

Equity in coronavirus disease 2019 vaccine development and deployment



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The coronavirus disease 2019 pandemic exposed weaknesses in multiple domains and widened gender-based inequalities across the world. It also stimulated extraordinary scientific achievement by bringing vaccines to the public in less than a year. In this article, we discuss the implications of current vaccination guidance for pregnant and lactating women, if their exclusion from the first wave of vaccine trials was justified, and if a change in the current vaccine development pathway is necessary. Pregnant and lactating women were not included in the initial severe acute respiratory syndrome coronavirus 2 vaccine trials. Therefore, perhaps unsurprisingly, the first vaccine regulatory approvals have been accompanied by inconsistent advice from public health, governmental, and professional authorities around the world. Denying vaccination to women who, although pregnant or breastfeeding, are fully capable of autonomous decision making is a throwback to a paternalistic era. Conversely, lack of evidence generated in a timely manner, upon which to make an informed decision, shifts responsibility from research sponsors and regulators and places the burden of decision making upon the woman and her healthcare advisor. The World Health Organization, the Task Force on Research Specific to Pregnant Women and Lactating Women, and others have highlighted the long-standing disadvantage experienced by women in relation to the development of vaccines and medicines. It is uncertain whether there was sufficient justification for excluding pregnant and lactating women from the initial severe acute respiratory syndrome coronavirus 2 vaccine trials. In future, we recommend that regulators mandate plans that describe the development pathway for new vaccines and medicines that address the needs of women who are pregnant or lactating. These should incorporate, at the outset, a careful consideration of the balance of the risks of exclusion from or inclusion in initial studies, patient and public perspectives, details of “developmental and reproductive toxicity” studies, and approaches to collect data systematically from participants who are unknowingly pregnant at the time of exposure. This requires careful consideration of any previous knowledge about the mode of action of the vaccine and the likelihood of toxicity or teratogenicity. We also support the view that the default position should be a “presumption of inclusion,” with exclusion of women who are pregnant or lactating only if justified on specific, not generic, grounds. Finally, we recommend closer coordination across countries with the aim of issuing consistent public health advice.

Key words: antibody-dependent enhancement, clinical trials, coronavirus disease 2019, gender-equity, lactation, neonatal immunity, pregnancy, randomized trials, research-equity, safety and efficacy, severe acute respiratory syndrome coronavirus 2, Task Force on Research Specific to Pregnant Women and Lactating Women, vaccine development, women, World Health Organization

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Introduction

The year 2020, defined by coronavirus disease 2019 (COVID-19), will be bookmarked as the moment in history when biomedical science demonstrated its growing mastery over infectious agents on a global scale. Identifying the causal pathogen, sequencing the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) genome, developing rapid diagnostic testing, optimizing treatments, generating vaccines, and commencing immunizations within a year from the first appearance of the disease, represents an extraordinary achievement. However, this accomplishment, as with other aspects of the response to the pandemic, has exposed weaknesses, specifically in the vaccine development pathway, and has widened gender-based inequalities. As the first vaccines begin roll out in mass immunization programs, we discuss the implications of current vaccination guidance for pregnant and lactating women, if their exclusion from the first wave of vaccine trials was justified, and if a change in the current vaccine development pathway is necessary.

Current United Kingdom and United States Guidance

The United Kingdom (UK) was the first country to announce regulatory approval for a COVID-19 vaccine, the Pfizer-BioNTech messenger RNA (mRNA) product, on December 2, 2020. Given the lack of evidence, the UK Joint Committee on Vaccination and Immunisation (JCVI) recommended a precautionary approach, advising against COVID-19 vaccination during pregnancy.¹ UK government advice published on December 6, 2020, to women who are pregnant, think they may be pregnant, or are planning to get pregnant was to not receive the vaccine, and advice to women who are breastfeeding was to wait until they have stopped breastfeeding before getting the vaccine.² Revised advice published on December 18, 2020, made no mention of breastfeeding.³ On December 30, 2020, the UK approved the use of the Oxford AstraZeneca vaccine and the JCVI issued further revisions to the previous guidance.⁴ They currently advise that a

pregnant woman who meets the definition of being clinically extremely vulnerable or who is a frontline worker, may discuss the option of COVID-19 vaccination with her doctor. They further advised that breastfeeding women are eligible to receive the vaccines. The current UK recommendations regarding prioritization are to vaccinate frontline healthcare and social care workers first, and those with conditions that place them at risk for more severe disease.¹

In the United States, the Food and Drug Administration issued an “Emergency Use Authorization” for the Pfizer-BioNTech mRNA vaccine on December 11, 2020. This was followed, on December 13, 2020, by advice from the American College of Obstetricians and Gynecologists’ (ACOG) Immunization, Infectious Disease, and Public Health Preparedness Expert Work Group on “Vaccinating Pregnant and Lactating Patients Against COVID-19.”⁵ On December 15, 2020, the US-based Society for Maternal-Fetal Medicine, a nonprofit, membership organization, recommended that pregnant and lactating women have access to COVID-19 vaccines.⁶ In contrast with the initial UK advice, the ACOG did not recommend withholding COVID-19 vaccines from women who are pregnant or lactating if they meet the criteria for vaccination based on the Advisory Committee on Immunization Practices priority group recommendations. The Advisory Committee on Immunization Practices also recommended prioritizing healthcare workers and long-term care facility residents.⁵

These recommendations exposed major problems. Approximately three-quarters of frontline healthcare and social care staff are women and of these, a substantial proportion are of childbearing age. Was the expectation that they should defer pregnancy until a vaccine is available? Even if this were the case, such advice would be unlikely to be effective given that around half of all pregnancies are unplanned. Pregnant women are also at risk for more severe disease than women who are not pregnant. This is also the case for other viral infections, including influenza,

swine flu, Ebola, Middle East respiratory syndrome, and SARS. Pregnant women are more likely to require intensive care admission and ventilation, and are more likely to die, irrespective if they are in high-, middle-, or low-income countries.^{7,8} The exclusion of pregnant and lactating women from COVID-19 vaccination programs in high-income countries will likely lead to a much bigger effect than in low- and low-middle-income countries in which the majority of pregnancies occur, because local regulators are unlikely to take a different view.

Women face other additional risks and inequities. They are more likely to contract the infection from children, a group that will not receive the vaccine until much further down the line, because women still carry the major share of childcare responsibilities.

Inconsistent recommendations such as these also place pregnant women and their physicians in an impossible situation. In the UK, pregnant and lactating women were initially unable to access the vaccine, and therefore their choices were to stop working to protect themselves, without guarantee of paid leave, or to risk contracting the disease. Current US guidance forces pregnant women to choose between voluntarily accepting the unknown risk of vaccine-associated harm in the knowledge that there will be no compensation should they suffer ill effects, or risk severe disease. In the UK, authorities initially advised women who were breastfeeding to choose between accessing the vaccine and stop breastfeeding or continue breastfeeding and risk contracting the disease. This was an invidious situation, setting a woman’s immediate wellbeing against that of her baby and against the World Health Organization (WHO) and UK government advice to breastfeed for at least 6 months.

In the United States, guidance places healthcare staff responsible for administering the vaccine in an equally difficult situation because without efficacy, effectiveness, and safety studies in pregnant and lactating women, it is impossible to provide honest advice. In

addition, conflicting advice from, in this case, the UK and the United States, and rapidly changing advice, damages public confidence in vaccine safety. This is of particular concern because of the rising prevalence of antivaccine rhetoric and sentiment.

Was it Right to Exclude Pregnant Women from Initial Coronavirus Disease 2019 Vaccine Trials?

The extrapolation of research conducted in men and nonpregnant women is potentially dangerous because immune responses and kinetics may differ substantially during pregnancy. The lack of data poses substantial risk to the unborn baby. Vertical transmission of SARS-CoV-2 occurs, but appears rare and, to date, the effects on the developing fetus are unknown.^{9–13}

The traditional approach to vaccine and drug development is sequential. Using this approach, researchers first conduct efficacy trials in men and nonpregnant women and conduct follow-ups on pregnancy outcomes when these occur. If initial studies show efficacy, research sponsors conduct so-called bridging studies that include pregnant women. The rationale is that this stepwise approach protects pregnant women and their unborn children from risks during the early period of vaccine testing. The initial focus is on the detection of potential signals of harm through observation and on toxicity and teratogenicity studies in animal models, the so-called “developmental and reproductive toxicity” (DART) studies. The downsides of this approach are that vaccine delivery to women of child-bearing age is delayed and a substantial proportion of first responders and essential workers remain unprotected. COVID-19 vaccine developers seem to have adopted the traditional approach although regulators considered this unnecessary during the Ebola and Zika outbreaks.¹⁴

Vaccination during pregnancy is routine for tetanus, diphtheria, pertussis, and hepatitis B, but not for live vaccines. However, the SARS-CoV-2 vaccines are not live. The Johnson &

Johnson Services, Inc SARS-CoV-2 vaccine is adenovirus-based, as is the company's Ebola vaccine, which is used during pregnancy and is considered safe. mRNA vaccines are relatively new. They consist of mRNA encapsulated in a lipid nanoparticle that stimulate generation of the coronavirus spike protein, which in turn stimulates the production of anti-SARS-CoV-2 antibodies. The mRNA vaccines do not contain live virus particles, do not enter the nucleus, and do not alter human DNA.¹⁵ The ACOG therefore concluded that it would be unlikely that the safety and efficacy profile of the vaccine differed between women who are pregnant and those who are not. At the time of writing, regulators imminently anticipate receiving data from initial animal reproductive toxicity studies conducted by Pfizer.

Data from studies in animal models raised concerns of a theoretical risk for COVID-19 vaccine-associated, enhanced respiratory disease. This informed recommendations to exclude participants at a higher risk for severe COVID-19 from early-phase studies until additional data were available. The exclusion of pregnant women from early vaccine trials may therefore have possibly been justifiable on the grounds of a greater risk for vaccine-associated, enhanced respiratory disease. However, this does not seem to be the justification for excluding lactating women.

Is a Change in the Drug and Vaccine Development Pathway Necessary?

Traditional practice considers women and children to be “vulnerable groups” who are in need of enhanced protection from the dangers of research. This view has its origins in the research abuses during the first half of the last century, and the recognition of the possibility of adverse fetal effects. Many groups have since questioned the blanket imposition of this well-intentioned, but nonetheless paternalistic attitude. Recent decades have also seen the evolving recognition of clinical research as an integral component of good patient care. With this, patients have a right to be protected (from nonevidenced practice) “through

research,” as opposed to protected from (the dangers) “of research.” Thus, the exclusion of so-called vulnerable groups has also meant that evidence of efficacy, safety, pharmacokinetics, and pharmacodynamics has been lacking, leaving these groups vulnerable to harm, instead of providing protection. Therefore, for example, the extent to which antibody-dependent enhancement may be a factor in pregnant and lactating women and newborns is unknown.^{16,17} This shift in perspective gained ground in the 1980s and 1990s when, for example, women's health groups and acquired immune deficiency syndrome advocates drew attention to the inequities in the research agenda and when organizations such as the British Paediatric Association in the UK, voiced support for the inclusion of children in clinical research.¹⁸

In 1994, the US Institute of Medicine (now National Academy of Medicine) published a report entitled “Ethical and Legal Issues Relating to the Inclusion of Women in Clinical Studies.” Current guidance is for a “presumption of inclusion,” in which inclusion is the default unless there are clear reasons that justify exclusion.^{14,19} In addition, the WHO has highlighted the need for COVID-19 vaccine data specifically related to pregnancy, noting they “warrant particular consideration,” because they have been long disadvantaged with respect to the development and deployment of vaccines. They said, “It is imperative that data specific to pregnancy be generated now from, for example, pregnancy-specific safety and bridging studies and from participants who inadvertently become pregnant during Phase III trials.” The WHO also stated, “Vaccine developers and funders should prioritize an assessment of vaccine safety and immunogenicity among pregnant women in their clinical development and of safety and effectiveness in post-marketing surveillance plans.”²⁰

The US Department of Health and Human Services' Food and Drug Administration Center for Biologics Evaluation and Research issued

nonbinding guidance for industry in June 2020 in the report “Development and Licensure of Vaccines to Prevent COVID-19.”²¹ In this report, they cited their April 2018 guidance, “Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials Guidance for Industry,” which however, remains in draft.²² Recently, the 21st Century Cures Act established the Task Force on Research Specific to Pregnant Women and Lactating Women to advise the Secretary of Health and Human Services regarding gaps in knowledge and research on safe and effective therapies for pregnant and lactating women, and support their inclusion in clinical and translational research.^{23,24} Concerns about the exclusion of pregnant and lactating women are also growing around the world.^{25,26}

Conclusions

Current vaccination guidance is inconsistent across countries. The consequences are serious, far-reaching, and damaging to women, their babies, and wider society. Inconsistent guidance creates anxieties in the public mind and is likely to fuel antivaccine sentiment. It either places the burden of decision making upon women and their health-care providers without information to assist in making an informed choice or imposes a paternalistic decision without the involvement of the women themselves. In the face of an unprecedented pandemic, research sponsors and regulators could have considered data from relevant DART studies to reach a view about the inclusion of these groups of women in first phase trials and put in place mechanisms to obtain data systematically from women inadvertently vaccinated during pregnancy. As we write, we are pleased to note that trials commencing in 2021 will include pregnant and lactating women, but we have to ask whether the delay in obtaining evidence relevant to their needs was justified.

Going forward, we recommend, first, that regulators mandate the development of “pregnancy-investigation plans” to describe the development pathway for vaccines and medicines that will be used

in pregnancy in an approach analogous to the European Medicines Agency’s “paediatric investigation plans” for medicines used in children.²⁷ These plans should incorporate, at the outset, careful consideration of the balance of the risks of excluding or including pregnant and lactating women in initial studies. This requires consideration of any previous knowledge about the mode of action of the vaccine or medication and the likelihood of toxicity or teratogenicity. The development plan should include the close involvement of patient and public perspectives, the initiation of DART studies at the outset, and a layout of the approaches to collect data systematically about immunogenicity and pregnancy-specific indicators of safety from participants who are unknowingly pregnant at the time of exposure or become pregnant shortly following vaccine administration. Second, we support the view that the a priori, default position should be a “presumption of inclusion,” with exclusion only if justified on specific, and not generic, grounds. Third, we recommend closer collaboration before new vaccine releases, ideally coordinated by the WHO, with the aim of issuing consistent advice across countries. ■

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