

- How safe are the vaccines? Very safe. These vaccines have been evaluated in over 56,000 individuals in clinical trials and have now been given to over 71 million people in the US. That is like giving everyone in the United Kingdom, France, Thailand or South Africa a vaccine! An early review of serious side effects in 1.8 million people found that only 21 had serious allergic reactions and ALL recovered.
- 2. What are the long-term side effects? We carefully followed patients in the early stages of the trials (March 2020) and there have not been any long-term side effects. The science behind these vaccines has been in development for over 10 years.
 - a. Pfizer/Moderna: The shell or coating around the active component of the vaccine has been studied for a long time without any reports of problems. Your body will beat the active component of the virus, the "mRNA" in about a day or so. It is actually quite fragile and cannot stay in the body very long before it falls apart.
 - b. Johnson + Johnson (Janssen): the outer shell is from an adenovirus that cannot make copies of itself within our bodies. This has been studied for decades to deliver the active parts of a vaccine. Inside of it is DNA coding for the spike protein which degrades within about a day.
- 3. What are the short-term side effects of these vaccines? These vaccines work so well because they train your immune system to fight the virus. As your body learns to fight it, some people may feel unwell for a day or so after the vaccine. Most people reported mild pain when they got the shot. About half had mild headaches, some had body aches for about a day or so. Pain and swelling at the injection site that lasted longer was uncommon. Serious reactions (prolonged pain and redness at the injection site) were rare.
- 4. What are the ingredients of these vaccines? The Pfizer vaccine has "lipids" (a simple form of fat that can actually be constructed in a lab, does not come from any animal products), the mRNA, salts, sugar. The Moderna vaccine additionally has a "buffer". Here is the scientific/detailed answer:
 - a. Pfizer vaccine:
 - mRNA: nucleoside-modified messenger RNA (mRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2

- Lipids: forms the nanoparticle that protects the mRNA until it gets into our cells
- Salts: potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate. Helps keep the pH, or the acidity, of the vaccine similar to that of our bodies
- Sugar: sucrose. Increases temperature stability of the vaccine
- PEG (polyethylene glycol): covers the lipid coating
- b. Moderna vaccine:
 - mRNA: nucleoside-modified messenger RNA (mRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2
 - Lipids: forms the nanoparticle that protects the mRNA until it gets into our cells
 - Salt: sodium acetate. Helps keep the pH, or the acidity, of the vaccine similar to that of our bodies
 - Buffer: trisaminomethane. A commonly used ingredient that helps keep the pH, or the acidity, of the vaccine similar to that of our bodies
 - Sugar: sucrose. Increases temperature stability of the vaccine
 - PEG (polyethylene glycol): covers the lipid coating
- c. Johnson and Johnson (Janssen):
 - adenovirus that has been modified so that it cannot make copies of itself
 - dsDNA for the spike protein: genetic code for production of the coronavirus spike protein. It cannot integrate into our genetic material because it doesn't have the structure that allows for integration.
- 5. Do the vaccines contain pork or anything else that may compromise other believe systems? No pork. This vaccine is considered halal by many prominent religious leaders (Imam Quari Muhammad Asim-UK) and considered kosher by the Orthodox Union, US Rabbinic Council. The United Arab Emirates and Israel are leading the world in the percentage of people vaccinated.
- 6. Was this vaccine made with fetal tissue? No. The Vatican has issued a statement stating that taking this vaccine is in alignment with Catholic practices and beliefs. The Johnson and Johnson vaccine did use *cell lines* derived from fetal tissue over 40 years ago to produce the adenovirus vector only. *Cell lines are not considered to be fetal tissue*. This is the same construct for the AstroZeneca vaccine which was available when Pope Francis/Vatican issued a statement about taking the COVID vaccines. So, the Vatican was aware of the slight differences in production of these vaccines. The US Conference of Catholic Bishops issued a statement that Catholics should avoid the Johnson and Johnson vaccine because the adenovirus construct was produced in cell lines. This is at odds with the statement from the Vatican.
- 7. Do the vaccines contain eggs? No eggs

8. How long does the protection of the vaccine last?

The earliest patients were enrolled in studies in March 2020, so that is how long we have information about how long the vaccine protects us. We need to follow the patients for a longer period of time to really know for sure.

- 9. Is this an annual or seasonal vaccine? Or do we need to get this vaccine every year like flu vaccine or is it just depend on pandemic? I think this will become clearer once we can follow people for longer. We do know that the virus can change a bit over time, something that is observed with all viruses. We also know that some of these changes could impact the strength of the vaccine. Improving the vaccine to respond to these new "variants" is happening now. But the vaccines we have now still have a tremendous amount of protection, even against these new variants.
- **10.** Do we know why people are allergic to these vaccines? We are actively studying this right now. Some experts think that the polyethylene glycol, a component in the Pfizer vaccine, may be causing the severe reactions but we are doing more research. If you are someone who has a history of severe allergic reactions, we will ask you to wait in a safe, post-vaccine waiting area for 15 minutes so that you can receive immediate medical attention if you have a reaction. Everyone is invited to wait after their vaccine, for easy access to medical care if anything happens! It is important that you talk to your provider about your specific situation if you have allergies.
- **11. Once the pandemic is over, we do not need to get the vaccine, correct?** Actually, it is likely that this will become a regular vaccine. This virus is part of a broader family of coronaviruses, that are seasonal much like the flu. There are examples of vaccines wiping out viruses, such as smallpox. But this virus is very different from smallpox so we will need to see how things progress this year to know for certain.
- **12. How mandated is this in health care system?** There are no mandates that require people to take this vaccine.
- 13. How effective are these vaccines? Initial results of studies of the Pfizer and Moderna vaccines show that the vaccine decreased the risk of developing COVID-19 by about 95% at 42 days (after the second shot). The Johnson and Johnson vaccine studied a different outcome—moderate to severe COVID-19 and was overall 66% effective at 14 days. By comparison, the influenza vaccine each year is about 40-70% effective.
- 14. For the Pfizer and Moderna vaccine, what does 95% effective mean anyway? Does that mean that my chances of getting COVID are now only 5%? Not exactly. In the Pfizer study, out of over 43,000 participants, 162 participants who received placebo (a saline injection) got sick with COVID-19 and only 8 participants who received the vaccine got sick with COVID-19. So, of the people who got COVID in the clinical trial, only 5% were among people who got the vaccine and the other 95% got the placebo (saline injection that did not have any active parts of the vaccine.)

- 15. It sounds like the Johnson and Johnson vaccine isn't as good as the others. Why would I want the Johnson and Johnson vaccine over the Pfizer and Moderna? Totally understandable why at first glance anyone would wonder this. However, they are nearly impossible to compare directly and here's why:
 - They were all enrolling in different countries and at different periods of time.
 - They measured different outcomes
 - The outcomes they measured were at different time periods after the first dose of the vaccine: Johnson and Johnson was at 14 and 28 days, for Pfizer and Moderna it was at 42 days.
 - People in the trials had different exposures to variants and in the case of Johnson and Johnson, had much more exposure to variants that we know impact the effectiveness of Pfizer and Moderna

So how do you know which one is right for you? Talk to a provider if you are unsure about your individual situation. While they are very difficult to compare across their main outcome, the endpoint that was similar across the different trials, lines up fairly well. The endpoint that all trials measured was the prevention of severe/critical COVID-19 at 28 and 42 days. For Pfizer this was 75%, for Moderna it was 100% and for Johnson/Johnson, it was 94%. Johnson and Johnson is only one shot which is pretty convenient by comparison and may have better protection against the South African variant.

- 16. Is this effective in Black people above the age of 70? What about other people of color? Both the Pfizer and Moderna vaccines included people from diverse backgrounds (30% in the Pfizer study and 37% in the Moderna study). They both included older adults with at least 20% of individuals being over the age of 65. When each study evaluated the outcomes of each trial, they did not find any differences by age or race/ethnicity. For the Johnson and Johnson, there was even more representation from people of color: almost 20% of people recruited into the trial identified as Black, overall, 75% identified as being a person of color.
- **17.** I heard this vaccine might make me sterile and I am trying to become pregnant. Is that true? No. There is no evidence linking the vaccines to infertility.
 - a. <u>More detailed answer:</u> Since FDA authorization of these vaccines, information has circulated on the internet that the antigen created by the vaccine (the SARS-CoV-2 spike protein) is similar to another protein that is important for placental attachment (syncytin-1), and that vaccination results in antibodies that target syncytin-1. Neither COVID-19 mRNA vaccines contain syncytin-1, nor does the mRNA used in the vaccines encode for syncytin-1. In addition, the spike protein formed as a result of vaccination with either COVID-19 mRNA vaccines and syncytin-1 are structurally very dissimilar. No data indicates the antibodies formed as a result of COVID-19 mRNA vaccination target syncytin-1.

- **18.** Will this vaccine get incorporated into my DNA? No. Some people may get confused because the messenger RNA makes people think of DNA. But it is a very different thing. The messenger RNA cannot get inside the nucleus of the cell where DNA is housed. It also is very fragile and will not last long inside your body. In the case of the Johnson and Johnson vaccine, it is constructed from DNA and can get into the nucleus. However, it doesn't have the right structure to incorporate into our DNA. i.e., it doesn't have the right key to unlock our DNA and enter it. They used DNA because it is less fragile than messenger RNA, so the vaccine is easier to store.
- **19. If I get COVID even though I got the vaccine, will it prevent me from getting really sick with COVID?** Yes! The studies show that the COVID-19 vaccine will keep people from getting really sick with COVID-19.
- 20. I have heard that if I had COVID and now I get the vaccine that my side effects may be more severe. Is that true? This may be true. We are certainly now starting to hear from people who had COVID in the past who received the vaccine are that they experience more symptoms of fevers, chills, or body aches. These symptoms are from the immune system doing its job and are not harmful but are uncomfortable. Most symptoms resolved by the next day.
- 21. If a heath care worker (or anyone else) has had COVID-19 and recovered, should they still get vaccinated? Yes. The vaccination may provide stronger or longer lasting protection than just having beat the vaccine on your own. For that reason, we are recommending that you still receive the vaccine after you have recovered from COVID. However, we also believe that natural immunity may protect someone for around 90 days, so it is also safe to wait.
- **22.** Is wearing a mask and socially distancing still recommended after receiving a COVID-19 vaccine in the community? Yes. While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, it will be important for everyone to continue using all the tools available to us to help stop this pandemic, like covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others. Together, COVID-19 vaccination and following CDC's recommendations for how to protect yourself and others will offer the best protection from getting and spreading COVID-19. Experts need to understand more about the protection that COVID-19 vaccines provide before deciding to change recommendations on steps everyone should take to slow the spread of the virus that causes COVID-19. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.
- 23. If I am vaccinated as well as my friends/family, can we be around each other without masks indoors for small gatherings? Yes—with some additional precautions. This is evolving as we get more information in about how effective the vaccines are at

preventing us from passing COVID to one another. <u>Here's</u> the latest. Fully vaccinated people can:

- Visit with other fully vaccinated people indoors without wearing masks or physical distancing
- Visit with unvaccinated people from a single household who are at low risk for severe COVID-19 disease indoors without wearing masks or physical distancing
- Refrain from quarantine and testing following a known exposure if asymptomatic
- **24.** Do you need to quarantine from family if you receive the vaccine? No. There is no virus in the vaccine so quarantine after receiving the vaccine is not necessary.
- **25.** Are there vaccines for children coming? Yes!. The Pfizer vaccine started to include children age 12-16 years in the last 2 months, so we may know more about this population soon, The other vaccines are planning trials in children down to 6 months. Moderna announced that it will start to enroll children down to 6 months. Pfizer will enroll children down to age 5 in the next few months, and Johnson and Johnson will start in a few months down to age 6. It will take some time before we have information on how well they work for children, so I wouldn't expect them to be available outside of a trial probably until at least fall of this year.
- **26. Can the vaccines cause COVID-19? How do they work?** No. Vaccines do not contain the whole virus so they cannot cause COVID-19. The vaccines consist of mRNA or DNA that causes your body to make a protein that is on the surface of the virus and your body makes an immune response to this protein.
- **27.** If I am or might be pregnant, should I get the COVID vaccine? While the COVID-19 vaccines are safe, the trials did not enroll pregnant women. What we do know is that pregnant women are dying from COVID-19 and are at higher risk of complications. There is not an answer at this point that will fit everyone's situation. However, most infectious disease physicians, <u>obstetricians and gynecologists</u> recommend pregnant women be considered for the vaccine if they are also in another risk category (healthcare worker for example). This is because pregnant women are at high risk for complications from COVID disease.
- 28. Is the vaccine safe if I am breastfeeding? Breastfeeding mothers were not enrolled in the studies, and therefore we do not have definitive data about the safety of the vaccine in this scenario or any impact on lactation. Most infectious disease physicians, <u>obstetricians and gynecologists</u> recommend breastfeeding women be considered for the vaccine if they are also in another risk category (healthcare worker for example). However, we do not have strong data about whether the vaccine may affect breastfeeding, because breastfeeding women were not enrolled in the study.

- **29. Can I receive the vaccine if I am immunocompromised?** Yes. The COVID-19 vaccine was studied in only a small number of immunocompromised individuals in the Pfizer and Moderna trials. Within the Johnson and Johnson trial there were just over 1200 individuals living with HIV who were included in their trial which still wasn't large enough to tell us how effective it is in people with HIV. Side effects didn't seem to occur more often in immunocompromised people but the number of people who are immunocompromised or are living with HIV was small across the trials. While it is not expected to be harmful to individuals who are immunocompromised, it may not be as effective in this population. Because each immunocompromised patient can have different health issues, we recommend that immunocompromised individuals discuss the risks and benefits with their primary provider.
- **30.** I have heard on the internet that there is a chip in the vaccine. Is that true? No, there is not a chip in the vaccine.
- **31.** I am worried about getting the Pfizer vaccine because of what happened in the study of meningitis in Nigeria. Can I ask for a specific type of vaccine? I get this completely. Totally justifiable given the outcome of that trial. The Moderna vaccine or the Johnson and Johnson vaccine will likely be used most often for outreach because it can be stored more easily outside of the clinic setting. I believe (Dr. Haas here) that you have a right to request the vaccine you prefer. I personally received the Pfizer vaccine because it was the only one available to me and I am okay.
- **32.** Can I receive the vaccine if I have a severe penicillin allergy? Yes. There is no crossreactivity between the penicillin antibiotics or any other antibiotics and the vaccine.
- **33.** Is it recommended to administer the COVID vaccine to any person who has received the flu shot this season? Yes! You can get both in the same season!
- **34.** Is the vaccine a 2-step vaccine requiring another injection? If yes, when is the second one due? There are multiple vaccines coming out and some of them do require a second dose. The Pfizer and Moderna mRNA vaccines both require a second dose. The second dose of the Pfizer vaccine is given about 21 days after the first. The second dose of the Moderna vaccine is given about 28 days after the first. The Johnson and Johnson vaccine is one dose only.
- **35.** How do you track the 2nd dose for the two shot vaccines? What happens if people do not come back? We will record your vaccine schedule in your medical record and/or give you a card that has your vaccine date on it. If you are getting your vaccine at an outreach event, the outreach staff will come back to the same location when it is time for the second dose. If people do not come back, we will do our best to contact them. Based on the trial data we know that even if we never find them, that they will have some protection after the first dose (and that looks like quite a lot.)

- **36. Why are some two doses? Is this unusual?** No. Many vaccines have to be given in more than one shot to trigger an immune response (hepatitis A, Hepatitis B, HPV among others).
- **37. Who is paying for it? Is it free?** Yes. Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at no cost.
- **38.** How long after an individual has received another vaccine (i.e., Shingrix, influenza) should the COVID vaccine be administered? There is not much information about the best timing of other vaccines and the COVID vaccine. So right now, we are being very cautious. The recommendation is that the vaccine series should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccine. If mRNA COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.
- **39.** I have severe allergy to latex, and I have to carry an EpiPen. Can I still get a vaccine? latex is not a component of either the Pfizer or Moderna vaccine: "CDC recommends that people with a history of severe allergic reactions not related to vaccines or injectable medications—such as food, pet, venom, 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." "If you have had a severe allergic reaction to any ingredient in an mRNA COVID-19 vaccine, you should not get either of the currently available mRNA COVID-19 vaccines. If you had a severe allergic reaction after getting the first dose of an mRNA COVID-19 vaccine, CDC recommends that you should not get the second dose."
- 40. I have heard that the mRNA vaccine was based upon DNA from white persons, so I am worried about whether the vaccine is right for me. Can you talk about how this vaccine was evaluated? Yes. First, race is a completely social construct. While individuals may have different ancestral backgrounds, a person's ancestry may better reflect differences in for example, kidney function than self-identified race/ethnicity. Additionally, mRNA or DNA (Johnson and Johnson) cannot interact with DNA in our cells. The mRNA/DNA that is in the vaccine is not from any person at all, it is from the virus. This virus does not have any human genetic material in it at all—it is purely viral mRNA and not any human mRNA.
- **41. Will the vaccine card will need to be carried with you everywhere you go because it may be needed to enter a place of business?** There has been some discussion about "vaccine passports" in the media but at this time there have not been any businesses, healthcare organizations or other entities that are considering implementing such a policy.
- **42. How well does it work against the new variants?** The information from the clinical trial of Johnson and Johnson indicates very good protection against the variants in the trial

(South African, Brazil, no UK variants were identified). For the Pfizer and Moderna, early data indicate that they both may have reduced strength against the South African variant. At this time the South African variant has been identified in Colorado but so far appears rare. Overall, it is estimated 3-6% of COVID-19 disease in Colorado is due to a variant strain. There are studies ongoing for the mRNA vaccines to evaluate the efficacy of a booster shot so would anticipate an update later in the year.