

Frequently Asked COVID-19 Vaccine Questions

1. Can the Viral mRNA in the vaccine replicate our DNA?

Messenger ribonucleic acid (mRNA) is a copy of DNA. DNA does not leave the nucleus of the cell, where it is protected. The viral mRNA in the COVID-19 vaccine, does enter our cell's nuclei. Messenger RNA is produced from DNA, and it cannot produce DNA. The viral mRNA is only good for a short time after it loses its liposomal cover.

2. Do we have any vaccines today that are made the same way as this vaccine?

There are vaccines which utilize this same type of mRNA vaccine technology. Some cancer medications, and vaccines for Zika and Rabies viruses use mRNA methodologies. However, these vaccines have not had wide spread use. This mRNA vaccine modality was selected because it is faster and easier to produce large amounts of vaccine. It has been studied for many years already (over a decade), but only used on a very narrow basis. Messenger RNA biology and technology is not new. The ability to mass produce it is.

3. If I get both doses of the COVID-19 vaccine, and am exposed to an individual who has tested positive, do I still need to quarantine?

This still needs to be determined. If you received two doses and it has been four weeks since your second dose, you would be at 5% risk without PPE, not 100% protected. We will follow CDC and OHA guidance, and utilize our employee health center for clarifications as needed. Currently, even if you have been vaccinated, there are no changes to the PPE expectations.

4. Will mRNA affect me in other ways?

With the large number of people included in both the Pfizer-BioNTech and Moderna COVID-19 vaccine studies, nothing has been identified that was not expected. The long-term effects are unknown. The vaccine studies identified the expected immune response signs and symptoms which last for 24-72 hours. After that, no other side effects were noted.

It is important to note that viral mRNA will be eliminated in a few hours. The viral spike protein made from the mRNA will be present in the body for 2-3 days prior to being destroyed. After a couple of days, the viral mRNA and its viral spike protein it codes for, are no longer present in the body.

5. If you have had Covid-19, what are the recommendations regarding receiving the vaccine?

Both COVID-19 vaccine studies (Pfizer-BioNTech and Moderna) showed better protective immunity to COVID-19 infection than patients who contracted COVID-19 disease. These findings indicate that the vaccine provides better protection than that provided from active COVID-19 infection. Professionals are recommending/encouraging individuals to get the vaccine, regardless of previous Covid-19 exposure, for maximal protection.

6. If I get the vaccine, how long will the immunity last?

This is unknown. The vaccine provides a stronger immune response than getting Covid-19 disease. Studies indicate that protection after receiving the COVID-19 vaccine lasts at least 6 months, and is anticipated to last longer than that. The studies have not stopped. They are ongoing.

7. Will I require a yearly booster?

This is unknown at this time. Some vaccines do require regular boosters. Influenza (flu) and tetanus vaccines require periodic boosters. Some vaccines require a single booster, like the MMR and the Herpes Zoster (Chicken Pox / Shingles) vaccines.

8. Will this be an annual shot, like the Flu vaccine?

It is unknown what the frequency will need to be for this vaccine at this time. Ongoing studies will help us determine the need and timing for revaccinations.

9. Why are there 2 doses for this vaccine?

As indicated previously, many vaccines require multiple exposures to achieve beneficial protection levels. After the first dose of the COVID-19 vaccine, around 50% of patients were protected. After the second dose, this rose to over 95%. Sometimes our immune systems just need a reminder to set the immunity protection it provides for us.

10. What can you tell me about infertility and pregnancy with the vaccine? What about breastfeeding?

Pfizer-BioNTech, Moderna, CDC and the OHA state clearly, that the vaccine MAY be administered to pregnant women. If you are pregnant, you are able to get the COVID-19 vaccine, however, it is important to discuss the vaccine in detail with your obstetrics provider.

While studies are not routinely performed on pregnant women, around a dozen pregnancies occurred in recipients of the vaccine. No adverse events have been reported surrounding these pregnancies to date.

No hard data is available regarding the COVID-19 vaccine and breast feeding. Knowing the vaccine mechanism, and how long the viral mRNA and the viral protein sheath are present in the body (generally less than 72 hours), assist us in determining the specific risk benefit ratio for your situation. This is best discussed with your provider to minimize any potential exposure to the infant.

11. What are the studies being done for children and the vaccine? Can children be vaccinated?

Pfizer-BioNTech studied the vaccine with individuals 18 and older. Moderna's study included participants 16 and older. Neither are recommended for pediatric use. More studies are being conducted by Pfizer-BioNTech for the pediatric population to produce more data. Data from this pediatric study is not expected for many months. It is not yet clear what age range is actually being studied.

12. What about the immune-compromised population, or other underlying health conditions?

The point of the vaccine is to create an immune response in our bodies. Some medications and/or conditions blunt the body's ability to create this response. It is recommended that if you are immune-compromised, discuss your situation with the provider who manages your condition. However, the CDC says it is a good idea to get vaccinated. The immunity provided, even if not optimal, will still provide some level of protection.

Most underlying health conditions will not affect the process of the immune response generated by vaccination. Even so, it is best to check with your healthcare provider prior to getting the vaccine in these cases.

13. What are the side effects?

Long term side effects are simply not known. Again, knowing the vaccine mechanism, how long the viral mRNA and the viral protein sheath are present in the body – generally less than 72 hours - leads most scientist to believe the long term side effects to be very minimal.

Some reports indicate the side effects are pretty robust.

An important detail to remember about vaccinations is that most of the symptoms (side effects) our bodies experience during vaccination are the result of our own body's immune response.

The robust nature of COVID-19 vaccination side effects may be due to a strong immune response, which in turn may lead to a strong immunity. This certainly would begin to explain why the vaccine is producing stronger, longer lasting immunity than the disease itself.

Moderna COVID-19 Vaccine Side Effect Listing

Ages (18-65)*	<u>Dose 1 (Day 0)</u>	<u>Dose 2 (Day 28+)</u>
○ Fatigue (tired)	38.4 %	67.6 %
○ Headache	35.3 %	62.8 %
○ Myalgias (aches)	23.7 %	61.6 %
○ Nausea/Vomiting	9.4 %	21.4 %
○ Chills	9.2 %	48.6 %
○ Fever	0.7 %	17.4 %

**Side effects for adults older than 65 years of age were LOWER in every aspect*

14. What do you say to a 25-year-old, healthy, healthcare worker who states they are inclined not to get the vaccine, saving it for someone who needs it?

The CDC and OHA looked carefully at this when beginning the rollout of the vaccine. It is difficult to get herd (or Community) immunity if all who are offered the vaccine, do not receive it. Each of us who gets the vaccine protects themselves, their family, our patients, and the community at large. Once enough of our community becomes vaccinated, and community protection rises, we will begin to see a relaxing of current COVID-19 restrictions.

15. When will you begin administering the vaccines?

COVID-19 vaccine has been shipped to, and received by, Grande Ronde Hospital. **We have begun vaccinating our workforce as a part of the 1a tier (Healthcare Workers) indicated by the CDC and the OHA.** After healthcare workers, other members of the 1a tier include:

- First Responders
- LTC Residents and Workers

Vaccination clinics will be held periodically, as supply of vaccine is available. Please watch for updates from our Employee Health Department.

16. Are there any contra-indications for the COVID-19 Vaccine?

The only contraindication for the vaccine is previous anaphylactic reactions to any previous vaccine.

17. If I react to the other vaccines, including the Flu shot, should I get the COVID-19 Vaccine?

To answer this, you will need to define the Risk – Benefit balance for you personally. Your healthcare provider would be a great asset to you in this discussion.

18. Is there reason to suspect the vaccine may cause fertility issues?

At this point, there is no indication of any fetal, placental or any other reproductive issues tied to the COVID-19 vaccine. As noted above, around a dozen women became pregnant during the studies for the vaccine, and no issues have been reported with their pregnancies to date.

Concerns regarding similarities of protein sequences of the COVID-19 spike coded for in the vaccine and other tissues of the reproductive system (fetal or placental) have not shown to be of clinical significance.

19. What does the process of FDA approval look like? (Vaccines and other medications)

Drug companies petition the FDA to begin studies on a potential treatment option.

- 1- Phase 1 studies
 - a. To demonstrate SAFETY for human consumption
 - i. Typically 10-15 enrollees
 - b. Typically last days (1-7)
- 2- Phase 2 studies
 - a. Dose determination
 - i. Typically 100-150 enrollees
 - b. Determine minimum effective dose
 - c. Determine maximum effective dose without SE/Toxicities
 - d. Typically last days (7-14 is typical)
- 3- Phase 3 Studies
 - a. Therapeutic trials (does it really work?)
 - i. Typically 1,000 to 1,500 Enrollees
 - b. Monitor Side Effects, Effectiveness of treatment
 - c. Typically last weeks (4-13 weeks is typical)

Studies may be terminated early for exceptionally poor results. This happens sometimes.

Some studies are granted Emergent Use Authorizations (EUA) based on exceptionally positive results. This happens less frequently. EUAs happen especially during urgent need, or studies with very small negative risks and large positive benefits. This is not a new route for the American people to access medications.

Most medications are approved after having fewer than 3000 individuals studied taking the medication. Most study durations are from 4 to 12 weeks in duration. Much of the time is spent in data production, and evaluation.

For all medications, post marketing monitoring continues as much larger populations of people begin to use the new medication. This is standard for ALL medications approved.

20. How many people were in the COVID vaccine trials?

The Pfizer-BioNTech study enrolled over 44,000 participants, while the Moderna trial enrolled 33,000. Around 50% of each actually received the actual vaccine, or around a total of 38,000 individuals. This is well above 10 TIMES the usual number of patients a new medication is studied in prior to approval.

21. Was the COVID-19 Vaccine approval 'rushed'?

Based on the information in the previous question, absolutely not. These vaccines have shown a huge positive benefit, while exhibiting a very small (and short lived) risk profile. Most studies last 1-3 months. This study has already undergone 6 months, and will continue. The results are just really positive.

22. When can I stop wearing face-masks?

Not yet. The more people who get vaccinated, the sooner we will be able to eliminate wearing masks. However, realistically, this will be months down the road. Community immunity, sometimes called herd immunity, only happens once a large percentage of our population becomes protected. This will take time.

23. Do I need to be Screened DAILY after I am vaccinated?

Unfortunately, the vaccine protection is not 100%. It is very, very high, above 95%. Until further information is provided, and we begin to see infection rates drop, daily screening will continue.

24. How long after getting the vaccine do antibodies develop in your system?

Most vaccines produce an immune response in just a few weeks. 3-4 weeks following the final dose of a vaccine series, you will have a fully developed immune response. This means you will have antibodies to the covid-19 viral spike protein.

25. What is in the vaccine?

The vaccine consists of the COVID-19 viral mRNA segment, the liposomal sheath (fatty membrane layer), and the serum in which it is suspended. No preservatives, or stabilizers have been added to this vaccine – hence the Ultra Cold storage and short shelf life of this product. The ingredients lists in the package insert are provided here.

Each dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.12 mg sodium acetate, and 43.5 mg sucrose.

26. What do I do if I get the vaccine and develop symptoms?

Remain calm. Remember, it is frequently difficult to differentiate between the immune response of disease, and that of vaccination. Call employee health or your healthcare provider with any specific concerns or questions.

27. If someone misses their initial tier offering, can they receive the vaccine later?

Yes, when the vaccine is initially declined, it may be given at a later time.

28. Will the virus be effective if the virus mutates?

It is possible that even with some minor mutations, the vaccine will still provide some protection. If the virus changes significantly enough, then, the vaccine will also need to be altered, and additional dosing provided to maintain effectiveness.

29. Is there a possibility I will get paralysis for the COVID vaccine?

No, the vaccine is administered intramuscularly, usually in the arm. Paralysis was not seen in any of the 35,000 study participants who received the vaccine.

30. When will COVID-19 vaccine be available to the general public?

The CDC recommended tier structure will be followed. Timing to arrive at the general public vaccinations, depends on the number of vaccinations available, and the demand for them during earlier tiers. This will likely take several months.

31. If I am otherwise healthy, why would I get the vaccine?

For the same reason that we vaccinate against other diseases – to avoid the potential future illness. In this case, COVID-19 has shown that it is hard to predict who will be most sensitive to the illness, and this disease can kill. As with all medication decisions, each of us needs to answer the following question. Do the potential benefits of the COVID-19 vaccine outweigh any potential risks. In the case of most vaccines, including the COVID-19 mRNA vaccine, the risk is minimal, and the benefit is great.

Community (or Herd) immunity is also a factor. The more individuals in our community that are vaccinated, the less disease spread will occur. This is a secondary benefit of vaccinations, but a real benefit nonetheless.

32. Where can I get more information?

The Centers for Disease Control (CDC) and the Oregon Health Authority (OHA) both have excellent resources available on the websites.

33. If I get the vaccine, then contract the COVID-19 disease, do I still have to quarantine?

YES. Remember, no vaccine is 100% effective in preventing disease. If you were to contract the COVID disease after being vaccinated, the disease course would likely be shorter in duration, and less severe in nature than it would have been without the vaccination. Even so, individuals are contagious, and more likely to spread the disease, during active infection.

34. Can employers require employees to become vaccinated for COVID-19?

Health departments make recommendations to civic and government bodies, like our public school districts, regarding required vaccinations. Even so, there are exceptions to these requirements.

To be clear, Grande Ronde Hospital is offering the vaccines to those employees who desire to be vaccinated. Vaccination is not mandatory for employment at Grande Ronde Hospital.