Centers for Disease Control and Prevention Center for Preparedness and Response



Updated Guidance for Clinicians on COVID-19 Vaccines

Clinician Outreach and Communication Activity (COCA) Call

Thursday, February 24, 2022

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- In compliance with continuing education requirements, all planners and presenters must disclose all financial relationships, in any amount, with ineligible companies over the previous 24 months as well as any use of unlabeled product(s) or products under investigational use.
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 use, with the exception of Sarah Mbaeyi's discussion of vaccine use. She will be discussing vaccine use
 under Emergency Use Authorization or Emergency Use Instruction.
- CDC did not accept financial or in-kind support from ineligible companies for this continuing education activity.

Objectives

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

- 1. Discuss current recommendations related to COVID-19 vaccination for people who are moderately or severely immunocompromised.
- 2. Describe the simplified recommendations for COVID-19 vaccination after a patient has received passive antibody therapy.
- 3. List key points for healthcare providers to use when talking about COVID-19 vaccination with people who are moderately or severely immunocompromised and with people who have received passive antibody therapy.

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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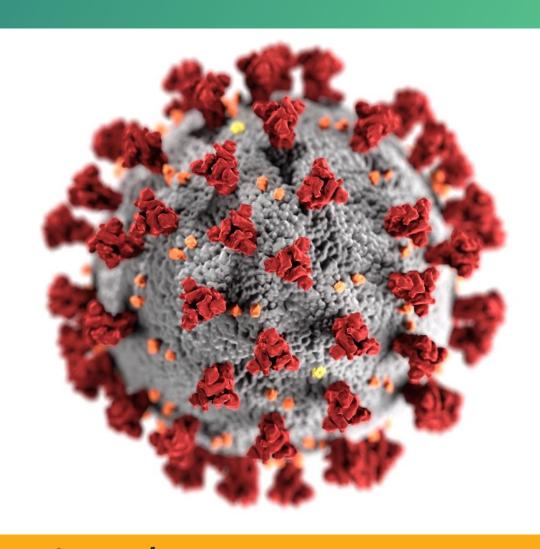
Chief Medical Officer, Vaccine Task Force COVID-19 Response Centers for Disease Control and Prevention

Updated Guidance for Clinicians on COVID-19 Vaccines

Sara Oliver, MD, MSPH Elisha Hall, PhD, RD Evelyn Twentyman, MD, MPH

CDC COCA Call February 24, 2022





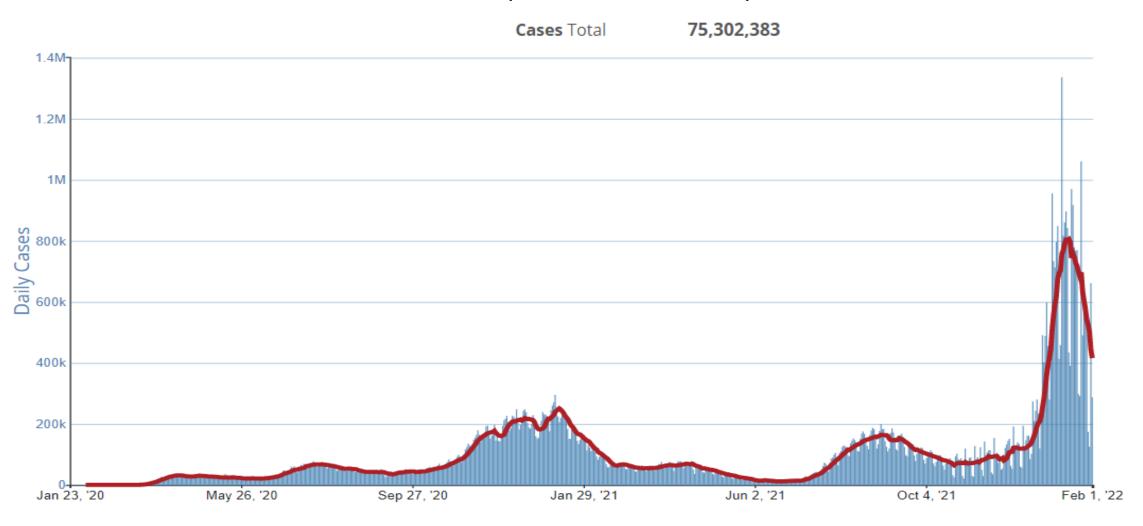
cdc.gov/coronavirus

Agenda

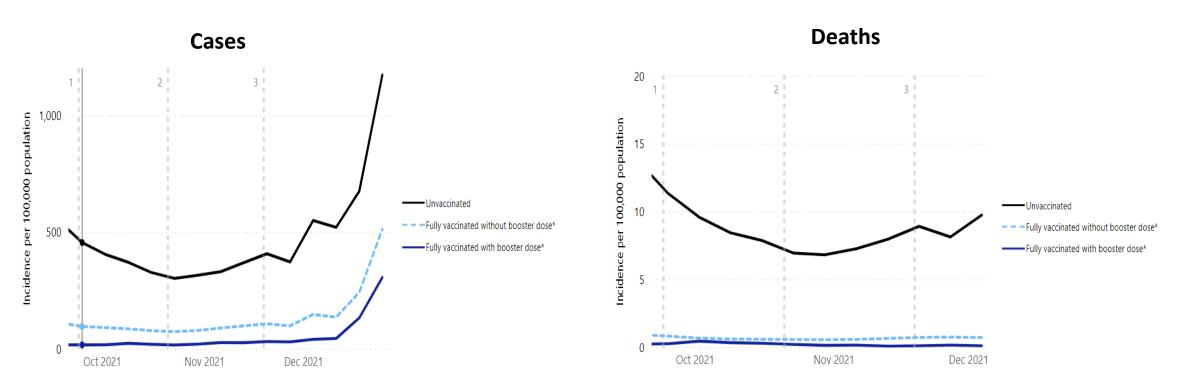
- Update from February 4, 2022, Advisory Committee on Immunization Practices (ACIP) meeting
- Extended interval between the 1st and 2nd mRNA COVID-19 vaccine dose: a review of evidence
- Updates to CDC's Interim Clinical Considerations:
 - Vaccination schedule
 - Guidance for people who are moderately to severely immunocompromised
 - Guidance on COVID-19 vaccination and passive antibody product use
- Summary of current recommendations for COVID-19 vaccination by age group

Trends in daily number of COVID-19 cases in the United States

January 23, 2020 – February 1, 2022



Rates of COVID-19 cases and deaths by vaccination status, August 29 – December 25, 2021 (25 U.S. Jurisdictions)



In November, unvaccinated adults ages 18 years and older had:

13X

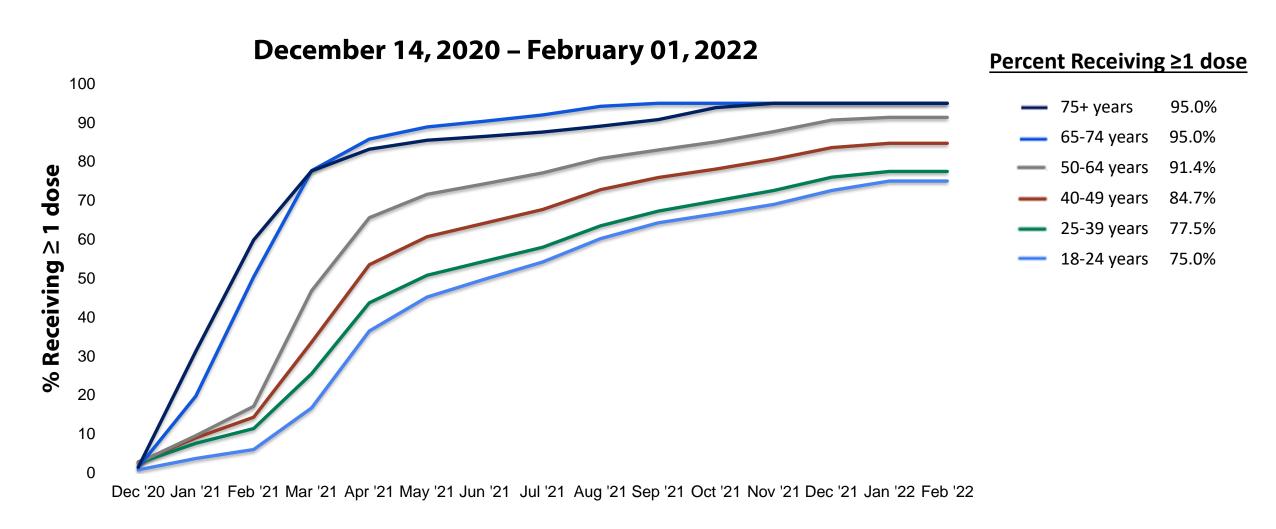
Risk of Testing Positive for COVID-19

AND

Risk of Dying from COVID-19

compared to fully vaccinated adults with booster dose

Percent of COVID-19 vaccination coverage by age and date administered, United States



COVID-19-associated hospitalizations and deaths prevented by COVID-19 vaccination in the United States

- COVID-19 associated hospitalizations prevented¹⁻²:
- Estimated up to 10.3 million hospitalizations averted through November 2021
- COVID-19 associated deaths prevented¹⁻³:
- Estimated up to 1.1 million deaths averted through November 2021

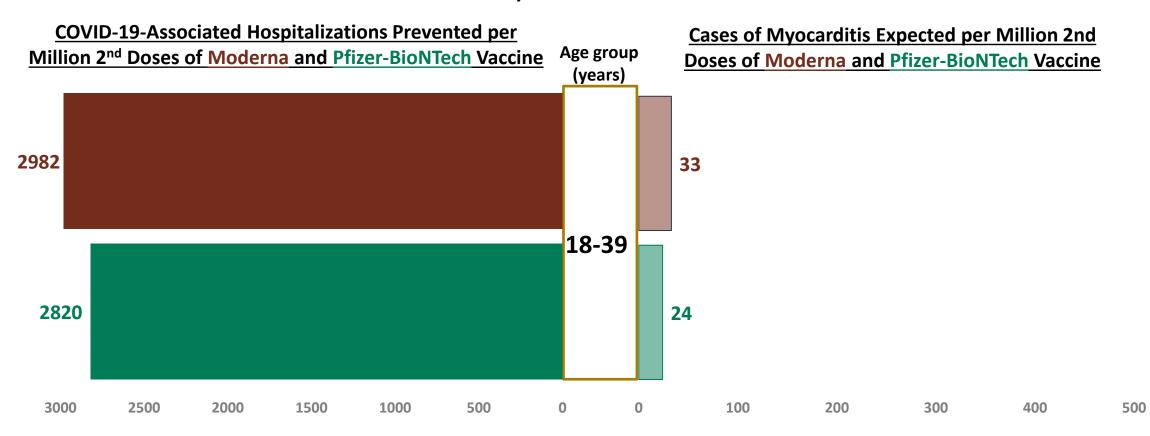
^{1.} Moghadas SM, Sah P, Fitzpatrick MC, et al. COVID-19 deaths and hospitalizations averted by rapid vaccination rollout in the United States. medRxiv. Published online July 8, 2021:2021.07.07.21260156. doi:10.1101/2021.07.07.21260156

^{2.} Eric C. Schneider, Arnav Shah, Pratha Sah, Seyed M. Moghadas, Thomas Vilches, Alison Galvani. The U.S. COVID-19 Vaccination Program at One Year: How Many Deaths and Hospitalizations Were Averted.

^{3.} Gupta S, Cantor J, Simon KI, Bento AI, Wing C, Whaley CM. Vaccinations Against COVID-19 May Have Averted Up To 140,000 Deaths In The United States. Health Aff (Millwood). 2021;40(9):1465-1472.

Benefits and risks after mRNA COVID-19 vaccines among persons ages 18–39 years

per million 2nd doses



- COVID-19-associated hospitalizations prevented by mRNA COVID-19 vaccines compared with myocarditis cases expected
- Presented by vaccine product

COVID-19 vaccines are safe and effective

- COVID-19 vaccines have been a critical tool in this pandemic, preventing millions of COVID-19 associated hospitalizations and deaths
- To date, hundreds of millions of doses of mRNA COVID-19 vaccines have been given with over a year of closely monitored real-world safety and effectiveness data
- Vaccinating the unvaccinated with a primary series continues to be important
 - Additional protection from all recommended COVID-19 vaccine doses are important in evolving pandemic

Update on Moderna COVID-19 vaccine

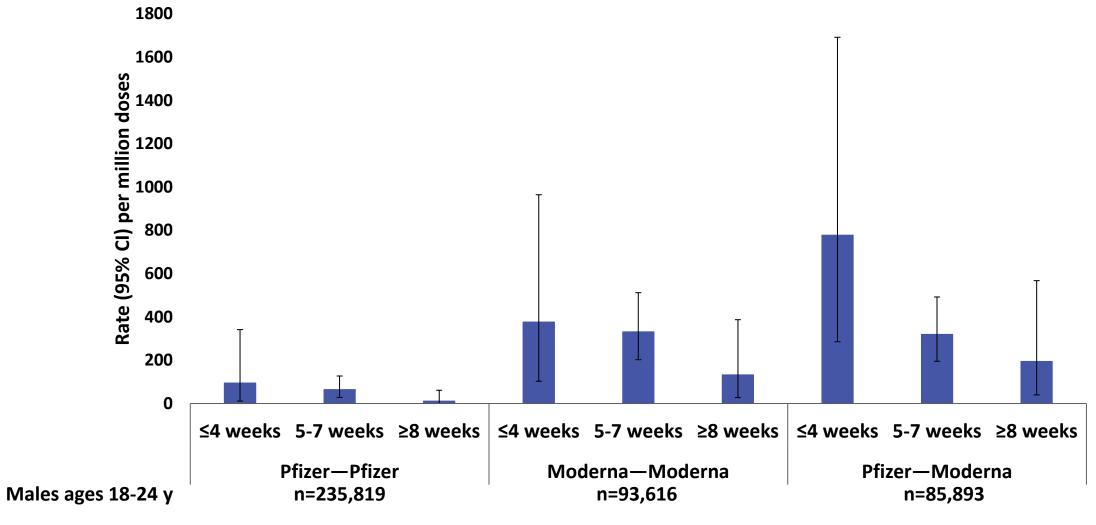
- On January 31, 2022: FDA approved the Moderna COVID-19 vaccine (Spikevax) for individuals 18 years of age and older
 - Spikevax biologics license application (BLA) builds upon the data and information that supported the EUA, such as preclinical and clinical data, as well as details of the manufacturing process and sites where the vaccine is made
 - Moderna COVID-19 vaccine remains under EUA for the following indications:
 - Third primary series doses for individuals 18 years of age and older who have been determined to have certain kinds of immunocompromise
 - Single booster dose for individuals 18 year of age and older at least five months after completing a primary series
- On February 4, 2022, ACIP revised its interim recommendation to a standard recommendation for use of Moderna COVID-19 vaccine in persons aged ≥18 years

Extended interval between 1st and 2nd mRNA COVID-19 vaccine dose: review of evidence

 ACIP reviewed evidence related to an extended interval between the 1st and 2nd dose of mRNA vaccines

 Some studies in adolescents and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness may be increased with an interval longer than 4 weeks

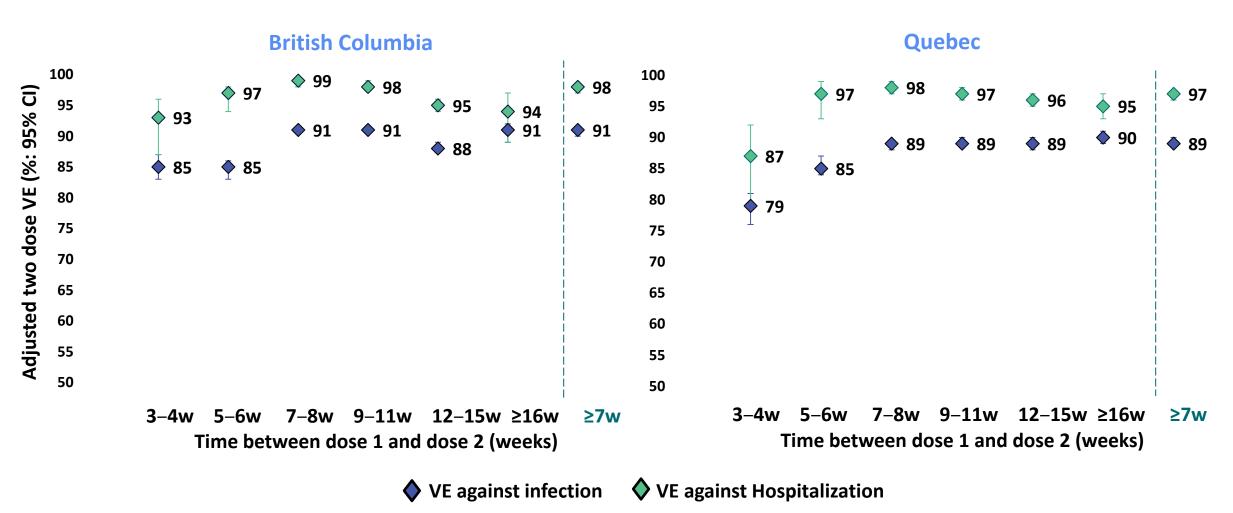
Ontario, Canada: Reporting rate of myocarditis/pericarditis per million doses among males ages 18–24 years by vaccine product* and interval



Source: Buchan S et al. Dec 2021, MedRxiv preprint.

^{*}Moderna-Pfizer not shown here because there were no reported events in males ages 18–24 years; a smaller number of males in this age group received this schedule (n=8,853).

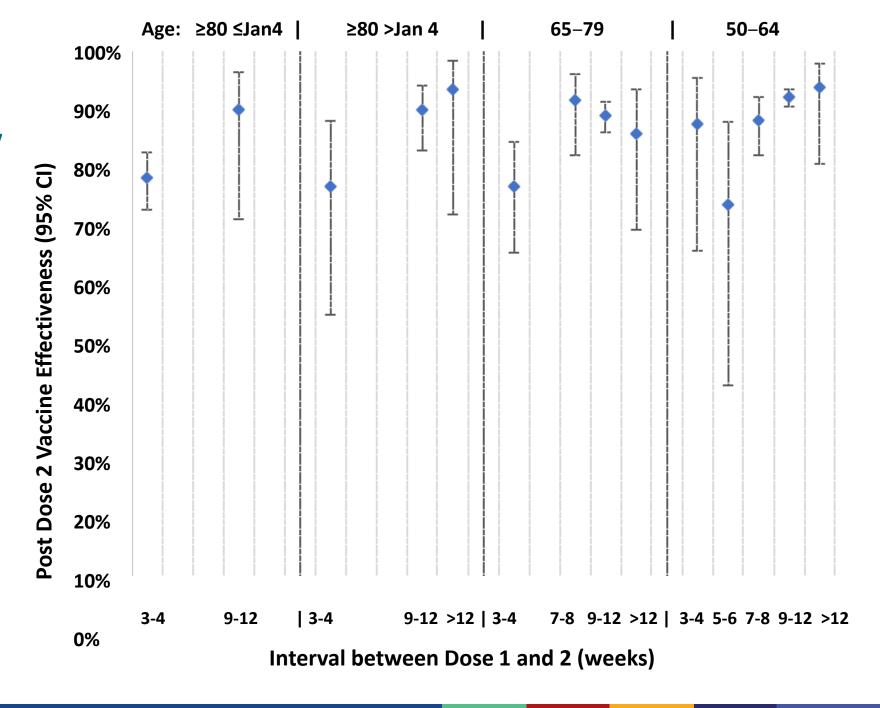
British Columbia and Quebec, Canada: Vaccine effectiveness of any two doses of mRNA vaccines by primary series interval



Source: Skowronski DM. 2021, MedRxiv preprint.

England: Pfizer vaccine effectiveness by primary series interval

Pfizer vaccine
 effectiveness against
 symptomatic SARS-CoV 2 infection was higher
 with an extended
 interval (>6 weeks)
 compared to a standard
 interval (3–4 weeks) for
 all age groups.



Immunogenicity with extended primary series interval

- Payne et al. (UK): Among SARS-CoV-2 infection naïve persons in an observational cohort, serological responses were higher after an extended dosing interval (6–14 week) compared to a standard interval (3–4 week).
 - Among persons with an extended interval, there were higher antibody and B cell responses, as well as sustained B and T cell responses, compared to a standard interval.
 - An extended interval may promote efficient T cell expansion and long-term memory cell persistence.
- Amirthalingam et al. (England), Parry et al. (England), & Grunau et al (Canada):
 Neutralizing antibody titers were higher following an extended dosing interval with
 mRNA vaccine, compared to a standard interval.

Summary

- Rates of myocarditis/pericarditis were lower with extended interval between first and second dose of mRNA vaccine primary series.
- Extended primary series interval may improve immunogenicity and vaccine effectiveness.

Self-knowledge Check

Extending the interval between the 1st and 2nd mRNA COVID-19 vaccine dose to 8 weeks may help to:

- A. Reduce the small risk of myocarditis
- B. Increase vaccine effectiveness
- C. A and B

Self-knowledge Check

The correct answer is: <u>C</u>.

Some studies in adolescents and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness may be increased with an interval longer than 4 weeks.

Updates to the Interim Clinical Considerations for People who are Moderately or Severely Immunocompromised



People Who Are Moderately or Severely Immunocompromised

- People with immunocompromising conditions or people who take immunosuppressive medications or therapies:
 - Are at increased risk for severe COVID-19
 - May not mount a protective immune response after initial vaccination
 - Have waning protection over time

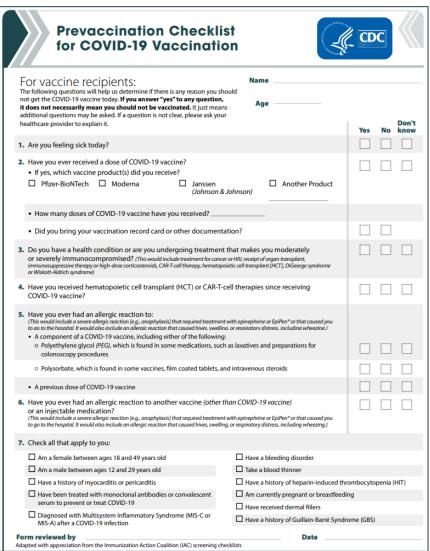
People Who Are Moderately or Severely Immunocompromised

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (HCT) (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#vaccination-people-immunocompromised

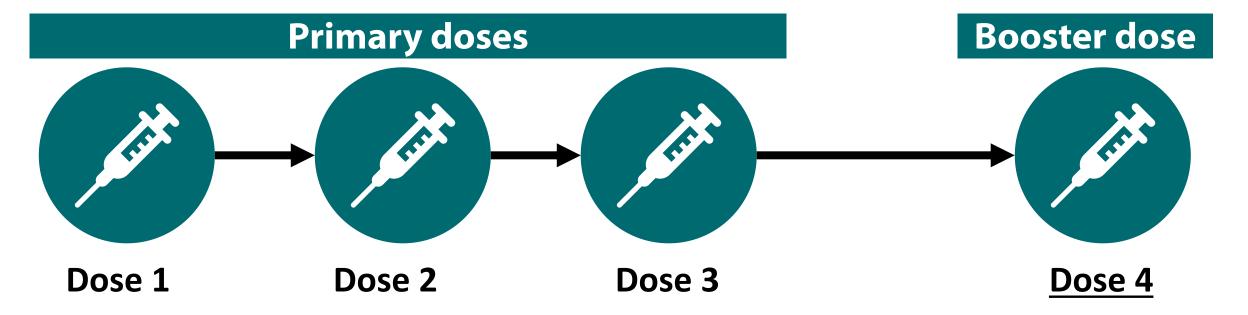
People Who Are Moderately or Severely Immunocompromised

- Individuals can self-attest.
- Patients do NOT need to provide documentation.
- Vaccinators should NOT deny COVID-19 vaccination to a person due to lack of documentation.
- People who are moderately or severely immunocompromised can discuss questions with their healthcare provider about whether this schedule is appropriate for them.
- CDC offers a prevaccination checklist, where people can check if they are considered moderately or severely immunocompromised.



Clarification of Existing Recommendation for mRNA COVID-19 Vaccine Primary Series

- People who are moderately or severely immunocompromised should receive:
 - 3-dose primary series
 - 1 booster dose



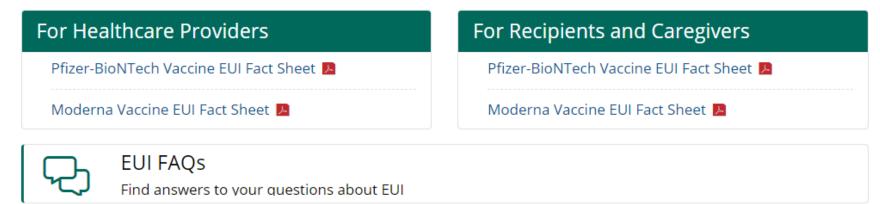
Emergency Use Instructions (EUI)

- Enacted under the Pandemic and All-Hazards Preparedness Reauthorization Act of
 2013 and delegated to the CDC Director
 - Allows creating and disseminating emergency use instructions to healthcare providers and/or recipients
 - EUI only apply to FDA-approved, licensed or cleared medical products regarding their approved indications
- Provides information about emergency use of FDA-approved medical products that may not be included or differ from the information provided in the FDA-approved labeling package insert.
- Applies only to the use of:
 - Spikevax (Moderna) for people ages 18 years and older
 - Comirnaty (Pfizer-BioNTech) for people ages 12 years and older

Emergency Use Instructions (EUI)

COVID-19 Vaccine Emergency Use Instructions (EUI) Resources

CDC issued initial Emergency Use Instructions (EUI) for the Pfizer-BioNTech COVID-19 vaccine on November 17, 2021, and another EUI for the Moderna COVID-19 vaccine on February 11, 2022. EUI provide information about emergency use of FDA-approved medical products that may not be included in or differ in some way from the information provided in the FDA-approved labeling (package insert). See below the CDC-issued EUI fact sheets for healthcare providers and recipients/caregivers regarding Pfizer-BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine, and FAQs.



Page last reviewed: February 11, 2022

Content source: National Center for Immunization and Respiratory Diseases

Updated Guidance for a 3-Month Booster Interval After an mRNA COVID-19 Vaccine Primary Series

- People who are moderately or severely immunocompromised should receive a booster dose at least 3 months after the last (third) dose of an mRNA COVID-19 vaccine.
- Previously at least 5 months

^{1.} Kamar, N., Abravanel, F., Martion, O. (2021). Assessment of 4 Doses of SARS-CoV-2 Messenger RNA–Based Vaccine in Recipients of a Solid Organ Transplant. *Infectious Diseases, 4*(11), e2136030.

^{2.} Benotmane, I., Bruel, T., Planas, D., et al. (2021). A fourth dose of the mRNA-1273 SARS-CoV-2 vaccine improves serum neutralization against the delta variant in kidney transplant recipients. *medRxiv*. Preprint. doi.org/10.1101/2021.11.25.21266704

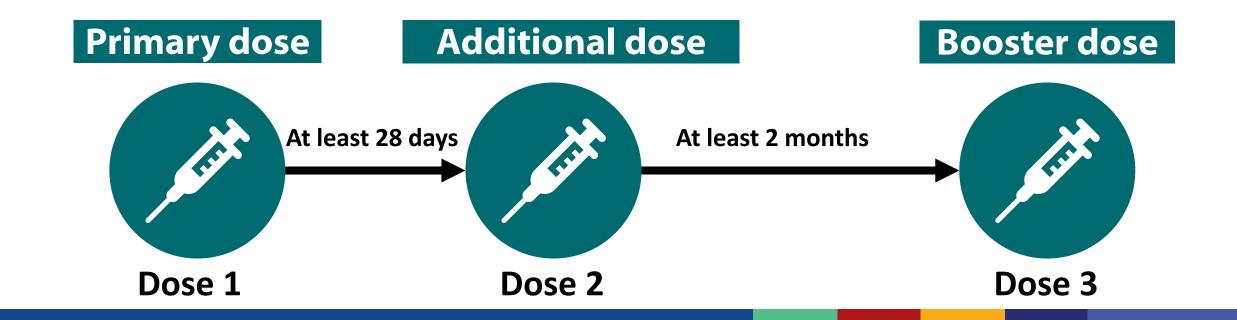
^{3.} Alejo, J.L., Mitchell, J., Chiang, T., et al. (2021). Antibody Response to a Fourth Dose of a SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients: A Case Series. Transplantation, 105(12), e280-281.

^{4.} Munro, A., Janani, L., Cornelius, V. (2021). Safety and immunogenicity of seven COVID-19 vaccines as a third dose (booster) following two doses of ChAdOx1 nCov-19 or BNT162b2 in the UK (COV-BOOST): a blinded, multicentre, randomised, controlled, phase 2 trial. *Lancet*, 398, 2258-76.

^{5.} Atmar, R.L., Lyke, K.E., Deming, M.E. (2021). Heterologous SARS-CoV-2 booster vaccinations-preliminary report. medRxiv. Preprint. doi: 10.1101/2021.10.10.21264827

Updated Guidance for People Who Received a Janssen COVID-19 Vaccine Primary Series

- Janssen COVID-19 vaccine recipients
 - Recommended to receive a 2nd (additional) dose using an mRNA
 COVID-19 vaccine at least 28 days after the Janssen dose, followed by a booster dose 2 months after the mRNA dose



Case-by-Case Decision Making Based on Clinical Judgment

On a case-by-case basis, providers who care for moderately or severely immunocompromised patients may administer mRNA COVID-19 vaccines outside of the FDA and CDC dosing intervals based on clinical judgment when the benefits of a different vaccination schedule or dosage are deemed to outweigh the potential and unknown risks.

Self-knowledge Check

At this time, how many total doses of COVID-19 vaccine should a moderately or severely immunocompromised person receive?

- **A.** 2
- **B**. 3
- **C.** 4
- D. Depends on their age and which vaccine they received for their primary series

Self-knowledge Check

The correct answer is: _D_.

mRNA COVID-19 vaccine recipients: A 3-dose primary series is recommended for people ages 5 years and older who are moderately or severely immunocompromised. People 12 and older should receive a booster dose, **for a total of 4 doses.**

Janssen COVID-19 vaccine recipients: A primary Janssen vaccine dose is recommended for people ages 18 years and older who are moderately or severely immunocompromised, followed by a second (additional) dose using an mRNA COVID-19 vaccine and a booster dose, **for a total of 3 doses.**

Additional Updates and Current COVID-19 Vaccination Recommendations by Age Group



Updated Guidance Passive Antibody Products

- Updated guidance
 - No recommended deferral period
 - However, tixagevimab/cilgavimab (EVUSHELD™) should be deferred for at least two weeks after vaccination
- Previous guidance was to defer COVID-19 vaccination for
 - 30 days if product used for post exposure prophylaxis
 - 90 days if product used for treatment

Recommendations for the Interval Between the First and Second mRNA COVID-19 Vaccine Doses

- Some people ages 12 through 64 years—and especially males ages 12 through 39 years—may benefit from getting their second mRNA COVID-19 vaccine dose 8 weeks after receiving their first dose
- Providers should continue to recommend the 3-week (Pfizer-BioNTech) or 4-week (Moderna) interval for patients who:
 - Are at higher risk of having an inadequate response to the first mRNA vaccine dose
 - People who are moderately or severely immunocompromised
 - Are at higher risk for severe COVID-19
 - Adults ages 65 years and older
 - Need rapid protection, such as during high levels of community transmission
 - Children ages 5–11 years

General Recommendations

- COVID-19 primary series vaccination is recommended for everyone ages
 5 years and older in the United States for the prevention of COVID-19
 - This includes people both with and without underlying medical conditions
 - People with moderate or severe immunocompromise have additional considerations and need more doses than most people.
- In most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for primary and booster vaccination.

Figure 1. COVID-19 Vaccination Schedule*

Vaccine	0 month	1 month	2 month	3 month	4 month	5 month	6 month	7 month
Pfizer- BioNTech (ages 5–11 years)	1 st dose	2nd dose (3 weeks after 1 st dose						
Pfizer- BioNTech (ages 12 years and older)	1 st dose	2nd dose† (3-8 weeks after 1 st dose) Booster dose‡ (at least 5 months after 2 nd dose)						nd dose)
Moderna (ages 18 years and older)	1 st dose	2 nd dose† (4-8 weeks after 1 st dose) Booster dose‡ (at least 5 months after 2 nd dose)					after 2 nd dose)	
Janssen (ages 18 years and older)	1 st dose		Booster dose‡ (at least 2 months after 1 st dose)					

Note: Timeline is approximate. Intervals of 3 months or fewer are converted into weeks per the formula "1 month = 4 weeks". Intervals of 4 months or more are converted into calendar months.

- * See <u>Guidance for COVID-19 vaccination for people who are moderately or severely immunocompromised</u> for schedule for people who are moderately or severely immunocompromised.
- † An 8-week interval may be optimal for some people ages 12 years and older, especially for males ages 12 to 39 years. A shorter interval (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for: people who are moderately or severely immunocompromised; adults ages 65 years and older; and others who need rapid protection due to increased concern about community transmission or risk of severe disease.
- ‡ An mRNA COVID-19 vaccine is preferred over the Janssen COVID-19 Vaccine for booster vaccination of people ages 18 years and older. For people ages 12–17 years, only Pfizer-BioNTech can be used. People ages 5–11 years should not receive a booster dose.

02/23/22

Figure 2. COVID-19 Vaccination Schedule for People Who Are Moderately or Severely Immunocompromised

Vaccine	0 month	1 month	2 month	3 month	4 month	5 month
Pfizer- BioNTech (ages 5–11 years)	1 st dose	2nd dose (3 weeks after 1 st dose)	3rd dose (at least 4 weeks after 2 nd dose)			
Pfizer- BioNTech (ages 12 years and older)	1 st dose	2 nd dose (3 weeks after 1 st dose)	3rd dose (at least 4 weeks after 2 nd dose)		(a m	ooster dose* t least 3 onths after d dose)
Moderna (ages 18 years and older)	1 st dose	2 nd dose (4 weeks after 1 st dose)	3rd dose (at least 4 weeks after 2 nd dose)			Booster dose* (at least 3 months after 3 rd dose)
Janssen (ages 18 years and older)	1 st dose	2 nd (additional) dose [†] using an mRNA COVID-19 vaccine (at least 4 weeks after 1 st dose)		Booster dose* (at least 2 months after additional dose)		

Note: Timeline is approximate. Intervals of 3 months or fewer are converted into weeks per the formula "1 month = 4 weeks". Intervals of 4 months or more are converted into calendar months.

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^{*} An mRNA COVID-19 vaccine is preferred over the Janssen COVID-19 Vaccine for booster vaccination of people ages 18 years and older. For people ages 12–17 years, only Pfizer-BioNTech can be used. People ages 5–11 years should not receive a booster dose.

[†] Only Pfizer-BioNTech or Moderna COVID-19 Vaccine should be used. See Appendix B for more information on vaccinating people who are moderately or severely immunocompromised and who received Janssen COVID-19 Vaccine for the primary series.

Self-knowledge Check

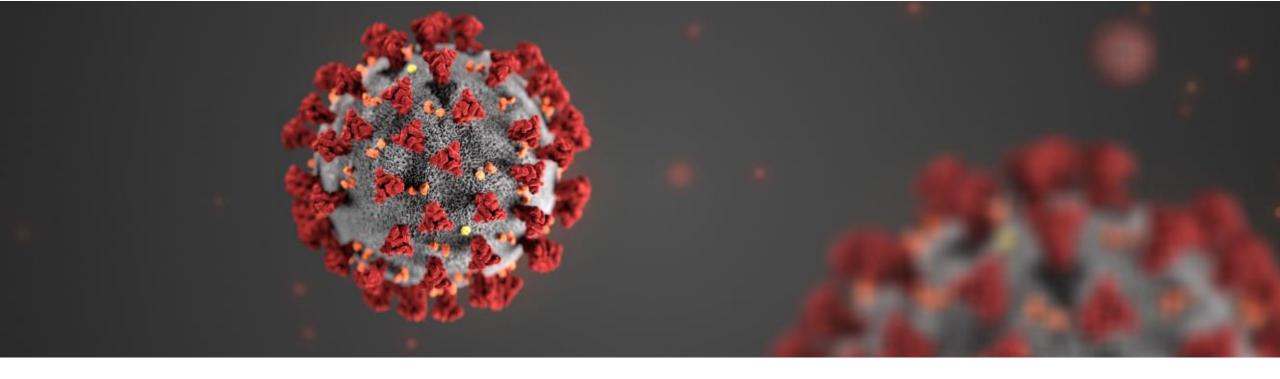
Which people are among groups who should continue to receive their 2nd mRNA COVID-19 dose at 3 or 4 weeks after their 1st dose?

- A. People who are moderately or severely immunocompromised
- B. Adults ages 65 years and older
- C. People in areas of high levels of community transmission
- D. Children ages 5–11 years
- E. All of the above

Self-knowledge Check

The correct answer is: <u>E</u>.

A 3- or 4- week interval is still recommended for people who are at higher risk of having an inadequate response to the first mRNA vaccine dose, are at higher risk for severe complications of COVID-19, or need rapid protection.



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.



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- 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

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- 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 before March 28, 2022, with the course code WC4520-022422. The access code is COCA022422.
- Those who will participate in the on-demand activity and wish to receive continuing education should complete the online evaluation between March 29, 2022, and before March 29, 2024, and use course code WD4520-022422. The access code is COCA022422.
- 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_022422.asp

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

Upcoming COCA Calls & Additional COVID-19 Resources

- Continue to visit https://emergency.cdc.gov/coca/ to get more details about upcoming COCA Calls, as COCA intends to host more COCA Calls to keep you informed of the latest guidance and updates on COVID-19.
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