Covid Vaccine Information
While Pregnant or Breastfeeding
(as of 12/22/20)

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Dear Colleagues,

We have encountered an avalanche of patients inquiring about the safety of COVID19 vaccines in pregnancy, and undoubtedly you have as well. We hope to provide assistance in answering this question and those that follow. Attached are the SMFM/ACOG statements regarding vaccination.

Quick summary in bold:

Almost anyone including pregnant/lactating women can receive the COVID vaccine, all will likely be fine, but they need to know we have no data regarding safety/side effects. The Pfizer and Moderna vaccines facilitate the same immune protection that older vaccines, do but with a faster start. FDA, ACOG, and SMFM all endorse vaccinating pregnant women with disclosure of lack of data. As soon as more info emerges, we will update everyone.

COVID Vaccination?

Presently, Pfizer's mRNA-based vaccine has received FDA approval. The distillation of the message from ACOG and SMFM (as of 12/16/2020) is as follows:

1. The Pfizer vaccine should be made available to all pregnant and lactating women, and not withheld.

2. Patients should know that the safety of this vaccine in pregnancy/lactation is unknown given lack of inclusion of these patients in trials.

3. Time will bring more data.

The CDC has made it clear that priority for the vaccine is for health care personnel, the majority of which are women, and current/recent pregnancy should not thwart vaccination.

A quick vaccine review:

There are several types of vaccines, and the new vaccines from Pfizer and Moderna (like similar ones in development) are a new form of technology. All vaccines aim to introduce pathogenic antigens to the immune system in order to generate antibodies that activate host defenses in response to viral exposure. Traditional vaccines achieve this antigen exposure either through administration of:

a. live attenuated viruses (stronger immune response, ie MMR, varicella, rotavirus), or

b. inactivated viruses (weaker immune response, boosters needed, ie Hep A, influenza, polio, rabies)

c. subunit/recombinant/polysaccharide/conjugate vaccines (stronger immune response to specific protein parts, not as useful to rapidly mutating viruses, needs booster, ie Hib, hep B, Pertussis, shingles)

d. toxoid (similar to recombinant, needs booster, ie TD)

When cells are infected with coronavirus, the virus uses the host cell's own organelle to produce mRNA that instruct host cells to produce many proteins including a unique "spike" protein. The host defense machinery recognizes these proteins, shreds them, and displays the pieces of the viral proteins their cell surfaces via major histocompatibility complex (MHC) molecules for immune cells to learn and build immunity against. The next generation mRNA vaccines simulate infection by giving short-lived instructions for host cells to produce these spike proteins in cells without any other viral proteins, thus allowing the immune system to learn about and prepare immune response to future viral exposure. Instead of a dilute mixture of attenuated/dead virus/protein/toxoid, the antigens are synthesized by the cells themselves, building a very large transient burst of high antigen levels for the immune system to learn from. This is thought to provide a stronger immune response faster.

The mRNA is delivered into the cytoplasm of host cells via lipid nanoparticles (endocytosis of nanoparticles), and are then translated by the host ribosomes into these spike proteins. These spike proteins are then recognized and bound by host defense machinery, then delivered to the cell surface on MHC-I molecules for antigen presentation and immune response. Pfizer uses a positively charged mini lipid droplet (100 micrometers, the size of coronavirus itself) that binds the negatively charged mRNA within. The nanoparticle melts into the cell membrane via endocytosis, facilitating transport of mRNA into the cytoplasm. This essentially "cuts out the middle man," bypassing a virus transcribing DNA into mRNA that is then translated, and skips th toxoid/antigen-based immunity that is slow to mount and fast to lapse. One downside to this technology is that RNA is inherently unstable and needs to be kept at extreme cold (-80C) for preservation.

Older vaccination techniques that employ replication of the entire virus or processing of dilute protein in serum for immune responses are time consuming, weaker, and may produce more side effects, whereas mRNA-driven protein production in theory and emerging practice produces a stronger immune response with less side effects.

There is no risk for permanent viral incorporation into host cell DNA as the mechanisms for reverse transcription are absent. No mutagenesis potential is anticipated. Testing for prior infection is also not recommended prior to administration.

Side effects?

Low grade fever, malaise, myalgia, nausea, vomiting may be experienced upon taking the vaccine. No need for fetal monitoring unless severe illness arise.

Our honest opinion?

Offer the vaccine with disclosure that it's likely safe, it's ultimately doing the same thing traditional vaccines do (just faster), but there is no human pregnancy data yet. The FDA, ACOG, and SMFM all endorse this posture.

Ultrafast update on consequences of COVID in pregnancy

There is a <1% risk of vertical transmission of COVID in pregnancy, but pregnant women are 3x more likely to be admitted to an ICU and require mechanical ventilation (2.9/1000 pregnant infections) and 2.4% more likely to require ECMO (0.7%/1000 pregnant infections), and 1.2x death (1.5/1000 pregnant infections). Emerging reports of COVID infection in pregnancy have demonstrated visible placental damage (ie, microthrombi) on pathologic examination.

Antenatal surveillance for COVID?

Reports from the UK showed that stillbirth and poor OB outcomes increased during the COVID era tripled, even in absence of known COVID infection. As risks are higher and causes unknown, we recommend that if COVID infection arises at any point in pregnancy, obtain serial growth, NST twice weekly at 32 weeks, and delivery by 39 weeks. SMFM states that delivery plans should be individualized for patients with COVID infection at term. Cesarean is not recommended to reduce risk of transmission to neonates and staff.

Fetal/neonatal risks?

ACOG, SMFM, and the FDA recommend offering the vaccine to pregnant and lactating patients with the anticipation of very low risks of fetopathy or neonatal complications. There is no data, but risks are anticipated to be low.

Lovenox, COVID, and pregnancy oh my?

Emerging data has shown that severe COVID infection produces hypercoagulative state and life threatening thrombosis. This has lead many centers starting anticoagulation on patients admitted with COVID. Given lack of data, we are presently recommending treating these situations like thrombophilia/history of DVT, and that if a patient is started on lovenox in the hospital for COVID infection or admitted to the ICU for COVID, continue prophylactic lovenox until 6 weeks postpartum.

Thank you for your referrals, we are always happy to help! Stay safe, and happy holidays!

Jeff, Rosa, and Brian

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