Covid-19 vaccines: How they are made and how they work to prime the immune system to fight SARS-CoV2**

Vaccines are a safe way to prevent viral infections. Vaccination is critical to lower overall morbidity and mortality of all SARS-CoV2 variants. While there are different vaccines, all vaccine technologies try to do the same thing: activate the immune system to be prepared to fight against the actual virus should the individual become infected. Currently, there are 242 vaccines being developed to protect the population from Covid-19. This document provides answers to frequently asked questions regarding vaccines.



^{**}This document was prepared by members of the Orthodox Theological Society in America (OTSA).

Frequently asked questions regarding vaccines:

- 1. Which vaccine should I get?
- 2. Should I trust the "new" mRNA vaccines or wait for a vaccine using previous technology?
- 3. Have the mRNA vaccines relied on fetal cells at any point?
- 4. Are the vaccines unethical because of the use of aborted fetal cells?
- 5. Some new COVID vaccines (such as Johnson and Johnson) are grown in fetal cells. Are these vaccines in particular unethical, and should we avoid them?
- 6. Is it possible to insert a microchip into the Covid-19 vaccine?
- 7. Do I still need to wear a mask after I receive the Covid-19 vaccine?
- 8. Will the vaccine change my DNA?
- 9. Does the Covid-19 vaccine cause Covid-19?
- 10. How are vaccines made in general?
- 11. How do the mRNA (Pfizer and Moderna) vaccines work?
- 12. How does the Johnson and Johnson vaccine work?
- 13. How efficacious is the Johnson and Johnson vaccine?
- 14. Will the vaccine still work if I become infected with one of the new SARS-CoV2 variants?
- 15. Was the safety of the vaccine undermined because it was achieved so fast?
- 16. Will I have adverse reactions to the vaccine?
- 17. Protection after vaccine: How soon after getting the vaccine will I be protected?
- 18.I am immunocompromised should I get the vaccine?
- 19. Is it safe to receive the vaccine after I have had Covid-19?
- 20.1 am pregnant, can I get the vaccine?
- 21. Does the Covid-19 vaccine affect the fertility of child-bearing age females?
- 22. What is an Emergency Use Authorization (EUA) and how was an EUA used for vaccines?
- 23. Who decides on the safety and efficacy of the vaccine?

1. Which vaccine should I get?

Answer: The goal of all vaccines is the same: to activate the immune system to be prepared to fight against the actual infectious agent (e.g. a virus) should the individual become infected.

If we take the approach to never miss an opportunity to vaccinate, we will more easily end this pandemic.

Because vaccines are a safe way to prevent viral infections, including Covid-19, physicians and scientists generally recommend that individuals take the authorized vaccine that s/he is being offered. In special circumstances such as pregnancy or immunocompromised individuals, a doctor should be consulted.

2. Should I trust the "new" mRNA vaccines or wait for a vaccine using previous technology?

Answer: Inserting mRNA into cells is not new technology. Both BioNTech (collaborator of Pfizer) and Moderna (Mode "rna") are established companies with years of expertise in mRNA therapeutics. Scientists simply implemented the mRNA technology into the already established vaccine platforms. The novelty was in merging the mRNA technology with available vaccine platforms.

3. Have the mRNA vaccines relied on fetal cells at any point?

Answer: The Pfizer and Moderna mRNA vaccines (as well as the not yet approved Novavax and Inovio vaccines) were not made from fetal cells that came from aborted fetuses. The vaccines were tested in culture against fetal cells to help ensure that they would not harm a fetus as well as to ensure that the technology works in a human cell. These tests were done with cells derived from the 1960's and 1970's from therapeutic abortions. **No new fetuses have been sacrificed** since that time for any vaccine tests.

Different from the mRNA vaccines, many of the other Covid-19 vaccines (e.g. AstraZeneca and Johnson and Johnson) are grown using the same fetal cell line. To "grow" the vaccine in fetal cells is a term that scientists use because all viruses are dependent on cells for "growth", which for a virus means to replicate, and thus, the production of viral vaccines will require cells for production. Most vaccines do not "grow" well in adult cells, and therefore require the use of fetal cells. Importantly, mRNA vaccines are synthesized without cells. Vaccine synthesis and vaccine production are two separate steps in the vaccine making pipeline.

Some vaccines (e.g. Rubella, chicken-pox) used in the United States also come from viruses grown in aborted fetal cells (again, from those cells from the 1960's and 1970's). The United States government has banned the generation of any new cells or the sacrifice of any embryos for the purpose of investigation. Nevertheless, it is recognized that some vaccines would not be possible without growth of the viral vaccines in these fetal cells.

4. Are the vaccines unethical because of their use of aborted fetal cells?

Answer: Several significant factors lead to the conclusion that the vaccines present the best ethical option to promote health and life, despite their connection with the use of aborted fetal cells. These factors are: (1) The fetal cells in use today are derived from two or three therapeutic abortions performed several decades ago. The abortions were NOT for the purpose of the development of vaccines, and all parties (including the US government) have agreed that no new fetuses will be aborted or used for this purpose. (2) Many vaccines (other than COVID) that we use in the US and world-wide are made from these cells, and other substitute cell lines have not proven to be effective for growing the vaccines; this has been the

only alternative. (3) Most Church leaders have agreed that the many lives saved by vaccination are an important factor in permitting the use of these vaccines. While it is a sad reality that the origin of these cell lines is from these very few therapeutic abortions, the cell lines are already in existence, no new fetuses will be used, and as such it is far preferable to cure diseases as a result of the use of these cell lines than to totally forbid the use of these cell lines. The vaccines in no way legitimize or promote abortion; rather they combat disease and death, support health, and enable life—not death—to prevail, all of which are of the highest ethical value.

More information regarding the morality of using these cell lines can be found at the following links:

- (1) Ecumenical Patriarchate "Halki Summit IV Covid-19 and Climate change: Living with and Learning from a Pandemic". Metropolitan Nathanael touches upon this question. https://www.facebook.com/ecumenicalpatriarchate/videos/900946820672806/
- (2) The Vatican Congregation for the Doctrine of the Faith https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20201221_not_a-vaccini-anticovid_en.html
- (3) United States Conference of Catholic Bishops https://www.usccb.org/moral-considerations-covid-vaccines

5. Some new COVID vaccines (such as Johnson and Johnson) are grown in fetal cells. Are these vaccines in particular unethical, and should we avoid them?

Answer: No. Although the use of "more" fetal cells in one type of vaccine than another (for example, by growing the vaccine in the cells as opposed to simply testing them using the cell line) appears to suggest that more fetal deaths occurred or that more fetuses were involved, this is NOT accurate. All the cells used are clones from the same original fetal cell lines, and whether a few cells or many are used, there are NO new fetuses involved. The ethics of taking one vaccine is essentially no different from that of another.

6. Is it possible to insert a microchip into the Covid-19 vaccine?

Answer: No. First and foremost, today's microchips are too large to be implanted through a vaccine. This false rumor is discussed by Dr. Gayle Woloschak in the following article:

https://publicorthodoxy.org/2020/09/18/ready-for-the-covid-vaccine/

7. Do I still need to wear a mask after I receive the Covid-19 vaccine?

Answer: Yes. The reason for this is because the endpoint or goal of the Covid-19 vaccine clinical trials were to prevent severe Covid-19. Therefore, we do not yet know whether the vaccine will prevent transmission of virus. However, we will find out soon.

8. Will the vaccine change my DNA?

Answer: The Moderna and Pfizer vaccines are mRNA vaccines. mRNA is short-lived in all cells lasting only hours before being degraded. The mRNA in both the Pfizer and Moderna vaccines is protected by (1) stabilizing molecules and (2) a lipid coat allowing it to live up to 5-7 days before degradation by human cells. In the time before the mRNA degrades it will remain in the cell to make the spike protein that will provide immunity. mRNA cannot alter DNA and thus provides no danger to the host DNA.

Future vaccines from AstraZeneca, Johnson and Johnson, vaccines made in China, and others use an Adenovirus (**see figure, question 10**) to introduce DNA from the spike protein into human cells. These vector-based vaccines have the novel coronavirus spike protein encoded within the Adenovirus (a vector). Adenoviruses are DNA viruses which are recognized by the human body, and thus, cannot cause us harm. They are used as vehicles to deliver the genetic message to "make a spike protein" in our cells.

In the case of the Johnson and Johnson vaccine, the Adenovirus has been modified to be incapable of replicating itself in the human body. The DNA from the Adenoviruses cannot interact with the human DNA and will be eventually degraded by our cells.

9. Does the Covid-19 vaccine cause Covid-19?

Answer: No. The Pfizer and Moderna mRNA vaccines use only a piece of genetic material from the virus which makes the SARS-Cov2 spike protein to stimulate the immune system. **There is no virus that can cause Covid-19 in these vaccines.** Johnson & Johnson and AstraZeneca use an Adenovirus as a vehicle to deliver the piece of genetic material that makes the SARS-Cov2 spike protein to the body; however, Adenoviruses are well recognized by the human immune system and do not cause harm to humans.

10. How are vaccines made in general?

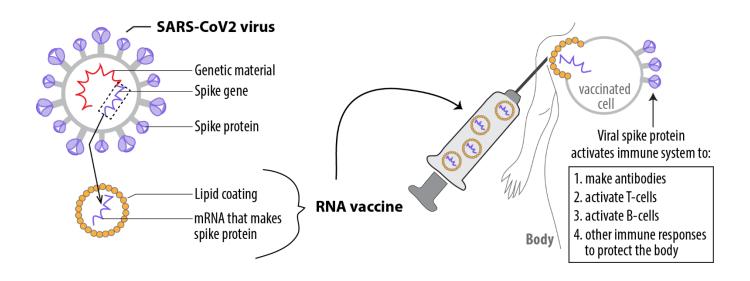
Answer: There are four main ways to make vaccines: (1) Attenuated vaccines involve weakening a virus to non-dangerous strength (these vaccines have viruses with attenuated virulence); (2) Inactivated virus vaccines are typically inactivated chemically with formalin making the virus inert; (3) Fractionation or a separation process is when the virus is broken up into components to make vaccines out of fragments of proteins; (4) Some vaccines are based on the ability to copy a piece of the virus' genetic material (a gene) of interest from the virulent virus that codes a protein and deliver this gene to the body to make the necessary viral protein. This, in turn, activates the immune system; (4a) Example showing the use of other viruses as vectors to deliver the gene of interest to the human body via the vaccine; (4b) Shows how a lipid coat (orange) can be used to protect the piece of DNA or RNA that codes the viral protein delivered to the body via the vaccine; (4c) Summarizes a vaccine made of fragments of viral proteins to activate the immune system.

The figure below is a summary of the four main ways vaccines are made.

Various vaccine technologies Virulent virus Attenuation Inactivation Separation process Copy a piece of virus' genetic material Virus is weakened to Virus is inert Fragments of viral non-dangerous strength proteins vaccine (e.g., 🍣 sinovac) Express proteins Genes of interest of interest 4b Virus vector vaccines DNA or RNA vaccines e.g., AstraZeneca 🤡 **Examples of vectors:** e.g., *Pfizer* (1) Adenovirus Protein fragments (2) Influenze virus Johnson Johnson vaccines (3) Vaccinia virus moderna (4) Measles virus e.g., S-putnik V (5) Horsepox virus **SANOFI NOVAVAX**

11. How do the mRNA (Pfizer and Moderna) vaccines work?

Answer: Both the Pfizer-BioNTech and Moderna vaccines deliver a "genetic message" or a specific nucleotide sequence (mRNA) from the virus to be inserted into the human host cell. This genetic message (mRNA) is protected by a lipid coat. The unique mRNA contains instructions for making the spike viral proteins that surround SARS-CoV2 (purple spikes below). The host cell translates this mRNA to make the spike viral protein in the human body. Given the right amount (or dose) of mRNA and spike viral proteins, the immune system will be able to respond by making specific antibodies as well as alert other immune cells as part of an immune system learning process to know how to fight this viral protein. In a subsequent SARS-CoV2 infection, the body will recall the "memo" it previously made against the spike viral protein and mitigate the severity of Covid19 by being prepared and equipped for the fight.



12. How does the Johnson and Johnson vaccine work?

Answer: Instead of using a lipid coat to deliver the genetic message (mRNA) to the human cell (described in question 11), both the Johnson & Johnson and AstraZeneca vaccines use an Adenovirus as a vehicle to deliver the mRNA that makes the viral spike protein to the body (see figure, question 10). Adenoviruses are recognized by our immune system and do not cause any harm. Moreover, Adenoviruses can be altered so as to not be able to replicate in the human body. The Adenovirus from the vaccine acts as a vehicle to go deeper into the human cell (i.e., in the nucleus) to deliver and transcribe the genetic message before making the spike viral protein outside of the nucleus (i.e. in the cytoplasm of the cell) of the human cell. Subsequently, the immune system will prepare to fight the spike viral protein with antibodies and other immune responses. Should the body become infected with the actual coronavirus, the immune system will be equipped to fight.

13. How efficacious is the Johnson and Johnson vaccine?

Answer: The Johnson & Johnson vaccine trial comprised 43,700 participants of which 468 symptomatic cases were reported—which is a good number to proceed to filing an Emergency Use Authorization (EUA).

The trial included four different geographies. Johnson & Johnson reported 66% overall efficacy (every country combined), 72% efficacy in the United States, 66% efficacy in Latin America, and 57% efficacy South Africa 28 days after vaccination of the single dose.

Efficacy in the case of the Johnson & Johnson vaccine is defined as preventing moderate to severe Covid-19. Importantly, the Johnson & Johnson vaccine is 85% effective at preventing severe disease and 100% effective at preventing hospitalization and death, thus far (based on the trial).

Moreover, the Johnson & Johnson trial revealed that after 49 days after the vaccine, no moderate or severe Covid-19 cases were noted. This means that, unsurprisingly, it takes time to create an immune response.

14. Will the vaccine still work if I become infected with one of the new SARS-CoV2 variants?

Answer: The different vaccines are still being evaluated against the new variants, and the data to date suggest different efficacy for the various vaccines and variants of the virus.

Overall there does seem to be a drop in efficacy against the South African strain but less of a drop in efficacy in cases of the UK variant. It is important to make note of the different types of efficacy or end points scientists talk about. For example, there is efficacy against moderate disease, efficacy against hospitalizations, or efficacy against severe diseases or death. If a vaccine prevents hospitalization or death and is a safe vaccine, then it is worthwhile to take the vaccine and to vaccinate the population.

Boosters that cover these variants, and other strains it is hoped, are already being planned and developed. It is too early to know if they will be needed, but it is reassuring to learn that scientists are already working on them. Importantly, at least for the Johnson & Johnson vaccine, which was tested in South Africa, there still appears to be very good protection against severe disease which may normally have resulted in hospitalization and death, even if vaccine participants became infected.

15. Was the safety of the vaccine undermined because it was achieved so fast?

Answer: It is true that this is the fastest vaccine achieved in the history of humankind. However, the speed with which scientists achieved this vaccine is related to other factors. Safety was not undermined.

First, the speed was accelerated by the numerous infections and people participating in the clinical trials. The more infections (while unfortunate), the quicker we were able to get an answer about the efficacy of the vaccine. If there were little to no infections, it would have taken years to get an answer regarding the efficacy of the vaccine. Instead, the rampant number of infections has allowed scientists to get an answer within only a few months.

Secondly, there was significant funding to support the development of the vaccine allowing the early vaccine phases to be conducted simultaneously rather than sequentially. For example, the speed was accelerated by funding the mass production of vaccine doses while still conducting the last phase (Phase 3) clinical trial. Funding for mass production of a vaccine is not usually available unless the Phase 3 clinical trial results are completed and show success. However, because this is a public health crisis affecting the world, significant funding was available to start mass production of the vaccine prior to knowing whether the vaccine was as successful as it ended up being.

Lastly, the mRNA technology of inserting genes into cells to express proteins is not new technology. Both Moderna and BioNTech (Pfizer's collaborator) have had years of experience with mRNA therapeutics. This mRNA technology was implemented into the well-established vaccine platforms for a smooth production of the Covid-19 vaccine.

16. Will I have adverse reactions to the vaccine?

Answer: Serious reactions (e.g. anaphylaxis) against the mRNA vaccines are quite rare, about 1 in 100,000 for the Pfizer vaccine, and 1 in 400,000 for the Moderna vaccine. However, some mild reactions are common, including a sore arm, swollen lymph nodes, fever, fatigue, body aches, or numbness or tingling in the arm. These typically start a few hours to up to 72 hours after the injection, and usually resolve after 1-2 days. Some people get swelling or redness at the injection site a week later after the Moderna vaccine, and this also goes away. If needed, acetaminophen (Tylenol) or ibuprofen or can be used for these reactions.

17. Protection after vaccine: How soon after getting the vaccine will I be protected?

Answer: Protection after the vaccine can be expected 14 days after the second Moderna shot, 7 days after the second Pfizer shot.

The clinical trial from Johnson and Johnson showed that individuals were 100% protected against hospitalization and death 49 days after the single dose. Therefore, protection after the Johnson and Johnson vaccine is expected after ~50 days after the single shot. It takes time to build immunity.

18. I am immunocompromised should I get the vaccine?

Answer: Patients should discuss vaccination with their physician. CDC does recommend vaccination of immunocompromised patients, including patients on chemotherapy, on steroids, patients living with HIV, and transplant patients, but notes that their immune response may be blunted.

19. Is it safe to receive the vaccine after I have had Covid-19?

Answer: The CDC recommends vaccinating people who have recovered from COVID and are out of isolation. People infected recently can likely wait 90 days if they choose since reinfection before 90 days has not been reported. This is especially important when the vaccine supply is limited. It is safe to vaccinate patients who have had recent infection, but again they should have recovered and be out of isolation.

However, if the patient has received COVID convalescent plasma or monoclonal antibody treatment for their COVID 19 infection, they should wait 90 days after their treatment because of concern that they would have a blunted response to the vaccine.

20. I am pregnant, can I get the vaccine?

Answer: We have no reason to suspect any risk from the vaccine to patient or fetus/child. There is known risk of COVID, which is higher in pregnant patients than in non-pregnant patients. There were women in the vaccine trials who became pregnant (23 in the Pfizer study, 13 in the Moderna study) with no complications or adverse effects reported. Moderna did study pregnant rats and postpartum rats and found no negative effects on fetal/embryonic development. ACOG (the American College of Obstetrics and Gynecology) recommends the mRNA vaccines be made available to pregnant women but stops short of a blanket recommendation.

In summary, there is no strong safety evidence but no evidence of harm either. There are plans to include pregnant women in upcoming trials.

Pregnant women should discuss vaccination with their physician.

21. Does the Covid-19 vaccine affect the fertility of child-bearing age females?

Twenty-three women who participated in the Pfizer-BioNTech Covid-19 vaccine study became pregnant during the trial. Of these 23 women, 11 received placebo and 12 received the Covid-19 vaccine. There were no unsolicited adverse pregnancy-related events that occurred. Similarly, 13 pregnancies were reported in the Moderna Covid-19 vaccine trial: 6 participants received the vaccine and 7 received the placebo. Two-pregnancy-related adverse events occurred; however, both of these were in the placebo group and not in the vaccine group. Based on these data, there is no evidence linking either the Pfizer-BioNTech or Moderna mRNA vaccines to infertility.

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.

22. What is an Emergency Use Authorization (EUA) and how was an EUA used for vaccines?

Answer: An Emergency Use Authorization is a mechanism to facilitate the availability and use of therapeutics including vaccines during public health emergencies such as the Covid-19 pandemic. In order to make an EUA the FDA required a wait period of 60 days from the time 50% of the participants in the trial received their last dose. The reason for this is because we know from history that most of the "long-term" vaccine effects occur between 30-45 days after the vaccine trial ends. Waiting these 60 days means that we are beyond the point in time when the so called "long-term" vaccine effects occur.

23. Who decides on the safety and efficacy of the vaccine?

Answer: The Data and Safety Monitoring Board (DSMB). They are a body independent from the government and comprised of scientists who oversee vaccine safety and efficacy during a clinical trial. The DSMB provides ongoing independent review of the data from the clinical trial to address safety concerns.

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