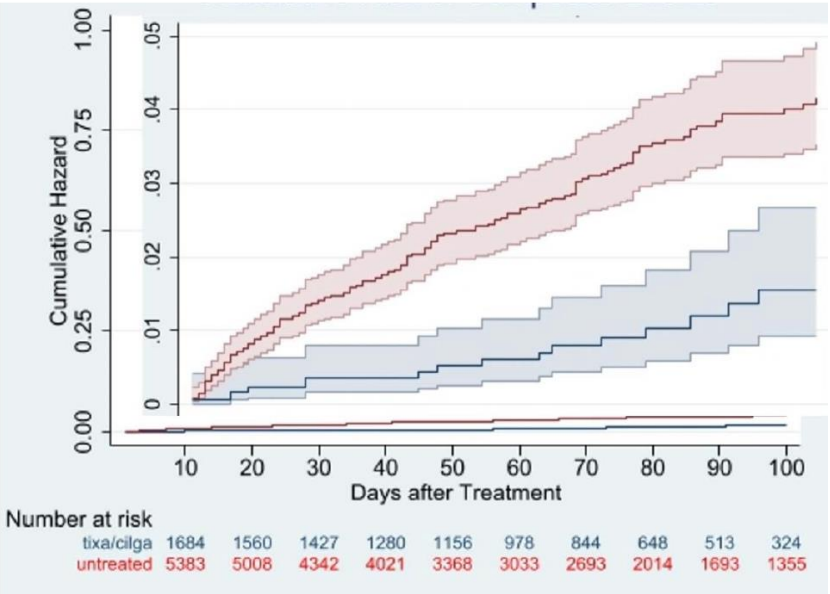
- Combination of two long-acting human monoclonal antibodies derived from B-cells donated by convalescent patients after SARS-CoV-2 infection
- **FDA's Emergency Use Authorization (EUA):**
  - Issued 12/8/21 for **pre-exposure prophylaxis** in individuals with moderate/severe immunocompromise or for whom COVID-19 vaccination is not recommended
  - Revised 2/24/22 to **increase dose to 300mg/300mg** (accounting for decreased neutralization activity against Omicron)
- Fact sheet for healthcare providers revised 6/29/22 for Evusheld to be administered **every 6 months**
- Evusheld must be prescribed by a healthcare provider
- Doses can be found through the USG therapeutic locator tool: https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/
- There are two ways for providers to order Evusheld:
  - HHS Health Partner Order Portal (HPOP), for large orders through the HPOP distribution process
  - A new direct clinical pathway established in July 2022 for Small Volume Orders of up to three doses, for providers not participating in the HPOP distribution process

Use of Evusheld is evidence-based

- A randomized clinical trial[1] and multiple retrospective and other studies[2-5] show that **Evusheld has efficacy against severe COVID-19 outcomes and provides protection against Omicron**.

- In vitro studies show that Evusheld is predicted to work against BA.4/5[6]

Figure 3. Cumulative Risk of Composite COVID-19 Outcomes for Tixagevimab-Cilgavimab Recipients Compared to Untreated Controls



1. Levin et al, Intramuscular AZD7442 (Tixagevimab-Cilgavimab) for Prevention of Covid-19, *New England Journal of Medicine*, 2022
2. Tixagevimab/Cilgavimab for Prevention of COVID-19 during the Omicron Surge: Retrospective Analysis of National VA Electronic Data | medRxiv
3. Serum neutralization of SARS-CoV-2 Omicron sublineages BA.1 and BA.2 in patients receiving monoclonal antibodies | Nature Medicine
4. Al Jurdi et al., American Journal of Transplantation;June 2022
5. Association between AZD7442 (tixagevimab-cilgavimab) administration and SARS-CoV-2 infection, hospitalization and mortality | Clinical Infectious Diseases | Oxford Academic (oup.com)
6. Takashita E, et al, Efficacy of Antibodies and Antiviral Drugs against Omicron BA.2.12.1, BA.4, and BA.5 Subvariants. N Engl J Med. 2022.

Most immunocompromised people in the US have not received Evusheld

- Number of individuals age ≥12 in the United States: **~290 million people**[2]
- Roughly **3%** of U.S. population is immunocompromised: **~8.7 million people**
- Therefore, % protected with Evusheld:

  ~5.3% of individuals who are eligible

- Supply far exceeds administration to patients: **>390,000 doses available**
- Evusheld is distributed by the US government at no cost to recipients, although there may be administration fees depending on location

Therapeutic[2]	Courses Ordered	Courses Administered
Evusheld (300 mg doses)	850,106	459,572

Data is for states, territories, and federal entities, including HRSA.

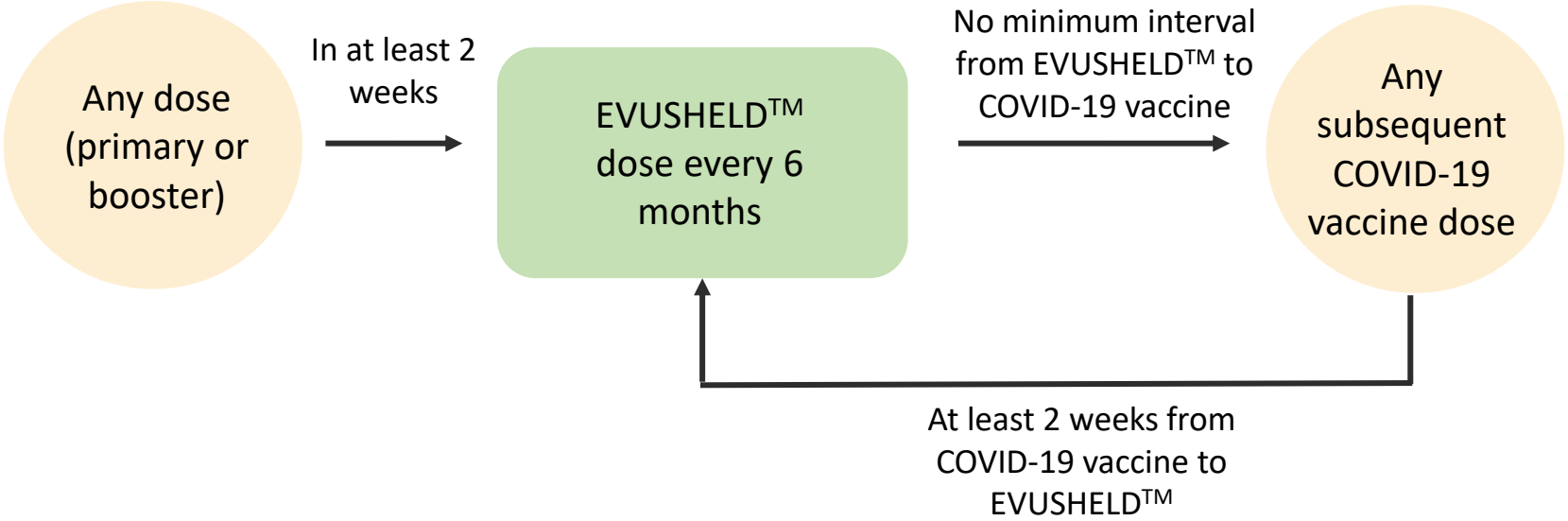
Courses administered is based on 92% of sites as of August 21, 2022

1. National population estimates: CDC wonder (wonder.cdc.gov)
2. Data source: HHS-Tiberius: https://aspr.hhs.gov/COVID-19/Therapeutics/orders/Pages/default.aspx

Supplementing COVID-19 vaccination with pre-exposure prophylaxis

Monoclonal antibodies (EVUSHELD™) for COVID-19 pre-exposure prophylaxis

People ages 12 years and older (must weigh at least 40 kg)



CDC Webpage pre-exposure prophylaxis updates for healthcare providers and the public

- Updated website content for healthcare providers:
  - Patient eligibility
  - Evusheld administration guidance
- Updated website content for the public:
  - How to know if you're eligible for Evusheld
  - How to access Evusheld
- Updated website language for Interim Clinical Considerations
  - How use of Evusheld compliments COVID-19 vaccination in people with moderate or severe immunocompromise

Self-knowledge Check

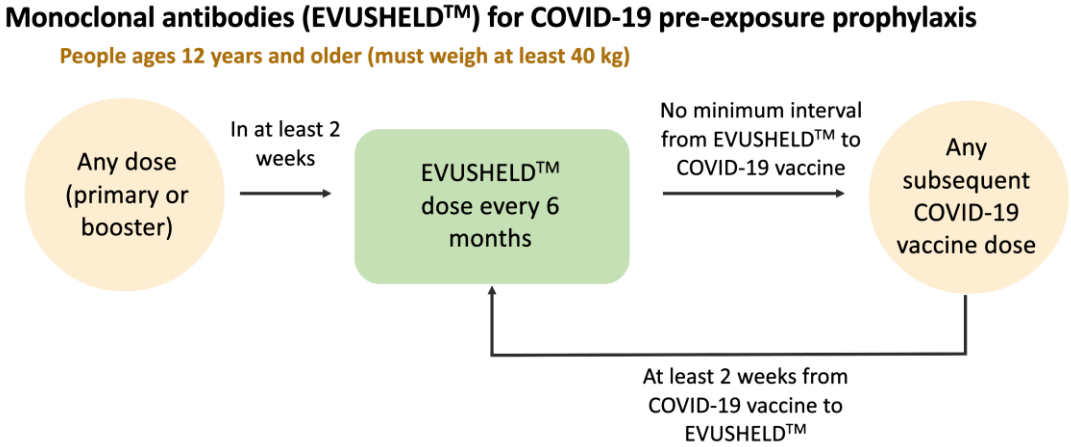
Which of the following is true regarding administration of Evusheld:

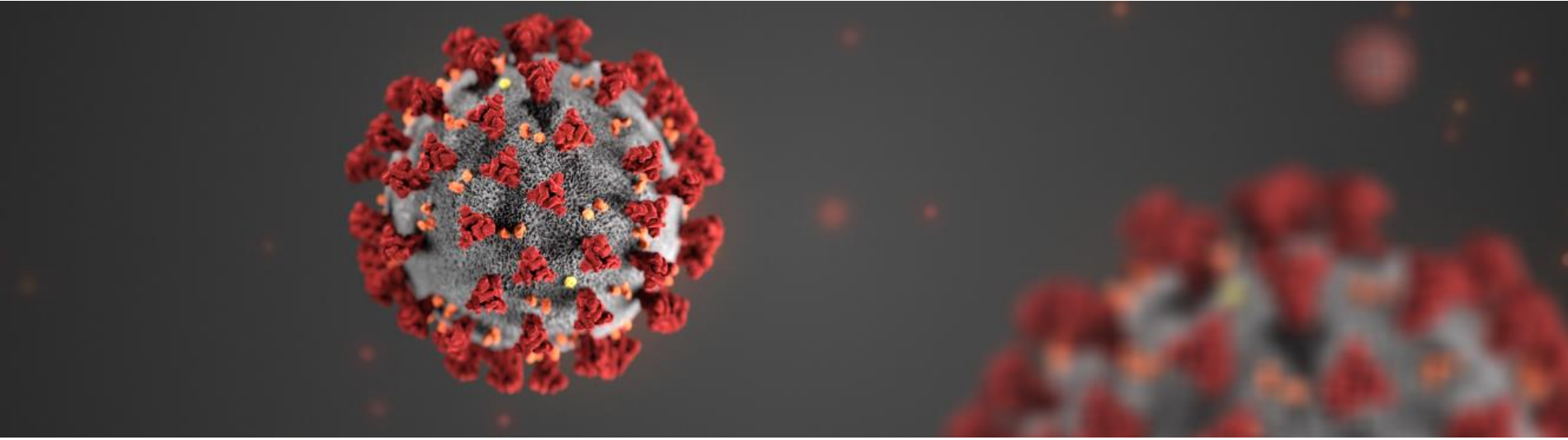
A. There is no minimum interval between an Evusheld dose and any subsequent COVID-19 vaccine dose
B. To receive Evusheld, persons must be 12 years or older and at least 40 kg
C. There is a 2-week minimum interval between a COVID-19 vaccine dose and a subsequent Evusheld dose
D. A and C only
E. A, B, and C

Self-knowledge Check

The correct answer is E: A, B and C

- It's true that there is **no** minimum interval between an Evusheld dose and any subsequent COVID-19 vaccine dose.
- There **is** a minimum interval of at least 2 weeks between a COVID-19 vaccine dose and a subsequent Evusheld dose.
- And to receive Evusheld, persons must be 12 years or older and at least 40kg.





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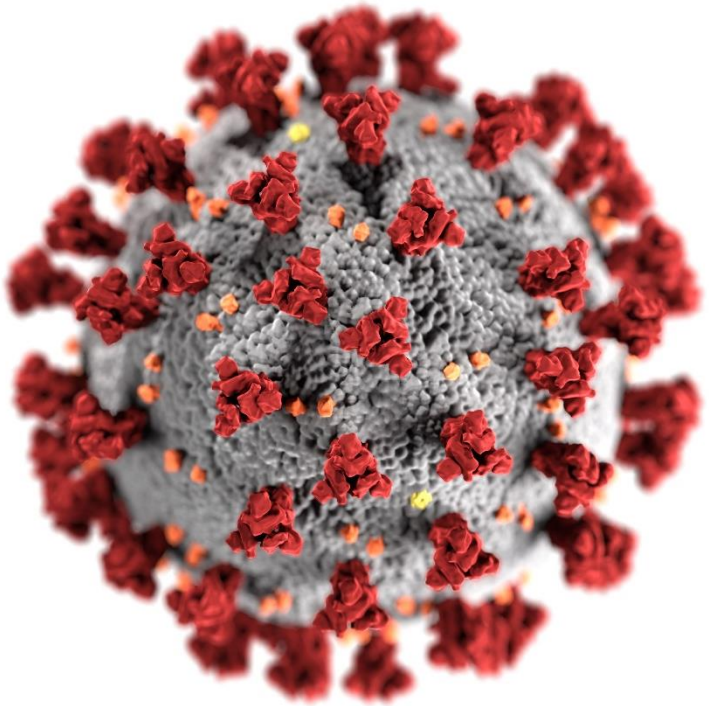
Early Safety Monitoring for COVID-19 Vaccine Doses: Reports to VAERS and v-safe



Anne M. Hause, PhD MSPH
v-safe Team Co-Lead

COCA Call

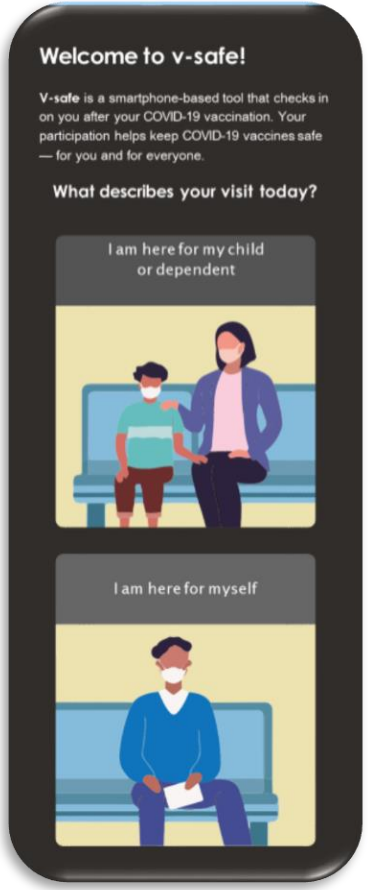
September 13, 2022

cdc.gov/coronavirus

V-safe: Smartphone-based safety monitoring for COVID-19 vaccines

V-safe conducts active safety monitoring for authorized COVID-19 vaccines in the United States

- Self-registration on smartphone – open to anyone who has received a COVID-19 vaccine, starting after any dose
- Children ages 15 years and younger are added to a registered parent's account
- Text message reminders prompt survey completion
- To register or access your account go to https://vsafe.cdc.gov/en/



V-safe uses text messages and web surveys to check in

- Surveys are brief – can be completed in less than a minute
- Questions solicit adverse events and health impacts after COVID-19 vaccination
  - Local and systemic reactions (e.g., pain, redness, fatigue, headache, joint pain)
  - Health impacts (e.g., unable to perform normal daily activities, missed school or work, or received care)
- Surveys include questions to identify participants who may be interested in and eligible for a pregnancy registry
- **V-safe** languages: English, Spanish, Chinese, Korean, and Vietnamese

Promoting v-safe in practice – we need your help!

How:

- Direct patients to https://vsafe.cdc.gov/en/
- Provide **v-safe** information sheet to patients
- Display posters about **v-safe**

https://www.cdc.gov/coronavirus/2019ncov/vaccines/safety/vsafe/printresources.html

Get vaccinated.
Get your smartphone.
Get started with v-safe.

What is v-safe?

V-safe provides personalized and confidential health check-ins via text messages and web surveys so you can quickly and easily share with CDC how you or your dependent feel after getting a COVID-19 vaccine. It takes just a few minutes to enroll and your participation in **v-safe** helps us monitor the safety of COVID-19 vaccines for everyone.

V-safe features:

- **Enroll your dependents** and complete check-ins on their behalf
- **Enter** and report how you feel after **first, second, additional, and booster doses**

How can I enroll and how does it work?

You can enroll in **v-safe** after any dose of COVID-19 vaccine by using your smartphone and going to vsafe.cdc.gov.

During the first week after each vaccination, **v-safe** will send you a text message each day to ask how you are feeling. After that, you will receive occasional check-ins, which you can opt out of at any time. Depending on your answers, someone from CDC may call to get more information. Your personal information in **v-safe** is protected so it's safe and private*.

How can I enroll my child or dependent?

You can enroll any family member (or friend) who is eligible to be vaccinated in **v-safe.** Children under 16 years old must be enrolled using a parent or guardian's **v-safe** account. You can add a dependent to your existing account or create a new account if you don't have one yet. Creating an account to enroll a dependent does not require that you enter your own vaccination information or complete health check-ins for yourself.

Need step-by-step instructions? Go to: www.cdc.gov/vsafe

*v-safe uses existing information systems managed by CDC, FDA, and other federal agencies. These systems use strict security measures to keep information confidential. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

v-safe
after vaccination health checker

Sign up with your smartphone's browser at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

Need help with *v-safe*?
Call 800-CDC-INFO (800-232-4636)
TTY 888-232-6348
Open 24 hours, 7 days a week
Visit www.cdc.gov/vsafe

CS324195-L 06/10/2022

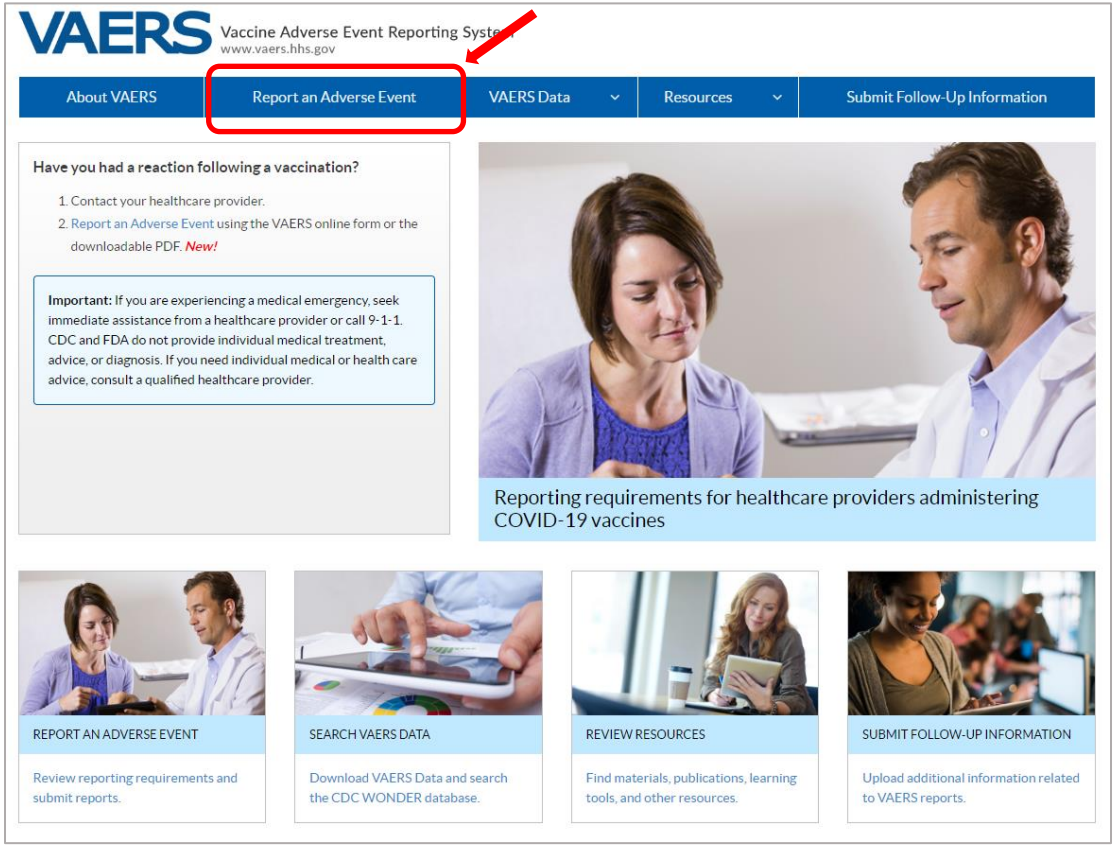
VAERS is the nation's early warning system for vaccine safety

Vaccine Adverse Event Reporting System

- National, passive surveillance system
- Covers entire US population
- Accepts reports of possible side effects from anyone
- Early signal detection

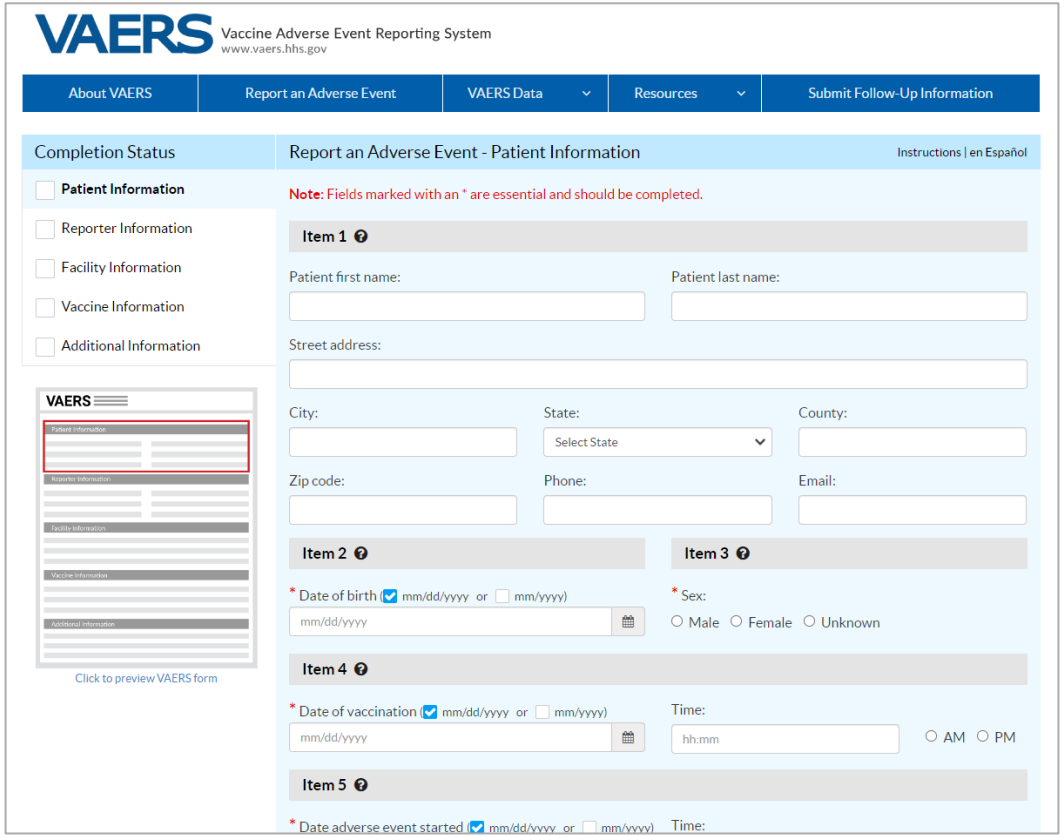
http://vaers.hhs.gov

VAERS resources available online



http://vaers.hhs.gov

VAERS Data Entry Form



https://vaers.hhs.gov/esub/index.jsp

To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov

Continuing Education

- All continuing education for COCA Calls is issued online through the CDC Training & Continuing Education Online system at https://tceols.cdc.gov/.

- Those who participate in today's COCA Call and wish to receive continuing education please complete the online evaluation by **October 17, 2022,** with the course code **WC4520-091322**. The access code is **COCA091322.**

- Those who will participate in the on-demand activity and wish to receive continuing education should complete the online evaluation between **October 18, 2022,** and **October 18, 2024,** and use course code **WD4520-091322**. The access code is **COCA091322.**

- Continuing education certificates can be printed immediately upon completion of your online evaluation. A cumulative transcript of all CDC/ATSDR CEs obtained through the CDC Training & Continuing Education Online System will be maintained for each user.

Today's COCA Call Will Be Available to View On-Demand

- **When:** A few hours after the live call ends*
- **What:** Video recording
- **Where:** On the COCA Call webpage https://emergency.cdc.gov/coca/calls/2022/callinfo_091322.asp
- **Sign up to receive future COCA Call Announcements and other timely information:** https://emergency.cdc.gov/coca/subscribe.asp

**A transcript and closed-captioned video will be available shortly after the original video recording posts at the above link.*

Upcoming COCA Call & Additional Resources

- **Next COCA Call**
  - **Day/Date:** Thursday, September 15, 2022
  - **Time:** 2:00 – 3:00 PM ET
  - **Topic:** 2022–2023 Recommendations for Influenza Prevention and Treatment in Children: An Update for Pediatric Providers

- Continue to visit https://emergency.cdc.gov/coca/ to get more details about upcoming COCA Calls.

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