Maternal Health Amidst COVID-19

Joint Democratic Policy Committee, hosted by the Women's Health Caucus

February 10, 2021 at 11 a.m.

Opening Remarks

Senator Katie Muth, *Senate Policy Chair*
Representative Ryan Bizzarro, *House Policy Chair*
Senator Judy Schwank, *Co-Chair of Women's Health Caucus*
Representative Mary Jo Daley, *Co-Chair of Women's Health Caucus*
Senator Amanda Cappelletti, *Vice Chair of Women's Health Caucus*
Representative Morgan Cephas, *Vice Chair of the Women's Health Caucus*

Panel 1: Maternal Care During COVID-19, Vaccines & Pregnancy

Group A: Maternal Care

Mark Woodland, M.S., M.D., FACOG, Chair & Clinical Professor OB-GYN, Reading Hospital/Tower Health, Interim Academic Chair, OBGYN Drexel University College of Medicine
Hyagriv "Hy" Simhan, UPMC Magee-Women's Hospital, Division Chief of Maternal Fetal Medicine
Richard Beigi, UPMC Magee-Women's Hospital, President, OB-GYN
Aasta Mehta, M.D., M.P.P., FACOG - Philadelphia MMRC, Philadelphia Dept of Health, PA MMRC

Break for Q&A (due to time constraints, panelists from Panel 1, group A must depart by noon)

Group B: COVID-19 Vaccine

Elizabeth Morgan, Maternal Fetal Health Specialist, Baystate Health
Richard S. Legro, M.D, Chair, Department of Obstetrics and Gynecology, Professor of Obstetrics and Gynecology and Public Health Sciences, Penn State Health College of Medicine and Penn State Health
Catharine I. Paules, M.D., Assistant Professor, Infectious Diseases, Penn State Health College of Medicine and Penn State Health

Break for Q&A

Panel 2: Telemedicine, Prenatal Care, & Labor & Delivery

Sindhu K. Srinivas, M.D., MSCE, Director of Obstetrical Services at the Hospital of the University of Pennsylvania, Vice Chair for Quality and Safety, Physician Lead, Women's Health Service Line, Penn Medicine
Nicole Chaney, Certified Nurse-Midwife, Reading Hospital
Markita Glenn, Doula, Pettaway Pursuit Foundation

Break for Q&A

Panel 3: The Impact of Quarantine on Pregnant & Postpartum Individuals

Rhonda C. Boyd, Ph.D., Psychologist in the Department of Child and Adolescent Psychiatry and Behavioral Sciences at The Children's Hospital of Philadelphia
Demia Horsley, M.P.H., CLC (DONA), LCCE, Director of Strategic Initiatives, Healthy Start, Inc.

Reading Hospital
TOWER HEALTH
Advancing Health. Transforming Lives.

Drexel University
College of Medicine
In the tradition of Woman's Medical College of Pennsylvania and Hahnemann Medical College

Mark B. Woodland, MS, MD, FACOG
Department Chair, OBGYN
Academic Chair (Interim), OBGYN
Clinical Professor

Department of Obstetrics and Gynecology

PA Joint Democratic Policy Committees & Women's Health Caucus Testimony Briefing Materials Wednesday February 10th, 2021

Professional Titles:

Mark B. Woodland, MS, MD, FACOG
Chair, Department of OBGYN, Reading Hospital/Tower Health
Interim Academic Chair, Department of OBGYN, Drexel University College of Medicine
Member and Chair, PA State Board of Medicine

Background Comments:

1. **123 for Maternal Health Awareness**- This year health on 126, Maternal Mental Health
2. **February is Black History Month** – founded by a son of ex-slaves and black historian in 1926, Carter G. Woodson to celebrate black history and contributions, but disparities still exist and are only emphasized in maternal health and mortality.
3. **Heart Health Month** – NIH and AHA 1st Friday "wear red day" until COVID, heart disease the number one cause of death for men and women annually (CDC 2019)
    a. Heart disease: 659,041
    b. Cancer: 599,601
    c. Accidents (unintentional injuries): 173,040
    d. Chronic lower respiratory diseases: 156,979
    e. Stroke (cerebrovascular diseases): 150,005

Women's/Maternal Health and COVID:

1. **COVID & Women/Maternal Health** –
    a. PA Case: 754,240 (women>men), Deaths: 22,467 (women=> men)
        i. Death Rate: 2.97%
    b. CDC Pregnancy Report: cases:64,075, deaths: 74
        i. Death rate: <0.2%
    c. Disparity, more per capita black and Hispanics with COVID

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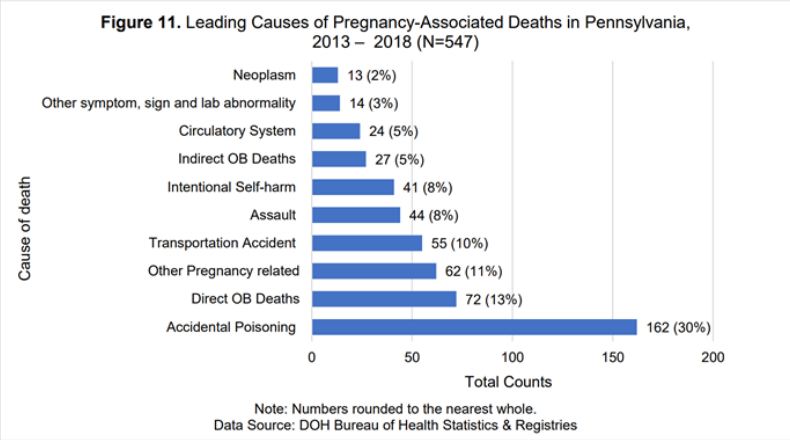
2. **Vaccine & Pregnancy** – 2 ways to gain immunity, disease and potential morbidity/mortality risk or vaccine and minimized risk of adverse event.
   a. **ACOG/SMFM** – COVID-19
      i. vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on recommended priority groups
      ii. vaccines should be offered to lactating individuals like non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP.
   b. **WHO** – confusion, original statement was if low risk of exposure, don't get vaccine if pregnant or breast feeding. This statement has been walked back.
   c. **PA Vaccine Distribution**
3. **Diversity & Disparity of Maternal Health Care** –
   a. **HRSA Maternal Morbidity & Mortality 2019 Summit** – since 1990 worldwide maternal mortality rate dropped 44%, but in US it has increased. In 2015, US ranked 46 among 181 countries
      i. Causes: maternal mental health, obesity and related diseases (diabetes and hypertension), OUD and public health emergencies)
   b. **COVID & Race/Ethnicity** – C19 is a "public health emergency" – per capita, more Hispanic and black women infected and get sick from C19.
      i. More diverse provider population is directly correlated with better care.
4. **Maternal Mental Health and Maternal Mortality –** PA MMRC established by Act 24 in 2018 report
   a. **Mortality –** while pregnant up to 1-year post-partum
      i. **"Accidental Poisoning" –** 2013 19% to 2018 44%
      ii. **Indirect/Direct OB Deaths –** only about 19% of deaths



5. **Importance of Provider Wellness and Maternal Health –** Medscape Report "Death by 1000 Cuts: 2021 Report on Burnout & Suicide"
   a. Almost 50% of providers feel burned out.
   b. Maternal health providers is top 10 profession
   c. During COVID, female providers 51% more likely to be burnout then male 36%

d. Good news, exercise is number 1 stress relief.

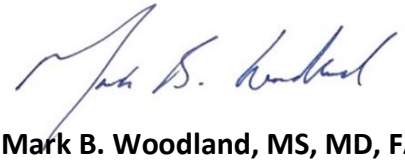
Recommendations:

1. Support diversification of our provider work force by improving the pipeline:
    a. Encourage institutions to recruit students in percentage that resembles the state population.
2. Support education of public and providers as to the risks associated with racial and ethnic effects on health care.
3. Enhance monitoring and education of maternal mental health issues.
4. Understand the impact of "public health emergencies" on providers as well as patients

References:

1. PA C19 Dashboard -https://www.health.pa.gov/topics/disease/coronavirus/Pages/Cases.aspx
2. PA 2019 Report on State of Health Equity - https://www.health.pa.gov/topics/Documents/Health%20Equity/The%20State%20of%20Health%20Equity%20in%20PA%20Report%20FINAL.pdf
3. CDC C19 Report - https://covid.cdc.gov/covid-data-tracker/#pregnant-population
4. ACOG C19 & Pregnancy - https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19
5. WHO Vaccine & Pregnancy - https://www.who.int/news-room/feature-stories/detail/the-moderna-covid-19-mrna-1273-vaccine-what-you-need-to-know
6. HRSA 2019 Summit on Maternal Mortality - https://www.hrsa.gov/sites/default/files/hrsa/maternal-mortality/Maternal-Mortality-Technical-Report.pdf
7. PA Report on Pregnancy associated Deaths - https://www.health.pa.gov/topics/Documents/Diseases%20and%20Conditions/Pregnancy%20Associated%20Deaths%202013-2018%20FINAL.pdf
8. MS Death by 1000 Cuts - https://www.medscape.com/slideshow/2021-lifestyle-burnout-6013456

Thank you,



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New Study Finds Women Who Develop High Blood Pressure After Giving Birth at Greater Risk of Developing Chronic Hypertension

Washington, DC — Blood pressure that remains elevated over of time — known as chronic hypertension — has been linked to heart disease, which is the leading cause of death in the United States. Recent research has shown that persistent high blood pressure may also increase the risk for stroke and overall mortality. Yet, only about 1 in 4 adults with chronic hypertension have their condition under control, according to the Centers for Disease Control and Prevention.

In a new study to be presented today at the Society for Maternal-Fetal Medicine's (SMFM) annual meeting, The Pregnancy Meeting™, researchers from the University of Pittsburgh will unveil findings that suggest that women who develop high blood pressure during pregnancy and who continue to have elevated blood pressure postpartum are at an increased risk for developing chronic hypertension.

The study looked at 368 women who had normal blood pressure during pregnancy and followed them for six to 18 months after delivery. For six weeks following childbirth, women took their blood pressure at home using a remote monitoring system connected to their smart phones. A total of 5,958 blood pressure readings were collected.

Results found that at their first postpartum visit, nearly half of the women (49.5 percent or 182) had developed high blood pressure. These women had a slower decline in blood pressure in the first six weeks following delivery and higher blood pressure at their postpartum visit compared to the remaining women (50.5 percent or 186) who did not develop high blood pressure.

"By leveraging data from our widely scaled postpartum hypertension remote monitoring program, we were able to discover that a woman's blood pressure in the first six weeks after childbirth appears to be an important indicator of whether she is likely to develop chronic hypertension six to 18 months later," said one of the study's lead authors, Eesha Dave, MD, a resident physician in obstetrics and gynecology at UPMC Magee-Womens Hospital in Pittsburgh.

"This information helps us to better identify women who may be at risk of developing cardiovascular problems later in life and take preventative steps," said another one of the study's lead authors, Alisse Hauspurg, MD, a maternal-fetal medicine subspecialist and assistant professor at University of Pittsburgh.

For a copy of the study, please contact Karen Addis at karen@addispr.com; 301-787-2394.

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About SMFM

The Society for Maternal-Fetal Medicine (SMFM) is a non-profit, membership organization based in Washington, DC. With more than 5,000 physicians, scientists, and women's health professionals around the world, the Society supports the clinical practice of maternal-fetal medicine by providing education, promoting research, and engaging in advocacy to optimize the health of high-risk pregnant women and their babies. SMFM hosts an annual scientific meeting where new ideas and research related to high-risk pregnancies are unveiled and discussed. For more information, visit SMFM.org and connect with the organization on Facebook and Twitter. For the latest 2021 Annual Meeting news and updates, follow the hashtag #smfm21.

Society for Maternal-Fetal Medicine

TELEHEALTH: OPPORTUNITIES TO INCREASE ACCESS TO QUALITY HEALTH CARE AND ADVANCE EQUITABLE MATERNAL HEALTH

December 2020

An Issue Brief by The Society for Maternal-Fetal Medicine

BACKGROUND

Each year, approximately 700 people in the United States die during childbirth or in the year following delivery.[i] Another 50,000 patients will experience severe pregnancy complications.[ii] The United States remains one of the most dangerous places in the developed world to give birth. The alarming state of maternal health is driven, in part, by barriers preventing patients from receiving timely, quality prenatal and postpartum care. Patient barriers include residing in a community with no maternity care providers, lacking transportation to medical appointments, work schedules that make attending appointments difficult, limited English proficiency or understanding of the health care system, and requiring childcare support, among others.[iii] With this statement, SMFM highlights how telehealth can help patients overcome these barriers to **improve health care access** and **advance equity** for patients experiencing high-risk pregnancies.

Telehealth uses technology (computers, mobile devices, etc.) to educate, share information, and provide care to patients without an in-person visit. A component of telehealth, called telemedicine, refers specifically to delivering healthcare remotely using technology. While legislation often alternates between the terms telemedicine and telehealth, the term telehealth generally refers to a broad definition of health services, while telemedicine refers specifically to the delivery of clinical services.[iv]

Maternal-fetal medicine (MFM) subspecialists specialize in the care of patients with complex pregnancies. In 2010, there were 1,355 MFM subspecialists in the United States, and 98% of these subspecialists lived in metropolitan counties. Some states, such as North Dakota and Wyoming, have no MFMs practicing in the state.[v] Telehealth has the potential to improve access to MFM subspecialists for people experiencing high-risk pregnancies, especially those that live in rural or underserved areas. Rural residents have a 9% greater probability of severe maternal morbidity and mortality compared with urban residents.[vi] Further, the telehealth infrastructure developed for remote MFM services can also be used to provide other critical health care services – such as mental health care – to patients experiencing both high- and low-risk pregnancies during the prenatal and postnatal period.

More than 1 in 6 births happen in rural facilities, and rural residents have a greater probability of severe maternal morbidity and mortality than urban residents; yet 98% of MFMs practice in urban centers.

With telehealth, patients and their local providers can consult with an MFM subspecialist regardless of their

location. Improved access to MFM consultations through telehealth has been shown to improve maternal and infant health outcomes. For example, telehealth consultations for rural residents lead to lower rates of premature delivery and neonatal intensive care unit admissions.[vii] Improved health outcomes may also lead to significant cost savings. For example, the total cost associated with premature birth in the United States is $26.2 billion each year.[viii]

Even in urban communities, telehealth has the potential to address barriers to care. Particularly for patients who require frequent appointments for a high-risk pregnancy, telemedicine visits may confer a number of advantages for both patients and providers.

PATIENT ADVANTAGES

- Reducing expenses associated with traveling to appointments (e.g. parking, gas, taxi or public transit fares)
- Minimizing time away from work
- Avoiding the need for childcare during appointments
- Decreasing wait time in an office
- Alleviating unnecessary environmental exposures

PROVIDER ADVANTAGES

- Improved continuity of care with patients who previously had to overcome challenges to attend frequent office visits
- Flexible scheduling
- Expanding the reach of MFM subspecialists to underserved areas
- Increased clinical support for local providers caring for patients experiencing high-risk pregnancies, which ensures those providers can continue to care for less complex patients while referring those with the most complex pregnancies to facilities with that can provide more specialized care
- Reducing overhead costs associated with in-person visits

ADDRESSING DISPARITIES IN PATIENT CARE

Significant disparities in pregnancy outcomes exist in the United States. Black mothers are three to four times more likely to die from a pregnancy-related death than White mothers.[ix] Emerging data indicate that telehealth may be an effective tool in addressing these disparities. For example, one study found that monitoring postpartum patients' blood pressure via a text-message system led to a 50% reduction in racial disparities for tracking blood pressure from patients compared to standard in-person blood pressure checks.[x]

While telehealth has been shown to decrease racial disparities, it is critical that telehealth is implemented in a way that intentionally reduces barriers to telehealth services for underserved populations. For example, many public and private insurance plans require the use of videoconferencing for telehealth services. This policy exacerbates health inequities by limiting access to telehealth for those individuals that do not have access to broadband internet or video-enabled devices due to where they live or their income.

POLICY RECOMMENDATIONS

The COVID-19 pandemic has emphasized the importance of telehealth capabilities, which offered a vital avenue to provide care while minimizing risk of disease spread among patients and providers. Adoption and utilization of telehealth were accelerated during the pandemic due to both increased demand and regulatory flexibility. As policymakers consider making regulatory changes permanent, the Society for Maternal-Fetal Medicine (SMFM) offers the following recommendations to ensure that telehealth is implemented in ways that allow providers to offer equitable care to all patients and preserve telehealth as a viable practice option to ensure access for patients in the future.

ADVANCING EQUITY THROUGH TELEHEALTH

Increase access to broadband services. As the COVID-19 pandemic has highlighted, reliable access to broadband internet in the home is critical to allow people to work, attend school, and access doctors' appointments via telehealth modalities. Policymakers should strengthen and expand federal, state, and local initiatives to make affordable broadband internet access available to Americans in every community.

Commit to improving digital literacy. Sixteen percent of American adults are not digitally literate.[xi] On average, these adults are less educated and more likely to be Black, Latino, or foreign born. If efforts to increase access to technology are not met with an equal commitment to increase digital literacy, this may exacerbate health inequity. Therefore, states should support initiatives focused on increasing digital literacy. One possible intervention includes the use of community health workers to identify high-risk patients and teach basic skills in computer and smartphone use.

Payment parity for audio-only (telephonic) telehealth visits. Not all patients have access to computers, smartphones, tablets, and broadband service, and this should not be a barrier to accessing care. Public and private insurance providers should consider a live and interactive conversation with or without video a qualifying telehealth service. Recent data indicate that audio-only virtual prenatal visits, when combined with in-person appointments, meet patient needs and offer unique advantages over video visits.[xii]

Pay for medical equipment necessary for remote prenatal visits. Telehealth prenatal visits can require patients to use fetal dopplers, blood pressure monitors, and weight scales to measure vital signs and report readings to their clinicians. Purchasing this durable medical equipment is a barrier for many people with lower incomes. Medicaid and private insurance plans should cover the cost for this equipment to increase access to maternity care through telehealth.

Culturally-competent translation and interpretation services should be required in telehealth settings. Currently only one state explicitly requires the provision of interpretation and translation services for patients with limited English proficiency in a telehealth setting. Quality language services are essential when trying to explain complex fetal anomalies and other high-risk pregnancy complications. Policymakers should guarantee payment for language services during telehealth visits to provide quality care to every patient experiencing a high-risk pregnancy.

IMPROVING ACCESS THROUGH TELEHEALTH

The following recommendations may increase the number of MFM subspecialists who are able to offer telehealth services and, therefore, increase the number of high-risk patients who can receive the specialized care provided by MFM subspecialists.

Telehealth services should be reimbursed at rates comparable to in-person visits. Currently, many state Medicaid programs and private payors reimburse for telehealth services at only a percentage of the rate paid for in-person services or don't reimburse for all telehealth services. As of late 2019, only four states have private payer parity laws that govern how private insurance plans should reimburse for telehealth services.[xiii] Only eight state Medicaid programs reimburse for all modalities of telehealth, and certain limitations apply.[xiv] Payment parity is critical to allowing providers to offer telehealth services. To ensure all patients have access to appropriate telehealth, every state should enact laws that reimburse for telehealth services at rates comparable to those paid for in-person services and reimburse for all telehealth modalities.[xv]

Providers should be able to deliver telehealth services across state lines. A key benefit to telehealth is that it allows patients living in areas of physician shortage to access care. SMFM commends the nearly 30 states and territories that are part of the Interstate Medical Licensure Compact, which allows participating states to streamline the licensing process for physicians who want to practice in multiple states. SMFM urges the remaining states and territories to enact legislation to join the compact, as well as pursuing other pathways to make it easier for physicians to practice across state lines.[xvi] This would help high-risk pregnancy patients access MFM care regardless of where they live.

Increase transmission and facility fees to encourage providers to offer telehealth services. Transmission and facility fees allow health care providers to invest in technologies needed to provide telehealth services. Insufficient fees deter some providers from maintaining that infrastructure. Thirty-four states will reimburse either a transmission fee, facility fee, or both.[xvii] Among those states, there is variation in fees and which providers are eligible. Implementing transmission and appropriate facilities fees across public and private payors in all states will allow more MFMs to provide telehealth services.

Pursue new payment models that incentivize telehealth. Current insurance reimbursement models are not designed for the delivery of services through telehealth and, therefore, stymie innovation and improvements in patient care. State Medicaid programs and other payors should explore new payment models that financially incentivize MFMs to invest in telehealth technologies and coordinate with local providers and community health workers.

References

[i] Centers for Disease Control and Prevention. Pregnancy-Related Deaths. Last Reviewed February 26, 2019. Retrieved from https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-relatedmortality.html

[ii] Centers for Disease Control and Prevention. Severe Maternal Morbidity. Last Reviewed January 31, 2020. Retrieved from https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html

[iii] Emily Peterson, Nicole Davis, David Goodman, et al. Vital Signs: Pregnancy-Related Deaths, United States, 2011-2015, and Strategies for Prevention, 13 States, 2013-2017. Morbidity and Mortality Weekly Report. May 2019. Retrieved from https://pubmed.ncbi.nlm.nih.gov/31071074/

[iv] Center for Connected Health Policy. State Telehealth Laws and Reimbursement Policies. Spring 2020. Retrieved from https://www.cchpca.org/sites/default/files/2020-05/CCHP_%2050_STATE_REPORT_SPRING_2020_FINAL.pdf

[v] William Rayburn, Jeffery Klagholz, Erika Elwell, & Albert Strunk. Maternal-Fetal Medicine Workforce in the United States. American Journal of Perinatology. October 2012. Retrieved from https://pubmed.ncbi.nlm.nih.gov/22773289/

[vi] Katy Kozhimannil, Julia Interrante, Carrie Henning-Smith, & Lindsay Admon. Rural-Urban Differences in Severe Maternal Morbidity and Mortality in the US, 2007-15. Health Affairs. December 2019. Retrieved from https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.00805

[vii] Cassandra Leighton, Molly Conroy, Andrew Bilderback, et al. Implementation and Impact of a Maternal-Fetal Medicine Telemedicine Program. American Journal of Perinatology. June 2019. Retrieved from https://www.thieme-connect.com/products/ejournals/abstract/10.1055/s-0038-1675158

[viii] Institute of Medicine (US) Committee on Understanding Premature Birth and Assuring Health Outcomes. Preterm Birth: Causes, Consequences, and Prevention. 2007. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK11358/

[ix] Elizabeth Howell. Reducing Disparities in Severe Maternal Morbidity and Mortality. Clinical Obstetrics and Gynecology. June 2019. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915910/

[x] Adi Hirshberg, Mary Sammel, Sindhu Srinivas. Text Message Remote Monitoring Reduced Racial Disparities in Postpartum Blood Pressure Ascertainment. American Journal of Obstetrics & Gynecology. September 2019. Retrieved from https://www.ajog.org/article/S0002-9378(19)30669-6/fulltext

[xi] Saida Mamedova, Emily Pawlowski. Stats in Brief: A Description of U.S. Adults Who Are Not Digitally Literate. US Department of Education. May 2018. Retrieved from https://nces.ed.gov/pubs2018/2018161.pdf

[xii] Denisse Holcomb, Mary Ann Faucher, Jennifer Bouzid, et al. Patient Perspectives on Audio-Only Virtual Prenatal Visits Amidst the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV 2) Pandemic. Obstetrics & Gynecology. August 2020. Retrieved from https://journals.lww.com/greenjournal/Fulltext/2020/08000/Patient_Perspectives_on_Audio_Only_Virtual.16.aspx

[xiii] Center for Connected Health Policy. State Telehealth Laws and Reimbursement Policies. Spring 2020. Retrieved from https://www.cchpca.org/sites/default/files/202005/CCHP_%2050_STATE_REPORT_SPRING_2020_FINAL.pdf

[xiv] Ibid.

[xv] Institute of Medicine (US) Committee on Health Literacy. Health Literacy: A Prescription to End confusion. 2004. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK216032/

[xvi] Interstate Medical Licensure Compact. U.S. State Participation in the Compact. Accessed November 2020. Retrieved from https://www.imlcc.org/#map

[xvii] Center for Connected Health Policy. State Telehealth Laws and Reimbursement Policies. Spring 2020. Retrieved from https://www.cchpca.org/sites/default/files/202005/CCHP_%2050_STATE_REPORT_SPRING_2020_FINAL.pdf

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For a copy of the study, please contact Karen Addis at karen@addispr.com; 301-787-2394.

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Commentary

The need for inclusion of pregnant women in COVID-19 vaccine trials

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[h] Center for Immunization Research, Department of International Health, Johns Hopkins Bloomberg School of Public Health, United States

Since the recognition of SARS-CoV-2 virus in December 2019 there have been more than seventy-two million cases and greater than 1.6 million deaths globally, as well as more than 300,000 deaths in the United States attributable to COVID-19 [1]. COVID-19 has had a dramatic impact on modern global society and will be a major part of the collective global biosphere for the foreseeable future. Similar to the response to other modern-era infectious disease outbreaks (Human Immunodeficiency Virus, H1N1 Influenza, Ebola virus, and Zika virus) vaccination is a potent mitigation strategy being aggressively pursued against SARS-CoV-2. The strategic approach to vaccine development has been outlined by global scientific leaders [2]. As the approach unfolds for the development, testing, and implementation, pregnant women represent an important albeit scientifically complex population(s) that warrants consideration and responsible inclusion throughout the entire process. The complexity of pregnancy should be viewed as an opportunity to generate much needed evidence through responsible inclusion of these women in research, rather than a barrier to progress and reason for unjust exclusion, which has been the norm for decades.

For many respiratory infectious diseases, pregnant women and neonates are two high-risk populations that suffer disproportionate rates of morbidity and mortality. The cumulative data thus far suggest that pregnant women are at a higher risk for serious morbidities from COVID-19, albeit more modest than other pathogens, such as 2009 H1N1 Influenza. These heightened morbidities are noted in terms of an increased need for intensive care, mechanical ventilation and death among symptomatic pregnant women, as well as suggestions of increased rates of preterm birth [3,4]. For many decades the powerful concept of passive immunization of the neonate via maternal infection or immunization and transplacental passage of protective antibody into the fetal/neonatal circulation has been recognized, with protection afforded against tetanus, smallpox, influenza, and pertussis, among other pathogens [5]. Thus, maternal vaccination can protect the mother, the fetus, and the infant. As one example, influenza vaccination during pregnancy decreases the risk of severe disease in the mother, which positively impacts the fetus by reducing the risk of preterm birth and/or pregnancy loss, as well as providing protection for the infant during the first few months of life [5]. Therefore, a single intervention offers powerful protection for two susceptible individuals who are at increased risk of a disease and its consequences.

There is an important need to demonstrate safety of vaccine products specifically during pregnancy. Moreover, given the distinct physiologies and susceptibilities of pregnancy, response to vaccination may differ from that of the general population (although this has not generally been noted to date). Consequently, optimal public health programming and clinical use requires pregnancy-specific data. Evidence from research evaluations of vaccines in pregnancy may increase vaccine confidence in pregnant women and their obstetric providers so that women themselves are protected, as well as facilitate efforts to achieve herd immunity among the entire population. These efforts will help also to decrease household transmissions among children potentially too young to receive vaccination, as vaccine becomes available for public use. Additionally, as prioritization schemata have been designed for novel coronavirus vaccines, it is apparent that reproductive-age and pregnant women represent a significant proportion of the health-care workforce that are at top priority for receipt. Pregnancy-specific data will help to ensure that those at highest risk have access to vaccine. Encouragingly, some pharmaceutical manufacturers, working in collaboration with the National Institutes of Health, are beginning to share their plans in designing and sponsoring pregnancy-specific trials. This is a welcome development and in line with a United States Lawmakers' requests written near the outset of the pandemic [6].

While there is a clear need to include pregnant women in COVID-19 vaccine research efforts, there are barriers to gathering needed data and ensuring that this population is protected in the epidemic response. Pregnant women have been historically

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0264-410X/

excluded from vaccine trials, except those that were carried out for 2009 H1N1 influenza vaccines (due in large part to years of use of seasonal influenza vaccines in pregnancy), pertussis vaccines, and most recently vaccines expressly developed for maternal immunization. Without timely and robust evidence about safety and efficacy during pregnancy, pregnant women have previously been denied opportunities to receive vaccines that would have protected them and their offspring in numerous epidemics. When pregnant women are neither expressly considered nor prioritized in early efforts to develop vaccines, they are in turn excluded from participating in research and the generation of evidence, which then results in exclusion from vaccine delivery programs. This perpetuated cycle of exclusion (Fig. 1) is profoundly unjust and deeply problematic. As a recent important example, exclusion of pregnant women from earlier Ebola vaccine trials in 2015–2016 meant that suboptimal data were available only from the small number of inadvertent exposures during pregnancy. This in turn led to the exclusion of pregnant women from subsequent Ebola vaccine trial and deployment activities in 2018–2019, despite clear signals that Ebola-related outcomes were worse during pregnancy, including devastating consequences for the woman and fetus [7]. The global medical and research establishment can and should do better with the response to COVID-19.

If this pattern persists in the context of COVID-19, we risk a double injustice: (1) pregnant women would be unfairly denied opportunities to participate in COVID-19 vaccine studies that may directly benefit them and/or their offspring and (2) as the response continues, all pregnant women, their providers, and health policymakers would have to make unnecessarily difficult decisions because of inadequate evidence about vaccine use in pregnancy, leading to overall less vaccine use and its afforded protections in this population. These inequitable outcomes are not, however, inevitable. Global efforts to change the status quo have been underway in recent years. Among the many global efforts in this space, the PREVENT Working Group [8] issued 22 specific recommendations in 2019 to promote equity for pregnant women and their offspring in epidemic vaccine development and response. Below, we highlight a few key points from the PREVENT report's recommendations on the inclusion of pregnant women in vaccine studies.

Pregnant women should have opportunities to enroll in COVID-19 vaccine studies whenever the prospect of benefit outweighs the risks to themselves, their offspring, or both. Trials of a multitude of candidate SARS-CoV2 vaccines are progressing rapidly with many efficacy trials underway (or recently completed). These trials are anticipated to be large and enroll thousands of participants [9].

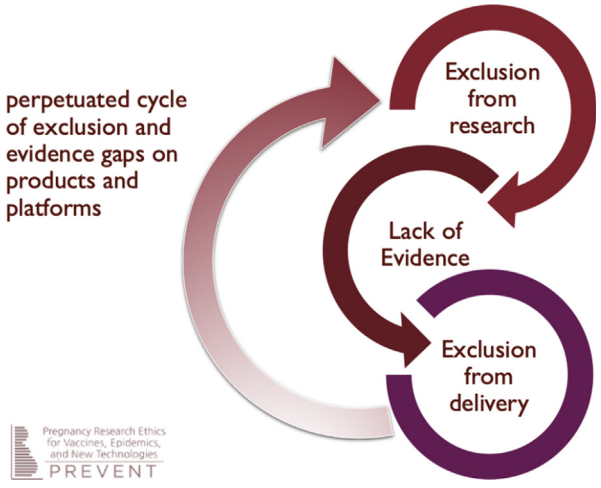

Fig. 1. Cycle of exclusion [8].

There is an urgent need to proactively plan for appropriate evaluation of vaccine candidates in pregnancy, with attention to which trials meet ethical standards for fair inclusion based on risk–benefit assessment, approaches to generate needed evidence on pregnancy-specific indicators and outcomes, and ensuring compliance with regulatory prerequisites.

Ethical standards generally consider pregnant women eligible for enrollment when there is a reasonable judgment that research participation is likely to be at least as beneficial to the pregnant woman and the fetus as alternatives to participation. Applied to the context of COVID-19 vaccine trials, this would entail an assessment of the prospect of benefits and risks from receiving an investigational vaccine as compared to the risk of exposure to community-acquired infection and progression to severe COVID-19 disease amidst available treatment options—taking into account that the benefits and risks in both scenarios apply across the maternal-fetal dyad. Determining whether the prospect of benefit outweighs the risk in these and other trials depends on several factors, including characteristics of vaccine candidates as well as the epidemiological context in which trials are conducted (8, table 1 specifically). When the full range of harms and risks to pregnant women and their neonates of contracting SARS-CoV-2 virus is considered, this criterion is likely to be satisfied for many vaccine candidates. Consideration of the background risks of infection and severe disease as part of the risk–benefit assessment may be particularly relevant for the subset of pregnant frontline and essential workers, who face an unavoidable increased risk of infection and disease.

When the prospect of benefit exceeds the risks, enough pregnant women should be recruited to allow an assessment of safety and immunogenicity to gather as much evidence as possible using standardized outcome measures [10]. Clinical development plans and study protocols may adopt a range of approaches for collecting data from pregnant women, including the conduct of parallel or companion studies to the main efficacy trial, or through a substudy of the main trial.

In addition, it should be anticipated that some of the women of childbearing potential who participate in these large efficacy trials will become pregnant within a relevant window following immunization. It is important to know now whether sponsors of current vaccine trials (and for forthcoming trials soon to launch) have protocols in place to capture data on immunogenicity and pregnancy-specific indicators of safety that can be systematically collected from these individuals [10]. Again, where benefit exceeds risks, women who become pregnant while participating in a trial should be given the opportunity to receive all doses in a vaccine series.

Because certain non-clinical studies are often a prerequisite for including pregnant women in trials, such as developmental and reproductive toxicology studies, investigators and developers should coordinate with national regulatory authorities to determine what will be required and initiate required non-clinical studies for promising candidates, depending on vaccine platforms used and historical experience with these platforms. Doing so as possible will allow for timely participation of pregnant women in appropriate future trials.

In conclusion, there are many compelling scientific, public health, and ethical reasons pregnant women need to be considered and included in vaccine investigations and eventual use in our global efforts to mitigate COVID-19. The current pandemic presents a critical opportunity to correct the current practice of exclusion and the paradoxical harms such an approach produces. Professional societies such as the American College of Obstetricians & Gynecologists have recently recommended that authorized COVID-19 vaccines should not be withheld from pregnant individuals who are otherwise eligible to be immunized [11]. This was based on a situational-appropriate decision by both the FDA and the ACIP to

use permissive language for this population given the lack of safety signals from ongoing animal studies nor a strong biologic plausibility of harm from the newer mRNA vaccine platforms. While this is an appropriate and welcome decision and direction, much more needs to be done to generate an equitable evidence base in pregnancy [11]. The time to do better is now.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

[1] Coronavirus Resource Center. Available at: www.coronovirus.jhu.edu. Retrieved December 15, 2020.
[2] Corey L, Mascola JR, Fauci AS, Collins FS. A strategic approach to COVID-19 Vaccine R&D. Science 2020. https://doi.org/10.1126/science.abc5313.
[3] Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. https://www.bmj.com/content/370/bmj.m3320.
[4] Zambrano LD, Ellington S, Strid P, et al. Update: characteristics of symptomatic women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status — United States, January 22–October 3, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1641–7. https://doi.org/10.15585/mmwr.mm6944e3external icon.
[5] Omer SB. Maternal immunization. N Engl J Med 2017;376(13):1256–67. https://doi.org/10.1056/NEJMra1509044.
[6] Warren E, Murray P. United States Senate. https://www.warren.senate.gov/oversight/letters/senators-warren-and-murray-urge-nih-and-fda-to-incorporate-the-needs-of-pregnant-people-and-other-underrepresented-populations-as-companies-develop-vaccines-and-therapeutics-for-covid-19. Retrieved September23, 2020.
[7] Beigi R. Emerging infectious diseases in pregnancy. Obstet Gynecol. 2017;129(5):896–906. https://doi.org/10.1097/AOG.0000000000001978.
[8] Krubiner CB, Faden RR, Karron RA, Little MO, Lyerly AD, Abramson JS, et al. PREVENT Working Group. Pregnant women & vaccines against emerging epidemic threats: ethics guidance for preparedness, research, and response. Vaccine. 2019;S0264-410X(19)30045-3.
[9] WHO R&D Blueprint. Novel Coronavirus: An international randomised trial of candidate vaccines against COVID-19. April 19 2020. https://www.who.int/blueprint/priority-diseases/key-action/WHOCOVID-2019_SolidarityVaccineTrial_ExpandedOutline_19April_Web.pdf?ua=1.
[10] 7. Bonhoeffer J, Kochhar S, Hirschfeld S, Heath PT, Jones CE, Bauwens J, et al. GAIA project participants. Global alignment of immunization safety assessment in pregnancy - the GAIA project. Vaccine. 2016;34(49):5993–97. doi:10.1016/j.vaccine.2016.07.006. Epub 2016 Oct 14.PMID: 27751641.
[11] Vaccinating Pregnant and Lactating Patients Against COVID-19, Practice Advisory. Available at: https://www.acog.org/en/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-Pregnant-and-Lactating-Patients-Against-COVID-19. Retrieved December 15, 2020.

Joint Senate and House Democratic Policy Committee Hearing w/ Women's Health Caucus

COVID-19 Prevention in Pregnancy

Richard S. Legro, M.D.
Chair, Department of Obstetrics and Gynecology
Professor of Obstetrics and Gynecology and Public Health Sciences
Penn State College of Medicine and Penn State Health

Catharine I. Paules, M.D.
Assistant Professor, Infectious Diseases
Penn State College of Medicine and Penn State Health

February 10, 2021

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Milton S. Hershey Medical Center

Coronavirus Family

- Wide range of hosts; greatest diversity in bats
- Respiratory illness in humans and GI illness in animals
- Four human coronaviruses
  - Circulate each year
  - Common cold symptoms
- Animal coronaviruses can "jump species" (zoonotic) and cause severe human disease
  - SARS
  - MERS

Coronavirus Structure

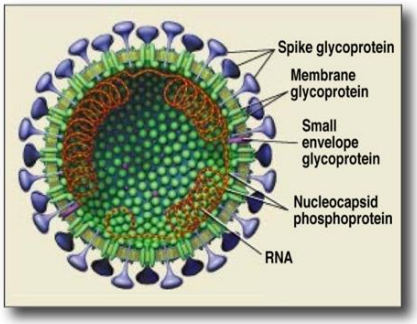

Image credit: JM Drazen *New Eng. Journ. Med.* 2003.
AS Fauci/NIAID

- Enveloped, positive strand RNA viruses
- Largest genome size of any virus (~30 kilobases)

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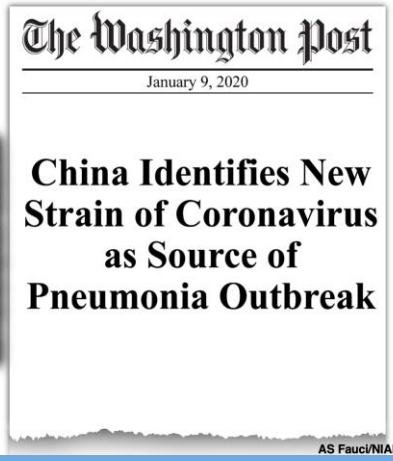
Emergence of the Third Zoonotic Human Coronavirus



AS Fauci/NIAID

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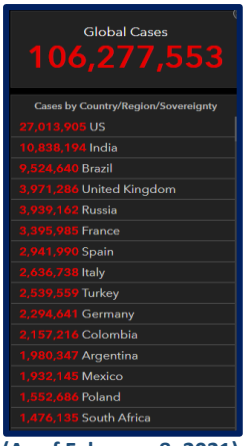
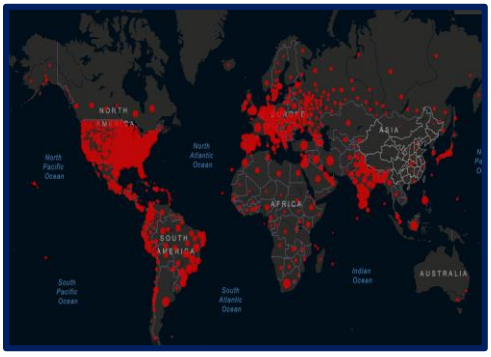
COVID-19 Has Caused Substantial Global Morbidity and Mortality…



(As of February 8, 2021)



Source: John Hopkins CSSE

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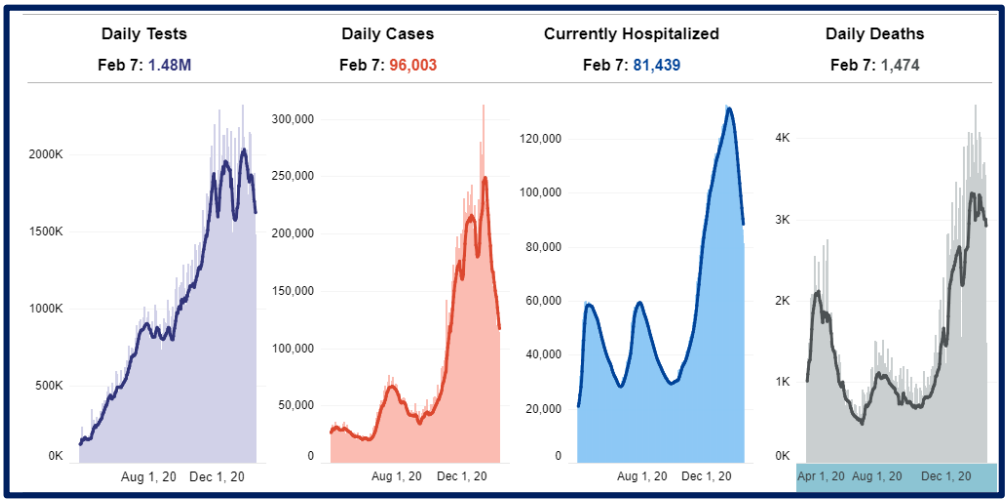
…and the United States is no Exception



(As of February 8, 2021)

Source: COVID Tracking Project

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COVID-19 Clinical Presentation

- **Transmission:**
  - Primarily respiratory droplets
- **Incubation period:**
  - 2-14 days (median 4-5)
- **Symptomatic infection:**
  - 81% mild
  - 14% severe
  - 5% critical
- **Fatality rate**
  - Case fatality rate: 2-4%
  - Infection fatality rate: 0.5-1%?

Symptom	Frequency
Fever	43%
Cough	50%
Shortness of breath	29%
Fatigue	70%
GI symptoms	12-20%
Myalgia	36%
Olfactory or Gustatory Dysfunction	10% (much higher some studies)
Headache	34%
Sore throat	20%
Dermatologic manifestations	Rare

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Pregnancy is a Risk Factor for COVID-19 Complications

- Pregnant women at increased risk for:
  - Severe COVID-19
  - Hospitalization/ICU admission from COVID-19
  - Death from COVID-19
- Pregnant women may be at increased risk for:
  - Preterm birth related to COVID-19
  - Increased rates of cesarean section
- Transmission to the fetus/newborn is very rare

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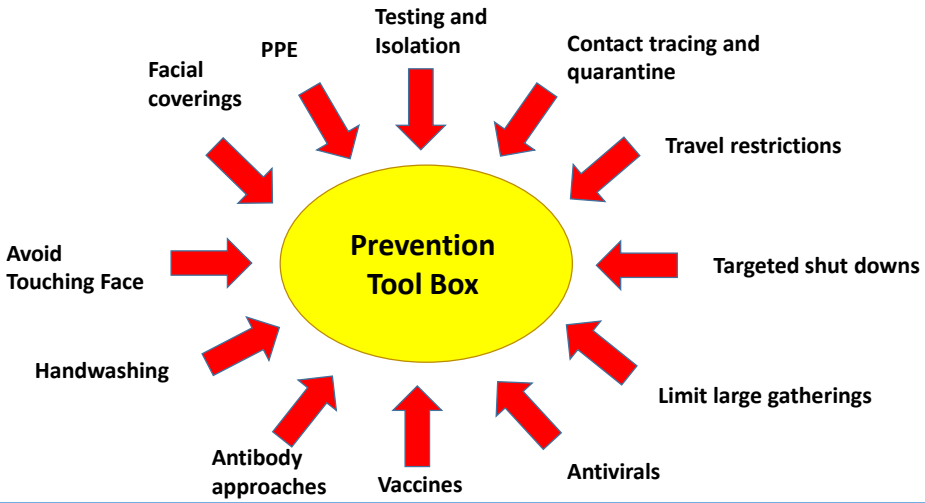
COVID-19 Prevention Tool Box



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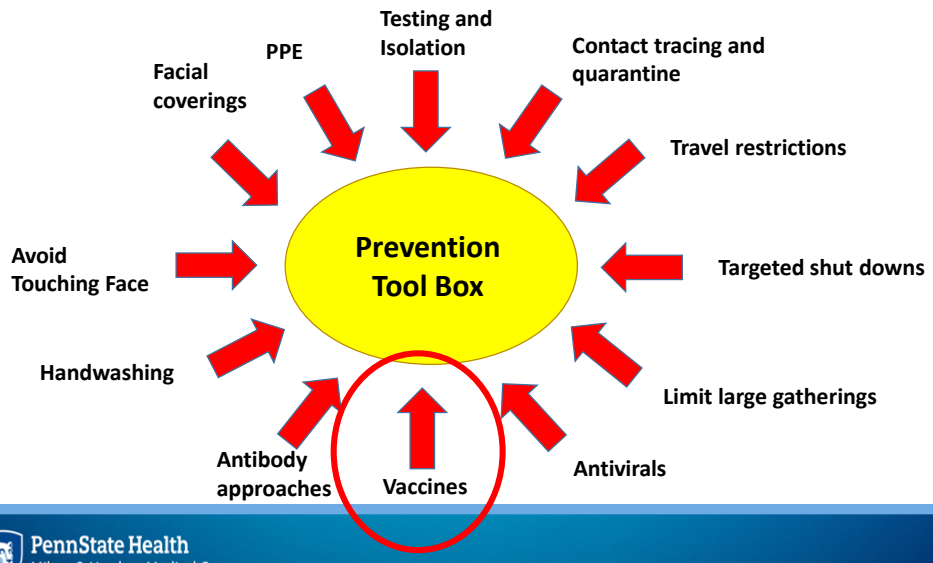
COVID-19 Prevention Tool Box



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Vaccine Design for COVID-19

- Choose a Target
- Choose a Technology
- Safety and Efficacy Data
- What is known about COVID-19 vaccine safety in pregnancy and lactation
- COVID-19 Vaccine recommendations for pregnant or lactating women

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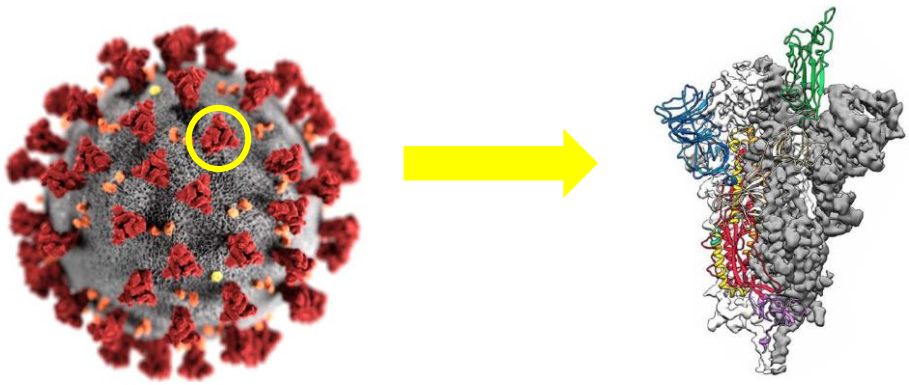
Choose a Target



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Vaccine Design for COVID-19

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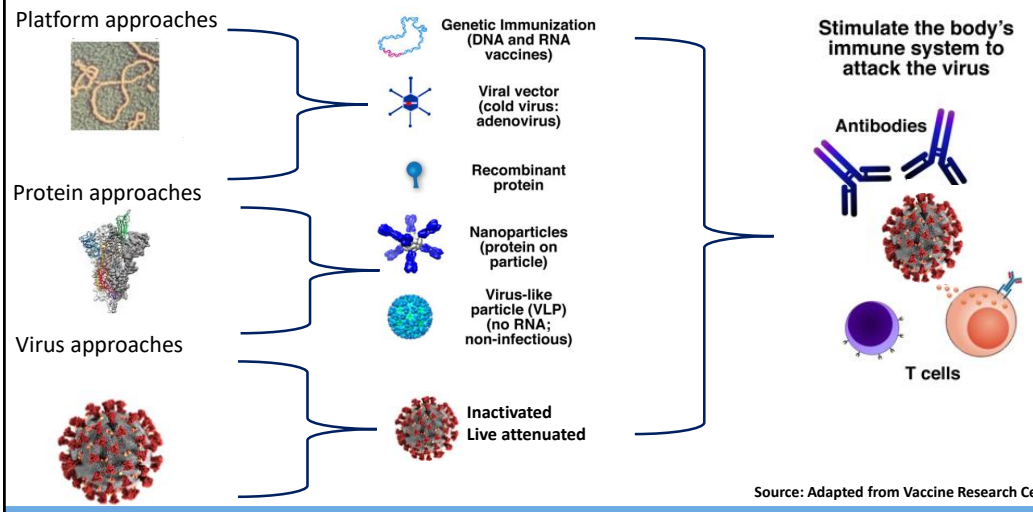
Vaccine Technologies



Source: Adapted from Vaccine Research Center

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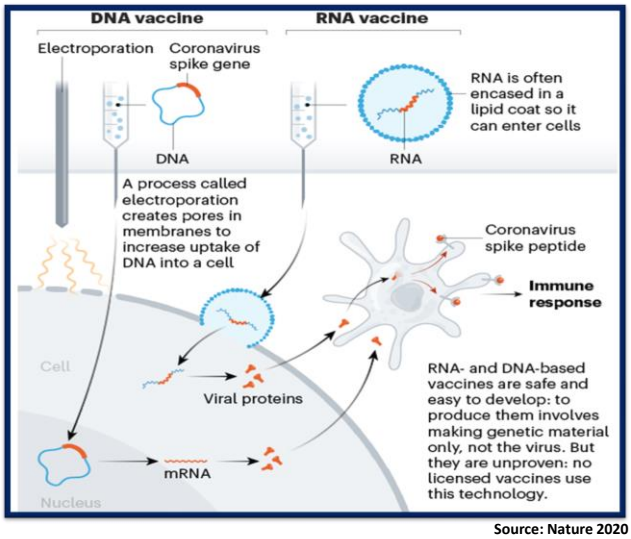
Genetic Immunization

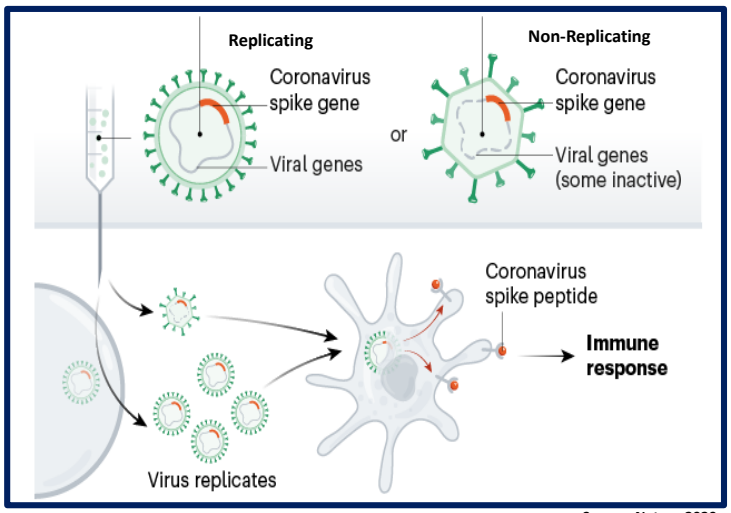
- Examples:
  - Pfizer
  - Moderna



Source: Nature 2020

Viral Vector Vaccines

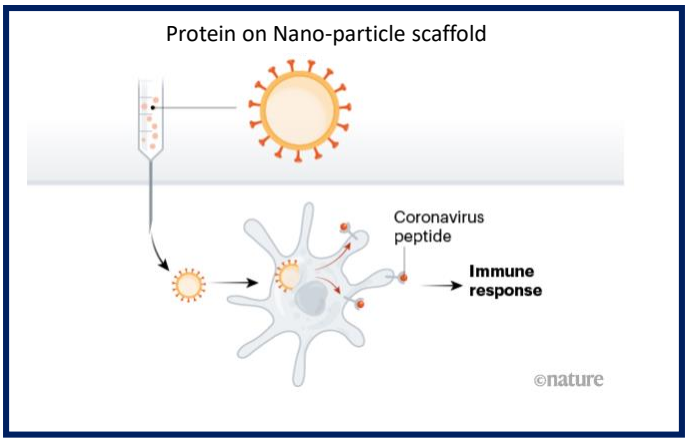
- Examples:
  - Astra-Zeneca
  - J&J



Source: Nature 2020

Protein-Based Vaccines

- Examples:
  - Novavax



Source: Adapted from Nature 2020

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Safety and Efficacy Data

Vaccine	Platform	Doses	Approximate # included in analysis	COVID-19 Positive Cases		Efficacy against symptomatic disease	Severe COVID-19 Cases		Severe side effects or Mortality Vaccine	
				Vaccine	Placebo		Vaccine	Placebo	Vaccine	Placebo
Pfizer	mRNA	2	37,000	8	162	95%	1	9	0	0
Moderna	mRNA	2	30,000	11	185	94.1%	0	30	0	0
Astra-Zeneca	Viral vector	2	17,000	63	150	82.4% (best-12 week boost) • 74% UK • SA halted for concern no efficacy	0	15	0	0
J&J	Viral vector	1	43,788	71	397	66% • 72% US • 66% Latin America • 57% South Africa	85% efficacy-no numbers		0	0
Novavax	Protein based	2	15,000 UK 4,400 SA	6 15	56 29	• 89.3% UK • 60% South Africa	0 0	1 1	0	0

Source: Polack et. al. NEJM 2020, Baden et. al. NEJM 2021, Voysey et. al. Lancet 2021 J&J press release 2021, Novavax press release 20201

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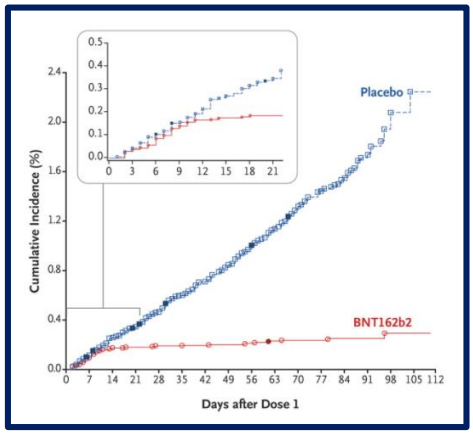
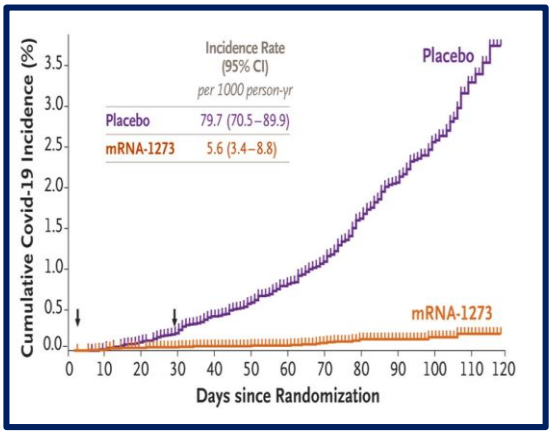
Efficacy Data Illustration

Pfizer



Source: Polack et. al. NEJM 2020

Moderna



Source: Baden et. al. NEJM 2021

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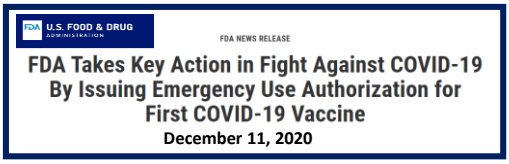
FDA Emergency Use Authorization

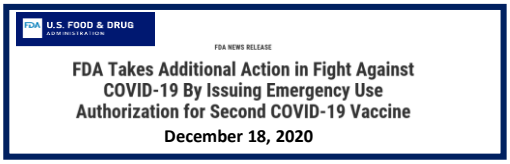

U.S. FOOD & DRUG ADMINISTRATION

FDA NEWS RELEASE

FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine

December 11, 2020

- "Today, the U.S. Food and Drug Administration issued the first emergency use authorization (EUA) for a vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The emergency use authorization allows the Pfizer-BioNTech COVID-19 Vaccine to be distributed in the U.S."


U.S. FOOD & DRUG ADMINISTRATION

FDA NEWS RELEASE

FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine

December 18, 2020

- "Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the second vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The emergency use authorization allows the Moderna COVID-19 Vaccine to be distributed in the U.S. for use in individuals 18 years of age and older."

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Safety data as of January 20, 2021

- People receiving 1 or more doses:
  - 12,153,536 Pfizer
  - 9,689,497 Moderna
- V-safe registration:
  - 997,042 Pfizer
  - 1,083,174 Moderna
- Rare
  - Anaphylaxis
    - Pfizer: 50 cases to VAERS
      - 5 per million doses
    - Moderna: 21 cases to VAERS
      - 2.8 per million doses
  - Death: 196 cases to VAERS
    - Current data do not suggest signal above background in terms of death

V-Safe: Local and Systemic Reactions D0-7	All Vaccines %
Pain	70.7
Fatigue	33.4
Headache	29.4
Myalgia	22.8
Chills	11.5
Fevers	11.4
Swelling	11.0
Joint Pain	10.4
Nausea	8.9

Source: Adapted from ACIP slides January 2021

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Vaccine Design for COVID-19

- Choose a Target
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- What is known about COVID-19 vaccine safety in pregnancy and lactation
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COVID-19 Vaccine Safety in Pregnancy

- No studies of any COVID-19 vaccine in pregnant women
  - None of the discussed candidates contain live virus
  - Not thought to cross placenta or into breast milk
  - Developmental and reproductive toxicity studies in animals thus far reassuring
- Women who became pregnant during trials are being monitored
  - Thus far no concerning findings
- Pregnant and lactating women are being monitored in V-Safe, VAERS, and pregnancy registries
  - Per ACIP meeting, 15,131 pregnancies reported in V-Safe as of January 20, 2021
- Vaccine studies in pregnant women being planned

Vaccine Design for COVID-19

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Current COVID-19 Vaccine Recommendations for Pregnant or Lactating Women

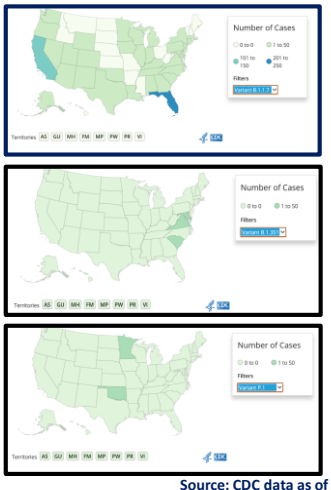
- Centers for Disease Control and Prevention:
  - If pregnant or lactating people are part of a group that is recommended to receive a COVID-19 vaccine, they may choose to be vaccinated.
- The American College of Obstetricians and Gynecologists :
  - Do not withhold from pregnant women in a group otherwise recommended to receive vaccine
  - Offer to lactating women in a group otherwise recommended to receive vaccine
- World Health Organization
  - Pregnant women at high risk of exposure to SARS-CoV-2 (e.g. health workers) or who have comorbidities which add to their risk of severe disease, may be vaccinated in consultation with their health care provider.

Our Recommendations

- COVID-19 vaccination in pregnancy should be an informed personal choice
- Health care provider role:
  - Help facilitate risk-benefit discussion
  - Communicate new information as it becomes available
  - Support pregnant women regardless of decision
  - Encourage other prevention measures

The Next Challenge: Emerging SARS-CoV-2 Variants

- **B.1.1.7**
  - First identified: UK
  - Notable mutation: N501Y
  - Up to 50% more transmissible
  - Possible increase in deaths
  - *Acquisition of E484K
- **B.1.351**
  - First Identified: South Africa
  - Notable mutation: E484K, N501Y, K417N
  - Likely more transmissible
  - Immune escape
    - Convalescent or post-vaccination serum: Decreased neutralizing ability
    - Monoclonal antibodies likely less effective
    - Decreased vaccine efficacy: Examples-Astra-Zeneca, Novavax and J&J
- **B.1.1.28**
  - First identified: Brazil
  - Notable mutation: E484K, K417N/T, N501Y
  - Likely more transmissible
  - Likely immune escape



Source: CDC data as of Feb 8, 2021

PennState Health
Milton S. Hershey Medical Center

PennState Health
Milton S. Hershey Medical Center

February 10, 2021

Dr. Richard S. Legro, M.D.
Chair, Department of Obstetrics & Gynecology
Penn State College of Medicine
Penn State Health

Dr. Catharine I. Paules, M.D.
Assistant Professor, Infectious Diseases
Penn State College of Medicine
Penn State Health

Joint Meeting of the House & Senate Democratic Policy Committees & Women's Health Caucus

Good morning, Senators Muth, Schwank and Cappelletti, and Representatives Bizzarro, Daley and Cephas, members of the Women's Health Caucus and members of the House and Senate Democratic Policy Committees. Thank you for convening such an important and timely discussion on the overall impact that the COVID-19 pandemic has had on maternal health while determining which steps should be taken to ensure the safety and wellbeing of pregnant women related to vaccine administration, quarantine, implications related to mental and behavioral health, and other factors that may present concern or challenges to women who are pregnant or nursing during the pandemic.

Today, Penn State Health is represented by Dr. Richard Legro, Chair, Department of Obstetrics & Gynecology, and Dr. Catharine Paules, Assistant Professor of Infectious Diseases. Drs. Legro and Paules are pleased to share insights on what the potential risks may be for pregnant and nursing women who choose to take the COVID-19 vaccine or those who choose to defer until more data about the vaccine in pregnancy is available.

Like colleague institutions presenting at today's meeting, Penn State Health has been on the front lines of the COVID-19 pandemic, slowly stemming the tide as the health system begins to vaccinate its patient population, adjusting treatment protocols as the science dictates, gaining valuable knowledge and insight along the way on how this virus presents heightened risk to special populations based on age, ethnicity, gender, preexisting health conditions and other factors. Insights gained are already allowing Penn State Health to initiate research trials that will help to develop highly specialized treatments protocols and targeted therapies for its most vulnerable populations as variants of the COVID-19 virus begin to surface.

Today's presentation will provide some general background on the emergence of the COVID-19 virus, then examine more specifically whether pregnant and nursing women are at greater risk of complications related to COVID-19

By way of background, Dr. Richard Legro is University Professor and Chair of the Department of Obstetrics and Gynecology at Penn State College of Medicine. He is a member of the National Academy of Medicine and has been continuously-funded by the National Institutes of Health (NIH) for 25 years as a principal investigator having designed and led many practice-changing clinical trials in Women's Health and Infertility, and publishing over 285 peer-reviewed articles.

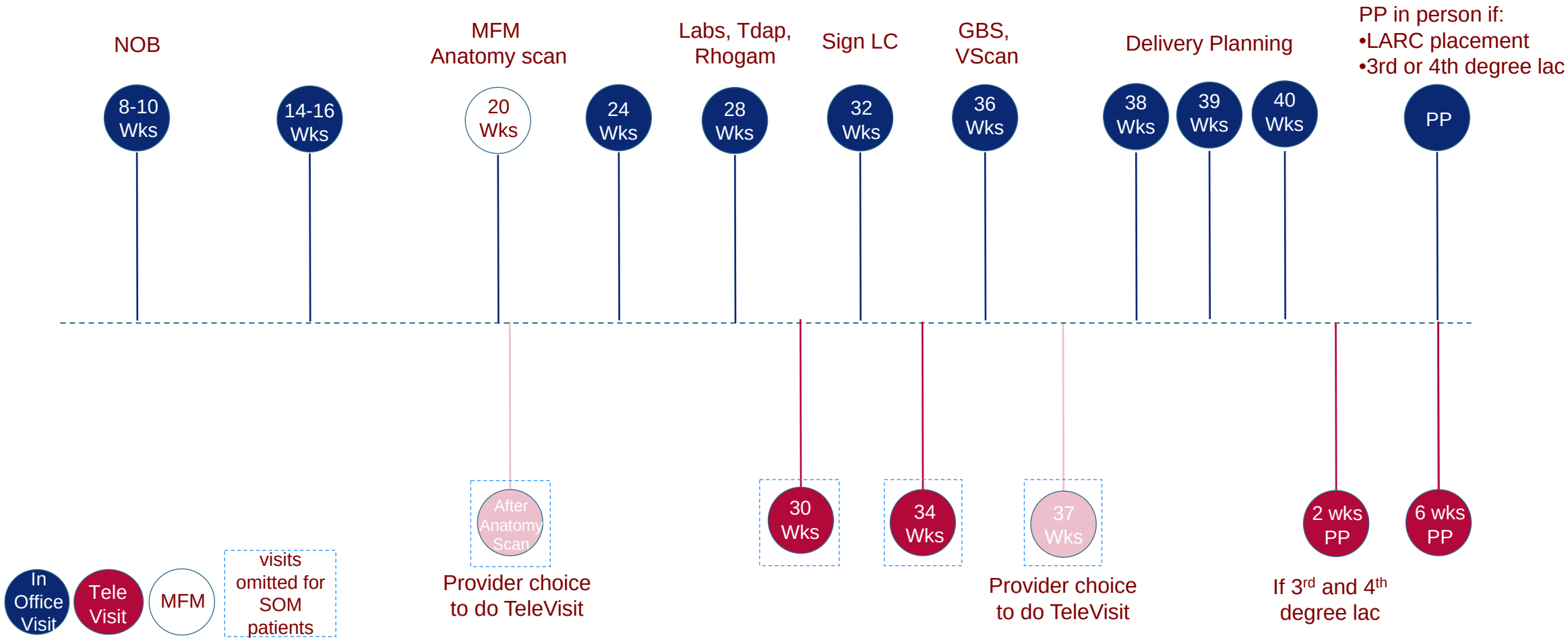
Dr. Paules recently came to Penn State Health from the NIH where her research focused on influenza vaccines, specifically the development of a universal influenza vaccine, and influenza therapeutics. During her time at NIH, Dr. Paules co-authored several articles with Dr. Anthony Fauci that were published in the New England Journal of Medicine. When the COVID-19 pandemic emerged, Dr. Paules was deployed to focus on improving COVID-19 care at the Penn State Health Milton S. Hershey Medical Center and is the site principle investigator for the NIAID sponsored Adaptive COVID-19 Treatment Trial which led to the FDA approval of Remdesivir for treatment of patients hospitalized with COVID-19.

Dr. Paules and Dr. Legro will be speaking to the slides attached to this testimony as part of their formal presentation.

Thank you again for the opportunity to present to the Women's Health Caucus and the House and Senate Democratic Policy Committees. Drs. Legro and Paules will be happy to address any questions from the committee and caucus members following their presentation.

Penn Medicine's Duet Model for Prenatal Care

Leveraging technology to make it more convenient for you



Written Testimony

Joint Democratic Policy Committee Hearing on Maternal Health Amidst COVID-19

February 10, 2021

Submitted by:

Sindhu K. Srinivas, MD, MSCE

Professor

Director of Obstetrical Services

Vice Chair for Quality and Safety, Department of OBGYN

Co-Founder Heart Safe Motherhood

Physician Lead, Women's Health Service Line,

Penn Medicine

Chair Health Policy and Advocacy Committee, Society for Maternal Fetal Medicine

Good morning. Thank you for inviting me to participate in this very important and timely policy hearing. My name is Dr. Sindhu Srinivas. I am a practicing obstetrician and maternal-fetal medicine physician at Penn Medicine. I am also the Director of Obstetrical Services, Vice Chair for Quality and Safety, Physician Lead of the Women's health Service Line and Co-Founder of the Heart Safe Motherhood program at Penn Medicine. Additionally, I Chair the Health Policy and Advocacy Committee of the Society for Maternal-Fetal Medicine (SMFM). I am honored to be here today.

As a practicing OBGYN- Maternal Fetal Medicine specialist I am among many of us who are on the front lines of the maternal morbidity and mortality crisis and am deeply troubled by rising morbidity and mortality rates and associated disparities. Prior to the current COVID 19 pandemic, we were actively working on developing many innovative strategies in partnership with patients to improve our care delivery during pregnancy and postpartum with a specific focus on reducing morbidity and mortality and disparities. While the COVID 19 pandemic has taken a significant toll on all of us, it has also inspired us to significantly accelerate the development and implementation of these innovative models with the goal of improving care with a focused, deliberate patient centered approach. Today, I will share a few examples of programs developed and implemented at Penn Medicine and also discuss important legislative opportunities that are critical to ensuring programs such as these continue to accelerate, and flourish.

The first two programs I will highlight are innovative remote and telehealth programs **during pregnancy.**

First, the Duet model of prenatal care was created by Dr. Florencia Polite and the general OBGYN providers based at the Hospital of the University of Pennsylvania. The goal is to standardize the approach to prenatal care that combines telehealth and in person visits. This has led to significant patient satisfaction and continued adherence to recommended prenatal care during the pandemic. This approach is one that likely should continue long term well after the pandemic is over.

Aligning payment approaches with this deliberate combination of in person and telehealth visits will be critical to the continued success of this model. This includes considering parity between video and audio visits as well payment and access to important tools needed for patients to have a successful telehealth visit, such as a blood pressure cuff.

Second, is a program called THEA led by a Penn Medicine colleague, Dr Anna Graseck. THEA is a current program for antenatal, home BP monitoring. All prenatal patients are enrolled in this bi-directional text-based program. Reminders are sent to patients via text message weekly or bi-weekly. It allows for regular blood pressure surveillance with automated feedback to patients and standardized escalation for concerning blood pressures that alert providers for early intervention. This creates an opportunity for more surveillance and care to occur in between visits. While this program was started pre-Pandemic, the Pandemic has certainly helped accelerate implementation. The next version of this program will include weekly push educational content for expecting patients providing information on topics such as dietary

considerations, mental health and physiological changes during pregnancy as a method of enhancing prenatal education in a more systematic innovative way with the goal of supporting patients throughout their pregnancy. Future legislative opportunities include direct mechanisms at the state level to support development, implementation and evaluation of this type of program. We appreciate our partnership with payers to date who have prioritized assisting with patients more easily obtaining blood pressure cuffs during the Pandemic. We want to ensure that this commitment continues and does not change or go away post pandemic.

What is striking about the maternal morbidity and mortality crisis is that more than half of the mortalities occur in the postpartum period, a time when patients are home, less connected to care, but still need us. This only underscores the importance of thinking out of the box and being innovative in developing patient centered approaches to care in the postpartum period as well.

At Penn medicine we are proud of a few programs that focus on this **4th trimester time period**. We have developed and successfully deployed a program called Heart Safe Motherhood at multiple Penn Medicine Hospitals and will soon be deployed at all the Philadelphia obstetric hospitals in partnership with the City Health department. The Heart Safe Motherhood program was co-founded by Dr. Adi Hirshberg and I and takes a scary diagnosis of hypertension in pregnancy–a leading cause of maternal morbidity and mortality - and turns it into a process of engagement and empowerment in self-management and self-monitoring. Patients have a home BP cuff, often now obtained during the pregnancy and if they do not have one, they are given one. They are enrolled into a bidirectional text-based platform that allows us to monitor them safely at home by providing information that we can act on when needed. It also leads to tremendous satisfaction from patients and improved health care engagement. Through this program we have been able to initiate blood pressure medications on patients at home and prevent significant morbidity that previously led them to being readmitted to the hospital. We have caught dangerously high blood pressures prior to their escalation and have prevented morbidity. Importantly, this program has eliminated health disparities in obtaining and treating dangerously high blood pressures in the postpartum period. We have taken a condition that has disproportionately impacts black women in the postpartum period and have improved the health for all women equally. The success of this program is in its patient centered approach and the engagement of patients in its development. Despite the multiple studies demonstrating its significant impact and elimination of disparities, the wide scale deployment in our current payment structure has been challenging. Legislative opportunities include mandating implementation of certain evidence-based programs, like this one as well as funding demonstration projects across the state where hospitals are given the support they need to implement programs like this. Not many programs have clearly shown that they can address not only morbidity but also disparities.

Finally, the last program I will mention, founded by another colleague at Penn Medicine, Dr. Kirstin Leitner, is called Healing at Home. In the traditional postpartum care model, patients face a variety of challenges. Complications post-delivery and mental health needs almost universally occur well before the routine scheduled visit and as we know nearly 50% of maternal morbidity and mortality occurs in this time period.

Healing at Home supports the postpartum needs of parents and babies in the setting they prefer using an innovative approach. Healing at home uses "Penny your virtual postpartum assistant," a text-based automated postpartum chatbot, to help bridge the gap in fourth-trimester care by providing parents with around-the-clock access to clinical guidance. In addition to answering parents' concerns and providing just-in-time education, Penny the chat bot enables increased and more efficient lactation support and postpartum depression screening and facilitates triage to high-value care if necessary.

After pilot testing and partnership with patients, Healing at Home was implemented as a clinical program at HUP in March 2020. Since launching, more than 380 patients have enrolled in the program. Penny correctly and automatically answers 80 percent of patient inquiries providing patients with timely responses to their questions. The tool has also proven to work as an early-warning system for postpartum conditions. Of parents completing the postpartum depression screening on Penny, 25 percent have scored as at risk which has allowed providers to enact early clinical intervention. Recently, Penny also helped identify a patient having concerning heart symptoms postpartum which allowed that patient to get the care she needed at the right time-preventing a potentially devastating complication.

These programs demonstrate the tremendous opportunities for a patient centered, innovative approach to prenatal and postpartum care delivery that utilizes remote monitoring, artificial intelligence/chat bots, text-based platforms and telehealth visit strategies. Patients are engaged; they are looking for new and innovative ways to be active participants in their care and it is our job to partner with them and move these strategies forward.

There are many legislative and policy opportunities that will help accelerate the journey of these solutions from ideas, to programs that are piloted, tested and scaled. Importantly, these programs should be scaled in a way that promotes equity and eliminates disparities. In order to address this, polices should include provisions that:

- Increase broadband access for all patients
- Support and pay for medical equipment necessary for remote prenatal visits-such as blood pressure cuffs
- Support innovative strategies that enhance digital literacy, such as the use of community health workers
- Guarantee payment for language services during telehealth visits to provide quality care to every patient
- Reimburse telehealth visits at rates similar to in-person visits; create parity between video and audio visits as video visits are not always necessary and may actually lead to disparities in care
- Increase transmission and facility fees to encourage providers to offer telehealth services and incentivize implementation of innovative programs such as those described as well as telehealth services

The mission to ensure the health of our population during and after pregnancy is one that I know all of us share and are passionate about.

We are at a critical junction of tremendous interest and engagement from all sectors to be innovative in our approach to care delivery leveraging all of these new strategies. With a focus on policies that incentivize the integration of systems and accelerate and fund the development of innovative care delivery models as well as the deployment of programs that have shown evidence-based benefit like Heart Safe Motherhood, we can and will make a big difference in the lives of our patients and their families. Thank you again for providing me the opportunity to speak with all of you today. I look forward to continuing to work together.

Joint Democratic Policy Committee Hearing
Maternal Health Amid COVID-19
Nicole Chaney- Certified Nurse-Midwife

I'm honored to be the voice today for the pregnant and postpartum folks that I care for in Berks County, and I am grateful to Judy Shwank and her staff for inviting me today and everyone that helped organize this. I am a Certified Nurse-Midwife that provides prenatal and postpartum care for pregnant individuals, and I catch babies at Reading Hospital in Berks County. I also provide gynecologic care from the teenage years through later adulthood, which includes cancer and primary care screenings, contraception, STD treatment, gynecologic problems, and referrals to specialists and mental health providers. We have a wonderful collaborative midwifery and obstetric practice that focuses on building relationships and continuity in our care, and I work with the best and most midwife friendly obstetrician in the world.

Everyday in the hospital and outpatient office, I see firsthand the toll that COVID-19 has taken on pregnant people. Those currently birthing their babies have spent the entirety of their pregnancy living and dealing with isolation and the difficulties of the pandemic.

I have seen unprecedented levels of pregnancy and postpartum depression and anxiety. People are overwhelmed balancing their careers, (or the loss thereof,) and virtual school for their children. Many suffer the stress of food and housing instability, being ill themselves, and the illness or death of loved ones.

A group of researchers at the Brigham and Women's Hospital at Harvard Medical School conducted a study of predominantly affluent, white individuals, in which their findings showed 36.4% reported clinically significant symptoms of depression within the past week. These findings are likely worse in communities of color where the effects of the pandemic have been more severe. It's hard to understand postpartum depression if you or someone you love hasn't experienced it. Postpartum depression is feeling alone in a room full of people, it's feeling isolated, it's feeling disconnected from yourself and your body, it's not connecting with your baby, not enjoying time with your baby, it's crying every single day for months, it's your brain telling you that your baby and the world would be better off without you, it's a mother ending her life, and it's a child growing up without the unconditional love of their mother.

The only way out is by stopping the pandemic. We MUST get through this faster by increasing access to vaccines. As I write this our state is ranked 43rd out of 50 in percentage of vaccine distribution nationwide. I understand we have a geographically larger, older and more diverse state than some of the others, and I watched the vaccine hearing last week, and I saw legislators from both parties advocating for us, but as a state, we absolutely can and must do better. And we need YOUR leadership and action.

So many people ask me how to get their vaccine: my pregnant patients, my octogenarian patients, family, friends and neighbors. So many people ask me and I am at a loss.

I have spent countless hours on the Pennsylvania Department of Health vaccine map clicking on links, trying to find vaccine clinics for them. All of my efforts have been fruitless.

I find it disgraceful that instead of helping their constituents get access to vaccines, some senators and representatives from our commonwealth have spent their time and energy recently introducing legislation that would essentially make abortion illegal in Pennsylvania.

Having access to a safe abortion is a basic human right yet our state has been deemed hostile when it comes to this important service. On top of challenges related to COVID, abortion restrictions in Pennsylvania have made access to care severely limited. Meanwhile, we must recognize that abortion is essential to improve our maternal mortality rate and the overall health and wellbeing of families in our state. The Turnaway study, conducted at the University of San Francisco, followed women turned away from an abortion for a variety of reasons, and showed the negative impact this had on their life, including 2 women who died in childbirth. Instead of restrictions, we should allow for the prescription of medication abortion via telemedicine, as to decrease COVID exposure to patients, families, and healthcare workers - which is recommended by the American College of Obstetricians and Gynecologists. Right now we need to focus on legislation that supports parents throughout the pregnancy and postpartum period, with paid maternity and paternity leave, workplace protection for pregnant and nursing mothers, expanded medicaid coverage, high quality, affordable childcare, housing, nutrition, and mental health support. Instead of introducing baseless restrictions on reproductive healthcare, we need to be focused on supporting families through COVID and beyond.

Medicaid covers 34% of births in Pennsylvania. When you look at the Smart Start study, which was a five-year study that published findings in 2018, it showed that Medicaid recipients had the best outcomes at a lower cost for birth center care versus traditional care, this was whether they went on to birth their baby at a birth center or hospital. These very compelling results showed better outcomes for birth weight, cesarean rate, gestational age, preterm birth, all things that affect the mother and child for the rest of their lives.

Surprisingly, despite these excellent outcomes and lower cost, Medicaid insurers reimburse very poorly for birth center care and they reimburse very poorly and unsustainably for birth center providers. This results in an equity issue in which Medicaid recipients have less access to birth center care, when often they are the ones that would benefit most from it.

On a legislative level, I urge all of you to increase support for pregnant and postpartum individuals, with a value based payment structure for maternity care, Medicaid coverage for doulas, expanding Medicaid in the postpartum period, supporting telemedicine, expand access to substance use treatment, improve reimbursement for out of hospital births and maintain and improve our access to safe, legal abortions.

From a leadership level, I encourage you to do anything within your power to improve equitable vaccine distribution in our state, so we can decrease the burden COVID-19 has on our communities and get through this. Partner with and apply pressure on your local health

department, your local health systems, and try for yourself to navigate the Pennsylvania vaccine map so you can empathize with your frustrated constituents.

And on a personal level, if you know someone that is the primary caregiver for young children, thank them, support them, and bring them a veggie lasagna.

1. Peace Study, Cindy Liu, et al. https://www.sciencedirect.com/science/article/pii/S0165178120332133
2. Strong Start study: p. 136 https://downloads.cms.gov/files/cmmi/strongstart-prenatal-finalevalrpt-v1.pdf
3. Turnaway Study: https://www.ansirh.org/sites/default/files/publications/files/the_harms_of_denying_a_woman_a_wanted_abortion_4-16-2020.pdf
4. PA abortion facts https://www.guttmacher.org/fact-sheet/state-facts-about-abortion-pennsylvania#
5. ACOG Statement on Abortion Access during COVID https://www.acog.org/news/news-releases/2020/11/acog-updates-committee-opinion-on-increasing-access-to-abortion
6. The best veggie lasagna recipe: https://www.thepioneerwoman.com/food-cooking/recipes/a11693/vegetable-lasagna/

Impact of COVID-19 on Maternal Health

Testimony Prepared By:

Rhonda Boyd, PhD

Child Psychologist, Department of Child and Adolescent Psychiatry and Behavioral Sciences

Children's Hospital of Philadelphia

Pennsylvania General Assembly

Joint Senate and House

Policy Committee Hearing

Wednesday, February 10, 2021, at 11:00AM

Good afternoon,

My name is Rhonda Boyd, and I serve as a child psychologist in the Department of Child and Adolescent Psychiatry and Behavioral Sciences at the Children's Hospital of Philadelphia and a researcher at CHOP PolicyLab. I am also an Associate Professor at the University of Pennsylvania Pereleman School of Medicine.

On behalf of CHOP, I'd like to thank Representative Morgan Cephas for the invitation, the Chairs, and members of this Committee for the opportunity to provide testimony and holding a hearing on this vital issue.

The impact of the COVID-19 pandemic on maternal mental health and functioning is an issue which is hugely important to me and that I witness the importance of every day in my work. As a child psychologist, I recognize the intergenerational impact of perinatal mental health. The pandemic has posed major challenges to new mothers and shed a harsh light on disparities that exist for certain mothers, especially women of color and those from lower economic conditions. In my testimony, I will emphasize three points interrelated to the effects of the pandemic on: 1) postpartum mental health; 2) economic stressors on new mothers; and 3) potential exacerbation of disparities in access to mental health services for postpartum women.

1) Perinatal depression is sadly a common occurrence, with estimates that 12-20% of women experience it. Since the start of the pandemic, there have been increased levels of depression and anxiety symptoms for perinatal mothers. Significant depression and anxiety symptoms in mothers can have a negative impact on their parenting, mothers' attachment to her infants, and a child's emotional, behavioral, and developmental outcomes. For example, mothers with depression may be more withdrawn or harsh in their interactions with their infants. Another example is that children of mothers with depression are more likely to have developmental delays and sleep and feeding problems. The public health social distancing protocols put in place during the pandemic have also increased social isolation. This has left new mothers lacking social support, social interactions, and help with childcare. For perinatal women who are of

color, especially Black, Latina, and Indigenous mothers, they are also disproportionally being impacted by family members contracting COVID-19 or dying from it. This situation understandably results in increased stress, worry and grief. Also, mothers have added responsibilities of assisting with virtual education for their older children.

2) COVID-19 has caused additional economic stressors for new mothers and families. As a result of job loss and reduced income, new mothers and their partners have concerns about paying bills, eviction from their homes, and feeding their families. For essential workers, who are more likely to be people of color and low-income, working outside of the home during the pandemic puts them and their families at risk for contracting COVID-19. For example, people of color comprise 45% of essential workers while they represent 40% of the US population.[1] With grocery store supply shortages, particularly early in the pandemic, low income mothers had difficulty getting necessary household and infant items, such as diapers.

3) Finally, there are long-standing issues of health disparities in accessing mental health treatment for postpartum mothers, especially for mothers of color and for specific populations like adolescent mothers. Many studies have shown that even when mothers screen positive for postpartum depression, few receive the mental health services that they need. When depression is not treated, it persists and can have longstanding negative effects on a mother and her ability to function at home and work. Barriers to care include lack of or inadequate health insurance, family demands, limited knowledge about treatment, limited availability of treatment, stigma, lack of child care, and many others. The pandemic has clearly shown this disparity and has likely exacerbated this problem. While there is an increased need, there is a shortage of mental health providers, and especially those with expertise in postpartum mental health. We must urgently address this gap, while also leveraging the potential of early intervention

[1] https://www.epi.org/blog/who-are-essential-workers-a-comprehensive-look-at-their-wages-demographics-and-unionization-rates/

services, home visiting, and expanding telehealth access as vehicles for the provision of services for the most underserved.

I think it is important to note that we are still in the midst of this pandemic. The precise impact to children and mothers is not fully known. However, hearings like the one today and policies to address screening and access to care are necessary steps to acknowledging this issue and addressing it.

Again, I thank the members of this committee for allowing me to testify. I look forward to answering any questions you may have. Thank you.

My pregnancy experience during covid-19 by Kiana Colón.

I found out I was pregnant for the first time in February 2020, right before the pandemic shutdown in the U.S. I was already scared finding out I was going to be a first time mother, then adding a pandemic to the mix was of course frightening. I didn't have my first official pregnancy appointment until early March, right before they declared the pandemic in the states. That was just an ultrasound to see how far I was, I still pretty nervous but I let myself get a little excited. Perhaps a little too soon.

I decided to schedule the rest of my appointments at the Reading Birth Center in Reading, PA going forward because I received great recommendations by a family member to them. My next 3 appointments were there and they were very kind to me. Even though covid had everyone in a frenzy, they allowed my husband with me for those appointments except for one, so I was so grateful. It was just disappointing he couldn't be there to hear the heartbeat on the little doppler one of the midwives used, I didn't have good connection to FaceTime him so I just recorded the sound. Fast forward to May and us needing to go to the birth center in Exeter for my ultrasound to find out the gender and just routine prenatal checkup.

It was my first time at that office and I'll be honest, it first felt cold. Because of covid , they needed to be extra cautious of course, so when I got there, I already knew my husband would not be allowed in the room with me. It was okay though because we were going to have them write the gender of the baby down and find out together after the appointment. Well that didn't go as planned. The ultrasound tech was very nice and she kept trying to get pictures of baby's face but he kept moving. Once again due to my poor cell phone service I couldn't FaceTime him so once again, he missed the heartbeat thanks to covid. After the ultrasound, she went to see the doctor to show him the pictures. Dr.Camarrano then came in and he told me the baby may have down syndrome and the reasons why. He then told me he'd have the midwife come in and talk to me to help me process everything. Thanks to the pandemic, I was left alone and afraid in the room after getting this devastating news and had to process it by myself. Then that's when I met Nicole Chaney, she gave me so much strength during my high risk pregnancy, along side of my husband of course. She started talking to me about children who have down syndrome and how I will need to get testing done first to determine if that's what he has. I couldn't stop crying and I said I needed my husband by my side so she had the front desk allow him to come in with me. We were all crying but she provided so much comfort during unsure times. She was the greatest advocate for me, a first time pregnancy PLUS high risk during the pandemic, in making sure I could be as comfortable as possible and allowing my husband to accompany me to all my appointments going forward.

Going forward I had some appointments at that Exeter office and some appointments at maternal fetal medicine. All places thankfully allowed my husband with me in the room. Unfortunately he couldn't come to one of the appointments because he has gotten no sleep and he works 3rd shift so I pretty much forced him to stay home and sleep and I had my mother come with me. Well, THAT was when it got worse. I was referred there because I had low amniotic fluid so that's a reason it was hard to get a good ultrasound of the baby. So I'm there and I'll never forget the day because it was my birthday, they're doing the ultrasound and the doctor comes in to tell me the news. Dr. Richard Deveaux, sweetest doctor ever, broke the news to me that I won't be making it full term because of all the problems the baby has at that point. He said there was a strong possibility I'd go to one of those weekly appointments and we wouldn't hear a heart beat. He then recommended I go to CHOP to get more testing done. Long story short, CHOP just confirmed what he told me, and also added on that it wouldn't be safe for me to carry full term even if I could since I was at risk for pre-eclampsia.

My husband and I are obviously sad and frustrated at this point, especially since the pandemic made appointments even more difficult to talk to the doctors, nurses, and midwives because of our masks. It was hard to connect with them in a way since we couldn't really see their expressions. We had our last

pre-delivery appointment with Nicole on July 20th to discuss a birth plan and induction date. I believe I had just hit 29 weeks so since I was high risk, she has mentioned inducing me around 37 weeks I believe. After that conversation she gave me an ultrasound to check on baby and that was the day we stopped hearing his heartbeat. Nicole gave my husband and I time to process as best we could, we then scheduled a date 2 days later for induction, since I was most comfortable with her I made sure she'd be the nurse on call and luckily she was. When it was time for me to be induced, the nurses were so nice to me and even though they had to wear their masks and I mine, they told me I could take it off when they weren't in the room so I could be more comfortable. After being given medicine to induce me and pain medicine, it was time to deliver and Nicole had done an amazing job the whole time I was pushing. She helped me stay calm and I believe that was her first delivery for a stillborn she told me.

After leaving the hospital, the birth center kept checking in on me and I was very appreciative. I think they all did an amazing job at helping to provide care during a pandemic. Not only were they sanitary at both birth centers and cautious, but they made sure they all wore masks and were socially distant when possible. I'll never forget how much stress I had worrying about being pregnant during a pandemic and thinking I would have to go to all my appointments alone. I'm so grateful they allowed my husband to accompany me to those appointments to help give me a little peace where possible. If we do decide to start a family again, we will for sure be going back to the birth center. The pandemic only proved how strong they are as a unit. <3