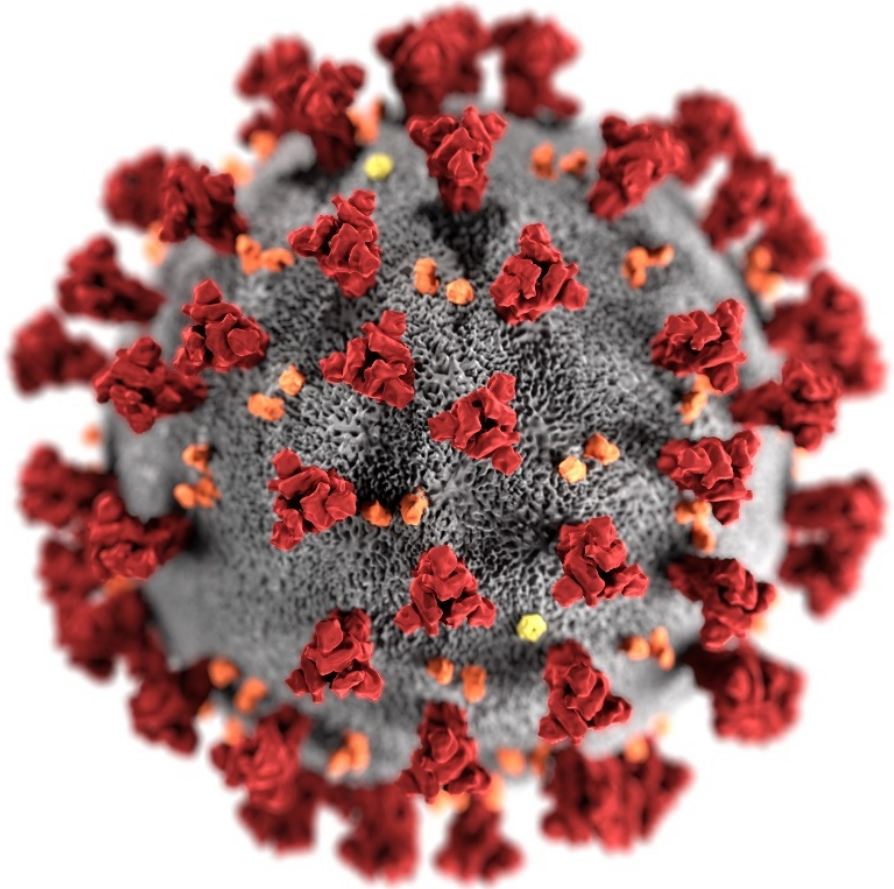
Interim Clinical Considerations for Pfizer-BioNTech COVID-19 Vaccine Booster Doses



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Definition of ‘fully vaccinated’

- For public health purposes, people who have completed a primary vaccine series (i.e. 2-dose mRNA vaccine series or a single dose of the Janssen vaccine) are considered fully vaccinated ≥2 weeks after completion of the primary series

- The above definition applies to all people including those who receive an additional dose as recommended for moderate to severely immunocompromised people and those who receive a booster dose

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html

Administration- Booster dose

- Pfizer-BioNTech COVID-Vaccine (BTN162b2), 0.3ml, intramuscular administration
- Timing: ≥6 months after completion of the primary series
  - Immunity wanes gradually over time, therefore a booster may be given at an interval greater than 6 months
- Co-administration: a Pfizer-BioNTech COVID-Vaccine booster dose may be given with other vaccines, without regard to timing. This includes simultaneous administration of COVID-19 and other vaccines on the same day.

Groups at risk for severe COVID-19 or SAR-CoV-2 infection after primary series vaccination

Age-Based Group: people aged ≥ 65 years

- Increased risk of severe COVID-19 (including hospitalization and death) this age group of fully vaccinated people compared to younger fully vaccinated people
- Waning of COVID-19 vaccine effectiveness against severe disease has been observed in people aged ≥65yrs

Risk-Based Group: Long Term Care Facility (LTCF) residents

- Residents of LTCFs, aged ≥18 years
- Likely increased risk of severe COVID-19 (including hospitalization and death) among fully vaccinated residents compared to fully vaccinated people living independently
- Waning of COVID-19 vaccine protection against infection has been observed in LTCF residents
- Congregate living setting associated with increased risk of COVID-19

Risk-Based Group: occupation or setting

- Aged ≥18 years
- Fully vaccinated persons may be at increased risk of SARS-CoV-2 infection due to occupation or setting
- Absence from occupation due to SARS-CoV-2 infection may hinder societal functions

Examples

- Essential workers* (frontline and non-frontline)
- Unpaid caregiver of a frail or immunocompromised person
- Paid and unpaid workers who interact within <6ft of others
- Live in a congregate setting (e.g. homeless shelter, correctional facility)

* Guidance on the Essential Critical Infrastructure Workforce | CISA

Risk-Based Group: underlying medical conditions

- Aged ≥18 years
- Fully vaccinated persons with underlying medical conditions may be at risk of severe COVID-19 if they become infected with SARS-CoV-2

Examples:

• Cancer • Cerebrovascular disease • Chronic kidney disease • COPD (chronic obstructive pulmonary disease) • Diabetes mellitus, type 1 and type 2	• Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies) • Obesity (BMI ≥30 kg/m2) • Pregnancy and recent pregnancy • Smoking, current and former

Underlying Medical Conditions for Clinicians (cdc.gov)

Considerations for the individual level assessment of benefits and risks of a COVID-19 booster dose

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Potential Benefits

- May confer reduced risk of severe disease
  - Strongest evidence in older adults
  - Vaccine effectiveness of an mRNA primary series remains high in younger age groups
- May confer reduced risk of SARS–CoV-2 infection
  - Waning of vaccine protection via a combination of time since vaccination and delta variant has been observed in most age groups
  - Infection may be symptomatic or asymptomatic
  - May reduce work absence and preserve capacity of important sectors
  - May reduce transmission of SARS-CoV-2 infection to other at-risk persons

Considerations for the individual level assessment of benefits and risks a COVID-19 booster dose

Potential risks

- Myocarditis and myopericarditis, although very rare, may occur following mRNA vaccination. It is more common in younger age groups, particularly males aged <30 years.
  - Most patients with myocarditis have been hospitalized for short periods, with the majority achieving resolution of acute symptoms
  - The rate of myocarditis following a booster dose is not yet known
- Anaphylaxis, although rare, may occur following mRNA vaccination. The rate of anaphylaxis following a booster dose is not yet known
- Reactogenicty, including transient local and systemic symptoms, are common following mRNA vaccines. The 3rd dose of Pfizer-BioNTech COVID-19 vaccine appears to have similar reactogenicity as the 2nd dose.

Considerations for the individual level assessment of benefits and risks a COVID-19 booster dose

Consider individual risk of SARS-CoV-2 exposure

- Risk of exposure in occupational, living and transportation settings
- Ability to consistently wear a mask, maintain social distance, and other mitigation measures
- Rates of SAR-CoV-2 infection in the community

Consider individual risk of developing severe COVID-19, if infected

- Underlying medical conditions, particularly if not well controlled

Consider personal characteristics

- Living with or caring for a frail or immunocompromised person
- Consequences of inability to meet personal or occupational obligations due to SARS-CoV-2 infection

Contraindications, Precautions & other Adverse Events Following Immunization

Contraindications & Precautions

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the Pfizer BioNTech COVID-19 vaccine
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine

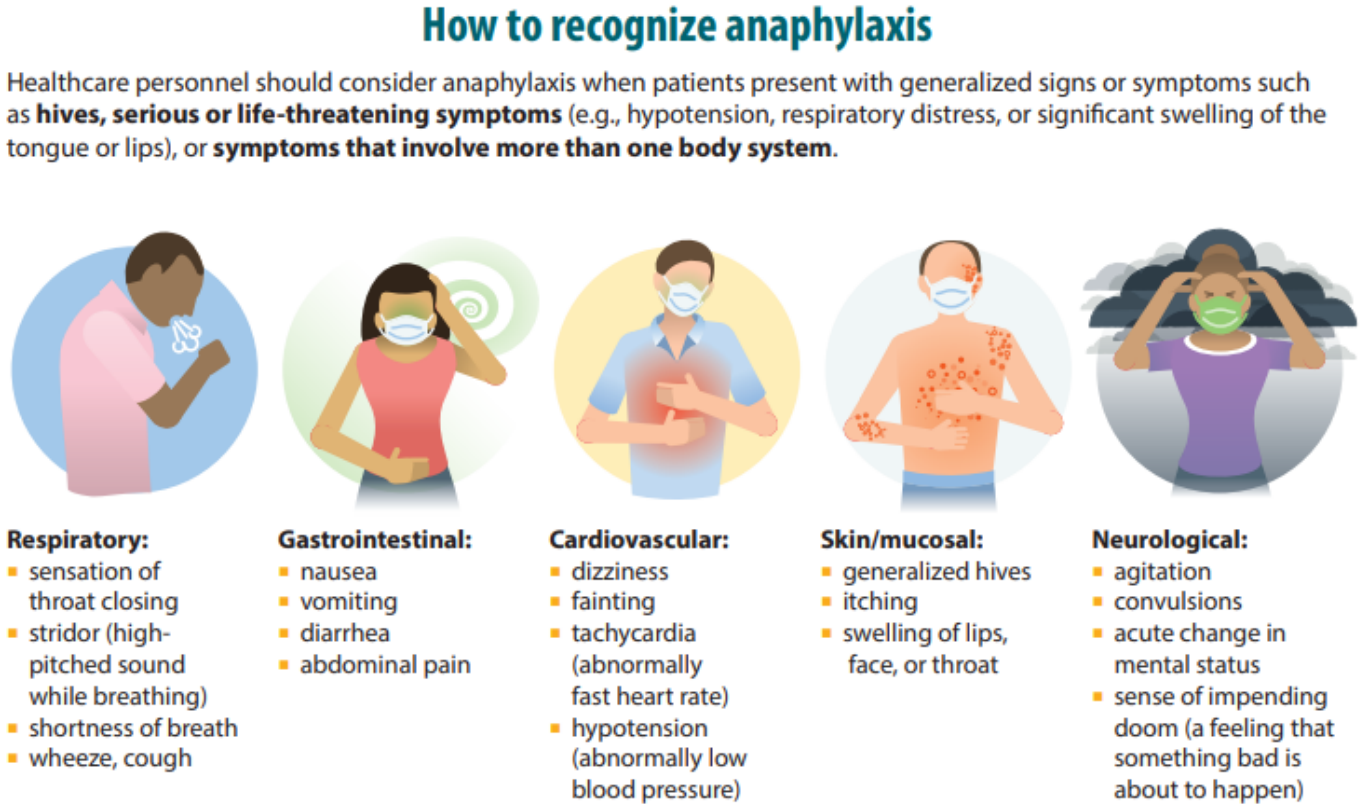
- Known polysorbate allergy is a precaution to mRNA COVID-19 vaccination

Myocarditis or myopericarditis after a dose of mRNA COVID-19 vaccine:

- Recommend deferral of a subsequent dose
- People who choose to receive a sequent dose should wait until myocarditis or myopericarditis has completely resolved

Anaphylaxis

- Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines.
- https://www.cdc.gov/vaccines/covid-19/downloads/IntermConsid-Anaphylaxis-covid19-vaccine-sites.pdf

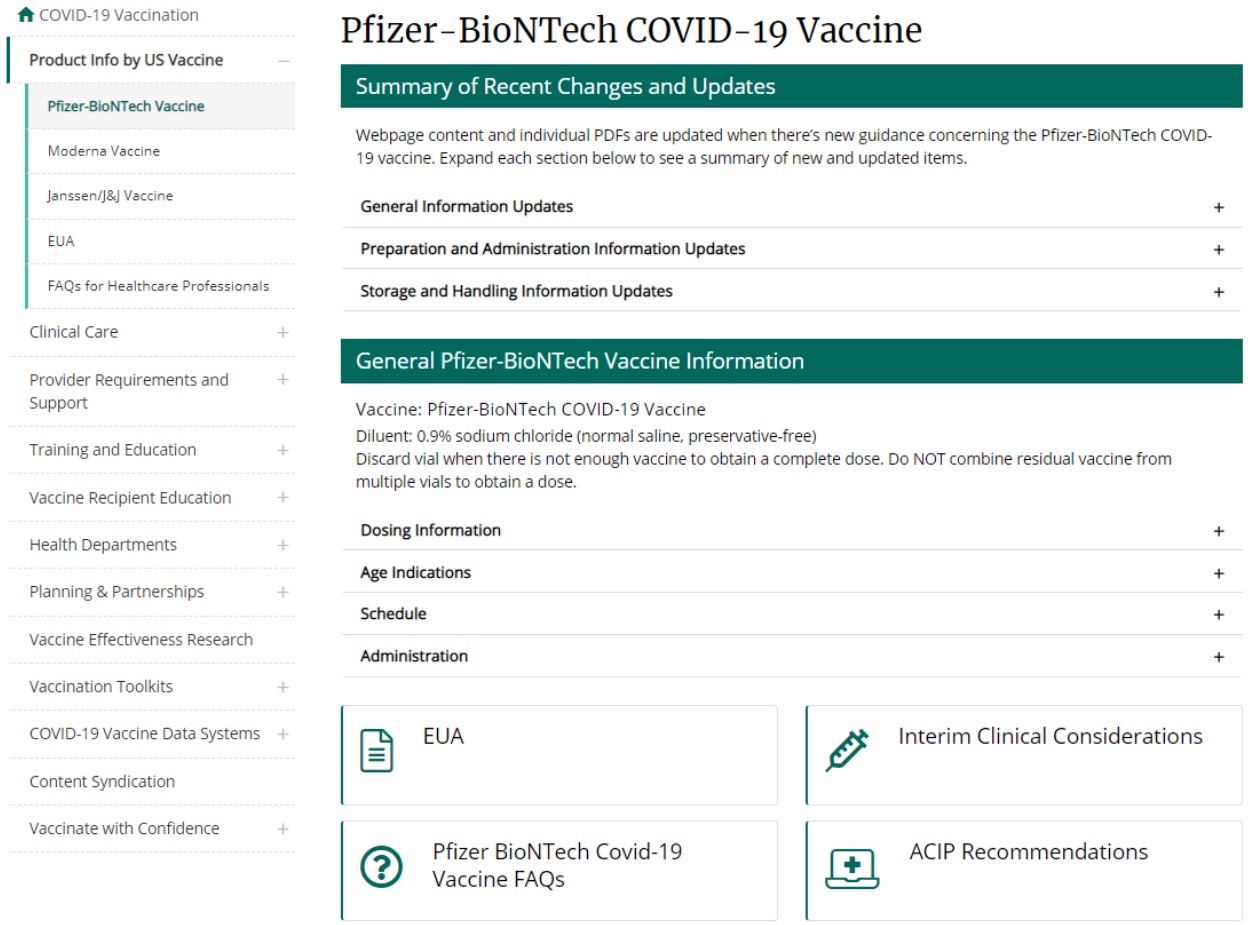


Additional resources

CDC Resources

Learn more with **CDC's COVID-19 vaccine tools and resources.** Find information for COVID-19 vaccination administration, storage, reporting, patient education, and more.

- COVID-19 Vaccination: https://www.cdc.gov/vaccines/covid-19/index.html
- For Healthcare Professionals: https://www.cdc.gov/vaccines/covid-19/hcp/index.html



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.

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