



Protect the health of pregnant people

Commit to the inclusion of pregnant people in clinical trials in the United States

View of clinical research in pregnancy

While nearly every pregnant person in the United States reports taking at least one medication during pregnancy, over two-thirds of clinical trials explicitly exclude enrollment of pregnant people.^{1,2,5} The results of clinical trials provide clinicians with vital information on the safety and efficacy of medications, which is used to guide evidence-based decision-making. During pregnancy, the body undergoes substantial changes in the way it processes substances, which suggests the potential for differential drug safety profiles in pregnant vs. non-pregnant people.

Without this information, clinicians and pregnant people often struggle to make decisions about which medications to prescribe and continue in pregnancy. Most recently this was evident with the COVID-19 vaccine, in which a lack of information led to a months-long delay in professional organizations recommending the COVID-19 vaccine for pregnant people, resulting in increased avoidable death and illness.



Professional medical societies support including pregnant people in clinical trials

- **The American College of Obstetricians and Gynecologists^{4,5}**
“... reduce barriers for pregnant women’s participation in clinical trials.”
- **Society for Maternal-Fetal Medicine⁶**
“...prioritize investment in and expansion of research and clinical trials in pregnancy.”

90%

of pregnant people report taking
≥1 medication in pregnancy^{1,5}

50%

of pregnant people receive the influenza
and/or Tdap vaccine in pregnancy³

69%

of clinical trials exclude
pregnant participants^{2,5}

What we know

Research Question

Even though pregnant people are at increased risk of severe disease and pregnancy complications due to COVID-19 infection, some pregnant people remain hesitant to get vaccinated.^{7,8} We sought to determine the reasons for COVID-19 vaccine hesitancy in pregnancy.

Methods

Using four databases for peer-reviewed literature, we conducted a scoping review (to be published) of all research articles published in English between 2019-2022 focused on COVID-19 vaccine hesitancy in pregnant people. A total of 44 articles from 39 countries were included in our final analyses.

Findings

The leading reasons for COVID-19 vaccine hesitancy in pregnancy were (1) fear of effects on the fetus, (2) fear of effects on self, and (3) a belief that the vaccine was too new or not studied enough in pregnancy.

Discussion

A fear of unknown side effects, pregnancy complications, and fetal outcomes led some pregnant people to forgo COVID-19 vaccination during pregnancy. **If pregnant people were included in COVID-19 vaccine clinical trials, clinicians would have been better equipped to provide evidence-based counseling regarding vaccination.**



The case for including pregnant people in clinical trials

Pregnant people continue to be left out of clinical trials.^{2,9} The most recent high-profile example of the detrimental effects of excluding pregnant people from research is the case of the COVID-19 vaccine. Our research shows that **many pregnant people who were hesitant to be vaccinated against COVID-19 felt this way due to a lack of research on COVID-19 vaccine safety in pregnancy.**

The classification of pregnant people as ‘vulnerable subjects’ in research suggests a desire to protect them from harm.¹⁰ However, to do this, scientists and doctors must understand how medications and vaccinations may impact pregnant people and their pregnancy. Unlike other ‘vulnerable subjects’ such as incarcerated individuals, pregnant people are not uniquely susceptible to coercion. **They are fully capable of making informed decisions regarding their participation in research – and should be able to do so.**

The National Institutes of Health (NIH) urges the inclusion of people with diverse identities and lived experiences in clinical trials to understand how different people may experience the same disease, medication, or vaccination.¹¹ Why should pregnant people, particularly given the unique ways their bodies process substances, be excluded from this diversity?¹² **Pregnant people want to do what is best for themselves and their babies and including them in clinical trials will empower them with the information to do so.**



Key take-aways

- 90% of pregnant people take at least one medication in pregnancy, but 69% of clinical trials exclude pregnant participants.
- Lack of safety information in pregnancy is a key reason for COVID-19 vaccine hesitancy among pregnant people.
- Several professional medical societies advocate for the inclusion of pregnant people in clinical trials.



Reasons for COVID-19 vaccine hesitancy in pregnancy (Morgan et al. unpublished literature review)

Reason	Examples
Fear of effects on the fetus	<ul style="list-style-type: none"> • Unknown effects due to lack of data • Pregnancy complications • Negative effects on fetal development
Fear of effects on self	<ul style="list-style-type: none"> • Side effects/adverse reactions • Belief that the vaccine will cause infertility
Belief that the vaccine is too new or has not been studied enough in pregnancy	<ul style="list-style-type: none"> • The vaccine is experimental • Lack of data on effects on baby • Lack of safety/efficacy data in pregnancy • Concerns about vaccine quality/efficacy due to speed of development

You can urge congress to:

- Vote YES on HR1117, the Advancing Safe Medications for Moms and Babies Act^{5,13}
- Remove pregnant people from the list of vulnerable research subjects in the Code of Federal Regulations⁹
- Commit to collecting safety data for pregnant people in clinical trials
- Commit to continued funding for the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)¹⁴





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Authors

Alyssa M Kretz,^{1,2} Imaima Casubhoy,¹ Heang-Lee Tan,¹

Rosemary Morgan¹

¹Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD

²Johns Hopkins University School of Medicine, Baltimore, MD

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<https://www.genderandcovid-19.org/>

