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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. 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.: 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. 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.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. 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.

**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 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.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

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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

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