



COVID-19

DRAFT FAQ for Planned Parenthood Staff on COVID-19 Vaccines

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This document has been compiled in order to answer some of the questions Planned Parenthood staff may have about the COVID-19 vaccines that are quickly becoming available in the U.S. PPFA supports FDA-approved vaccines that help keep our communities healthy and strong. Our goal is to provide medically accurate and helpful information and this FAQ document will be updated as the vaccine landscape evolves. We recognize that beyond these questions many of you have legitimate, deep-seated fears about the vaccine and the pandemic itself. We also want to name that there is well-founded distrust of the medical system and public health authorities particularly among Black, Latinx, and Indigenous communities that is rooted in historic and ongoing racism, abuse, and discrimination against people of color by providers and the medical establishment.

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1. Why are healthcare workers prioritized for COVID-19 vaccination and who is included in the definition of healthcare worker?

In December the [CDC Advisory Committee on Immunization Practices \(ACIP\)](#) recommended that healthcare personnel and those working and living in long term care facilities receive highest priority in the early phases of COVID-19 vaccine distribution. The committee defined health care personnel as “paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious material.” This includes both licensed and non-licensed staff. Health care personnel are being prioritized because you are on the front lines and risk being exposed to people with COVID-19 each day on the job.

Additional resource: CDC - [Why Get Vaccinated?](#)

2. Why is the FDA using emergency powers to approve a vaccine?

The Food and Drug Administration (FDA) has emergency authority to issue temporary approvals of medical products to get them to the public more quickly during public health emergencies. Since February, the FDA has used this power to authorize coronavirus tests and a few treatments. The FDA announced on October 6, 2020 that before approving a potential COVID-19 vaccine, it will need to see two months of follow-up data after volunteers get their second vaccine doses in a clinical trial. While this timeframe is shorter than non-emergency vaccine trials, it is a safeguard that ensures that vaccines are given to thousands of people under stringent monitoring for safety before the vaccine is available to the public more broadly.

Additional resources:

- [CDC slide set on FDA licensure process](#)
- [Public Health Collaborative Vaccine FAQ document](#) and [infographic](#) on steps taken to ensure the vaccines are safe
- [FDA's Emergency Use Authorization for Vaccines Explained](#)

3. How will we know the vaccine is safe?

Many people were recruited to participate in these trials to see how the vaccines offer protection to people of different ages, races, and ethnicities, as well as those with different medical conditions. The FDA reviewed all the available safety and effectiveness data and determined that the [“vaccine’s known and potential benefits clearly outweigh its known and potential risks.”](#) In addition, the FDA review process also includes public and independent reviews, as is standard for all emergency use authorizations. Even after emergency use authorization is issued, the CDC and other federal partners will continue to monitor the new vaccines for serious side effects (known as adverse events) using well-established vaccine safety monitoring systems. This continued monitoring can pick up on side effects that may not have

been seen in clinical trials. If an unexpected side effect with the new COVID-19 vaccines is seen, experts can quickly study it further to determine if it is a true safety concern.

4. How does the vaccine work?

COVID-19 vaccines help our bodies develop immunity to the virus that causes COVID-19 without us having to get the illness. The Pfizer and Moderna COVID-19 vaccines are mRNA vaccines. mRNA vaccines contain pieces of the virus that give our bodies instructions for how to recognize the virus, and build certain white blood cells that will remember how to fight the virus if you're infected in the future.

For more information see: CDC - [Understanding How COVID-19 Vaccines Work](#)

5. What are the potential side effects of the COVID-19 vaccine?

Pfizer Vaccine:

Data from Pfizer's application for emergency use authorization indicates that the vaccine is safe and effective. Pfizer's Phase 3 clinical trial included approximately 38,000 participants ≥ 16 years of age who were followed for at least 2 months after receiving the second vaccine dose. While research participants did experience side effects from the vaccines including sore arm (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), and fever (14.2%), there were very few ($<0.5\%$) serious side effects and no differences across age groups, genders, ethnic and racial groups, or comorbidities. Younger participants (<55 years of age) tended to experience more side effects than older participants because younger people tend to have more responsive immune systems. These side effects are a sign that your immune system is doing exactly what it is supposed to do. It is working and building up protection against COVID-19. Importantly, the vaccine itself does not contain the virus and the side effects are not a sign that the vaccine has caused a COVID infection.

[FDA Briefing Document on the Pfizer vaccine](#)

Moderna Vaccine:

Data from Moderna's application for emergency use authorization indicates that the vaccine is safe and effective. Moderna's Phase 3 clinical trial included approximately 30,400 participants ≥ 18 years of age who were followed for at least 2 months after receiving the second vaccine dose. While research participants did experience side effects from the vaccines including sore arm (91.6%), fatigue (68.5%), headache (63.0%), muscle pain (59.6%), chills (43.4%), and joint pain (44.8%), there were few (0.2% to 9.7% of participants) serious side effects that were more frequent after the second dose and were generally less frequent in participants ≥ 65 years of age as compared to younger participants because younger people tend to have more responsive immune systems. There were no significant differences in the safety profile across genders, ethnic and racial groups, or comorbidities. These side effects are a sign that your immune system is doing exactly what it is supposed to do. It is working and building up protection against COVID-19. Importantly, the vaccine itself does not contain the virus and the side effects are not a sign that the vaccine has caused a COVID infection.

6. Is the vaccine recommended for people with a history of allergic reactions?

The FDA Pfizer vaccine instructions says: Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine (see Full EUA Prescribing Information).

The Pfizer [fact sheet for patients and parents/caregivers](#) states:

WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?

You should not get the Pfizer-BioNTech COVID-19 Vaccine if you had a severe allergic reaction after a previous dose of this vaccine or had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine, in addition to mRNA, includes a mix of salts, fatty substances and sugars to stabilize the vaccine including: lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3- phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

Additional Resource:

[MIT Technology Review: What are the ingredients of Pfizer's covid-19 vaccine?](#)

7. Does the COVID-19 vaccine cause COVID infection?

No. The vaccines do not cause infection and you cannot get COVID-19 from the vaccine. None of the COVID-19 vaccines currently authorized for use or in development in the United States use the live virus that causes COVID-19. However, it typically takes a few weeks for your body to build immunity after the second dose of the vaccination. That means it's possible you could get COVID-19 just before or just after vaccination and get sick.

8. How is the vaccine given and how does it work?

Both the Pfizer-BioNTech and Moderna COVID-19 Vaccine will be given to you as an injection into the muscle, typically in the upper outer arm. The Pfizer-BioNTech vaccine is a series of 2 doses given 3 weeks apart and the Moderna vaccine is a series of 2 doses given 4 weeks apart. If you receive one dose, you should receive a second dose of this same vaccine to complete the vaccination series. Neither vaccines contain SARS-CoV-2 and cannot give you COVID-19.

9. Is the vaccine recommended and/or safe for pregnant or lactating people?

In a [Practice Advisory](#) issued on December 13, 2020, the American College of Obstetricians and Gynecologists (ACOG) recommended that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on the [ACIP-recommended priority groups](#). ACOG also recommends that vaccines should be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP. ACOG notes that vaccines currently available under EUA have not been tested in pregnant women and noted that there is no

safety data specific to use in pregnancy currently available. ACOG recommends that pregnancy testing should not be a requirement prior to receiving COVID-19 vaccines, and that pregnant patients who decline vaccination should be supported in their decision. The [MS&Gs and Optimizing Care Document](#) was updated to reflect ACOG’s guidance and includes a blanket waiver.

10. Is the vaccine recommended for children?

To date, the Phase 3 COVID-19 vaccine trials did not include anyone 15 years of age or younger. More studies need to be conducted before COVID-19 vaccines are recommended for children aged 15 and younger.

11. What was the diversity and representation in the Phase 3 vaccine trials?

Pfizer:

Overall, the group of people included in the study of how well the vaccine works (the phase 2/3 evaluable efficacy population) included 49.4% females, 81.9% White, 9.8% African American, 4.4% Asian participants, and <3% from other racial groups; 26.2% of participants were Hispanic/Latino; 21.4% of participants were >65 years of age. The median age was 51 years. Many of the study participants reported The most frequently reported comorbidities were obesity (35.1%), diabetes (with and without chronic complications, 8.4%) and pulmonary disease (7.8%). Geographically, 76.7% of participants were from the US, 15.3% from Argentina, 6.1% from Brazil, and 2% from South Africa.

Overall, the group of people included in the study evaluating how safe the vaccine was (phase 2/3 safety population included)83.1% White, 9.1% African American, 4.3% Asian participants, and <3% from other racial groups; 28.0% of participants were Hispanic/Latino; 21.6% of participants were >65 years of age. The median age was 52 years, and safety data from a total of 103 participants 16 and 17 years of age were included in this submission. The most frequently reported comorbidities were obesity (35.1%), diabetes (without chronic complications, 7.8%) and chronic pulmonary disease (7.8%). Geographically, 76.7% of participants were from the US, 15.3% from Argentina, 6.1% from Brazil, and 2.0% from South Africa.

Moderna:

Overall, the group of people included in the study of how well the vaccine works (the phase 2/3 evaluable efficacy population) included 47.4% females and 25.3% of individuals ≥65 years of age. The racial breakdown of the study group included 79.4% White, 9.7% African American, 4.7% Asian and 20% Hispanic/Latino. A majority of the participants (82%) were considered at occupational risk for SARS-CoV-2 exposure, with 25.4% of participants being healthcare workers. At least one protocol-defined high-risk condition for severe COVID-19 was present in 22.3% of participants, and 4% of participants had two or more high risk conditions.

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|--|-----------------|---------------|---------------|-----------|
| | Pfizer Efficacy | Pfizer Safety | Moderna Study | 2019 U.S. |
|--|-----------------|---------------|---------------|-----------|

| | Population | Population | Population | Census Bureau Estimates |
|------------------------|------------|------------|------------|-------------------------|
| White | 81.9% | 83.1% | 79.4% | 60.1% |
| African American/Black | 9.8% | 9.1% | 9.7% | 13.4% |
| Asian | 4.4% | 4.3% | 4.7% | 5.9% |
| Hispanic/Latino | 26.2% | 28.0% | 20.0% | 18.5% |

12. Will I have to pay for the COVID-19 vaccine?

Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at no cost. However, vaccination providers will be able to charge an administration fee for giving the shot to someone.

13. What about the potential for the mRNA vaccine to alter DNA and potentially cause infertility or sterility?

A video being shared on social media makes the false claim that a vaccine for COVID-19 consists of chemicals that lead to infertility. mRNA vaccines cannot give someone COVID-19, nor do they affect or interact with our DNA in any way. According to the CDC’s [Learn About the New mRNA COVID-19 Vaccines](#) the mRNA strand never enters the cell’s nucleus or affects the vaccine recipient’s genetic material. Pfizer spokeswoman Jerica Pitts [confirmed to The Associated Press](#) the vaccine has not been found to cause infertility or sterilization.

“It has been incorrectly suggested that COVID-19 vaccines will cause infertility because of a shared amino acid sequence in the spike protein of SARS-CoV-2 and a placental protein,” she said in an email. “The sequence, however, is too short to plausibly give rise to autoimmunity.”

For more information see [Understanding mRNA COVID-19 Vaccines](#)

14. Why is there vaccine hesitancy among Black, Indigenous, and People of Color in particular?

Distrust of the medical system and public health authorities particularly among Black, Latinx, and Indigenous communities is rooted in historic and ongoing racism, abuse, and discrimination against people of color by providers and the medical establishment. It is important to acknowledge this context of mistrust and exploitation as valid concerns and different from the “anti-vax” stance. From the [Tuskegee syphilis study](#) to [J Marion Sims](#) (“the father of gynecology”) who performed reproductive experiments on enslaved Black women without anesthesia, the government has been directly involved in approving and supporting medical experiments targeting Black and Brown people without their consent. This has resulted in a destruction of trust between Black communities and the medical industry, something that

Planned Parenthood continues to work to repair and reckon with in terms of the direct role we have played in this harm. COVID has also been disproportionately lethal to Black and Brown communities, amplifying the health and economic disparities that come from years of underinvestment and systemic racism. As such, we will make sure staff have all the information they need as the vaccine becomes available to make decisions that are best for them. In the long term, Planned Parenthood will continue to do what we can to repair the mistrust amongst communities of color and the medical industry.

15. Is the vaccine actually preventing the spread of the virus or is it just preventing symptoms in the person who receives it?

The coronavirus vaccines stimulate our immune systems to produce antibodies, which keeps most people protected from getting sick with COVID-19. It is not clear from the Phase III trials of the Pfizer and Moderna vaccines though whether individuals who are vaccinated can still have the virus in their nose and potentially spread it to others. The current data from the vaccine trials looks at efficacy outcomes or protection from symptom development and death (i.e., trials were looking at people who got sick). There will be future study on the transmission of the virus. Therefore, even if you are vaccinated, you will still need to continue to follow prevention measures such as mask wearing, hand washing and socially distancing until we know more about the long-term impact of the vaccines on transmission rates.

Considerations for Health Care Workers: [Interim Considerations for COVID-19 Vaccination of Healthcare Personnel and Long-Term Care Facility Residents](#)

The Advisory Committee on Immunization Practices (ACIP) recommends that when a COVID-19 vaccine is authorized by the Food and Drug Administration (FDA) and recommended by ACIP, vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a) should be offered to both 1) health care personnel (HCP) and 2) residents of long term care facilities (LTCF). These considerations will be updated as additional information becomes available.

Background and Education for Healthcare Professionals on COVID-19 Vaccines (additional operational resources will be forthcoming):

Best place to start is the CDC's site: [Healthcare Professionals: Preparing for COVID-19 Vaccination](#).

- CDC's [Quick Answers for Healthcare Professionals to Common Questions People May Ask About COVID-19 Vaccines](#)
- [Preparing to Provide COVID-19 Vaccines to Your Patients](#): offers training for healthcare providers and information for identifying vaccine providers, tracking COVID-19 vaccines, storage and handling, and safe vaccination guidance

- [Talking to Patients about COVID-19 Vaccines](#): materials include communication strategies and tips for effectively setting expectations and addressing questions from patients
- [Making a Strong Recommendation for COVID-19 Vaccination](#): techniques and resources that provide support for discussing vaccination with patients before COVID-19 vaccines are widely available in the U.S.
- [Answering Patients' Questions](#): outlines some vaccine topics patients ask about most and tips for how to answer their questions
- New resource on mRNA - [Learn About the New mRNA COVID-19 Vaccines](#)
- CDC Clinical Outreach and Communication Activity: [What Every Physician Should Know About COVID-19 Vaccine Safety](#)

Below are slides and training tools that can be used to help further inform health center personnel about provision of COVID-19 vaccines.

- [COVID-19 Vaccine Basics: What Healthcare Personnel Need to Know](#)
- [Vaccine Storage and Handling Toolkit](#)
- [COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers](#)
- [COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals](#)
- Pfizer [Manufacturer COVID-19 Vaccine Training & Education Series](#) trainings for healthcare professionals Week of 12/14

References for other Q&A style information on COVID-19 vaccines:

1. NEJM - "[When Will We Have a Vaccine?](#)" — [Understanding Questions and Answers about Covid-19 Vaccination](#)
2. JAMA Network - [Answering Key Questions about COVID-19 Vaccines](#)
3. Johns Hopkins Bloomberg School of Public Health - <https://www.jhsph.edu/covid-19/articles/a-top-vaccine-expert-answers-important-questions-about-a-covid-19-vaccine.html>
4. Example of State Q&A for healthcare providers - [Minnesota Department of Health](#)
5. Children's Hospital of Philadelphia - <https://www.chop.edu/centers-programs/vaccine-education-center/making-vaccines/pr-event-covid>
6. CANVAX - COVID-19 Vaccine Safety Q&A - <https://canvax.ca/covid-19-vaccine-questions-and-answers-healthcare-providers>
7. American Academy of Pediatrics- [COVID-19 Vaccine: Frequently Asked Questions](#)

Additional Resources:

- [Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization](#)
- [Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers](#)
- [Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Patients](#)

- [COVID-19 Vaccines](#)
- [Emergency Use Authorization for Vaccines Explained](#)
- [Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry](#)
- [Development and Licensure of Vaccines to Prevent COVID-19; Guidance for Industry](#)

For questions related to vaccine guidance, please reach out to our general Covid-19 email address, covid19.info@ppfa.org, which is monitored 24/7.