Moderna COVID-19 Vaccine Frequently Asked Questions

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Though there are likely to be multiple vaccines available, the Suquamish Tribe has elected to protect its citizens from the COVID-19 virus with the Moderna vaccine. The following handout is based on information provided by the American Indian Health Commission.

1. How do we know the Moderna vaccine is safe?

The Moderna vaccine successfully completed clinical trials specifically designed to validate the vaccine's safety and efficacy. The multi-phase process included a randomized, double-blinded, and placebo-controlled trial with approximately 30,400 participants. Trial results were then thoroughly reviewed through a multi-step process. First by an independent advisory panel, then the FDA, then the CDC, and yet again as a redundant safety measure through the Western States Scientific Safety Review Workgroup. The workgroup was comprised of independent vaccine experts from Washington, California, Oregon and Nevada. Each of these steps entailed review by independent health and science experts to confirm the vaccine's emergency use authorization was granted using science-based merits to objectively assure its safety and efficacy.

2. How does the Moderna mRNA vaccine work?

The Moderna vaccine is a messenger RNA (mRNA) vaccine that instructs the body's cells to make a harmless product called a "spike protein." The spike protein is found on the surface of the virus that causes COVID-19. The vaccine is administered by injection to the upper arm muscle. Once injected, the body makes the spike protein.

After the spike protein is made, enzymes break down the mRNA from the vaccine. Cells then display this protein on its surface. The immune system recognizes this is a new, "foreign" protein and begins building an immune response by making protective antibodies, just as it does during a natural infection. As a result, the body learns how to protect against future exposure to the COVID-19 virus.

3. Is it one shot or a two-shot series?

The Moderna vaccine require two doses. The second dose is given 28 days after the first dose. **It is critical to receive the same vaccine for both doses.** In other words, if you receive the vaccine on January 1, you should receive the second dose on January 28.

4. Why are two vaccine doses needed? Are the two doses different?

The second vaccine dose is the same as the first dose. The second dose helps boost the immune system to produce a stronger immune response. This means more antibodies to protect against the COVID-19 virus. While the exact amount of antibody protection needed for adequate protection isn't known, in clinical trials, two doses of the vaccine produced a much more reliable response than one dose. The second dose must come from the same Manufacturer as the first.

5. What are the ingredients and what are their purpose?

The Moderna vaccine contains messenger RNA, which carries a recipe for a specific SARS-CoV-2 (the virus that causes COVID-19) protein called the spike protein. This mRNA is carried in a fat droplet called a lipid nanoparticle. The lipid nanoparticles protect and transport the active mRNA component of the vaccine to its target site inside our cells. There's also some buffer solution that contains electrolytes used to balance the pH of the liquid (potassium chloride, sodium chloride, etc.). There are no additives or preservatives in the vaccine.

6. Are messenger RNA COVID vaccines made with fetal cells?

No, there are no fetal cells required to manufacture the mRNA COVID-19 vaccines.

7. Is there any human or animal tissue in the either the Moderna vaccine?

No. The vaccine only contains the messenger RNA code and lipid particles that protect it so it can reach its target cells in the body.

8. How effective is Moderna's COVID-19 vaccine?

The vaccines developed by Pfizer and Moderna have reported efficacy of 94%-95%. This efficacy is among the best we have available for any currently used vaccine. For comparison, the efficacy of the MMR vaccine is 97% (2 doses); and chickenpox is 90-92% (2 doses).

9. Is there any chance the COVID vaccine could give me COVID-19?

No. The vaccine does not have the components necessary to make full copies of the virus that causes COVID-19, so it's not possible to get COVID-19 from a mRNA COVID-19 vaccine.

10. Is there any reason someone should not get a COVID-19 vaccination?

The FDA's emergency use authorization stipulates that the second dose of the vaccine should not be administered to anyone who had a severe allergic reaction to the first dose of the vaccine.

11. Can a person still get the virus even after they've been vaccinated?

It's possible, but it's very unlikely the virus will make you sick once your antibodies have been fully developed. In clinical trials, the Moderna vaccine showed an efficacy of 94% to 95% after the second dose. That means the vaccine might not be fully protective in about 1 in 20 people.

Even when you get the COVID-19 vaccine, it takes a few weeks for the body's immune response to gear up. Keep in mind, **one dose of the vaccine isn't good enough**. It's important to get both doses. All totaled, it will take about 6 weeks after you receive the first vaccine dose to get the full protection from the vaccine. That means it's important to continue to practice all the measures currently being recommended to reduce the spread of the virus, including:

- Washing your hands regularly with soap and water, or alcohol-based hand rub.
- Covering your mouth and nose with a mask when in public settings or around others.
- Avoiding the temptation to touch your face.
- Covering your mouth and nose when coughing or sneezing.
- Staying home if you feel unwell.
- Practicing physical distancing by avoiding unnecessary travel and staying away from large groups of people.

12. Is there one type of vaccine or different vaccines for different strains of the COVID virus?

There are several strains of the SARS-CoV-2 virus – the virus that causes COVID-19. However, among these strains, there are some common structural elements. One of these is a spike protein on the virus's surface. This protein is crucial to the virus gaining entry into the body's cells, which allows it to replicate and cause illness. The spike protein stays the same on the different strains of virus.

The Moderna vaccine contains a recipe that tells the body's cells to produce this specific spike protein. The presence of this new protein causes the immune system to produce antibodies directed against this protein. These antibodies protect against future COVID-19 infection.

13. Does this vaccine act in the same way as a flu shot, building up antibodies to help fight the virus?

Yes, basically. The vaccine stimulates the body to produce protective antibodies against the virus that causes COVID-19. It also stimulates immune cells called T cells, which help the body to "remember" the virus if exposed to it again. This makes it easier for our immune system to fight off the virus should it come into contact with the virus at a later date.

14. What's the difference between immunization and vaccination?

They're basically the same thing. Vaccines are what provide immunization. Vaccination is the process of getting a vaccine into the body. Vaccines stimulate the body's immune system to protect a person against subsequent infection or disease. Immunization is the process whereby a person is made immune or resistant to an infectious disease, typically by administration of a vaccine.

15. Is it safe for pregnant or breastfeeding women to get the COVID-19 vaccine?

To date, the COVID-19 vaccine has not been tested on pregnant or breastfeeding women, so there's no data to answer this question for sure. However, based on how the vaccine works, it is unlikely that vaccination would pose any additional risk to a pregnant or breastfeeding woman.

COVID-19 infection appears to be more dangerous to pregnant women compared to nonpregnant women. For this reason, the CDC is recommending that women in a high-risk category (for example, a healthcare worker) get vaccinated even if pregnant or breastfeeding. If you are in this category, you should discuss the pros and cons of vaccination with your healthcare provider.

16. Can the COVID-19 vaccine interfere with a woman's ability to get pregnant?

There's no reason to believe the vaccine is unsafe to use in women trying to conceive. The mRNA used in the COVID-19 vaccine does not integrate into our cell's genetic material. The mRNA in the vaccine shares a code that signals the body's cells make a protein, which in turn stimulates the production of protective antibodies. Once it does this job, the mRNA is naturally destroyed by enzymes in the cells.

17. I'm trying to conceive. Should I get a pregnancy test before vaccination?

Pregnancy testing before COVID-19 vaccination is not recommended.

18. Can I get the COVID-19 vaccine if I have a history of Guillain-Barre or other neurological conditions?

Healthcare experts don't know for sure, but there's no data to suggest people with a history of Guillain-Barre or other neurological condition should be excluded from COVID-19 vaccination.

The cause of Guillain-Barre is unclear, but it seems to be related to an overactive immune response from the body. Infections are thought to be one of the triggers that may provoke this immune response. Approximately two-thirds of patients with Guillain-Barre give a history of a recent respiratory tract or gastrointestinal infection. While Guillain-Barre has followed vaccinations, the risk of Guillain-Barre after receiving a vaccination is much smaller than the risk of Guillain-Barre after having an infection such as influenza.

19. Is this vaccine safe for older people who might have chronic health conditions?

Among the 30,000 participants in the Moderna trial, more than 7,000 Americans were over the age of 65. It also included more than 5,000 Americans who are under the age of 65 but who have high-risk chronic diseases that put them at increased risk of severe COVID-19, such as diabetes, severe obesity and cardiac disease.

Based on currently available information, the vaccine is just as safe and effective in older people with chronic diseases as it is in younger, healthy people.

20. Should I be vaccinated if I have a condition or take medication that weakens my immune system (e.g., HIV, cancer treatment, or rheumatologic illness)?

People whose immune systems are weak are at greater risk of developing severe COVID-19 infection. For this reason, the COVID-19 vaccine is recommended for people with conditions that suppress their immune system. Although the vaccine is recommended, people with immunosuppression may have a diminished response to the COVID-19 vaccine.

21. Does the COVID-19 vaccine cause autoimmune conditions to flare up?

In clinical trials of the COVID-19 vaccine, there were a small number of people with autoimmune conditions, and there was no evidence that receiving the COVID-19 vaccine caused their autoimmune conditions to flare up.

22. Is the vaccine safe for children?

The vaccine has been given emergency use authorization for use in people 18 years of age and older. That's mainly because early vaccine trials did not include children. However, studies are now enrolling children, so we will have more information about the safety and effectiveness of the COVID-19 vaccines in this age group soon.

23. What are the vaccines' side effects?

The most common side effects are at the site of injection, such as localized tenderness, redness, swelling, or pain. Less commonly, people may have chills, fatigue, fever, muscle/joint pain, or nausea. Most people experience mild side effects that don't interfere with everyday activities, and most symptoms don't last longer than 2 days. Some people experience, symptoms might be moderate and last up to 5 days.

In Moderna's latest trials, about 10 percent of participants experienced fatigue, roughly 9 percent reported muscle aches and about 5 percent had joint pain and headaches. The good news is, these side effects indicate the vaccine is working. None of them produced long-term consequences.

There is a remote chance that the vaccine could cause a severe allergic reaction. These reactions usually happen minutes to one hour after getting a dose of the vaccine. Signs of a severe allergic reaction include:

- Difficulty breathing
- Swelling of the face and throat
- Fast heartbeat
- Rash all over the body
- Dizziness and weakness

If you experience any of these side effects, contact your health care provider, call 911, or go to the nearest hospital.

24. Have there been any deaths so far from people taking the COVID vaccine?

There have been no deaths reported in the Moderna vaccine trials.

25. It seems that some people are experiencing some possible long-term symptoms from COVID-19. I understand the vaccine is also new but is there any data regarding possible long-term reactions from the vaccine?

Trials with the Moderna vaccine began in March, so we only have 6 to 9 months of data on the safety of these vaccines. Based on this data, there no indication of any long-term effects. Usually if you have a serious side effect from a new product, you'll find it out within the first few weeks, and no serious side effects have been identified in any of the Moderna vaccine trials. However, there is the remote possibility that a rare, serious side effect doesn't become apparent for some time after a vaccine is being used in large numbers of people. That's why participants in the vaccine clinical trials will continue to be tracked for at least two years, and there are several comprehensive national systems to monitor vaccine safety in the United States (for example, the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD)).

26. I have allergies and carry an Epi-pen. Is it safe for me to receive the COVID-19 vaccine?

The CDC considers a history of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a precaution but not a reason to avoid vaccination. Persons with a history of anaphylaxis to other vaccine or injectable therapy should consult with their health care provider.

There's no evidence that people with non-drug allergies (for example, shellfish, nut, latex allergy) have an increased risk of allergic reaction to the COVID-19 vaccine. Therefore, COVID-19 vaccination is recommended for these individuals.

If you have a history of anaphylaxis, it's recommended that you be monitored for 30 minutes after receiving the COVID-19 vaccine.

27. How long does immunity last?

We don't know for sure because the studies with the vaccine have only followed patients for less than a year. However, we know from other mRNA vaccines that immunity usually lasts for several years, often even decades. A "booster" vaccine dose may be necessary sometime after the initial two-dose regimen, but we're not certain about this right now. The CDC will make more specific recommendations once we have more information about the long-term immunity produced by the vaccines.

28. Can I get the COVID-19 vaccine at the same time as I get my influenza vaccine?

There's no information on the COVID-19 vaccine being administered with other vaccines. So, at this point, the CDC is recommending that the COVID-19 vaccine be administered separate from any other vaccine and preferably at least 14 days before or after another vaccination, such as the flu shot. However, if you inadvertently receive the COVID-19 vaccine less than 14 days after another vaccination, re-dosing is not recommended.

29. Will people have to get a two-part vaccine every year or will it become one-part vaccine every year?

We don't know yet. Vaccine studies are ongoing to help answer this question.

30. Who will be first in line to get the vaccine?

Vaccine will be in very limited supply for the next few months, therefore, priority groups for vaccination have been established. In an effort to reduce the spread and to protect those at greatest risk, initial priority will be to vaccinate healthcare workers and Tribal Elders over 65 with underlying health conditions. This is an objective risk-reduction approach consistent with CDC recommendations.

31. Will the vaccine be mandatory for Tribal employees?

Vaccination will be voluntary for most employees. It will be made available to all Tribal Government and enterprise employees in phases as supplies become available. Some specific positions, because of their potential risk to others, may eventually require vaccination. If and when these positions become identified, they will be addressed on a case-by-case basis.

32. Will I need to take the vaccine if I already had COVID-19?

Although many people who had COVID-19 develop protective antibodies, it's uncertain how long those antibodies last. Evidence suggests, the antibody response produced by the vaccine may be stronger and last longer than the antibody response mounted by the body in response to a natural infection. For this reason, vaccination is recommended for people regardless of whether or not they have had COVID-19 (symptomatic or asymptomatic) in the past.

33. I received monoclonal antibody treatment (bamlanivimab, casirivimab, imdevimab) for COVID-19. Am I still eligible to get the vaccine?

You can still receive the COVID-19 vaccine if you were treated with monoclonal antibody therapy for COVID-19 infection. However, it's recommended that the vaccine be administered no less than 90 days after you received treatment to avoid interference of the treatment with the vaccine-induced immune response.

34. I received convalescent plasma for the treatment of COVID-19. Am I still eligible to get the vaccine?

You can still receive the COVID-19 vaccine if you were treated with convalescent plasma for COVID-19 infection. However, it's recommended that the vaccine be administered no less than 90 days after you received treatment to avoid interference of the treatment with the vaccine induced immune response.

35. If I have recently recovered from COVID-19, should I wait to get the vaccine?

The best information we have suggests that antibodies to COVID-19 that are produced by the body last for at least a few months. However, there's no way to determine whether that's true for everyone. There's also evidence to suggest that the antibody response produced by the vaccine may be stronger and last longer than the antibody response mounted by the body in response to a natural infection. For this reason, vaccination is recommended regardless of whether you have had COVID-19 or not.

That said, if vaccine doses are very limited, it might make sense first to vaccinate people with no history of COVID-19, who definitely don't have antibodies to the virus and vaccinate individuals with a history of recent COVID-19 infection when more vaccine doses become available.

36. I understand the vaccine requires very strict temperature control. What are the possible negative consequences of receiving a vaccine where somewhere along the line temperature control wasn't optimal?

The Moderna vaccine does not require ultra-cold storage and is much less dependent on strict temperature control than other vaccines. The vaccine is stored using standard freeze and refrigeration capabilities. The Tribe has invested in the storage capability needed to maintain proper temperature control. This includes constant 24/7 temperature monitoring, and alert system, and backup power capability.

We don't have a lot of information to answer this question. However, based on previous experience, the most likely consequence is that the vaccine will be less effective or not effective at all. That's because the messenger RNA in the vaccine breaks down very easily, particularly if exposed to warm temperatures or light.

37. Does the vaccine work hand-in-hand with any of new treatment medications that have been authorized for use by the FDA?

Several medications such as bamlanivimab have been granted by the Food and Drug Administration (FDA) emergency use authorization (EUA) for patients with COVID-19. These drugs are used to treat patients who are confirmed to be COVID-19 positive through a laboratory test. They are not used to prevent infection.

Vaccines are intended to be used on healthy people to prevent infection. They stimulate the body's immune system to create protective antibodies. Vaccines work alone. No other medications need to be given for a vaccine to work.

38. Will the COVID-19 vaccine affect results of SARS-CoV-2 nucleic acid amplification (PCR) or antigen tests?

No. Results of PCR or antigen tests for SARS-CoV-2 infection are not affected by the COVID-19 mRNA vaccines.

39. Once we have the vaccine, will we still have to wear masks in public?

Remember, it takes about 6 weeks after the first dose of COVID-19 vaccine for the body to develop a protective immune response. It will also take several months for everyone who is eligible to get vaccinated. For these reasons, it's unlikely we'll see any changes to current recommendations for some time. The CDC will continue to modify recommendations based on COVID-19 case rates and trends throughout the world.

CDC References:

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States.

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020