

COVID Vaccine Q&A – August 2021

1. These vaccines were made available very quickly. How is it possible that this was able to be done safely?

- The technology the vaccine uses has been around for a long time. Other coronavirus vaccines have been made using this mRNA platform in addition to vaccines for other viruses (Zika, Ebola) although none has been approved for use. These other vaccines have been tested extensively in animals and humans.
- Creating a new vaccine using this technology is relatively straightforward. Pfizer and Moderna were in the perfect position to create these vaccines quickly and start testing right away.
- All the usual steps in assessing a new vaccine were followed not skipped. Clinical trials in humans were overlapped and were able to be completed quickly because so many people had COVID at the time and enrolled in the trials.
- In the clinical trials, subjects were observed for 2-3 months after receiving the vaccine. This is more than enough time to see the adverse events that can be triggered by a vaccine because those types of events are known to occur during that period of time following any immunization.

2. Since these vaccines have been given to humans for such a short period of time, how can we know about adverse events that could appear months or years from now?

- These vaccines deliver the blueprint (mRNA, or in the case of the Johnson & Johnson vaccine, DNA) for making the spike protein, which is a protein on the surface of the coronavirus.
- Once inside cells, this blueprint is used to by your cells to make a harmless piece of the protein. The blueprint teaches the immune system how to respond the next time it sees spike protein to protect against future infection.
- Both the mRNA/DNA blueprints delivered through the vaccine and the protein your body learns to make do not stay in the body. These are broken down by enzymes in the body and gets rid of them.

- Any adverse events from these vaccines would occur secondary to the immune system's typical response to vaccine and occur within days (local injection site reactions, early systemic reactions such as fever, fatigues) and are short lived or occur within a few weeks. These later immune reactions can be severe (see below about rare, severe, adverse event) but they are rare and occur within 2-3 months.
- No part of this vaccine stays in the body for more than a short time, therefore, it cannot cause new adverse events to appear months or years later.

3. Can the mRNA or DNA in the vaccines stay in my cells and lead to changes in my own DNA?

- No, the mRNA and DNA from the vaccines does not get into the nucleus of your cells and, therefore, cannot integrate into or change your DNA in any way.
- mRNA and DNA from microbes are produced in the body all the time. When you develop an infection with a virus, it uses your cells to help make mRNA and proteins to make copies of itself. This happens if you are infected with SARS-CoV-2 or any other virus. There are trillions of bacteria living in our bodies reproducing, making mRNA and proteins and copying their DNA.

4. Will COVID-19 vaccine cause me to have a positive test for the SARS-CoV-2 virus or be contagious and pass infection to others?

- No, this cannot happen with these vaccines because they do not contain live virus.
- Some other vaccines in routine use are made with live, but very weakened viruses, that copy themselves in your body.
- The COVID-19 vaccines contain the genetic material to make only one of many proteins found in a virus. For this reason, these vaccines cannot cause your body to be infected with the virus, give you a positive test or make you contagious.
- After you receive vaccine you will have a positive test for antibodies to the spike protein of the virus in your blood which is the desired response to the vaccine.

5. Can these vaccines cause me to have difficulty becoming pregnant?

- There are several reasons why this concern is completely unfounded:
 1. If the vaccines cause infertility then the infection should also cause infertility but it does not.

- Infection with SARS-CoV-2 leads to development of antibodies against the spike protein of the virus just like the vaccine does.
 - The naturally occurring antibodies would have the same effect as vaccine induced antibodies. So, if vaccines could cause infertility through very early miscarriage (i.e. interference with the formation of the placenta) then natural infection would as well. **This has not been seen.**
 - COVID-19 itself is dangerous to mother and child in pregnancy. It is more likely to be severe in currently or recently pregnant women than women of the same age who are not pregnant.
 - With the Delta variant, pregnant women who are unvaccinated are becoming very ill with some on ventilators with increased risk of maternal/fetal death.
 - COVID-19 also increases the risk of pre-term birth and male erectile dysfunction.
2. Some scientists have looked at the degree of similarity between the spike protein of SARS-CoV-2 and syncytin-1 (a protein needed for placental formation and successful pregnancies) and have found nothing of concern.
- There are online programs that can search for identical strings of amino acids in proteins. A search for similar sequences of amino acids between the spike protein and syncytin 1 reveals only very short sequences (5 amino acids) that match up. This is not even close to large enough to lead to this sort of issue.
 - Many reputable immunologists and molecular biologists have looked at this question and have obtained similar results.
 - Others have looked for sequence similarity of similar length between spike and other human proteins. They have found these short sequence similarities for common proteins like hemoglobin, actin, and collagen. If this length were a problem we would be seeing all kinds of health issues in vaccinated individuals. **We are not seeing these problems.**
 - Having a similarity of this length between two large proteins is not a problem. It would be like saying two phone numbers are the same because they both contain the number five.

3. In the COVID-19 trials, the same number of women in the vaccine and placebo arms of the study became pregnant (unintentionally, because were supposed to avoid pregnancy while enrolled in the trial). This indicates no effect of vaccine on fertility.

- Background:

- On December 1, 2020, two scientists filed an application with the European Medicines Agency (Europe's version of the Food and Drug Administration) for immediate suspension of all SARS-CoV-2 vaccine studies.
- The EMA stated a concern that the spike protein has segments that are similar to a critical human placental protein called syncytin-1 and that antibodies to the spike could cross react with antibodies to syncytin-1 and cause infertility.
- This was a purely theoretical concern as nothing had been seen in females given the vaccine in studies to date.
- This concern did not occur and vaccine studies were continued in human subjects.