Dr. Elizabeth Morgan, Baystate Health

Good morning Representative Cephas and colleagues of the Pennsylvania General assembly. Thank you for inviting me to speak at today's policy hearing on Maternal Health Amidst COVID-19.

My name is Dr. Elizabeth Morgan. As a Maternal Fetal Medicine Physician, I have subspecialty training and experience in treating women who have a high risk of maternal or fetal complications during pregnancy. I also hold a Master's degree in pandemic preparedness and emerging infectious diseases. As such, not only have I had the opportunity to witness firsthand the toll COVID-19 has taken on my patients, their pregnancies, and their families, but I also have a unique understanding of the importance of healthcare policy and a robust public health response in lessening the impacts of this global pandemic on our most vulnerable populations. I work at a tertiary care center in Western Massachusetts which has been impacted significantly by the COVID-19 pandemic. In addition to the complex medical problems our patients face, many also have other significant determinants of health including low income, food and housing insecurity and crowding, to name a few. We serve a diverse population including a significant LatinX community. I again want to thank you for all the work you are doing to address these issues.

COVID-19 in Pregnancy

Since the first COVID-19 cases were identified last spring, our understanding of the SARS-CoV-2 virus has grown exponentially, especially in terms of its effects on pregnant women. Initially, pregnant women were not thought to be at significantly higher risk of becoming critically ill if they became infected with COVID-19. However, we now know that this is not true. In fact, one to three out of every thousand pregnant women with COVID-19 will develop severe disease. Pregnant women have a three-fold higher risk of ICU admission, two to three-fold higher risk of breathing difficulties requiring mechanical ventilation or intubation, and are more likely to require extracorporeal membrane oxygenation (ECMO) – a procedure where we use a pump to circulate blood through an artificial lung and back to the mother. Pregnant women also have an increased risk of death.[i] We have now seen clear evidence of the virus crossing the placenta. Previously, we did not believe that this was the case.[ii] Emerging data suggests a higher risk of stillbirth, as well as preterm birth. The risk of preterm birth is not from preterm labor, but rather due to our interventions to save mothers with critical disease. All these risks are higher in obese women, women with other medical comorbidities such as diabetes or asthma and those of advanced maternal age. Like many other conditions in this country, they disproportionately affect Black and LatinX mothers.[iii]

The long-term health effects of COVID-19 on women and their infants remain unknown with emerging information about COVID "long haulers" who have long term symptoms including protracted respiratory sequelae such as shortness of breath, exercise intolerance or chronic cough, as well as fatigue, and neurologic symptoms. Compared to men, women are 4 times more likely to develop longer term symptoms. Given the average age of 40 for those affected,

this is significant for women of childbearing age in both their current, and possibly future, pregnancies.[iv] It also affects their abilities to care for their families beyond the pregnancy.

COVID-19 Vaccine in Pregnancy

There are two vaccines currently approved for emergency use in the United States, the Pfizer-BioNTech and Moderna vaccine. Both are mRNA-based vaccines and are the first of this kind available for wide distribution. mRNA vaccines utilize small bits of genetic information (or messenger RNAs) within a lipid capsule that gives our cells instructions for how to create a protein unique to the virus. Our bodies then build T-lymphocytes and B-lymphocytes in response to this foreign protein. These cells later help prevent us from getting infected if exposed or, even if infected, decrease the risk of severe disease. The risks of mRNA vaccines in pregnancy are theoretically thought to be low because of the rapid degradation of the mRNA in the circulation soon after injection. Additionally, the vaccines do not contain preservatives unlike those found in other types of vaccines, which is why they require extremely cold storage temperatures. These mRNA do not enter the nucleus of the cell, and therefore are not able to integrate or interact with the DNA of a vaccinated woman or her fetus.[v] And, though these are the first mRNA vaccines in use, this delivery system has been studied for over a decade prior to current distribution.[vi] Finally, these mRNA vaccines are extremely efficacious, cutting down symptomatic infections by 94-95%, and more importantly there has only been one severe COVID infection, and no deaths, resulting from trials conducted prior to distribution.[vii][viii]

Because of the vaccine's high efficacy and low theoretical risk of harm, coupled with increased short-term risks of COVID-19 in pregnancy and emerging data on long-term risks to pregnant women, the FDA and CDC have recommended that the vaccine not be withheld from pregnant and lactating women.[ix] This stance has been supported by the Society for Maternal Fetal Medicine and the American College of Obstetricians and Gynecologists as well as the American Academy of Pediatrics. This has not been true in all other countries. For instance, when the vaccine was first introduced in the UK, pregnant women were denied the option for vaccination. Further, the WHO recently suggested that pregnant women not be offered the vaccination because of unknown vaccine risks. This statement was retracted within 24 hours in the face of extreme public scrutiny.[x]

Unfortunately, one of the reasons for hesitation among various organizations, physicians, and women themselves, is that pregnant women have been summarily excluded from vaccine trials. As a recent article published in the American Journal of Obstetrics and Gynecology noted: "*Despite recommendations from public health advocates for pregnant women, including the CDC, the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP), pregnant women have not been included in any Phase 2 or Phase 3 COVID-19 vaccine clinical trials to date."* Additionally, while small studies on reproductive impacts in animals (also known as DART - developmental reproductive and toxicity testing studies) have shown little risk, human data is obviously lacking. This is not only ethically questionable in the midst of a global pandemic but can be sometimes considered

experimentation in and of itself. Furthermore, women of color and minorities, who are at the highest risks of COVID-19, have been subjected to a history of experimentation in the past that casts a pall, and rightly so, over any future medication where evidence for its safety remains limited. There is high distrust resulting from these unethical experimentations of the past.

The CDC has existing mechanisms to monitor vaccine safety through its Vaccine Adverse Event Reporting System (VAERS), and has developed a smart phone app, V-SAFE, to allow for individuals to track their symptoms after vaccination. Duke University, through the Clinical Immunization Safety Assessment (CISA) Project has also been funded to coordinate and conduct a multi-site prospective observational study which will evaluate the safety of COVID-19 vaccination of pregnant women. However, much of this data is not yet available to the public.

COVID-19 Vaccine Decision Guide

Back in December, it became clear that the two mRNA-based vaccines were going to receive approval for use by the FDA under an Emergency Use Authorization. At the University of Massachusetts Medical School – Baystate, we convened a collaborative working group named the "Shared Decision-Making: COVID Vaccination in Pregnancy" working group. This multidisciplinary group consisted of experts in the fields of OB/GYN, Maternal-Fetal Medicine, Infectious Diseases, Emergency Medicine, Shared Decision-Making, risk communication, and COVID-19 research. Our collaboration resulted in the development of a decision aid to help individuals who are pregnant, lactating, or planning on becoming pregnant decide whether to receive an mRNA COVID-19 vaccine. This aid is meant to be used by pregnant women as well as their healthcare providers to foster shared decision-making at a time of high risk to women due to the pandemic. [xi] While the initial guide was targeted to health care workers, it has been rewritten to appeal to a more general population as the vaccines have rolled out to a greater part of the population, and it has become clear that there is a lot of misinformation in the public sphere. It has since been downloaded over 35,000 times, and has been translated into 10 languages including Spanish, Russian, Arabic, Chinese and Somali. It is a living document which continues to be updated as new information is available. Our goal is to allow all women the opportunity to benefit from information presented in an unbiased fashion so that they can make the best decision for them and their families. It respects the autonomy of each woman but provides them with the best available current information to inform any decision.

Prenatal and Postpartum care during COVID-19

Aside from the immediate medical risks of COVID-19 in pregnancy, women face significant social and emotional burdens as a result of the pandemic. Women report feeling more isolated and have less support at home during their pregnancies and in the postpartum time period. They lack the advice and help of other family members while struggling with breastfeeding and caring for new infants after delivery. This is further compounded by an increased necessity to care for children who are in hybrid and remote learning situations. Many do not have large home

spaces to accommodate homeschooling and cannot quarantine when there is concern about exposures. Many women, especially at the start of the pandemic were afraid to come to clinics and hospitals to access care.[xii] In Italy, at the outset of the pandemic, there were studies showing an increase in ruptured ectopic pregnancies, or those that implant outside of the uterus.[xiii] Ruptured ectopic pregnancies are the leading cause of mortality in the first trimester of pregnancy, and delay in seeking care can be a fatal decision.

For other women, as their viable pregnancies progress, certain specialized ultrasounds are deferred or declined because of fears of in person visits. Fetal surveillance and testing are similarly declined. And, with new restrictions limiting visitors and support people during labor and delivery, there has been a higher proportion of women seeking home birth, which places women and their infants at higher risks of morbidity and mortality in childbirth.[xiv] When hospital systems are stressed it can also increase the response time in case of emergencies. We also face an increasing epidemic of maternal mortality in this country, especially among women of color, many of whom lose precious advocates when they lose the company of their friends and family on labor and delivery. I have heard this concern personally from my patients.

However, there are changes that benefit women's health care as well. These have come from the support of state governments. COVID-19 has changed much of the way we practice obstetrics and has allowed for rapid innovation. Early in the Pandemic, the Maternal Fetal Medicine division out of Thomas Jefferson University developed an algorithm for how to space out prenatal visits and ultrasound appointments to both reduce risk of transmission to patients and staff in outpatient clinics and the hospital setting, while balancing risks of decreased surveillance. Some of these changes will likely be adopted moving forward as models of prenatal care change. Other adaptations include expanded telehealth utilization and increased use of remote monitoring systems, for both fetal and maternal monitoring. Many states have helped support compensation for these new models and it will allow greater outreach into both rural and urban settings and to women who might not otherwise be able to access care in person. These are important not only during pandemic times but to improve access to usual care after the pandemic in areas where there is a dearth of specialist care.

In Conclusion

In summary, I would like to thank you all for this time because it indicates your desire to be champions in improving the care of pregnant women during the COVID-19 pandemic and beyond. Women of childbearing age make up a significant portion of our society and are at risk for the severe consequences of COVID-19. It is important that we not exclude them from participating in trials nor from receiving life-saving vaccines. We must also use this time to determine how to improve infrastructure and conditions within communities of color that are differentially affected by COVID-19. We must do so with the acceptance that there are systemic biases that we must identify, understand and overcome.

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