








COVID-19 Vaccine – Your Questions Answered:

1. Do the vaccines have side effects?

As with all vaccines, there is a chance that people who get the vaccine will have some side effects. This is expected, because the vaccine works by activating your immune system. This means some people might feel tired, have a headache or body aches, or a fever for a few days after getting the vaccine. In the study, these side effects lasted less than 3 days. As with most vaccines, people did experience a sore arm or some pain at the injection site.

Here's some side effects comparison among **other approved vaccines and placebo (salt water)**:

Vaccine Side Effects Compared

	 SHINGRIX <small>(ZOSTER VACCINE RECOMBINANT, ADJUVANTED)</small>	 COVID-19 <small>BNT162b2</small>	 <small>Influenza Vaccine</small> FLUCELVAX <small>QUADRIVALENT</small>	 Placebo <small>(saline)</small>
Local Pain	78%	83%	45%	14%
Redness	38%	5%	13%	1%
Swelling	26%	6%	4%	1%
Myalgia	45%	21%	15%	11%
Fatigue	45%	47%	18%	33%
Headache	38%	42%	19%	34%
Chills	27%	14%	6%	6%
Fever	21%	4%	1%	1%
GI Symptoms	17%	11%	7%	12%
Overall	38% 	26% 	14% 	13%

2. I heard a lot in the news about Bell's Palsy and the vaccine. What's the scoop?

There were very few cases of Bell's Palsy in both the vaccine **and placebo** group for the vaccine. The number of cases were the same as what we would expect to see regularly among people, regardless of getting a COVID vaccine.

3. Was there enough diversity and inclusion in the clinical vaccine trials?

Representation of Black, Indigenous, and People of Color (BIPOC) in the vaccine studies is greater than in previous clinical trials. Diversity was greater among the study participants for the Moderna vaccine. There were no differences between vaccine response and safety among the different racial and ethnic groups included in the study.

That being said, we know that COVID-19 has disproportionately impacted communities of color. We also know that the medical, scientific, and healthcare systems have a longstanding history of racist and unethical treatment of BIPOC. The distrust of medicine and this vaccine is valid and real. BNHC is dedicated to promoting equitable access to COVID-19 care that is inclusive and

mindful of the lived experience of staff, patients, and community members who are Black, Indigenous, and from other communities of color.

4. Was this vaccine made and approved too quickly?

The technology for developing this type of vaccine (mRNA vaccines) has been around for quite some time, since the 1990s. When MERS (Middle Eastern Respiratory Syndrome) and SARS-CoV-1 were circulating, there was work done on an mRNA vaccine for these viruses. Scientists had also been investigating this type of vaccine for Zika and Rabies viruses.

The Food and Drug Administration (FDA), which approves all vaccines, has made sure that all of the usual steps for safety and monitoring have been followed for these vaccines. **No study steps were cut out and the studies were actually larger for the coronavirus vaccines than other approved vaccines.**

5. What's in the vaccine?

Moderna:

4.1 Vaccine Composition, Dosing Regimen

The Moderna COVID-19 Vaccine is a white to off-white, sterile, preservative-free frozen suspension for intramuscular injection. The vaccine contains a synthetic messenger ribonucleic acid (mRNA) encoding the pre-fusion stabilized spike glycoprotein (S) of SARS-CoV-2 virus. The vaccine also contains the following ingredients: lipids (SM-102, 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

Pfizer:

mRNA encoding for SARS-CoV-2 spike protein, lipids, potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dehydrate, sucrose

So both vaccines have basically the same ingredients: mRNA coding for Spike protein, some lipids (fats), salt, and potassium. There are no viruses, preservatives, eggs or other substances.

6. But what do these ingredients *mean*?

Some of them are added to make sure that the vaccine itself is stable as it's stored and transported. None of these ingredients, however, are preservatives. Both the Pfizer and Moderna vaccines are preservative-free.

Some of these ingredients are added to make sure that your body can "digest" the vaccine. Think of it like pouring oil into a cup of water. It won't mix, right? But if we pour oil into oil, they can mix. It's just some adjustments to make sure we don't end up with an "oil into water" situation in our bodies. Otherwise, the vaccine wouldn't work.

7. Is the vaccine safe?

Yes! No one has died from the COVID vaccine. Side effects from the vaccine have been minimal and typically go away within 3 days. A few people who have had anaphylactic reaction to vaccines in the past also had an anaphylactic reaction to the COVID vaccine. They were administered an Epi-Pen and recovered quickly.

8. Will I need a shot every year like the flu shot? Or a booster shot?

We don't know for sure yet. Right now, we know that protection from the shot lasts at least 6 months (this is as long as people have been followed – we will keep following them so we know how long the immunity lasts for sure!).

Right now, it is just the 2-shot series.

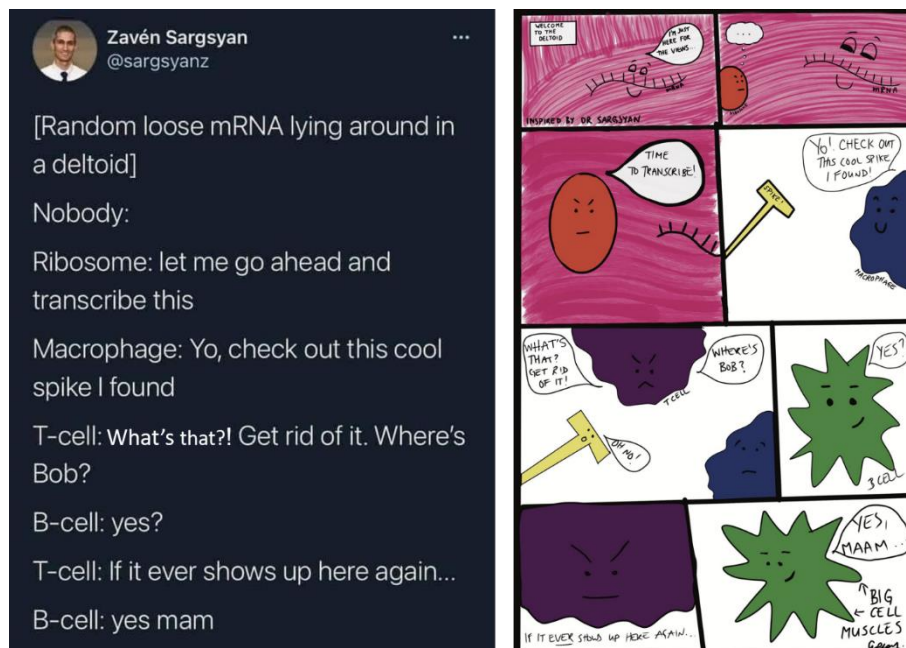
9. How does it work?

Both the Pfizer and Moderna vaccines work by teaching our bodies to create some of the Spike Protein (and **only** the Spike Protein, **not** the virus) so our body learns what the Spike Protein (the little spiky things around the outside of the COVID virus) on COVID-19 looks like. Our bodies have never seen this before, and this is why coronavirus can make us sick.

The vaccines are simply going to show our body what the Spike Protein looks like without making us sick, so that if we come into contact with coronavirus, our body will already know how to fight it!

The vaccine does **not** contain live coronavirus or the DNA/RNA/genetic material of coronavirus. The vaccine contains just a little snippet of mRNA that the body will “read” and use to learn what the Spike protein looks like.

The same idea, but in a funnier nutshell:



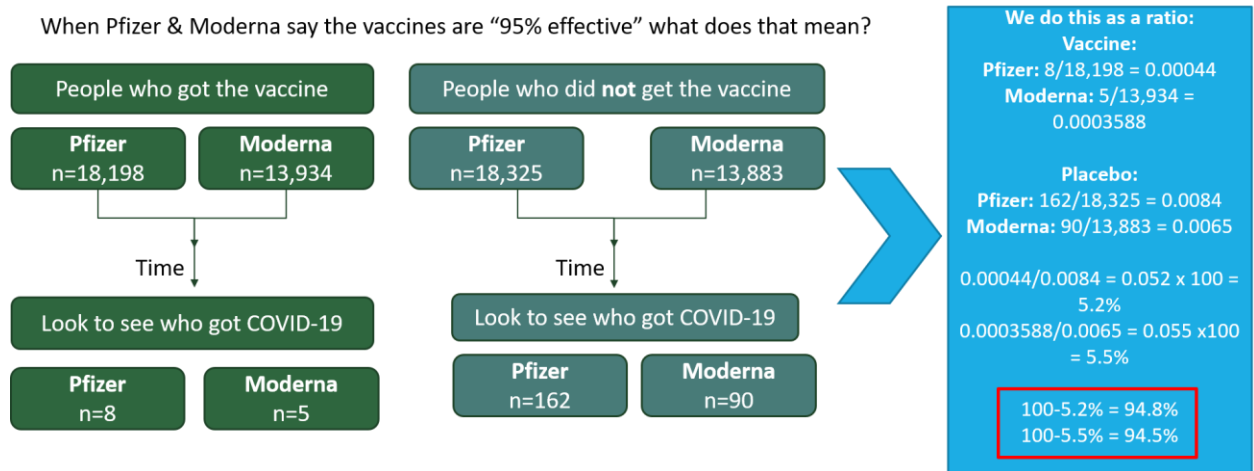
10. How do we know it works?

There are two main ways that we know the vaccine works. In the study, both researchers and study participants do **not** know which group of participants received the vaccine and which group received a placebo injection. As time goes on, we compare two things between the two groups to determine if the vaccine works: how many cases of COVID develop in both groups, and whether or not someone has developed any antibodies to COVID-19 (titers).

In both studies, there were significantly fewer COVID-19 infections among people who received the vaccine compared to people who got the placebo injection. People who received the vaccine also showed that they had antibodies for COVID-19 in their blood.

In the Moderna trial, we also know that people who have been vaccinated are much less likely to have a severe case of COVID-19 if they do get the virus. In the study, none of the people who received the vaccine who did get COVID had a severe case, compared to 30 people who got the placebo injection having a severe case of COVID-19.

In case you *really* want to see how the math works...



11. How has the vaccine been tested?

The vaccine was first tested in a series of non-clinical rat trials. This was followed up by a trial in Rhesus macaques (monkeys). Only after these first trials did the researchers move on to clinical human trials, which had 3 phases.

In Phase I, a small number of people (60 in Pfizer's trial and 160 in Moderna's trial) were given different doses of the same vaccine to see which dose triggered the best immune response against COVID, and also had the lowest side effects.

In Phase II, a larger number of people got the selected dose (chosen from Phase I results) for additional safety testing. Phase II included people who had health issues that put them at risk for serious COVID infection.

Lastly, in Phase III (only after safety was determined from the Phase II trial), a very large number of people received the vaccine, and then were tracked to see if they developed COVID (and if they did, how serious their infection was), any adverse effects possibly due to the vaccine, and measures of immune response (titers).

12. What about special populations?

a. Should people who are immunocompromised get the vaccine?

Both the Pfizer and Moderna studies included people who had complex health conditions, including heart disease, diabetes, and other chronic illnesses, and **also** people who were immunocompromised, such as people living with HIV/AIDS, people receiving cancer treatment, and people with autoimmune diseases. **It is safe and recommended that these groups of people receive the COVID-19 vaccine.** If someone has specific questions about their health and medical conditions, they should discuss their concerns with their Primary Care Doctor and make the decision that is right for them.

b. Should pregnant/breastfeeding people get the vaccine?

We don't have enough information yet to say for sure. Scientists and medical professionals think that it is probably safe for pregnant and breastfeeding people to get vaccinated, but we do not know for sure.

c. Will children be able to get the vaccine?

Yes, but not yet. The Pfizer vaccine is currently approved for people ages 16 years and older, so children ages 16+ would be able to get the Pfizer vaccine. Pfizer also included children as young as 12 years in its study, and is finishing collecting data in order to get approval for younger ages.

Moderna vaccine is approved for adults ages 18 years and older. As we know more information about safety and if the vaccine works in younger people, we will let everyone know.

13. I've heard a lot about a mutation in COVID in London, Brazil, and South Africa. Will these vaccines work for the mutated virus?

The answer is probably yes. We can't be 100% certain, but will learn more very quickly as more people become vaccinated. From what we know, the mutation made some very small changes to the Spike Protein, but not so much so that scientists believe the vaccine will not work. We do not know yet if any mutations will require people to get a booster shot later in time. We also know that the mRNA vaccines are very easy to safely make small changes to in order to provide protection against mutations. Most vaccine creators are already working on updating vaccines now.

14. Will I need to keep wearing a mask and social distancing after getting the vaccine?

Yes! Until we can get many more people vaccinated, we need to continue to use the protective measures we have. Also, when people are vaccinated, it can take up to 2 weeks after the second dose to get the most protection. We want to continue to protect everyone until a very large percent of the population can be vaccinated.

15. I heard that the COVID vaccines were made using human embryos. Is that true?

No. The Pfizer and Moderna vaccines have not been developed from human embryos. Other vaccines in the past have been developed using some human embryo tissue, but the COVID vaccines from both companies **have not**.

16. I am planning to conceive in the near future but am not currently pregnant. Is it safe to be vaccinated now?

Yes. While there is limited data about the safety of COVID-19 vaccines for people who are pregnant, vaccination is safe for people who are not pregnant but would like to conceive in the future.

17. Are the vaccines approved by the FDA?

Both the Pfizer and the Moderna COVID-19 vaccines **have been given Emergency Use Authorization (EUA) by the FDA**. This is different from ordinary FDA Approval, and is used in cases of emergency. **It still involves an extremely rigorous testing and vetting process.**

You may have seen information circulating that the vaccines “are not FDA Approved.” This is misleading. Full approval is a years-long process, and the FDA has determined that it is best to release the vaccine quickly as it has been thoroughly tested, vetted, and proven to be both effective and safe.

You can find more information about EUA here: <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>

18. Should I take Tylenol, Motrin, or another over-the-counter medication before I get my COVID-19 vaccine to try and prevent side effects?

No. Taking medications like Tylenol or Motrin in order to prevent side effects from the vaccine should be avoided. In some studies, people who took Tylenol or anti-inflammatories like Motrin before getting a vaccine had a reduced immune response, meaning that the vaccine might not work as well.

It is safe to take Tylenol, Motrin, or a similar medication **after you receive the vaccination**.

There are studies that show people who took these medications after the vaccine did not have a reduced immune response. So, if you have a fever or your arm hurts after the shot – feel comfortable taking one of these medications, or talking to your doctor about what is safe for you.

19. I have heard the COVID vaccine causes sterilization in both men and women. What is the truth behind this?

No, this is **not true**. There have been a number of false news stories about this, which have specifically mentioned information about the Spike Protein. While pregnant women were not included in the clinical trials, there have been pregnant women and women who became pregnant that have become sick with COVID-19. This means that their bodies were exposed to the Spike Protein, the same way that someone would with the COVID vaccine, and their fertility was not affected. The same is true for men, in this case – those who have tested positive for COVID-19 would have become infertile, which is not the case.

You can read more about this issue here: <https://apnews.com/article/fact-checking-9856420671>

20. What reaction to the vaccine would people who have already gotten sick with COVID-19 have?

People who have already had a COVID-19 infection should expect similar side effects to people who have not had COVID-19. There is a chance for injection site soreness, fever, chills, as mentioned above. **It is recommended that people who have had COVID-19 receive a vaccination.** We are not sure how long someone's natural immunity to COVID-19 lasts, and so vaccination is recommended after symptoms have cleared.

Currently, the CDC recommends that healthcare professionals **receive the COVID-19 vaccine after their symptoms are gone and have ended their quarantine period**. Because the risk for reinfection is low immediately after a COVID-19 infection, people may decide to wait 90-days. This is recommended especially if vaccine supply is low. BNHC has a sufficient supply of vaccine for staff so there is no need to wait.

Blood testing (serologic) for COVID-19 antibodies is **not recommended** prior to receiving the COVID-19 vaccine.

If you want to read the information directly from Pfizer and Moderna, as it was submitted to the FDA, you can do that here:

Pfizer:

<https://www.fda.gov/media/144245/download>

<https://www.fda.gov/media/144246/download>

Moderna:

<https://www.fda.gov/media/144434/download>