Pfizer-BioNTech COVID-19 Vaccine Frequently Asked Questions

On December 11, 2020, the U.S. Food and Drug Administration issued the first emergency use authorization (EUA (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization)) for a vaccine for the prevention of coronavirus disease 2019 (COVID-19 (/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. On May 10, 2021, the FDA expanded the emergency use authorization for the Pfizer-BioNTech COVID-19 Vaccine to include adolescents 12 through 15 years of age. The emergency use authorization allows the Pfizer-BioNTech COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine) to be distributed in the U.S.

Q: What data did the FDA use to make the decision to authorize Pfizer-BioNTech COVID-19 Vaccine for emergency use?

A: Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

FDA evaluated and analyzed the safety and effectiveness data from clinical trials conducted in tens of thousands of study participants and manufacturing information submitted by Pfizer-BioNTech. FDA has determined that the totality of the available data provides clear evidence that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 and support that the known and potential benefits outweigh the known and potential risks of the vaccine's use in millions of people 16 years of age and older, including healthy individuals.

Q: What data did FDA evaluate to support Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine in individuals 12 through 15 years of age? (added 5/10/21)

A: The available safety data to support the EUA in adolescents in this age group include 2,260 participants ages 12 through 15 years old enrolled in an ongoing randomized, placebo-controlled clinical trial in the United States. Of these, 1,131 adolescent participants received the vaccine and 1,129 received a saline placebo. More than half of the participants were followed for safety for at least two months following the second dose.

The most commonly reported side effects in the adolescent clinical trial participants, which typically lasted 1-3 days, were pain at the injection site, tiredness, headache, chills, muscle pain, fever and joint pain. With the exception of pain at the injection site, more adolescents reported these side effects after the second dose than after the first dose, so it is important for vaccination providers and recipients to expect that there may be some side effects after either dose, but even more so after the second dose. The side effects in adolescents were consistent with those reported in clinical trial participants 16 years of age and older. It is important to note that as a general matter, while some individuals experience side effects following any vaccination, not every individual's experience will be the same and some people may not experience side effects.

The effectiveness data to support the EUA in adolescents in this age group is based on immunogenicity and an analysis of COVID-19 cases. The immune response to the vaccine in 190 participants 12 through 15 years of age was compared to the immune response of 170 participants 16 through 25 years of age. In this analysis the immune response of adolescents was non-inferior to (at least as good as) the immune response of the older participants. An analysis of cases of COVID-19 occurring among participants 12 through 15 years of age seven days after the second dose was also conducted. In this analysis, among participants without evidence of prior infection with SARS-CoV-2, no cases of COVID-19 occurred among 1,005 vaccine recipients and 16 cases of COVID-19 occurred among 978 placebo recipients; the vaccine was 100% effective in preventing COVID-19. At this time, there are limited data to address whether the vaccine can prevent transmission of the virus from person to person. In addition, at this time data are not available to determine how long the vaccine will provide protection.

Q: What data is available to the public to review?

A: FDA posted data and analysis in a briefing document made available in connection with the December 10, 2020, meeting of the Vaccines and Related Biological Products Advisory Committee. Following issuance of the emergency use authorization (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs), the Letter of Authorization, Fact Sheets and Full EUA Prescribing Information are posted (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine) on FDA's web site. FDA has also posted the review memo (/media/144416/download) for Pfizer-BioNTech COVID-19 Vaccine, which summarizes FDA's review of the safety and effectiveness data, including clinical data, submitted in support of the request for emergency use authorization.

Q: How well does Pfizer-BioNTech COVID-19 Vaccine prevent COVID-19?

A: The data to support the EUA include an analysis of 36,523 participants in the ongoing randomized, placebo-controlled international study, the majority of whom are U.S. participants, who completed the 2-dose vaccination regimen and did not have evidence of SARS-CoV-2 infection through 7 days after the second dose. Among these participants, 18,198 received the vaccine and 18,325 received saline placebo. The vaccine was 95 percent effective in preventing COVID-19 disease among these clinical trial participants with 8 COVID-19 cases in the vaccine group and 162 COVID-19 cases in the placebo group. Of these 170 COVID-19 cases, 1 in the vaccine group and 3 in the placebo group were classified as severe.

Q: How long will the Pfizer-BioNTech COVID-19 Vaccine provide protection?

A: Data are not yet available to inform about the duration of protection that the vaccine will provide.

Q: Is the the Pfizer-BioNTech COVID-19 Vaccine effective at reducing the severity of COVID-19?

A: To date, only a small number of severe cases have occurred during the study, which makes it difficult to evaluate whether the vaccine reduces the severity of COVID-19. Pfizer-BioNTech COVID-19 vaccine is authorized to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

Q: Can people who have already had COVID-19 get the Pfizer-BioNTech COVID-19 Vaccine?

A: Among all study participants, 3% had evidence of infection prior to vaccination, and among participants with evidence of infection prior to vaccination, more confirmed COVID-19 cases occurred in the placebo group compared with the vaccine group. While relatively few confirmed COVID-19 cases occurred overall among participants with evidence of infection prior to vaccination, available data suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and could benefit from vaccination.

Q: If a person has received the Pfizer-BioNTech COVID-19 Vaccine, will the vaccine protect against transmission of SARS-CoV-2 from individuals who are infected despite vaccination?

A: Most vaccines that protect from viral illnesses also reduce transmission of the virus that causes the disease by those who are vaccinated. While it is hoped this will be the case, the scientific community does not yet know if the Pfizer-BioNTech COVID-19 Vaccine will reduce such transmission.

Q: How can we be so sure about the effectiveness of the Pfizer-BioNTech COVID-19 Vaccine when people participating in the trial were doing some level of mitigation (whether personal or government recommended)?

A: In a randomized, blinded clinical trial, participants are not aware of whether they received vaccine or placebo. Therefore, any mitigation efforts would have affected those who received vaccine and placebo equally. The relatively high infection rate among placebo recipients suggests that that any mitigation efforts among trial participants may not have been very effective.

Q: Did clinical trial participation include members of racial or ethnic groups at greater risk from COVID-19?

A: Yes. Overall, among the total participants who received either Pfizer-BioNTech COVID-19 Vaccine or placebo, 9.1 percent were Black or African American, 28.0 percent were Hispanic/Latino, 4.3 percent were Asian, and 0.5 percent were American Indian/Alaska native.

Q: Can pregnant or breastfeeding women receive the Pfizer-BioNTech COVID-19 Vaccine?

A: While there have been no specific studies in these groups, there is no contraindication to receipt of the vaccine for pregnant or breastfeeding women. Pregnant or breastfeeding women should discuss potential benefits and risks of vaccination with their healthcare provider.

Q: What safety information did FDA evaluate to authorize the Pfizer-BioNTech COVID-19 Vaccine for emergency use?

A: The available safety data to support the EUA include 37,586 of the participants enrolled in an ongoing randomized, placebo-controlled international study, the majority of whom are U.S. participants. These participants, 18,801 of whom received the vaccine and 18,785 of whom received saline placebo, were followed for a median of 2 months after receiving the 2nd dose. This is consistent with the recommendations set forth in

FDA's October 2020 *Guidance on Emergency Use Authorization for Vaccines to Prevent COVID-19 (/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19)*.

The most commonly reported side effects were pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, and fever. Side effects typically started within two days of vaccination and resolved 1-2 day later. Of note, more people experienced these side effects after the second dose than after the first dose, so it is important for vaccination providers and recipients to expect that that there may be some side effects after either dose, but even more so after the second dose.

FDA also evaluated additional safety data from the larger database that included participants enrolled later during the study who had shorter follow-up (the total database included 43,448 participants, 21,720 of whom received vaccine and 21,728 of whom received saline placebo) . FDA determined that the findings were similar to those in the population of participants with a median follow-up of 2 months after the 2nd dose.

Q: Is information available about serious adverse events?

A: Serious adverse events, while uncommon (<1.0%), were observed at slightly higher numerical rates in the vaccine study group compared to the saline placebo study group, both overall and for certain specific adverse events occurring in very small numbers. These represented common medical events that occur in the general population at similar frequency. Upon further review by FDA, these imbalances do not raise a safety concern, nor do they suggest a causal relationship to vaccination for the vast majority of reported serious adverse events.

Serious adverse events considered by FDA to be plausibly related to the vaccine or vaccination procedure were one case of shoulder injury at the vaccination site and one case of swollen lymph node in the armpit opposite the vaccination arm.

No safety concerns were identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection.

Severe allergic reactions, including anaphylaxis, have been reported following administration of Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of the clinical trial setting. Information pertaining to severe allergic reaction is included in the Fact Sheet for Vaccine Providers, Fact Sheet for Vaccine Recipients and the EUA Prescribing Information.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

Q: Are vaccine providers required to report side effects?

A: Providers administering Pfizer-BioNTech COVID-19 Vaccine must report to the Vaccine Adverse Event Reporting System (VAERS) and to Pfizer the following information associated with the vaccine of which they become aware:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Q: Must vaccine providers give a hard copy of the authorized Recipient and Caregiver Fact Sheet to the individual when they get their shot?

A: The EUA requires vaccination providers, prior to the individual receiving the vaccine, to communicate to the recipient or their caregiver information consistent with the "Fact Sheet for Recipients and Caregivers," and either to provide a copy of the Fact Sheet (/media/144414/download) or to direct the individual to the website (https://www.cvdvaccine.com/ (https://www.cvdvaccine.com/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)) to obtain the Fact Sheet.

Q: Can the Pfizer-BioNTech COVID-19 Vaccine protect recipients after a single dose?

A: The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart. The vaccine was not studied for use as a single dose.

FDA's conclusions regarding the safety and effectiveness of the Pfizer-BioNTech COVID-19 Vaccine, and the Agency's determination that the criteria for an Emergency Use Authorization (EUA) were met, were based on the evidence generated by the clinical trials that studied two doses and are reflected in conditions described in the emergency use authorization (EUA).

Individuals who have received one dose of the Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine on schedule to complete the vaccination series.

Q: Are the Pfizer-BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine interchangeable?

A: No. There are no data available on the interchangeability of Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines, including Moderna COVID-19 Vaccine. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

Q: Can you describe the mRNA technology of the Pfizer-BioNTech COVID-19 Vaccine? Are there any safety concerns considering the "newness" of this technology?

A: The Pfizer-BioNTech COVID-19 Vaccine is a messenger RNA (mRNA) vaccine. The vaccine contains a synthetic, small piece of the SARS-CoV-2 genetic material (mRNA) that instructs cells in the body to make the virus's distinctive "spike" protein. When vaccinated, the body produces copies of the spike protein, which alone does not cause disease, and the immune system learns to react defensively, producing an immune response against SARS-CoV-2.

Although this technology has not been used in any FDA-licensed preventive vaccine, FDA scientists have expertise with this technology as it has been used to develop other preventive investigational vaccines that have been tested in human clinical trials. FDA does not have specific safety concerns with a vaccine that utilizes this technology.

Q: Can the Pfizer-BioNTech COVID-19 Vaccine cause infertility in women?

A: There is no scientific evidence to suggest that the vaccine could cause infertility in women. In addition, infertility is not known to occur as a result of natural COVID-19 disease, further demonstrating that immune responses to the virus, whether induced by infection or a vaccine, are not a cause of infertility. Reports on social media have falsely asserted that the vaccine could cause infertility in women and the FDA is concerned that this misinformation may cause women to avoid vaccination to prevent COVID-19, which is a potentially serious and life-threatening disease. SARS-CoV-2 is the virus that causes COVID-19. The symptoms of COVID-19 vary and are unpredictable; many people have no symptoms or only mild disease, while some have severe respiratory disease including pneumonia and acute respiratory distress syndrome (ARDS), leading to multi-organ failure and death. The Pfizer-BioNTech COVID-19 vaccine is a mRNA vaccine. It contains a small piece of the SARS-CoV-2 virus's genetic material that instructs cells in the body to make the virus's distinctive "spike" protein. After a person is vaccinated, their body produces copies of the spike protein, which does not cause disease, and

triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2. Contrary to false reports on social media, this protein is not the same as any involved in formation of the placenta.

Q: What materials about the Pfizer-BioNTech COVID-19 Vaccine is FDA making available to vaccine providers and vaccine recipients?

- Fact Sheet for Recipients and Caregivers (/media/144414/download)
- Fact Sheet for Vaccination Providers (/media/144413/download), which also includes Emergency Use Authorization (EUA) Prescribing Information
- FDA's Decision Memorandum (/media/144416/download)

Q: How will additional safety monitoring be conducted for the Pfizer-BioNTech COVID-19 Vaccine?

A: The company has submitted a pharmacovigilance plan to FDA to monitor the safety of Pfizer-BioNTech COVID-19 Vaccine. The pharmacovigilance plan includes a plan to complete longer-term safety follow-up for participants enrolled in ongoing clinical trials. The pharmacovigilance plan also includes other activities aimed at monitoring the safety profile of the Pfizer-BioNTech COVID-19 vaccine and ensuring that any safety concerns are identified and evaluated in a timely manner.

Responsibility for additional post-authorization vaccine safety monitoring will be shared primarily by FDA and the U.S. Centers for Disease Control and Prevention (CDC), along with other agencies involved in healthcare delivery. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. There will be multiple, complementary systems in place with validated analytic methods that can rapidly detect signals for possible vaccine safety problems. The U.S. government has a well-established post-authorization/post-approval vaccine safety monitoring infrastructure that will be scaled up to meet the needs of a large-scale COVID-19 vaccination program. The U.S. government – in partnership with health systems, academic centers, and private sector partners – will use multiple existing vaccine safety monitoring systems to monitor COVID-19 vaccines in the post-authorization/approval period. Some of these systems are the Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink (VSD), the Biologics Effectiveness and Safety (BEST) Initiative, and Medicare claims data.

Q: How will additional data on the effectiveness of the Pfizer-BioNTech COVID-19 Vaccine be obtained?

A: Additional data on vaccine effectiveness will be generated from further follow-up of participants in clinical studies already underway before the EUA was issued, plus studies conducted by the manufacturer or by the U.S. government evaluating effectiveness of the vaccine as used under the EUA.

Q: How does the vaccine go from authorized for emergency use to licensed (approved)?

A: It is FDA's expectation that, following submission of an EUA request and issuance of an EUA, the manufacturer would continue to collect placebo-controlled data in any ongoing trials for as long as feasible to obtain additional safety and effectiveness information and would also work towards submission of a Biologics License Application (BLA) as soon as possible.

Q: Does the FDA foresee any instance in which a vaccine might receive an EUA and not meet the criteria for a Biologics License Application (BLA)? If a product doesn't meet the BLA standard, does the EUA get revoked?

A: If safety or effectiveness concerns arise with a vaccine under EUA, FDA has the authority to revoke the EUA. However, it is expected that the data supporting the EUA, together with those that will be collected during use of vaccine under EUA, and additional data collected from ongoing trials will be sufficient to support licensure (approval) of a vaccine authorized under EUA.

Q: How long will it take to get to a BLA? When does the clock start to get a BLA?

A: We cannot predict how long it will take for the manufacturer to submit a Biologics License Application (BLA). There is no "clock" for the submission of a BLA to FDA after issuance of an EUA or completion of clinical trials.

Q: What happens to other vaccines being studied?

A: FDA believes it is important for clinical trials for other COVID-19 vaccines to continue or initiate. It is important to have a portfolio of COVID-19 vaccines available to be able to vaccinate our population.

Q: Is it feasible to conduct placebo-controlled trials of COVID-19 vaccines after a vaccine is made available under an EUA?

A: FDA believes it is feasible to conduct placebo-controlled trials of COVID-19 vaccines after another vaccine is made available under an EUA, especially if that vaccine is not available in sufficient quantity for everyone who wants to receive it. Additionally, it may be feasible to conduct trials where safety and effectiveness of one or more COVID-19 vaccines are evaluated against a comparator COVID-19 vaccine that has been authorized for use under an EUA.

Q: Who made the decision to authorize the Pfizer-BioNTech COVID-19 Vaccine for emergency use?

A: FDA's career scientists and physicians in the Center for Biologics Evaluation and Research made a determination that the emergency use authorization request met the criteria for issuing an EUA. Our Chief Scientist, RADM Denise Hinton, signed the authorization.

Q: How are you going to educate the public about the safety and effectiveness of the the Pfizer-BioNTech COVID-19 Vaccine?

A: FDA has been embarking on an education campaign via social media, consumer content, media interviews, engagement with stakeholders and more to help the public understand our regulatory and scientific processes. These engagements will continue.

Q: Now that the Pfizer-BioNTech COVID-19 Vaccine is available, will the public still need to be vigilant and practice public health measures?

A: Yes. Because the vaccine will not be available immediately for most of the population, it will still be necessary to continue with the public health measures that we have been following. The best way to prevent illness is to avoid being exposed to the virus. The CDC recommends the following preventive actions:

- Wash your hands often with plain soap and water. The CDC recommends washing your hands often with soap and water for at least 20 seconds, especially after you have been in a public place, or after blowing your nose, coughing, or sneezing. If soap and water are not available, the CDC recommends using an alcohol-based hand sanitizer that contains at least 60 percent alcohol. Learn more about safely using hand sanitizer.
- Cover your mouth and nose with a cloth face covering or non-surgical mask when around others.
- Avoid crowds and practice social distancing (stay at least 6 feet apart from others).

Q: Previously, there were reports that vials of Pfizer-BioNTech COVID-19 Vaccine contained extra product after five doses of vaccine was obtained from a vial. The original letter of authorization (LOA) said that each vial contains 5 doses of 0.3 mL per dose. What's different with the latest version of the Fact Sheet regarding the number of doses per vial?

A: FDA previously advised that it is acceptable to use every full dose obtainable from each vial (the sixth, or possibly even a seventh), pending resolution of the issue of how many full doses are obtainable per vial of Pfizer-BioNTech COVID-19 Vaccine. FDA also advised that any further product remaining that does not constitute a full dose should not be pooled from multiple vials to create one.

Pfizer has submitted requests to FDA for the EUA to clarify the number of doses obtainable per vial of Pfizer-BioNTech COVID-19 vaccine. In order to provide flexibility to vaccine providers, FDA updated the Letter of Authorization (/media/144412/download) for the EUA for the Pfizer-BioNTech COVID-19 Vaccine to remove reference to the number of doses contained in one vial after dilution. The Agency also updated the Fact Sheet for Healthcare Providers (/media/144413/download) Administering Vaccine (Vaccination Providers) to note that, after dilution, one vial of Pfizer-BioNTech COVID-19 Vaccine contains six doses of 0.3 mL. This updated Fact Sheet for Vaccination Providers also notes that low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

Given that the original Letter of Authorization noted that each vial contained 5 doses, we recognize that some vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in the Fact Sheet regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

Because the Pfizer-BioNTech COVID-19 vaccine does not contain preservative, it is critical to note that any further remaining product that does not constitute a full dose should not be pooled from multiple vials to create one dose. The updated information in the revised Fact Sheet for Vaccination Providers should address any questions or confusion about whether these additional full doses may be used.

Q: What other changes or updates were made to the letter of authorization for Pfizer-BioNTech COVID-19 Vaccine?

A: The reissued LOA includes updated language (found at letter "T" of the LOA) to clarify the instructions for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS).

Q: The reissued LOA also mentions that changes pertaining to safety monitoring were made to the Fact Sheet for Healthcare Providers Administering Vaccine Vaccination Providers and the Fact Sheet for Recipients and Caregivers. What were these changes?

A: The Fact Sheet for Healthcare Providers (/media/144413/download) Administering Vaccine (Vaccination Providers) was updated to include in the Warnings section reference to guidelines from the Centers for Disease Control and Prevention for monitoring Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions. This is in addition to the warning that appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine. Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of the clinical trial setting.

The Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was also updated to instruct vaccination providers to provide information about v-safe to vaccine recipients. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination.

The original Fact Sheet for Recipients and Caregivers (/media/144414/download) informed vaccine recipients about a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction soon after vaccination. The Fact Sheet for Recipients and Caregivers was updated to inform vaccine recipients that because of the possibility of allergic reactions, their vaccination provider may ask them to stay at the place where they received their vaccine for monitoring after vaccination. The Fact Sheet for Recipients and Caregivers was also updated to provide information on **v-safe**.

Q: Why did FDA revise and issue a new LOA when the agency already posted information about the potential for extra doses in the vials?

It is not uncommon for FDA to update a LOA when new information regarding an authorized product becomes available and such a revision is appropriate to protect the public health or safety. As noted, there were several updates to the LOA, and the agency reissued the updated LOA in order to provide transparency about the EUA. There are no changes to the agency's determination that the vaccine's known and potential benefits outweigh its known and potential risks.