



# COVID-19 Update

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# Daily new confirmed COVID-19 cases

Shown is the rolling 7-day average. The number of confirmed cases is lower than the number of actual cases; the main reason for that is limited testing.



Source: Johns Hopkins University CSSE COVID-19 Data - Last updated 13 December, 06:06 (London time)

# Daily new confirmed COVID-19 deaths

Shown is the rolling 7-day average. Limited testing and challenges in the attribution of the cause of death means that the number of confirmed deaths may not be an accurate count of the true number of deaths from COVID-19.



Source: Johns Hopkins University CSSE COVID-19 Data - Last updated 13 December, 06:06 (London time)

DECEMBER 7, 1941

A DATE WHICH  
WILL LIVE IN  
INFAMY...



SEPTEMBER 11, 2001

AMERICA'S  
DARKEST DAY...



DECEMBER 9, 2020

JUST ANOTHER  
WEDNESDAY...



ROB

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# Clinical considerations for use of Pfizer-BioNTech COVID-19 vaccine

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# Administration

- 2-dose series administered intramuscularly 3 weeks apart
  - Administration of 2<sup>nd</sup> dose within 4-day grace period (e.g., day 17-21) considered valid
  - If >21 days since 1<sup>st</sup> dose, 2<sup>nd</sup> dose should be administered at earliest opportunity (but no doses need to be repeated)
  - Both doses are necessary for protection; efficacy of a single dose has not been systematically evaluated
- 

# Interchangeability with other COVID-19 vaccine products

- Pfizer-BioNTech COVID-19 vaccine not interchangeable with other COVID-19 vaccine products
  - Safety and efficacy of a mixed series has not been evaluated
- Persons initiating series with Pfizer-BioNTech COVID-19 vaccine should complete series with same product
- If two doses of different mRNA COVID-19 vaccine products inadvertently administered, no additional doses of either vaccine recommended at this time
  - Recommendations may be updated as further information becomes available or additional vaccine types authorized



# Coadministration with other vaccines

- Pfizer-BioNTech COVID-19 vaccine should be administered alone with a minimum interval of 14 days before or after administration with any other vaccines
- If Pfizer-BioNTech COVID-19 vaccine is inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine



## Persons with a history of SARS-CoV-2 infection

- Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
  - Data from phase 2/3 clinical trials suggest vaccination safe and likely efficacious in these persons
- Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision-making





# Persons with known current SARS-CoV-2 infection

- Vaccination should be deferred until recovery from acute illness (if person had symptoms) *and* criteria have been met to discontinue isolation
- No minimal interval between infection and vaccination
- However, current evidence suggests reinfection uncommon in the 90 days after initial infection and thus persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html>  
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>



# Persons who previously received passive antibody therapy for COVID-19

- Currently no data on safety or efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment
- Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses
  - Based on estimated half-life of therapies and evidence suggesting reinfection is uncommon within 90 days of initial infection



# Persons with a known SARS-CoV-2 exposure

- **Community or outpatient setting:**
  - Defer vaccination until [quarantine period](#) has ended to avoid exposing healthcare personnel (HCP) or other persons during vaccination visit
- **Residents of congregate healthcare settings (e.g., long-term care facilities):**
  - May be vaccinated, as likely would not result in additional exposures. HCP are already in [close contact with residents and should employ appropriate infection prevention and control procedures](#)
- **Residents of other congregate settings (e.g., correctional facilities, homeless shelters)**
  - May be vaccinated, in order to avoid delays and missed opportunities for vaccination
  - Where feasible, precautions should be taken to limit mixing of these individuals with other residents or non-essential staff

<https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html>

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>



# Persons with underlying medical conditions

- Vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccination
- Phase 2/3 clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities

<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>



# Immunocompromised persons

- Persons with HIV infection, other immunocompromising conditions, or who take [immunosuppressive medications or therapies might be at increased risk for severe COVID-19](#)
- Data not currently available to establish safety and efficacy of vaccine in these groups
- These individuals may still receive COVID-19 vaccine unless otherwise contraindicated
- Individuals should be counseled about:
  - Unknown vaccine safety and efficacy profiles in immunocompromised persons
  - Potential for reduced immune responses
  - Need to continue to follow all current guidance to protect themselves against COVID-19

<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>



# Pregnant women

- There are no data on the safety of COVID-19 vaccines in pregnant women
  - Animal developmental and reproductive toxicity (DART) studies are ongoing
  - Studies in humans are ongoing and more planned
- mRNA vaccines and pregnancy
  - Not live vaccines
  - They are degraded quickly by normal cellular processes and don't enter the nucleus of the cell
- COVID-19 and pregnancy
  - Increased risk of severe illness (ICU admission, mechanical ventilation and death)
  - Might be an increased risk of adverse pregnancy outcomes, such as preterm birth
- If a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine and is pregnant, she may choose to be vaccinated. A discussion with her healthcare provider can help her make an informed decision.





# Pregnant women

- Considerations for vaccination:
  - level of COVID-19 community transmission, (risk of acquisition)
  - her personal risk of contracting COVID-19, (by occupation or other activities)
  - the risks of COVID-19 to her and potential risks to the fetus
  - the efficacy of the vaccine
  - the known side effects of the vaccine
  - the lack of data about the vaccine during pregnancy
- Pregnant women who experience fever following vaccination should be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes
- Routine testing for pregnancy prior to receipt of a COVID-19 vaccine is not recommended.



# Breastfeeding/Lactating women

- There are no data on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or milk production/excretion
- mRNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant
- If a lactating woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated



# Reactogenicity

- Before vaccination, providers should counsel vaccine recipients about expected local and systemic post-vaccination symptoms
- Unless a person develops a contraindication to vaccination, they should be encouraged to complete the series even if they develop post-vaccination symptoms in order to optimize protection against COVID-19
- Antipyretic or analgesic medications may be taken for treatment of post-vaccination symptoms
  - Routine prophylaxis for the purposes of preventing symptoms is not recommended at this time, due to lack of information on impact of use on vaccine-induced antibody responses



# Vaccine efficacy

- Two doses required to achieve high efficacy
  - Efficacy after 2<sup>nd</sup> dose: 95.0% (95% CI: 90.3%, 97.6%)
- Patients should be counseled on importance of completing the 2-dose series in order to optimize protection



# Public health recommendations for vaccinated persons

- Protection from vaccine is not immediate; vaccine is a 2-dose series and will take 1 to 2 weeks following the second dose to be considered fully vaccinated
- No vaccine is 100% effective
  - Given the currently limited information on how well the vaccine works in the general population; how much it may reduce disease, severity, or transmission; and how long protection lasts, vaccinated persons should continue to follow all [current guidance](#) to protect themselves and others, including:
    - Wearing a mask
    - Staying at least 6 feet away from others
    - Avoiding crowds
    - Washing hands often
    - Following [CDC travel guidance](#)
    - Following quarantine guidance after an exposure to someone with COVID-19
    - Following any applicable workplace or school guidance

# Contraindications and precautions

## ■ Package insert:

- Severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 vaccine is a contraindication to vaccination
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine

## ■ Because of reports of anaphylactic reactions vaccinated outside of clinical trials, the additional following guidance is proposed:

- Persons who have had a severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) should not receive the Pfizer-BioNTech vaccine at this time
- Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
  - Persons with a history of anaphylaxis: 30 minutes
  - All other persons: 15 mins

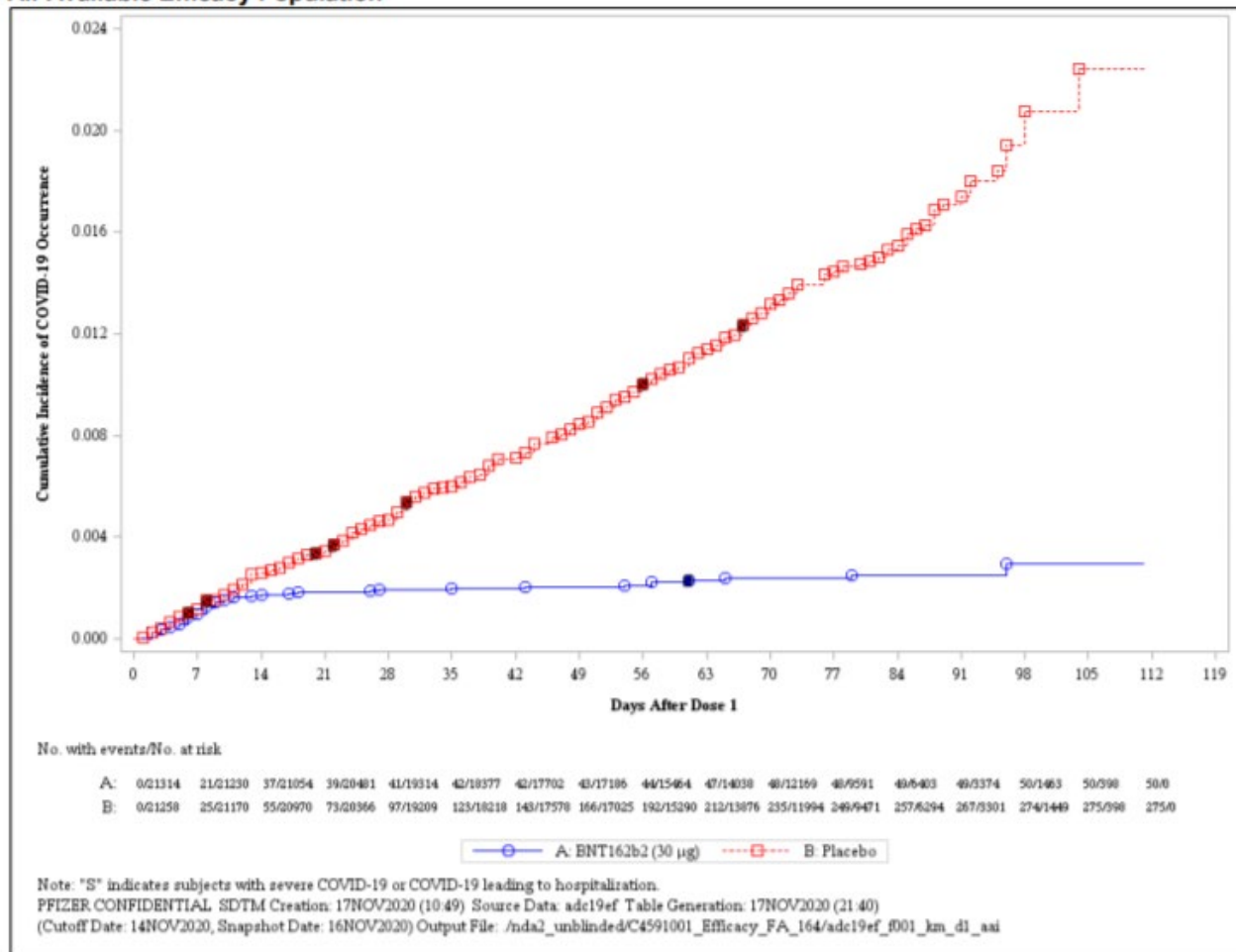


# SARS-CoV-2 tests

- **Viral tests:** Prior receipt of the Pfizer-BioNTech COVID-19 vaccine will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests
- **Antibody tests:**
  - Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to spike or nucleocapsid proteins
  - Pfizer-BioNTech COVID-19 vaccine contains mRNA that encodes the spike protein; thus, a positive test for spike protein IgM/IgG could indicate either prior infection or vaccination
  - To evaluate for evidence of prior infection in an individual with a history of Pfizer-BioNTech COVID-19 vaccination, a [test](#) specifically evaluating IgM/IgG to the nucleocapsid protein should be used

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance>

**Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1, Dose 1 All-Available Efficacy Population**

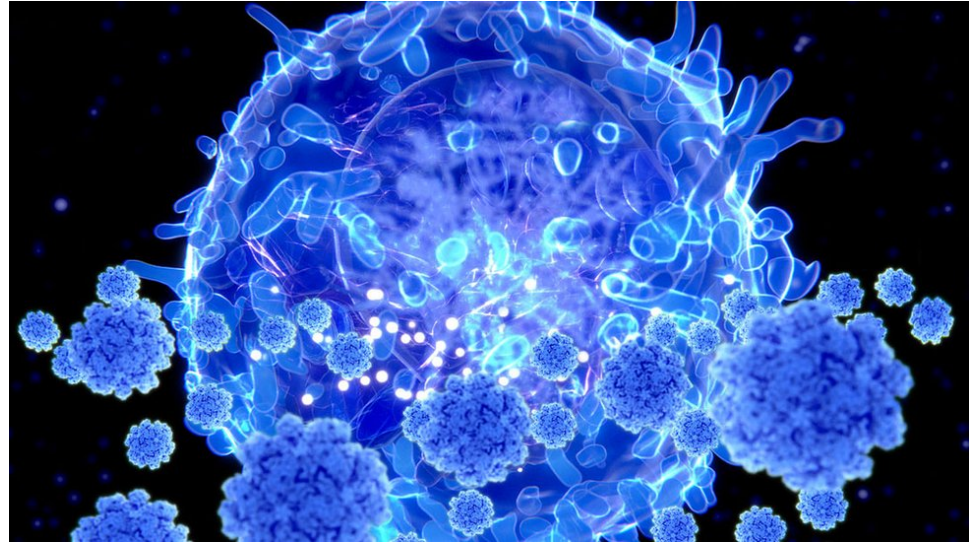


# Mix-n-Match

- Studies starting looking at giving one dose of one vaccine then a different vaccine 3+ weeks later e.g.

Pfizer + AZ/Oxford

AZ/Oxford + Sputnik V



All I want  
for Christmas  
is a ★ Vaccine





# Questions