MARCH OF DIMES

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Dear Dr. Foege and Dr. Gayle,

On behalf of March of Dimes, thank you for the opportunity to comment on the *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine* that the National Academies of Sciences, Engineering, and Medicine Committee on Equitable Allocation of Vaccine for Novel Coronavirus has produced. March of Dimes is the leading non-profit organization fighting for the health of all moms and babies and promotes the health of women, children and families across the life course, from birth through adolescence and the childbearing years, with an emphasis on preconception, prenatal, interconception, and infant health.

As our nation is fighting the current COVID-19 pandemic, we must continue to advocate for the health and safety for moms and their babies. As we continue to learn more about SARS-CoV-2, we know that COVID-19 strikes the lungs and cardiovascular system, which are the two systems that are already strained during pregnancy. Pregnancy affects every system in a woman's body and the immune system changes so that it can protect not only the mother, but the baby. This can make pregnant women more susceptible to certain infections as different parts of the immune system are enhanced while others are suppressed.[1] Furthermore, during the second and third trimester women's bodies are put under more stress as the lungs work harder to provide oxygen and the heart is supplying blood not only to the woman, but the baby as well.[2]

Recent data released from the CDC found that expectant mothers with the virus had a 50% higher chance of being admitted to intensive care and a 70% higher chance of being intubated than nonpregnant women in their childbearing years.[3] The data also showed that pregnant Latina and Black women were infected at significantly higher rates than white woman.[4] However, the data CDC provided was limited and missing crucial information for women such as data on race and ethnicity, underlying conditions, and outcomes. With limited data many questions about whether or not babies can contract COVID-19 from their mother remain. Early data suggested that babies born to mothers who were

[1] https://www.healthline.com/health/pregnancy/infections#causes
[2] https://www.marchofdimes.org/complications/influenza-and-pregnancy.aspx
[3] https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6925a1-H.pdf
[4] Id.

infected with the virus did not test positive for COVID-19. However, recent data published in the Journal of American Medical Association (JAMA) and The Canadian Medical Association Journal (CMAJ) suggest that transmission during pregnancy may be possible.[5] Therefore, it is imperative we continue to better understand the risk COVID-19 poses to pregnant individuals.

As the *Discussion Draft* highlighted from past experience, the Advisory Committee on Immunization Practices recommended that vaccination efforts for H1N1 should target five groups, which included pregnant women. [6] During the H1N1 flu epidemic of 2009, pregnant women accounted for 5% of deaths in the United States, although they constituted about 1% of the population.[7] This led to a larger conversation on the importance for women to get vaccinated during pregnancy for whooping cough and flu to protect herself and her baby.[8] By receiving these vaccines while pregnant, the baby's immune system is protected during the first month of life, as babies do not start getting vaccines until two months old.[9] This demonstrates the importance of pregnant women having access to a safe and effective COVID-19 vaccine to not only protect oneself - but also to protect their babies.

We are disheartened to see that pregnant individuals are not included in any of the COVID-19 vaccine allocation and distribution phases. We understand that pregnant individuals are currently excluded from Phase II/III trials and this exclusion creates barriers for pregnant individuals and are not able to protect themselves from COVID-19. However, we urge the advisory committee to reconsider including pregnant individuals in an earlier phase of receiving the COVID-19 vaccine when made available.

As the *Discussion Draft* states the primary goal of the committee's framework on equitable allocation of COVID-19 is to "[m]aximize societal benefit by reducing morbidly and mortality caused by transmission of the novel coronavirus."[10] Within this primary goal, the committee developed a risk-based criteria that is compatible within the foundational principles.[11] The general fertility rate for the United States in 2018 is 59.1 per 1,000 women aged 15-44.[12] If the committee does not take into account, not only pregnant individuals, but individuals who could become pregnant once a vaccine is made available, then a portion of the population is not being considered.

Pregnant individuals are at an increased risk for severe illness from COVID-19. As we mentioned above, pregnant individuals face different risks of contracting COVID-19 than the rest of the population and the history of recent outbreaks like H1N1, Zika, and Ebola have showed us that pregnant women are uniquely vulnerable to emerging infectious diseases. Additionally, women play different roles in society and women now make up over half of the American workforce.[13] If a pregnant women does not have

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[5] https://jamanetwork.com/journals/jama/fullarticle/2767060?resultClick=1; https://www.cmaj.ca/content/192/24/E647; https://www.medpagetoday.com/infectiousdisease/covid19/87511

[6] *Discussion Draft of the Preliminary Framework for equitable Allocation of COVID-19 Vaccine (pg. 6, line 49-50).*

[7] https://www.sciencemag.org/news/2020/08/why-pregnant-women-face-special-risks-covid-19#

[8] https://www.cdc.gov/vaccines/pregnancy/vacc-during-after.html

[9] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

[10] *Discussion Draft of the Preliminary Framework for equitable Allocation of COVID-19 Vaccine (pg. 44, line 965-966).*

[11] *Discussion Draft of the Preliminary Framework for equitable Allocation of COVID-19 Vaccine (pg. 46 box 5).*

[12] https://www.cdc.gov/nchs/products/databriefs/db346.htm

[13] https://time.com/5766787/women-workforce/

MARCH OF DIMES

the opportunity to work from home and is an essential or frontline worker, she is not only exposing herself to the infection, but her baby and others in the family home.

Risk of severe morbidity and mortality for pregnant individuals is also high. Before COVID-19 pregnant women were facing a public health crisis. The fact that over 700 women die each year in the U.S. from pregnancy related causes and more than 50,000 others experience dangerous complications that could have killed them, is unacceptable. Black women are three to four times as likely as white women to die from pregnancy-related causes. These striking health disparities exist among mothers and babies of different racial and ethnic backgrounds, which include Blacks, American Indians, and Alaskan Natives (AI/AN), who are more likely to have chronic conditions and makes them susceptible to complications from COVID-19. The data has shown that individuals with comorbidities have a disproportionate impact of being infected with COVID-19[14], which puts a pregnant individual who may have a comorbidity, at even a higher risk of contracting COVID-19.

The first six months of an infant's life depends on breast milk as it is the best source of nutrition.[15] The CDC currently does not have a full picture on whether mothers with COVID-19 can transmit the virus via breast milk, but the limited data available suggest this is not likely to be a source of transmission.[16] However, postpartum women have to take precautions if they are potentially exposed to COVID-19 to not expose the virus to their baby or other family members who may have contact with them.

The risk of transmitting disease to others for pregnant individuals may be low. However, limited data exists on differential transmissibility. Pregnant individuals may not transmit the disease to others at such a high rate as other individuals, but they may not be able to social distance or isolate as easily if pregnant individuals live in a multi-generational home or is an essential or frontline worker.

We strongly urge the committee to consider including pregnant individuals in phase 2 of allocating and distributing the COVID-19 vaccine. Pregnant individuals are among the cohort of individuals who may have comorbid and underlying conditions that put them at an increased risk of contracting COVID-19 and are at a higher risk of contracting COVID-19 due to the changes their bodies undergo during pregnancy or possibly due to being a frontline or essential worker.

We applaud the committee for addressing the costs associated with the vaccine and agree that once a vaccine is available it must be free to individuals enrolled in Medicare or Medicaid and private insurers and employers should not charge co-pays or deductibles.[17]We urge the committee to guide the ACIP to use existing vaccine programs such as Vaccines for Children program, the Early and Periodic Screening, Diagnostics, and Treatment (EPSDT) program, and the Section 317 Immunization Program. It is imperative the message to the public is that once the vaccine is approved as safe and effective, it is affordable to everyone.

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[14] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
[15] https://www.marchofdimes.org/baby/breastfeeding-your-baby.aspx
[16] https://www.cdc.gov/breastfeeding/breastfeeding-special-circumstances/maternal-or-infant-illnesses/covid-19-and-breastfeeding.html#:~:text=Breast%20milk%20is%20the%20best,a%20cloth%20face%20covering.
[17] *Discussion Draft of the Preliminary Framework for equitable Allocation of COVID-19 Vaccine (pg. 77, line 1813-1816).*

MARCH OF DIMES

The COVID-19 pandemic has helped people better understand the importance of vaccines. However, it is important to continue to educate individuals on the importance of getting vaccinated. We understand some people are "COVID-vaccine hesitant" and will want to wait before receiving the vaccine or may choose not to vaccinate at all. Certain ethnic populations like Black and Hispanic Americans are more skeptical about the safety of vaccines and one of the primary reasons for vaccine-hesitancy in these populations include systematic racism in health care.[18] Therefore, it may benefit for the committee to suggest a creation of a coalition of nongovernment organizations nationally renowned to engage in states and communities to launch a COVID-19 vaccination campaign that would ensure transparency and develop a clear communication strategy about the vaccine between federal, local, and state partners. This would be much like March of Dimes' successful grassroots efforts that had active public participation during the polio epidemic in the 1940s and '50s.

We thank the Committee on Equitable Allocation of Vaccine for Novel Coronavirus for producing the *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine* and encourage the committee to reconsider adding pregnant individuals to an earlier phase on allocating and distributing the COVID-19 vaccine. Please direct questions to Deema Tarazi, Deputy Director of Federal Affairs for Public Health at dtarazi@marchofdimes.org.

Sincerely,

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March of Dimes

[18] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5309123/