Frequently Asked Questions about the COVID-19 Vaccines

Presented by Comunidad Latina de Vashon, Greater Cleveland Congregations, and Union of Concerned Scientists

www.ucsusa.org/resources/covid-19-vaccine-faq

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Section 1: Topline Questions about the COVID-19 Vaccines

COVID-19 has taken an enormous toll on human health and caused millions of deaths around the world. However, after months of testing and trials, scientists have developed vaccines to protect people from the virus, and they are now being distributed globally.

The COVID-19 vaccine is widely available to all adolescents and adults ages 12 and up. In August 2021, the Pfizer vaccine received full approval by the US Food and Drug Administration (FDA) for people 16 years and older. If you, like many others, have questions about the vaccines, we offer these answers based on the best available scientific information.

How do vaccines work in general?

A vaccine trains a person's body to fight off a specific virus. Different types of vaccines work in different ways, but all vaccines stimulate the body to make specific immune cells that can fight that virus in the future.

How well do the COVID-19 vaccines work?

The US Food and Drug Administration (FDA) first approved the Pfizer-BioNTech vaccine, then the Moderna vaccine, and then the Johnson & Johnson (J&J) vaccine. For people 16 years and older, the Pfizer vaccine has received full FDA approval, the agency's standard and rigorous next step in the process for evaluating the quality, safety, and effectiveness of medical products. All three vaccines underwent a rigorous evaluation process and required extensive testing data and review by the FDA and external advisors. Large clinical trials with tens of thousands of people were held to test the vaccines' effectiveness at preventing COVID-19 (Table 1). Half the participants received the vaccine and half received a placebo—a shot containing no active ingredient. Scientists advising the FDA carefully analyzed the <u>Pfizer</u>, Moderna, and J&J data and confirmed that vaccines prevent COVID-19 symptoms, including severe symptoms, thereby protecting people from illness and death. It is not yet known how long their protective effects will last.

Table 1. Basic Facts about the COVID-19 Vaccines

Pfizer-BioNTech vaccine	Moderna vaccine	Johnson & Johnson vaccine
For people 12 years and older	For people 18 years and older	For people 18 years and older
2 doses, 3 weeks apart	2 doses, 1 month apart	1 dose
44,000 participants	30,400 participants	43,000 participants
95% effective at preventing COVID-19	94.5% effective at preventing COVID-19	66.9% effective at preventing COVID-19

SOURCES: Briefing Materials on Pfizer, Moderna, and J&J vaccines from FDA's Vaccine and Related Biological Products Advisory Committee.

Should I be concerned that the J&J vaccine's effectiveness is lower than the Pfizer and Moderna vaccines?

A vaccine does not need to be 100 percent effective to be considered a good vaccine. The annual flu vaccine, which is designed to protect people from flu strains and slow the spread of flu epidemics, is usually 40 to 60 percent effective. In June 2020, the FDA stated that, in order to be approved by the agency, a COVID-19 vaccine would have to prevent disease or decrease disease severity in at least 50 percent of the people who are vaccinated.

While the numbers may differ between the three vaccines, all three are considered extremely good at preventing you from getting the worst COVID-19 symptoms. Specifically, the J&J vaccine is 100 percent effective at preventing fatal cases of COVID-19 and is 85 percent effective at stopping severe COVID-19 symptoms that can result in hospitalization. The FDA noted that the J&J vaccine may be somewhat less effective in preventing illness in adults older than 60 who also had medical risk factors, but this finding was not certain and requires more research. In December 2020, J&J started a clinical trial to test a two-dose regimen, which Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, said could further increase the vaccine's effectiveness.

Box 1. How can I place my trust in COVID-19 vaccines knowing that some doctors have harmed people of color, especially African Americans, when carrying out medical research?

As Black and Brown communities across the United States weigh the decision of whether to take the COVID-19 vaccine, it is important to note that doctors and scientists of color are strongly endorsing the vaccines. Sixty African American health experts from the National Academy of Medicine have reviewed the research and expressed strong confidence in the safety and effectiveness of the vaccines.

Distrust of medical researchers in communities of color, especially African American communities, is a rational response to a long history of medical abuse. African Americans and other people of color in the United States continue to experience more illness, worse outcomes, and die younger compared with white individuals. African American women and Indigenous women are two to three times more likely to die from pregnancy-related causes than white women.

When Dr. Susan Moore, an African American physician, came down with a severe case of COVID-19 in November 2020, her white doctor downplayed Dr. Moore's reports of pain, initially refused to give her pain medicines, and tried to send her home from the hospital. Dr. Moore said, "I maintain if I was white, I wouldn't have to go through that." She later died of COVID-19.

During the 40-year-long Tuskegee Syphilis Study, the African American, low-income participants were denied treatments for their syphilis, a horrible ethical violation that resulted in extreme harm and death to the participants and their families. This is just one example of the long and troubled history of medical racism in the United States, which also includes the Guatemala syphilis experiments, the case of Henrietta Lacks and her legacy, the unnecessary surgeries without anesthesia performed on enslaved women, and the targeting of Indigenous, African American, and Puerto Rican women for involuntary sterilization throughout the 20th century.

In response, the federal government carried out a series of reforms. For instance, the Belmont Report, created in 1976, which was issued in response to the Tuskegee Syphilis Study, requires that all research with human participants follow three ethical guidelines: respecting persons, minimizing risk to participants, and considering issues of justice in how the burdens and benefits of research are distributed across society. In June 2000, the Office for Human Research Protections was established, which is housed in the US Department of Health and Human Services (HHS), to protect human subjects of research. Every university, hospital, and research center is required to carry out detailed ethical reviews of every proposed scientific and medical study to ensure the protection, rights, and safety of participants.

Because vaccines are administered to so many different types of people, vaccine trials are held to an especially high standard of safety. This includes COVID-19 vaccine research, in which a diverse group of scientists, medical doctors, and public health practitioners around the world worked to prove the vaccines would be safe and to ensure research participants would be protected during the trials. Dr. Kizzmekia Corbett, an African American female scientist at the National Institutes of Health (NIH), played a leading role in developing one of the COVID-19 vaccines. By the time you are offered a vaccine, millions of people of all races, genders, and age groups, in multiple countries, from the health care community to political leaders to vulnerable groups including elderly people, will have been safely vaccinated.

How do the COVID-19 vaccines work?

There are three types of COVID-19 vaccines currently undergoing large-scale clinical trials or have been approved for use in the United States. None can give you COVID-19 and none interact with your DNA.

- 1. One type, including the not-yet-approved Novavax vaccine, presents the body with harmless pieces of the virus that causes COVID-19. This technique has been used to make vaccines for hepatitis B, whooping cough, and other diseases.
- 2. Another type, including the J&J and AstraZeneca vaccines, uses the weakened, live version of a different virus that contains some of the genetic material of the virus that causes COVID-19. This technique, in use since the 1970s, recently led to the development of an Ebola vaccine.
- 3. The third type, including the Pfizer and Moderna vaccines, are called messenger RNA (mRNA) vaccines, which teach our cells how to make a protein—or even just a piece of a protein—that triggers an immune response inside our bodies. Researchers have used this technique for decades to study cancer and develop vaccines for the flu, rabies, and Zika.

Are the COVID-19 vaccines safe?

Yes. Getting a COVID-19 vaccine is associated with very few risks. Among the tens of thousands of people who received a Pfizer, Moderna, or J&J vaccine in the clinical trials, the most common side effects experienced were pain at the injection site, fatigue, headaches, muscle pain, joint pain, chills, or fever—the vast majority of which disappeared in a few hours or a few days. In rare cases, you can develop an allergic reaction, usually within the first 15 minutes of receiving the vaccine. The FDA is currently investigating a very rare allergic reaction to the Pfizer vaccine that has occurred in a handful of individuals.

After an investigation into a rare blood clot disorder, the CDC and FDA found that the J&J vaccine was safe enough to continue distribution, though the FDA added a warning label to the J&J vaccine. Women younger than 50 years old should be aware of the rare but increased risk. The FDA also added a warning to the J&J vaccine of a small risk of an extremely rare side effect called Guillain-Barré syndrome, in which the immune system attacks the nerves. Health officials emphasize that the benefits associated with getting the J&J vaccine far outweigh the risks.

Side effects are normal and common with all other vaccines (such as flu vaccines). They are a sign that the vaccine is working and that your body is building protection against the disease. Participants in each clinical study were monitored for eight weeks after they received the second dose to check for safety. In the past, other vaccines that produced bad reactions did so within six weeks of vaccination.

Are the vaccines safe and effective for people with my gender/ethnicity/ health condition/age?

Yes, they are safe and effective for people from different backgrounds. The Pfizer, Moderna, and J&J vaccines were tested among a wide group of participants, including people of color, different age groups, people with underlying health conditions, different genders, and people who previously had COVID-19 (Table 2). The data showed the Pfizer, Moderna, and J&J vaccines worked equally well and were equally safe across age groups, genders, and racial and ethnic groups. They also worked well and were safe for people with or without a wide variety of health conditions (Table 3).

In 2021, tens of thousands of pregnant and nursing individuals recieved the COVID-19 vaccine and data has shown that the vaccines are safe and effective for this population. This position is supported by two leading obstetrician groups, American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine. The Centers for Disease Control and Prevention (CDC) is recommending COVID-19 vaccination for people who are pregnant, breastfeeding, trying to become pregnant, or might become pregnant in the future.

Table 2. Racial and Ethnic Demographics of Participants in COVID-19 Vaccine Clinical Trials

Race/Ethnicity	Pfizer-BioNTech vaccine	Moderna vaccine	Johnson & Johnson vaccine
African American	3,929 people	3,090 people	8,515 people
	(9.8%)	(10.2%)	(19.4%)
Asian American	1,763 people	1,385 people	1,430 people
	(4.4%)	(4.6%)	(3.3%)
Latino	10,553 people (26.2%)	6,234 people (20.5%)	19,837 people (45.3%)
Native/Indigenous	253 people	230 people	4,143 people
	(0.6%)	(0.8%)	(9.5%)
White	33,006 people	24,023 people	25,696 people
	(81.9%)	(79.2%)	(58.7%)

SOURCES: Briefing Materials on Pfizer, Moderna, and J&J vaccines from FDA's Vaccine and Related Biological Products Advisory Committee.

Table 3. Other Demographics of Participants in COVID-19 Vaccine Clinical Trials

	Pfizer-BioNTech vaccine	Moderna vaccine	Johnson & Johnson vaccine
Women	19,901 people	14,355 people	19,722 people
	(49.4%)	(47.3%)	(45.0%)
Men	20,376 people	15,995 people	24,053 people
	(50.6%)	(52.7%)	(54.9%)
65 years and older	8,613 people	7,520 people	8,561 people
	(21.38%)	(24.8%)	(19.6%)
People with underlying health conditions	18,592 people	6,742 people	17,858 people
	(46.2%)	(22.2%)	(40.8%)

SOURCES: Briefing Materials on Pfizer, Moderna, and J&J vaccines from FDA's Vaccine and Related Biological Products Advisory Committee.

Will I need a vaccine booster shot?

COVID-19 vaccines continue to be remarkably effective at reducing risk of severe disease, hospitalization, and death. To continue this strong level of protection, health officials are currently considering recommendations for an additional vaccine shot, known as a booster. The recommendations for booster shots—including who should receive them—are changing, so it is best to visit the CDC's and FDA's websites for the latest information.

For people who are immunocompromised, the FDA strongly recommends a booster shot. These individuals should receive a vaccine booster at least 28 days after their second dose of either the Pfizer or Moderna vaccines. This recommendation does not currently include the J&J vaccine.

Section 2: Further Questions about the COVID-19 Vaccines

Are the COVID-19 vaccines safe and effective for people with diabetes?

Yes. All evidence from clinical trials suggests the vaccine is highly safe and effective in people with gestational diabetes, type 1 diabetes, type 2 diabetes, and severe diabetes complications.

- For the Pfizer vaccine, 3,150 people with diabetes were tested in the clinical trials. The vaccine worked 94.7 percent of the time for this group.
- For the Moderna vaccine, 2,858 people with diabetes were tested in the clinical trials. The vaccine worked 100 percent of the time for this group.
- For the J&J vaccine, 3,389 people with diabetes were tested in the clinical trials. The vaccine worked 52.9 percent of the time for this group.

The CDC states that people with type 2 diabetes are at increased risk of severe illness, including hospitalizations and death, if they catch COVID-19. People with gestational diabetes or type 1 diabetes may also be at increased risk. Because of this, a group of scientists advising the CDC has recommended giving people with diabetes priority for the COVID-19 vaccine.

Are the COVID-19 vaccines safe for people with allergies?

Yes. The CDC recommends that people with a history of severe allergic reactions that are not related to vaccines or injectable medications—such as food, pet, environmental, or latex allergies—get vaccinated. People with a history of allergies to oral medications or a family history of severe allergic reactions may also get vaccinated. People who are allergic to a specific component of the mRNA vaccines, including polyethylene glycol (PEG) or a related compound called polysorbate, should not get the Pfizer or Moderna vaccines unless evaluated by an allergy-immunology specialist.

However, there are some cases where you should talk to your doctor before getting the vaccine. If you have had an immediate allergic reaction—even if it was not severe—to a vaccine or injectable therapy for another disease, ask your doctor if you should get a COVID-19 vaccine.

Are there other COVID-19 vaccines being tested?

Yes. There are 99 vaccines currently being tested in clinical trials around the world; as of August 2021, 33 had advanced to the final stages. A vaccine developed by AstraZeneca has been approved by India, the United Kingdom, and some other countries, but because the FDA must carefully review the data from each vaccine's clinical trials before it can be approved, it is going to take some time before the AstraZeneca vaccine or others become available in the United States.

I read a news story about some people potentially being harmed by a **COVID-19 vaccine. Should I be concerned?**

No. As COVID-19 vaccines become more broadly used by millions of people, news stories will surface that question whether an individual person or a small number of people were hurt by the vaccines. In many cases, the incidents described will turn out to be random chance, in which someone who was already going to come down with a bad health condition had, by coincidence, just received a COVID-19 vaccine.

In other cases, this could be due to a very rare reaction to the vaccines. For instance, anaphylaxis—a potentially life-threatening allergic reaction—is a very rare side effect that has occurred with other vaccines. Anaphylaxis after vaccination occurred for the Pfizer vaccine at a rate of 4.7 cases per 1 million doses administered, and for the Moderna vaccine at a rate of 2.5 cases per 1 million doses administered. The individuals who experienced anaphylaxis recovered and there were no fatalities. For comparison, the death rate in the United States for COVID-19 is over 1.800 per 1 million people.

Are COVID-19 vaccines tested for safety after the clinical trial is over?

Yes. The CDC and FDA continue to monitor vaccines for quality and safety after they have been approved for use in the general public. Besides ensuring continued safety, this allows the agencies to change and update recommendations as needed. For example, polio vaccination protocols were changed to increase effectiveness and safety in 1997.

The CDC and FDA maintain three systems for monitoring vaccine safety:

- Vaccine Adverse Event Reporting System (VERS) allows individuals to report adverse reactions to any vaccine, which serves as an early warning system for potential safety issues.
- <u>Vaccine Safety Datalink</u> (VSD) helps the CDC and nine health care organizations conduct studies about rare and serious vaccine reactions.
- Clinical Immunization Safety Assessment Project (CISA) involves collaboration between the CDC and medical research centers investigating vaccine-related health risks.

Do I have to pay to receive a COVID-19 vaccine?

No. Vaccine doses will be given to people living in the United States at no cost. However, vaccination providers can charge an administration fee for giving you the shot, which can be reimbursed by your insurance company or, if you're uninsured, by the Health Resources and Services Administration's Provider Relief Fund.

When will a COVID-19 vaccine become available to the general public?

Currently, COVID-19 vaccines are available in the US to all adults and children 12 years and older at local hospitals, pharmacies, or other health centers. Trials are ongoing for COVID-19 vaccines for children younger than 12 years old and, if the data show they are safe and effective, they will be available later this year or next.

A committee of health experts advised the CDC on how to equitably distribute the COVID-19 vaccine, and recommended that the vaccine be offered first to health care workers, nursing home staff and residents, frontline and essential workers, and people 75 or older. Considering the virus's disproportionate impact on underserved communities, the National Academy of Sciences recommended that state and local governments prioritize delivering the vaccine to communities of color, low-income communities, and Indigenous communities.

Currently, COVID-19 vaccines are available to everyone in the US at local hospitals, pharmacies, or other health centers.

Who decides who gets the COVID-19 vaccines and when?

State and local leaders decide who gets the vaccine sooner, based on CDC guidelines. Different states, cities, and counties have different rollout plans in place; therefore, you should check your local government's website for its distribution plan and further information on vaccine availability. The state of Ohio, for example, prioritizes those working in essential and frontline jobs, including hospital and grocery store workers.

Currently, COVID-19 vaccines are available to everyone in the US at local hospitals, pharmacies, or other health centers.

Where will I need to go to get the vaccine?

There are already several thousand places across the country to get vaccinated, including doctors' offices, retail pharmacies, hospitals, and health centers. Check your state government's website for information on where the vaccine will be offered in your area.

Currently, COVID-19 vaccines are available to everyone in the US at local hospitals, pharmacies, or other health centers.

What are the risks associated with *not* getting a COVID-19 vaccine?

If you choose not to get vaccinated, you are at risk of catching a potentially deadly disease and spreading it to people around you, including your loved ones. While COVID-19 causes mild symptoms in most people, some people of all ages get severe symptoms and even die.

People over 65 and people with certain health conditions are at higher risk of severe symptoms, but severe symptoms and death can occur in anyone. Some people who survived COVID-19 have experienced long-term symptoms over a number of weeks or months, which can include shortness of breath, a persistent cough, fatigue, difficulty with thinking and concentrating, an intermittent fever, or a loss of smell or taste.

Can I spread COVID-19 even after I get the vaccine?

For the most part the answer appears to be no, but in rare circumstances the answer is ves. A vaccine helps prevent people from getting sick. People who are showing signs of sickness are believed to be more likely to spread the virus than people who are not showing signs of sickness. According to the CDC, studies show that a fully vaccinated people is unlikely to spread the virus to others, even if they do get COVID-19. A person is considered fully vaccinated two weeks after their second dose of the Pfizer or Moderna vaccine, or two weeks after the J&J vaccine.

A small percentage of people who are fully vaccinated will still get COVID-19 if they are exposed to the virus that causes it. These are called "<u>vaccine breakthrough</u>" cases. This means that while people who have been vaccinated are much less likely to get sick, it will still happen in some cases. If you do get COVID-19 after vaccination, your symptoms are likely to be less severe. The vaccines continue to show strong protection against COVID-19 and its variants.

For fully vaccinated people, the CDC states that you can participate in many of the activities that you did before the pandemic. To maximize protection from the Delta variant and prevent possibly spreading it to others, the CDC recommends that you wear a mask in indoor public spaces if you are in an area of substantial or high transmission. If you have a weakened immune system, or are living in a household with someone who has a weakened immune system, the CDC recommends that you continue to wear masks indoors in public regardless of the level of transmission in your area. For children under 12, the CDC has recommended continued mask wearing in schools and other settings outside the home.

Wearing a mask and social distancing continues to be of the utmost importance for nonvaccinated people. Mask wearing for all people is still required when riding public transportation (e.g. airplanes, trains, buses, etc) and when required by local workplaces and governments. The CDC recommends non-medical disposable masks or cloth masks made of tightly woven material, ideally with two or more layers of fabric to filter the air you breathe. The mask should fit snugly around the nose, chin, and sides to prevent unfiltered air from escaping. Dr. Anthony Fauci has recommended that people double up on masks to increase their effectiveness.

How many people need to get vaccinated before the pandemic is no longer a threat?

Dr. Anthony Fauci has estimated that 70 to 90 percent of the US population will need to be immune, either by surviving an infection or by getting a vaccine. This estimate is based on how easily the virus is spread, but experts do not yet know the exact percentage of people who would need to get vaccinated to prevent further spread. For most infectious diseases, 50 to 90 percent of the population needs to be immune to stop it from spreading.

Large-scale vaccination efforts have dramatically reduced COVID-19 cases, hospitalizations, and deaths across the country. States and counties with higher vaccination rates are reporting much fewer COVID-19 infections than states and counties with lower vaccination rates. However, variants of COVID-19, like the Delta variant are causing a worrying uptick in infections, especially in places with more unvaccinated people.

If I'm young and healthy, should I take the COVID-19 vaccine? Should I get vaccinated if I don't have any risk factors?

Yes. Getting a vaccine is a much safer option to build protection against COVID-19 than developing immunity by contracting the disease. Although severe COVID-19 symptoms including death—are more likely for certain people, they can happen to anyone, including healthy and young people.

Vaccination also reduces the likelihood of you spreading the illness to others in your household or social circle. Even if you do not have symptoms, you could give COVID-19 to someone who is more vulnerable to severe symptoms.

What about the recently discovered COVID-19 variants?

The virus that causes COVID-19, like any virus, will naturally change over time. Sometimes these changes can lead to a new strain or variant that behaves differently in people. New COVID-19 variants of concern have emerged: one was discovered in the United Kingdom (Alpha variant), another in South Africa (Beta variant), another in Brazil (Gamma variant), and another in India (Delta variant). The Delta variant is currently the dominant COVID-19 strain in the US and it spreads much more rapidly and possibly causes different or more severe symptoms than other strains.

All variants have been detected in the United States and are believed to spread much more easily than the original version of the virus that causes COVID-19 because they require a smaller amount of the virus and less exposure time to infect a healthy person. That means it requires a smaller amount of virus and less time in the same room with an infected person for someone to catch the mutated virus. Health experts are closely monitoring the situation and recommend continued social distancing measures to prevent spread of the disease.

Are the vaccines effective against the recently discovered variants?

Yes, but a little less effective. Because of the way the immune system responds to the virus, most health experts believe the <u>COVID-19 vaccines will work well</u> in people with the new variants. Even if COVID-19 mutates to a point where the current vaccines are not able to protect people, Pfizer and Moderna used a method that will allow them to update their vaccines in a matter of weeks.

Evidence is emerging that the Pfizer, Moderna, and J&J vaccines all offer strong protection against severe disease and death from the Delta variant, although the protection may be less strong against minor or moderate infections.

If I already had COVID-19, should I still get vaccinated?

Yes. Due to the severe health risks associated with COVID-19 and the fact that re-infection is possible after several months (though rare), you should be vaccinated even if you already had the disease. Experts do not yet know how long someone is protected from getting sick again after recovering from COVID-19; the immunity someone gains from having an infection varies from person to person. The Pfizer, Moderna, and J&J vaccines were shown to be safe for

people who previously had COVID-19, but it is less clear how protective the vaccine is against future COVID-19 infections for this group.

How long should I wait to get vaccinated if I am recovering from COVID-19?

You should wait to be vaccinated until after you have recovered and are out of quarantine. The length of your recovery may depend on the severity of your symptoms; if you are unsure, consult your doctor.

What are the factors I should consider when making the decision whether to get the COVID-19 vaccine?

WHAT IS YOUR RISK OF GETTING COVID-19?

- How many people do you come into contact with each day?
- Can you work at home?
- Are you at increased risk for severe symptoms/death from COVID-19?

YOUR RISK OF SPREADING COVID-19

- Are your loved ones at increased risk for severe symptoms/death?
- How would you feel if you gave COVID-19 to a friend or loved one?
- How many people do you come into contact with each day?
- Could you spread the virus to neighbors or essential workers?

OUALITY AND AVAILABILITY OF THE VACCINE

- Tested for safety and effectiveness
- Up to 95 percent effective in clinical trials
- Very few side effects
- Tested in many types of people
- Available without charge (or for a fee that can be reimbursed) at a nearby facility

THE HEALTH AND WELL-BEING OF YOUR COMMUNITY

To end the pandemic, a large percentage of people need to be vaccinated

Where can I get more information that I can trust about the COVID-19 vaccines?

"COVID-19 (Coronavirus Disease): Vaccines" by the CDC. The CDC's website contains lots of information on COVID-19, including eight things to know about the US vaccination program, what to expect at your vaccination, and frequently asked questions about vaccination.

"Emergency Use Authorization for Vaccines Explained" by the FDA. This website details the steps taken by the FDA to make sure COVID-19 vaccines are safe and that they work.

<u>Union of Concerned Scientists blog series on COVID-19</u>. We especially recommend posts that examine the <u>science of vaccine development</u>, the <u>complex scientific and ethical issues surrounding who gets the vaccine first</u>, and the <u>quandary of vaccine trials for African Americans</u>.

Because vaccine distribution is controlled at the state and local level, we recommend you look to your state or county health department's website to learn when and where you will be able to get vaccinated.

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