

COVID-19 Vaccine FAQ

** Please note that information about COVID-19 vaccines is changing rapidly. Please check back often for updates and additional information. We will continue to make updates as more information is available. Thank you. **

1. VACCINE DISTRIBUTION & PHASING/TIMELINE FAQ

Q: When can I get the vaccine?

From Friday, April 2, everyone in Colorado over the age of 16 is eligible to receive the COVID-19 vaccine. As the vaccine becomes available to the general public there is likely to be a high demand, so we cannot guarantee when you may receive your vaccination. Current vaccine distribution guidelines can be found on the CDPHE website.

Q. How can I get the vaccine?

Denver Health has simplified the process to sign up for a COVID-19 vaccine appointment. Now, you can simply go to DenverHealth.org/CovidVaccine to get to our direct scheduling platform. You can choose to schedule through your existing MyChart account or simply schedule as a "guest." You will be able to select a location by vaccine manufacturer or to simply choose the first available appointment that fits your schedule. Please remember anyone ages 16-17 must register for a Pfizer vaccine appointment. All adults 18 and over can sign up for any available vaccine appointment or type.

If you are unable to self-schedule a vaccine appointment online, you can call 303-436-7000 to be connected to our call center for scheduling. Due to high demand there may be a significant wait. Please schedule online if you are unable to make an appointment by phone.

This process is only for people scheduling their first dose as part of a complete vaccination.

Q: I've heard a about different COVID vaccines. Which one will I get from Denver Health?

Denver Health is using three vaccines: one from Pfizer, one from Moderna and a third from Johnson & Johnson

Patients who are 16 or 17 years old will be offered the two-dose Pfizer vaccine, as that is the only vaccine approved for use in this age group.

All three vaccines from Pfizer, Moderna and Johnson & Johnson are safe and effective.

Q: Can I choose which vaccine I am going to receive?

At the time that you make your appointment online, you'll be able to select a location by vaccine manufacturer or to simply choose the first available appointment that fits your schedule. Patients who are 16 or 17 years can only register for the two-dose Pfizer vaccine, as that is the only vaccine approved for use in this age group.

Q: Can I get my vaccine at my regular doctor's office?

If you are a Denver Health patient, you will be able to get your vaccine at your regular clinic. When making your appointment for the first dose of the vaccine, you will receive information on where it will be scheduled, and you will be given an appointment time. It is extremely important to be on time for these appointments.

Q: Why am I not able to schedule beyond a certain date?

Scheduling is limited based on the allotment of vaccines we currently have available. More appointment options will be added as we get additional doses of vaccine.

Q: Can I just call the appointment center to schedule my appointment?

If you have <u>MyChart</u>, you can choose an appointment at your convenience online. We will also be able to send you appointment reminders and automatically schedule your second vaccine dose as soon as the first dose is complete. Find out more about setting up a MyChart account <u>here</u>.

If you do not have access to MyChart, you can sign up as a guest through the link at DenverHealth.org/CovidVaccine. If you are unable to do so online, you are welcome to set up an appointment with the Denver Health vaccine hotline at 303-436-7000. Wait times may be long as volume has increased, but we want to help get your appointment scheduled as soon as possible.

Q: How do I sign up to get the vaccine if I am 16 or 17 years old, or if I have a child who is 16 or 17 years old?

Denver Health has simplified the process to sign up for a COVID-19 vaccine appointment. Now, you can simply got to DenverHealth.org/CovidVaccine to get to our direct scheduling platform. You can choose to schedule through your existing MyChart account or simply schedule as a "guest." You will have the choice of vaccine appointments by location and open time slots. Please remember anyone ages 16-17 must register for a Pfizer vaccine appointment, as that is the only vaccine approved for use in this age group. They will also be required to have a parental consent form signed at the time of vaccine administration.



Q: Will I still need to wear a mask after I am vaccinated?

The CDC has <u>guidelines for vaccinated individuals</u>. If you are fully vaccinated, you may visit inside a home or private setting without a mask with other fully vaccinated people, visit inside a home or private setting with one household of unvaccinated people who are not at risk for severe illness, travel domestically without a pre- or post-travel test or quarantine, travel internationally without a pre-travel test depending on destination, and travel internationally without quarantining after travel. You should still avoid visiting indoors with unvaccinated individuals at increased risk of severe illness and avoid large gatherings.

Q: Are there plans to provide proof of vaccination for those who get it? I can envision this becoming something that airlines will request or foreign governments may ask for in order to permit entry once travel resumes.

Yes, we are going to be handing out vaccine cards to everyone at the time of vaccination, which you should keep as proof that you received the vaccine and which one you received. There will be a place on the card for the second dose of the Pfizer and Moderna vaccines so you should bring the card to your second dose if you are receiving these as well. If the card is lost, information about the vaccine you received will also be saved in your medical record.

Q: Will I have to pay for the vaccine?

No, at this time all doses are being paid for by the U.S. government. Your insurance carrier may be billed for an administration fee, but you should not receive any bill.

Q: Do I need to be a U.S. citizen to get a vaccine?

Whether you are a U.S. citizen or not, we are all in this together. If you would like a vaccine, you will be able to get one according to what vaccine phase you are in. An ID should not be required for access to the vaccine. State and local public health agencies will never share your information for any immigration or law enforcement purposes. Receiving the COVID-19 vaccine will not count against you in any public charge determinations.

2. COVID-19 VACCINE SAFETY AND EFFICACY FAQ

Q: Are the vaccines safe?

The three current vaccines were administered to well over 100,000 people in large studies who have been closely monitored over several months for any adverse events. All three vaccines have been very carefully evaluated by the FDA prior to authorizing their use and they all appear to be very safe. Additionally, safety of these vaccines will be evaluated on an ongoing basis among people in the clinical trials as well as in the general public.

The Johnson & Johnson vaccine has been associated with a very small risk of a rare but serious clotting disorder called Thrombosis with Thrombocytopenia Syndrome (TTS). This has occurred in a small number of younger women after receiving the Johnson & Johnson vaccine. While Denver Health paused vaccination with this product for several days, we are now restarting its use based on updated <u>FDA and CDC recommendations</u>.

Q: How effective are these vaccines?

Initial results of studies of the Pfizer and Moderna vaccines show that the vaccine decreased the risk of getting sick with COVID-19 by about 95%. In addition, for people who received the vaccine but did get COVID-19, the infections tended to be less severe. The reduction in cases in the Johnson & Johnson trial was lower than the 95% which has caused some confusion, but the most important finding from the Johnson & Johnson trial was that it appeared to be 100% effective at preventing hospitalization and death, and that trial was conducted in several countries where newer variants were circulating compared to the Pfizer and Moderna trials which were largely conducted in the US.

Detailed information about each vaccine can be found on the CDC's COVID-19 vaccine website.

Q. What is the efficacy of the Johnson & Johnson vaccine?

The Johnson & Johnson vaccine was assessed as a single-dose in the recently completed ENSEMBLE 3 trial, which was conducted in multiple sites around the globe including the US, South Africa, and several countries in Latin America (it is important to remember that the ENSEMBLE 3 trial was conducted in multiple countries, including those in which coronavirus variants are more common, compared to the mRNA vaccines when comparing efficacy results). The trial enrolled nearly 45,000 subjects (data from ~40,000 are presented in the FDA document), and the company committed to enrolling subjects from communities of color who have been disproportionately impacted by the COVID-19 pandemic.

The FDA document released 2/24 stated a 66% efficacy at preventing moderate and severe COVID-19 at 28 days after vaccination; in the US efficacy was 72%. In South Africa, where perhaps the most concerning coronavirus variant was circulating during the trial the efficacy was 64% (7 points higher than reported in preliminary press-release) and 61% in Latin America. Moderate COVID-19 included manifestations such as pneumonia, DVT, difficulty breathing, or two or more symptoms of COVID-10 such as cough, sore throat, fever or chills. Severe COVID-19 indicated systemic illness, respiratory failure organ dysfunction, ICU admission, or death. Because the primary outcome included both moderate and severe outcomes, the lower efficacy numbers may be misconstrued as indicating that many cases of severe illness still occurred in the vaccinated group. However, analysis of the secondary outcome of severe/critical illness demonstrated 77% effectiveness at 14 days and 85% at 28 days; there were no hospitalizations and no deaths in the vaccinated group (compared to 5 deaths in the placebo group). Among persons <60 years, protection against severe outcomes was 90% at 28 days.

Q. Is the Johnson & Johnson vaccine safe? How do the side effects compare to the Pfizer and Moderna vaccines? Overall, the Johnson & Johnson vaccine appears to be safe, and the side effect profile is similar, but potentially slightly more favorable, compared to the mRNA vaccines. The most common side effect was soreness at the injection site, but the vast majority of these were minor: less than 1% of recipients had local soreness that required a pain reliever or had limitation in normal activity. Similarly, systemic side effects occurred frequently, including headache (39%), fatigue (38%) myalgias (33%), nausea (14%), and fever (9%). Higher grades of side effects were more rare, occurring in 1-2% of recipients. High grade fever >39 degrees occurred in 0.2% of recipients. As with the mRNA vaccines side effects were more common among younger recipients (<60 years).

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Q. If the Johnson & Johnson vaccine has lower efficacy, why should I get this one vs waiting for doses of Pfizer or Moderna?

All available vaccines are safe and extremely effective against severe illness, hospitalization and death from COVID-19. Because there are more people who need the vaccine than available doses, the best vaccine is the one that is available to you at the time you are scheduled.

- 1. Though the primary endpoint in the Johnson & Johnson study was the occurrence of moderate to severe disease, the end point that we really care about is the very severe disease that leads to hospitalization and death, because these are the events that overwhelm the health-care system and represent tragic events. Though the numbers of subjects with this endpoint are small, the Johnson & Johnson vaccine was highly effective (100%) against these outcomes.
- 2. The Johnson & Johnson vaccine was tested in settings that were more challenging to achieve high efficacy, particularly in South Africa where the B.1.351 variant was circulating. As such, this is the only trial with evidence of vaccine protection against such a variant, which we expect to circulate more and more widely.
- 3. The Johnson & Johnson vaccine is the first vaccine available in the US that comes with data on the impact of transmission from a large prospective clinical trial, which suggests that there may be a 74% reduction in the risk of transmission. This can be described as a major benefit—it will allow recipients to know that they are protecting family members who are not vaccinated, and will be particularly useful in congregate settings such as jails where transmission has been so devastating.



- 4. The fact that Johnson & Johnson vaccine is only a single dose means that people can get protection without having to do any more work to schedule and attend the second dose—one and done!
- 5. Because supply issues exist, the choice is between the immediately available vaccine and no vaccine, rather than a choice between the three manufacturers. Please take the soonest available vaccine appointment when you are eligible.

Q: What are the side effects of these vaccines?

It is important to recognize that part of why these vaccines work so well is that they cause a strong immune response, which can cause people to feel unwell for a day or so after the vaccine. For some, this is described as feeling like they have a hangover, and it is more common after the second dose of vaccine. In the Pfizer and Moderna studies, the most common side effects include soreness, redness, or swelling around the injection site, fatigue, body aches, or headache. These reactions can be treated with ibuprofen (Motrin, Advil) or acetaminophen (Tylenol) if needed. The side effects in the Johnson & Johnson vaccine were very similar, though of course they only occurred once since there is only one dose required.

Q: Should I take acetaminophen or an anti-inflammatory (for example, ibuprofen) before getting the vaccine to prevent side effects?

No. In the studies of these vaccines, these medications were not allowed prior to vaccination as they could possibly lessen the immune response to the vaccine.

Q: Should I get the COVID-19 vaccine if I have recently been given another vaccine?

There is little data about the safety and efficacy of COVID-19 vaccines when given too closely to another vaccine type. Therefore, it is recommended that the COVID-19 vaccine series should be given at least 14 days before or after administration of any other vaccine. Exceptions may be made at times where the benefit or need for vaccination would outweigh the possible, yet unknown, risks of taking them too close together – for example, a tetanus vaccine as part of wound management or a hepatitis A vaccine given to contain an outbreak. If aCOVID-19 vaccine is administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

Q: How long does the protection of the vaccine last?

We don't know at this time. The studies have followed people who received the vaccine for almost 6 months now without any evidence that the protection is wearing off. The hope is that the protection will be long-lasting, but it is possible that we will need booster shots in the future. We will have more information about this in the coming months.

Q: Why are there 2 doses for the Pfizer and Moderna vaccines?

Many vaccines require multiple doses, such as those for pneumonia, Hepatitis B and measles/mumps/rubella (MMR)--all require multiple doses to ensure full immunity. The first shot shows

the immune system a piece of the virus which stimulates an initial immune response. The second shot is the booster, allowing the immune system to fully develop responses that are both effective and long-lasting. The Johnson & Johnson vaccine was able to produce high levels of antibody after only one dose which is why for now a second shot is not needed. There is an ongoing study to see if a second dose of the Johnson & Johnson vaccine gives additional benefit, and there are also studies to see if only one dose of the Pfizer or Moderna vaccine will be enough.

Q: Do I really need the second dose of the Pfizer and Moderna COVID-19 vaccines?

Both the Pfizer and the Moderna vaccines were studied as 2 doses – Pfizer as 2 doses separated by 21 days and Moderna separated by 28 days—so the information we have about how well these vaccines work is based on people receiving both doses.

Q: What happens if I get only 1 dose of Pfizer or Moderna vaccine?

The FDA and CDC state that both doses are need for full immunity and no one should consider themselves protected with only 1 dose. You may not develop protection, or your partial immunity may also go away after some time and you could still be at risk for contracting severe disease associated with COVID-19. Thus, it is essential to get your second dose as soon as it can be scheduled. At the same time, because there are limited doses available, it is possible that the scheduling of a second dose may be delayed by up to a few weeks; this is ok as long as the second shot does happen.

Q: I heard some countries are spacing out the timing for the 2nd dose of the Pfizer or Moderna vaccine. Can I wait?

Some countries like the United Kingdom are delaying the second dose of the vaccines for weeks or months beyond what is recommended by the manufacturers. The best data we have comes from the clinical trials in which the second dose was scheduled at 21 days (Pfizer) or 28 days (Moderna). We have limited knowledge about how efficacy or side effects may be affected by delaying the second dose, so the current recommendations from the FDA and CDC are that people get the second dose as close to the intended time as possible. However, most experts believe that very short delays (up to a few weeks) if unavoidable because of vaccine supply will still work well. One of the significant advantages of the Johnson & Johnson vaccine is that it requires only one dose and is thus much easier for people to complete.

Q: Will the vaccines protect against the variants of the virus from South Africa, the UK and Brazil?

Several strains of coronavirus that have several mutations that help it spread more easily from person to person have been identified around the globe and these are now commonly found in the US. In addition to being more easily spread, there is some concern that some of these variants may also cause more severe disease and can infect people who were infected with the original strain. Fortunately, scientists believe that the current vaccines will work against this strain and probably the best strategy we have to

control these strains and prevent new ones from emerging is to get the population vaccinated as quickly as possible with any of the available vaccines.

Q. How well does the Johnson & Johnson vaccine work against the variants?

Efficacy against variants of coronavirus is one of the critical vaccine-related questions as these variants become more widespread. We don't have a full picture of the efficacy of the Johnson & Johnson vaccine against different variants (UK, South Africa, Brazil) but available data suggest that like the mRNA vaccines in use, the Johnson & Johnson vaccine provides protection but at a slightly reduced level compared to the initial circulating strains. The most direct evidence comes from ENSEMBLE 3 trial participants in South Africa, where the B.1.351 variant was circulating widely during the trial (95% of South African participants had the B.1.351 strain). Efficacy against moderate and severe disease was 64%, but importantly the protection against hospitalization and death remained complete (though smaller numbers of these events preclude a more definitive conclusion). As such, the Johnson & Johnson vaccine is likely to contribute to a reduction in the risk of spread and emergence of new variants.

Q: Do you need to quarantine from family if you receive the vaccine?

No. There is no active virus in any COVID vaccine so quarantine after receiving the vaccine is not necessary.

Q. How well does the Johnson & Johnson vaccine protect against transmission?

The Johnson & Johnson vaccine trial contained an explicit secondary outcome of asymptomatic SARS-CoV-2 infection. Diagnosis of infection was based on either PCR positive result or seroconversion without illness meeting COVID-19 definitions. Not all of this data is complete as the seroconversion data is reported from only a subset of participants (the remainder had not yet completed the required time period for inclusion the time of analysis). Vaccine efficacy was measured at two time points: 29 days and after 71 days. At 29 days there was very limited and non-significant impact on transmission. At 71 days, in the vaccine group there were 10 asymptomatic cases per 3098 person years and in the placebo group there were 38 cases per 3061 person years, resulting in vaccine efficacy of 74% (95% CI 47-88%). This is extremely encouraging and is an effect that should contribute significantly to reducing transmission. It is notable that there is emerging evidence that the mRNA vaccines from Pfizer and Moderna may also significantly reduce transmission from Israel and the UK.

Q: Are there pediatric vaccines coming?

According to the Food and Drug Administration, the Pfizer vaccine can be given to people 16 years and older. The Moderna and Johnson & Johnson vaccines are only for adults 18 years and older. The FDA is now evaluating evidence to support giving the Pfizer vaccine to children >12 years old. There are ongoing studies involving younger children and infants so we may learn more about how well they work and if they are safe in that age group. It is unlikely that a vaccine for younger children <12 will be

available any time in the first half of 2021, but experts believe that we can control the pandemic without needing to vaccinate small children.

Q. I heard about a delay in the Johnson & Johnson trial because of a serious event in a participant—is this something I need to know about?

The Johnson & Johnson phase 3 trial in the US was paused in September while an independent data safety monitoring board (DMSB) reviewed a serious adverse event in a participant. The case was described in the FDA documentation as a 25-year-old previously healthy vaccine recipient who developed cerebral sinus thromboses. Here is how they described the conclusions from the DSMB:

After thorough investigation and expert consultation no clear cause of the event was identified; however possible contributing factors, such as preceding infection and an anatomical anomaly, were suggested. The investigator's brochure and informed consent form were updated accordingly, and the study pause was lifted. The investigator and Sponsor's final assessment of this event was that it was not related to the study product.

The FDA documents describe a number of other events related to hypercoagulation, but such events occurred with essentially equal frequency in the placebo group.

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Q: Can the vaccines cause COVID-19? How do they work?

The Pfizer and Moderna vaccines do not contain whole virus so they cannot cause COVID-19. The vaccines consist of mRNA that cause your body to make a protein that is on the surface of the virus and your body makes an immune response to this protein. The vaccine is basically telling your immune system what to watch out for and to be prepared to respond quickly if it ever sees the real thing. "mRNA" often makes people think of "DNA" and wonder if the vaccines interact with our genes: they do not! mRNA works in a completely different part of our cells. The Johnson & Johnson vaccine is made using a cold virus that has had its ability to replicate removed. All the vaccine virus can do is make copies of the COVID spike protein for your body to recognize, and it is eliminated from the body after a short time.

Q: How many COVID-19 vaccines are currently under development?

As of March 30, more than 20 vaccines have begun and 6 have completed large-scale (Phase 3) clinical trials around the world and have been authorized in some countries. There are nearly 70 vaccines in

various earlier stages of development. In addition to the Pfizer, Moderna and Johnson & Johnson vaccines, a few others have already been authorized in other countries, including the AstraZeneca vaccine in the United Kingdom. It is likely that 2 more new vaccines will seek authorization by the Food and Drug Administration in the US in the first quarter of 2021.

You can keep track of which trials are going on and where they stand from several websites. Here are two good examples:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

Q: How do I report a problem or bad reaction after getting a COVID-19 vaccine?

The CDC and FDA encourage the public to report possible adverse events to the <u>Vaccine Adverse Event</u> <u>Reporting System (VAERS)</u>. This national system collects these data to look for adverse events that are unexpected, appear to happen more often than expected or have unusual patterns of occurrence. Learn about the <u>difference between a vaccine side effect and an adverse event</u>. Reports to VAERS help the CDC monitor the safety of vaccines.

The CDC has also developed an additional way of communicating concerns about vaccine adverse reactions called <u>V-safe</u>. V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through V-safe, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine

Q: If I am or might be pregnant, should I get the COVID vaccine?

Pregnant women are at increased risk of severe disease when they get COVID-19 and the FDA and CDC have stated that pregnant women may receive the Pfizer, Moderna or Johnson & Johnson vaccines. However, because the trials did not enroll pregnant women, at the present time it is not possible to say if there are additional safety concerns for pregnant women, or if the vaccine will work as well as it does in people who are not pregnant. There are no specific reasons to believe that an mRNA vaccine like the Pfizer or Moderna COVID vaccines or the adenoviral vector vaccines like the one from Johnson & Johnson would pose a risk to a pregnant woman or the fetus, but any certainty about safety in pregnancy will have to wait for future study. There is no evidence that any of the COVID-19 vaccines have any impact on fertility.

If you are or might be pregnant, you are encouraged to discuss with your doctor if you have questions; CDC information is also available here. It is not necessary to have a pregnancy test before receiving your vaccine. It is recommended that pregnant women avoid medications such as ibuprofen (Advil, Motrin) or Naproxen. Therefore, if you are or might be pregnant, it is important that you only use acetaminophen (Tylenol) for any symptoms that might arise after vaccination.

Q: Is the vaccine safe if I am breastfeeding?

Breastfeeding mothers were not enrolled in the Pfizer, Moderna or Johnson & Johnson vaccine studies, and therefore we do not know with certainty the safety of the vaccine in this scenario or any impact on lactation. However, there is no specific reason to suspect that the vaccine or any of its components would enter breast milk or be harmful to your baby. If you have questions or concerns, you are encouraged to speak to your doctor; <u>further information is also available from the American Academy of Pediatrics</u>. And CDC information is also available here.

Q: Can I receive the vaccine if I am immunocompromised?

The COVID-19 vaccine was not studied in immunocompromised individuals, though the vaccine studies did have some participants with HIV infection. While it is not expected to be harmful to individuals who are immunocompromised, we do not yet know if it will be as effective in this population. Because each immunocompromised patient can have different health issues, we recommend that those who are immunocompromised discuss the risks and benefits with their primary provider. CDC information is also available here.

Q: Should I get vaccinated if I already had COVID-19?

Yes. The CDC currently recommends vaccination for people who have had COVID-19 as long as they have fully recovered and are no longer required to self-isolate.

Q: I have heard about severe allergic reactions to the vaccine. What do I need to know about that? Severe allergic reactions were not observed in the vaccine studies but have occurred in a small number of individuals since the vaccine has been administered more widely. These events occurred in people with a history of severe allergy reactions. We are asking everybody who has had a severe allergic reaction (including to food or medications) that required medical treatment to stay in the post-vaccine waiting area for 30 minutes after the vaccine and to inform our staff immediately if there are any worrisome symptoms arise.

Q: Can I receive the vaccine if I have a severe penicillin allergy? What about eggs?

Yes. There is no cross-reactivity between the penicillin antibiotics and the vaccine. The Pfizer and Moderna vaccines are not manufactured using eggs so can be received by those with egg allergies.

Q: What are the ingredients in the vaccines?

The Pfizer and Moderna vaccines have a simple formulation and contain few ingredients, including the mRNA, a lipid capsule that protects the mRNA until it reaches our cells, sodium and potassium salts and other buffers to balance the pH to match our bodies, and sugars to help the vaccine stay effective at room temperature. Links to the precise ingredients in the <u>Pfizer</u> and <u>Moderna</u> vaccines are available.

The Johnson & Johnson vaccine contains the replication-incompetent viral vector as well as some preservatives and buffers to keep it stable at lower temperatures. The link to the precise ingredients for Johnson & Johnson is here.



Q: Is it recommended to administer the COVID vaccine to any person who has received the flu shot this season?

Yes, everyone who received the flu shot can get the COVID vaccine.

Q: Is there any risk because of the extreme cold that the Pfizer vaccine requires for storage?

No. This vaccine must be fully thawed to room temperature in order to prepare it for administration. While the long-term storage needs of this vaccine vary from those we normally administer, once the vaccine is brought to normal temperature range and prepared, the administration process is the same as other vaccines.

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