Vaccine Information — Addendum**

The Orthodox Theological Society in America (OTSA) has prepared this addendum to our previous document regarding Covid-19 vaccines entitled, "*COVID-19 Vaccines: How they are made and how they work to prime the immune system to fight SARS-CoV2*" (https://www.otsamerica.net/wp-content/uploads/2021/03/Covid19-VaccineTech.pdf). It is important to note that while this addendum in based on the CDC guidelines, state and local guidance may differ and take precedence over the CDC recommendations.

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

1. **Do I still need to wear a mask after I receive the Covid-19 vaccine?** (This is an update to Question #7 of the original document.)

Answer: The CDC updated the mask guidelines on 16 May 2021, stating that fully vaccinated individuals can resume activities without wearing a mask or physical distancing, except where required by federal, state, or local rules and regulations, including local business and workplace guidance. Masks should be worn by everyone on public transportation such as at train stations and airports or on trains, buses, airplanes, and at hospitals, clinics, and other businesses. However, people who have impaired immune systems, including those who have had transplants, often do not have a full immune response to the vaccine, and may have a poor response. Even when vaccinated, people with health issues that impair their response to the Covid-19 vaccines may need to continue wearing masks and maintain social distancing. A visual summary of the CDC recommendations can be found at https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/participate-in-activities.html

2. **Do I still need to wear a mask if I am not yet fully vaccinated?**

Answer: Yes. The CDC recommendations emphasize that unvaccinated individuals still need to wear masks for all indoor events as well as outdoor events where both vaccinated and unvaccinated individuals are present or people from multiple households are present.

3. **Can I safely attend fellowship/coffee hour at church if I am not yet vaccinated?**

Answer: This is an increasingly relevant question as more faithful return to worship at church and may gather after liturgy for fellowship coffee hours. At the moment we have not reached a level of containment in terms of infection spread, therefore caution is warranted. Many people focus on Covid-19 deaths; however, there are long term illnesses associated with Covid-19. Since fellowship or coffee hours are usually indoors and involve the removal of a mask in order to eat and drink, the level of risk for an airborne infection increases significantly. The same CDC recommendations apply to this setting. (Please see the link provided in question #1 of this document.)

4. **Will the vaccine change my DNA?** (This is an update to Question #8 of the original document.)

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.

AstraZeneca, Johnson and Johnson, vaccines made in China, and others use an Adenovirus (see figure, question 10 of the original document) 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 that 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.

5. **Can the Covid-19 vaccine cause an enhanced antibody response or vaccine-associated disease enhancement (VADE)?**

Answer: Although a rare phenomenon, vaccine-associated disease enhancement (VADE) is a valid concern, especially because it appears that most Covid-19 patients die of immunological related phenomena. Fortunately, in the past year and a half of experiencing this pandemic we have not seen evidence for VADE from either the vaccine clinical trial studies or from vaccinating the population at large. The VADE phenomenon would have been caught by now more than one year into the pandemic or among the wide distribution of vaccines that have been administered to millions of individuals. Therefore, we need not worry about VADE.

6. **Should I vaccinate my child?**

Answer: Yes, because it is important to protect children as well. To date, we have at least 300 children who have died from Covid-19 and estimates could be as high as 500 child deaths from Covid-19. Currently, children account for 24% of the infections and the number of confirmed multi-systemic inflammatory syndrome is approaching 4,000. Children are indeed at a lower risk of death and chronic complications compared to older adults; however, they are not at no risk and can be protected by vaccination.

On 19 May 2021 the FDA expanded the Emergency Use Authorization (EUA) for the Pfizer/BioNTech vaccine to include adolescents 12-15 years of age. The available safety data to support the EUA included 2,260 participants, ages 12 through 15 years old, enrolled in an ongoing (i.e. these vaccinated children will continue to be followed) randomized, placebo-controlled clinical trial in the United States. Of these, 1,131 adolescent participants who received the vaccine and had no prior Covid-19 infection, no cases of Covid-19 occurred, thus 100% protection for this age group.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use

7. **Where can I ask specific questions and receive more information regarding Covid-19 vaccines?**

Answer: In a statement (Covid-19 Vaccines & Immunizations) by the Assembly of Canonical Orthodox Bishops of the United States, both clergy and the faithful are encouraged to consult their physicians for guidance on individual medical related decisions.

In addition, the American Society for Virology is hosting a series of live town hall meetings to answer your specific questions about the Covid-19 vaccine. The town halls are free for the public.

More information here: https://asv.org/Education/

8. **I have had Covid-19 why do I still need to get vaccinated?**

Answer: Patients who have had Covid-19 do not have long lasting immunity as antibodies and cellular immunity wane to non-detectable levels after 3-6 months. This means that these individuals are not protected and can be re-infected with any of the SARS-CoV2 variants circulating in the population and then transmit the virus to others. Thus far, the variants that have emerged do not completely undermine the efficacy of vaccines or therapies, but there is no guarantee that this will remain the case. The virus is changing constantly and future changes in the genome of the virus can render our tools ineffective leading us back to square one. If everyone, including those who have recovered from Covid-19, are vaccinated we can slow down the rate with which the virus is changing. Every time an individual is infected with SARS-CoV2 provides an opportunity for the virus to change. Vaccines not only protect the vaccinated individual, but also significantly limit the possibility for transmitting the virus to others.

9. **Will the Covid-19 vaccine affect my menstrual cycle?**

Answer: Although this was not measured directly as a separate parameter in the vaccine study trials, it has not surfaced as a problem after millions of people have received the vaccine. The OB/GYNE society has stated that there is no evidence that Covid-19 vaccines have caused specific menstrual issues, but that all vaccines, because of the stress on the body, may cause temporary changes in the menstrual period. These changes may include a heavier or lighter than usual cycle, an early or late period, or a period in a woman who has not had one for a few months due to the onset of menopause. These changes are temporary and return to normal very quickly, typically with the next menstrual cycle, and are not connected to the vaccine but rather due to the overall stress of getting a vaccine in general as well as other environmental factors. Importantly, such temporary chances in the menstrual cycle do not confer an altered reproductive capacity affected by the vaccine.

10. **I am pregnant, can I get the vaccine?**
    (This is an update to Question #20 of the original document.)

Answer: As of 26 April 2021, over 100,000 pregnancies have been reported in vaccinated women. To date, no complications attributed to the vaccine have been recorded, and efficacy rates match those for the general population. There have been no increases in rates of preterm birth, small for gestational age, congenital abnormalities, or neonatal deaths over baseline community data. The ACOG (American College of Obstetrics and Gynecology) recommends pregnant women should receive the vaccine. No evidence of increased TTS (thrombotic thrombocytopenia syndrome—the syndrome seen in rare J&J recipients that causes unusual blood clots) has been seen in pregnant women. Pfizer, Moderna, and Janssen (J&J) are all enrolling pregnant women in ongoing vaccine studies.

One small study from Harvard showed women vaccinated during any trimester produced antibodies against SARS-CoV-2 and the antibodies worked against variants. All women tolerated the vaccinations well and had normal outcomes to their pregnancies.

Finally, another study looked specifically at the placenta of women who received the vaccine during pregnancy and found no evidence of any negative effect on the placenta. All of these women also developed a robust antibody response.

Collier et la., Immunogenicity of COVID-19 mRNA Vaccines in Pregnant and Lactating Women, JAMA, 325(23):2370-2380, 2021

Shanes et al., Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccination in Pregnancy: Measures of Immunity and Placental Histopathology, Obstet Gynecol, 2021

11. Does the Covid-19 vaccine affect the fertility of child-bearing age females?
(This is an update to Questions #21 of the original document.)

Answer: 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 PfizerBioNTech or Moderna mRNA vaccines to infertility.

Since FDA authorization of these vaccines, information regarding fertility has circulated on the internet that has not been accurate. The specific claim is that antibodies recognizing the SARS-CoV2 spike protein can cross-react with the human placental protein (syncytin 1) which is important for placental attachment, and thus, can subsequently damage the placenta. If this were the case, then, all Covid-19 vaccines as well as SARS-CoV2 natural infections would be expected to lead to placental damage. However, in studies, women who were infected with SARS-CoV2 shortly before conceiving or early in their pregnancy were no more likely to have a miscarriage than uninfected women. Moreover, there is, in actuality, no significant similarity between the amino acid sequence of SARS-CoV2 spike protein and syncytin 1. In fact, convalescent serum from patients with Covid-19 cannot even react with syncytn 1. Together, the data demonstrate that Covid-19 vaccination is safe during pregnancy and show that vaccination does not harm fertility.

For more information on this topic see Victoria Male, "Are Covid-19 vaccines safe in pregnancy?", Nature Reviews Immunology **21**, 200-201 (2021).

12. Does the Covid-19 vaccine affect male fertility?

Answer: No. A new study looking specifically at male fertility in men receiving the mRNA vaccines showed no impact on male sperm count or quality, demonstrating no impact on male fertility.

Gonzalez et al., Sperm Parameters Before and After COVID-19 mRNA Vaccination, JAMA, *Online ahead of print*, 2021.