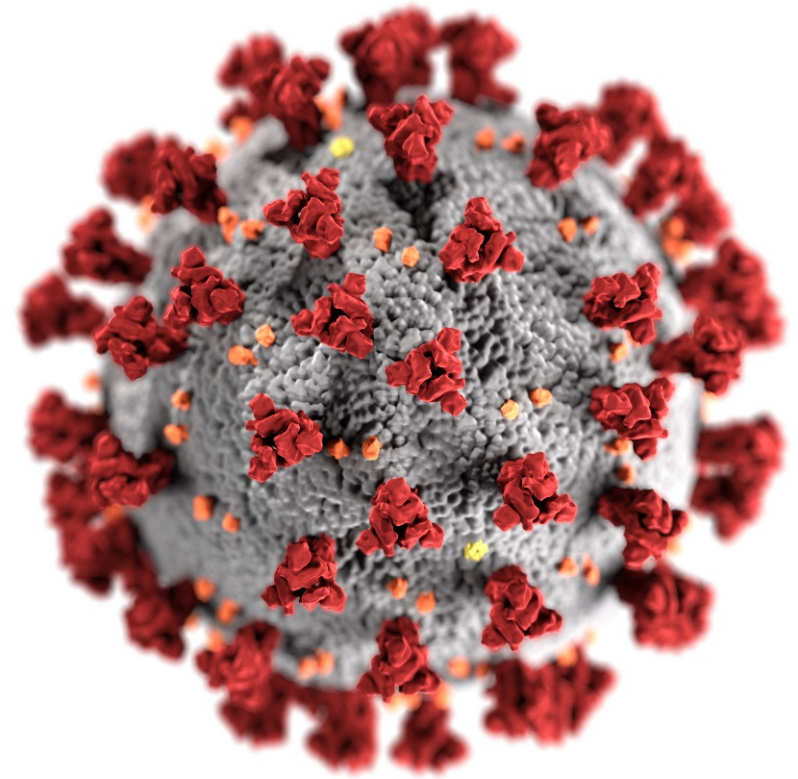


Interim Clinical Considerations for Use of COVID-19 Vaccines: Latest Updates

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Advisory Committee on Immunization
Practices Meeting, January 5, 2022



cdc.gov/coronavirus

Interim Clinical Considerations for Use of COVID-19 Vaccines

Summary of Latest Updates* and Anticipated Next Updates

Date of Update	Highlighted Updates to Interim Clinical Considerations
December 10, 2021	<ul style="list-style-type: none"> Updated guidance for booster dose: Pfizer-BioNTech in adolescents ages 16–17 years
December 17, 2021	<ul style="list-style-type: none"> Updated guidance on use of Janssen (J&J) with preferential recommendation for mRNA vaccines
December 23, 2021	<ul style="list-style-type: none"> Newest formulation of Pfizer-BioNTech – “gray top”
<i>Anticipated</i> January 6, 2022	<ul style="list-style-type: none"> Guidance to reflect outcomes of the ACIP meeting 1/5/22 Third Pfizer-BioNTech primary series dose for some children ages 5–11 years with immunocompromise Decrease in booster interval after Pfizer-BioNTech primary series: now 5 months

*Find all historical updates here: [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](#)

Latest Updates to Interim Clinical Considerations: December 2021



Adolescents ages 16–17 years may receive a booster dose of Pfizer-BioNTech ≥ 6 mos after completion of primary series

- Safe:
 - Vaccine safety surveillance data for adolescents ages 16–17 years included in data previously reviewed by ACIP
 - Myocarditis risk after booster less than that after 2nd dose¹
- Effective:
 - Relative vaccine efficacy (RVE) for booster vaccination of 95.3% among adolescents ages 16-17 years who received a booster dose in previous 2 months compared with those who had completed primary series only²
- Needed:
 - 4.7 million adolescents ages 16–17 years were fully vaccinated with Pfizer-BioNTech³
- Recommended:
 - Following amendment of Pfizer-BioNTech EUA, CDC recommended that people adolescents 16–17 years may receive a Pfizer-BioNTech booster dose based on their individual benefits and risks⁴

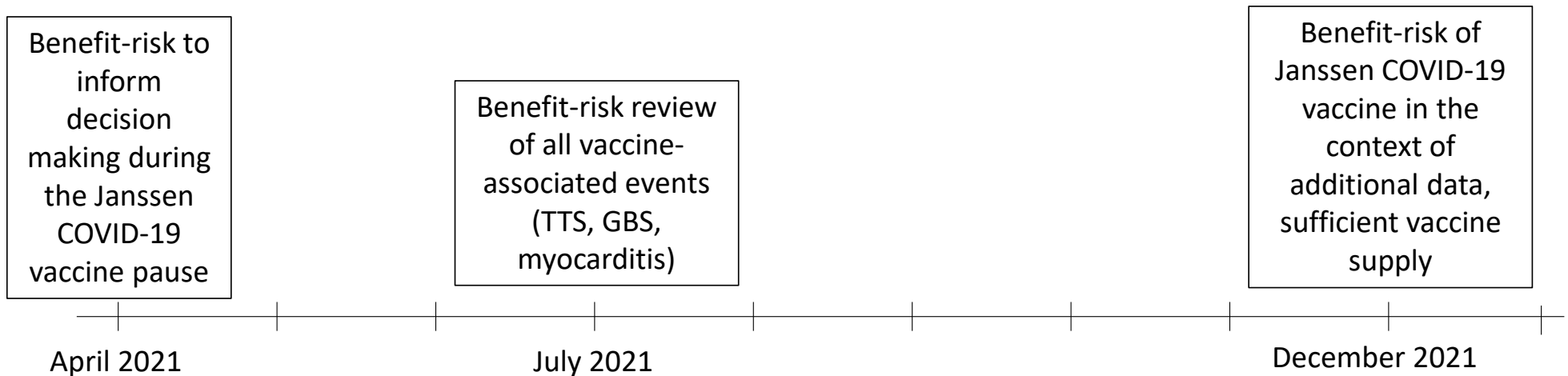
1 FDA Review Memorandum, describing Israel Ministry of Health Vaccine Safety Data, 8 December 2020

2 FDA Review Memorandum, Pfizer-BioNTech Booster for Ages 16-17, 8 December 2021

3 CDC Vaccine Surveillance Data, 8 December 2021




4 CDC Interim Clinical Considerations, 10 December 2021

Preferential recommendation for mRNA vaccines



- Additional case review and ongoing safety surveillance identified cases (previous and newly occurring) of TTS, including deaths
- No longer in the setting of limited mRNA COVID-19 vaccine supply in the US
- ACIP December 16 Vote: mRNA COVID-19 vaccines are **preferred** over the Janssen COVID-19 vaccine for the prevention of COVID-19 for those aged ≥ 18 years

Newest formulation of Pfizer-BioNTech COVID-19 Vaccine

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use
Age Group	12 years and older ^{1,2}	12 years and older ³	5 through 11 years ⁴ ("Age 5y to <12y" on vial label)
Vial Cap Color			
Dose	30 mcg	30 mcg	10 mcg
Dose Volume	0.3 mL	0.3 mL	0.2 mL
Amount of Diluent Needed per Vial [†]	1.8 mL	NO DILUTION	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)

Storage Conditions

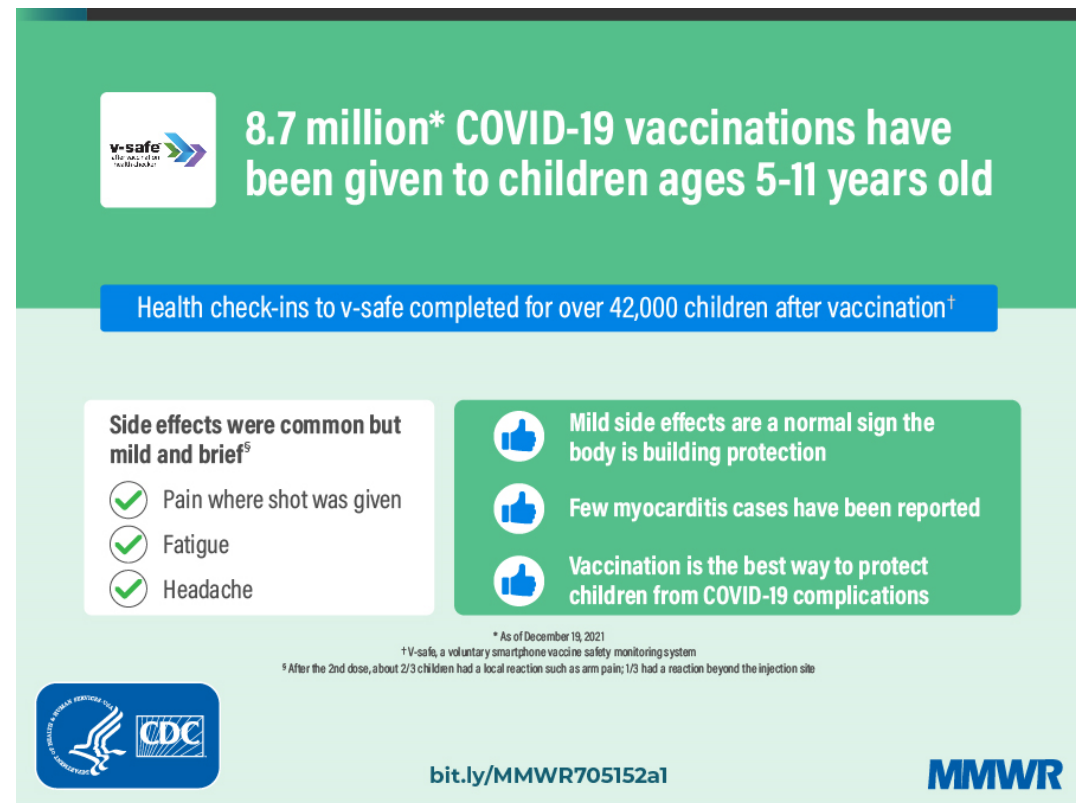
Ultra-Low-Temperature (ULT) Freezer [-90°C to -60°C (-130°F to -76°F)]	9 months [†]	6 months [†]	6 months [†]
Freezer [-25°C to -15°C (-13°F to 5°F)]	2 weeks	DO NOT STORE	DO NOT STORE
Refrigerator [2°C to 8°C (35°F to 46°F)]	1 month	10 weeks	10 weeks
Room Temperature [8°C to 25°C (46°F to 77°F)]	2 hours prior to dilution (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to dilution (including any thaw time)
After First Puncture [2°C to 25°C (35°F to 77°F)]	Discard after 6 hours	Discard after 12 hours	Discard after 12 hours

Anticipated Updates to Interim Clinical Considerations: January 6, 2022



Some children ages 5–11 years with immunocompromise should receive an additional Pfizer-BioNTech primary series dose

- Vaccine effectiveness is lower among patients with immunocompromise¹
- CDC recommends an additional primary series mRNA vaccine dose in people with immunocompromise aged ≥12 years²
- Approximately 1.4 million children ages 5-17 have an immunocompromising condition³
- Safety findings from VAERS and v-safe during administration of >8 million doses of Pfizer-BioNTech: rare reporting of any serious side effects⁴



Moderately and severe immunocompromise

- 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 (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., ≥ 20 mg 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



Pfizer-BioNTech booster 5 months after completion of a primary series of COVID-19 vaccination for those eligible

- People who have completed a primary series *and booster* may be better protected against symptomatic infection with Omicron than those without booster^{1,2}
- Two studies from Israel document the effectiveness of Pfizer-BioNTech booster dose 5 months after primary series against severe illness³ and death⁴ secondary to COVID-19
- 188 million (73%) of U.S. adults aged ≥ 18 years are fully vaccinated; 38% of those have received a booster⁵
- 4.74 million (57%) of U.S. adolescents* ages 16-17 are fully vaccinated with Pfizer-BioNTech COVID-19 vaccine; 6% have received a booster⁶
- Rare occurrences of myocarditis in people aged ≥ 16 years following a booster dose at 5 months occurred at less than half the rate observed following 2nd dose⁷

1 Andrews et al [MedRx preprint](#) 14 Dec 2021; 2 Ferguson et al [Report 49](#) 16 Dec 2021; 3 Bar-On et al NEJM 23 Dec 2021; 4 Arbel et al NEJM 23 Dec 2021; 5 CDC COVID Data Tracker, 4 Jan 2022; 6 CDC Immunization Data Lake 3 January 2022; 7 Israel Ministry of Health Vaccine Safety Update 15 Dec 2021

* Vaccination data is not available for Idaho

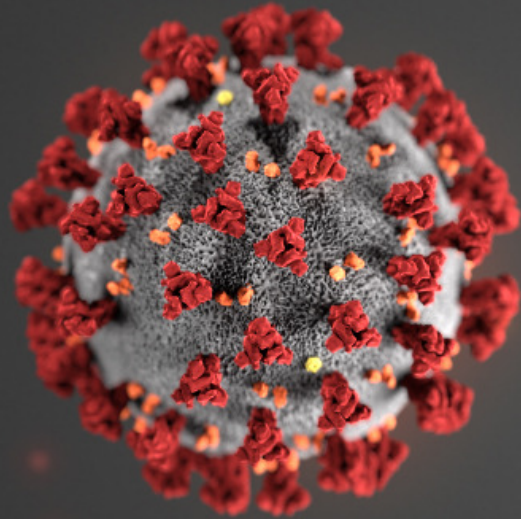
COVID-19 Vaccine Booster Dose by Primary Series, with Interval

Primary series COVID-19 vaccine product*	Age for vaccine booster (years)	Interval between final primary dose and booster dose	COVID-19 vaccine products that may be given as booster dose*
Pfizer-BioNTech	≥16 (may change to ≥12)	≥5 months	Pfizer-BioNTech Moderna Janssen/J&J
Moderna	≥18	≥6 months	Pfizer-BioNTech Moderna Janssen/J&J
Janssen/J&J	≥18	≥2 months	Pfizer-BioNTech Moderna Janssen/J&J

*Only Pfizer-BioNTech is authorized as primary series or booster dose for people aged <18 years. For the prevention of COVID-19 in those aged ≥18 years, mRNA vaccines (Pfizer-BioNTech; Moderna) are preferred over the Janssen/J&J COVID-19 Vaccine for both primary series and booster doses.

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- DAV Vaccine Team
- Vaccine Safety Team
- Epidemiology and Surveillance Task Force
- Vaccine Task Force



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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.

