

Breastfeeding and COVID-19 vaccine

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My messages

- Women missing from clinical drug/vaccine trials
- Breastfeeding and pregnancy should be considered separately
- COVID-19 vaccines probably safe for breastfeeding women and their infants





Gender and clinical trials

Photo by [Austrian National Library](#) on [Unsplash](#)

The female problem: how male bias in medical trials ruined women's health

Gabrielle Jackson,
The Guardian, 2019

“Not only have doctors, scientists and researchers mostly been men, but most of the cells, animals and humans studied in medical science have also been male: most of the advances we have seen in medicine have come from the study of male biology.”

Why were women excluded from drug & vaccine trials?

- Male research subjects were the default
- Lack of recognition that women have
 - Smaller body size/weight
 - Higher body fat
 - Slower stomach emptying
 - Different liver and kidney metabolism
- Women have menstrual cycles
 - Hormone variation may affect physiology
 - E.g. QT phase of ECG varies during cycle
- Possibility of pregnancy
 - Exposing a fetus to study drug/vaccine was considered “ethically unacceptable”

Changes began only 20 years ago

- USA in 1993/1994: National Institutes of Health (NIH) and Food & Drug Administration (FDA)
- Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs:
 - Both genders be included in all phases of drug development
 - Clinical data be analysed by gender
 - Potential pharmacokinetic differences between genders be assessed
 - Where indicated, specific additional studies in women be conducted

Council for International Organizations of Medical Sciences (CIOMS) in 2016

- International ethical guidelines for health-related research involving humans (2016)
- “It is imperative to design clinical research for pregnant and breastfeeding women to learn about the currently unknown risks and potential individual benefits to them, as well as to the fetus or nursing infant”
- <https://cioms.ch/wp-content/uploads/2017/01/WEBCIOMS-EthicalGuidelines.pdf>

National Institutes of Health (NIH), USA, 2017 -

Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)



its findings back to the Secretary.

The 21st Century Cures Act established PRGLAC to advise the Secretary of Health and Human Services (HHS) regarding gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women. PRGLAC was tasked with identifying these gaps and reporting

Task force includes bioethics experts as well as stakeholders and clinical and policy experts.

Recommendations from 2018 meeting:

- #1. Include and integrate pregnant women and lactating women in the clinical research agenda
- #4. Remove regulatory barriers to research in pregnant women
- #10. Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research

<https://www.nichd.nih.gov/about/advisory/PRGLAC>

Ethical Issues in Use of Medications During Lactation

Journal of Human Lactation
2020, Vol. 36(1) 34–39
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“Hence the rights of breastfed infants and their families have been breached. The principles of fairness and equity have been hindered by pharmaceutical companies and health professionals providing inappropriate advice about medications and lactation, irrespective of actual evidence. There is a need for more multistakeholder engagement and deliberation on medications and lactation, involving not just clinicians but drug companies, health authorities, professional groups, and consumers.”

#OpenAccess article

Key messages from *JHL* article

- “When using utilitarian ethical theory, with its foundational principle of utility, one should do a risk-benefit assessment for each medication decision.
- The moral values of fairness and equity imply that infants should not be denied human milk and that current gaps in evidence should be addressed.”
- “There exists a strong social responsibility to partner with consumers to generate greater evidence, and improve methods to communicate risks and benefits of medication use in lactation.”

Amir LH, Grzeskowiak LE, Kam LR. Ethical issues in use of medications during lactation. *J Hum Lact* 2020; 36(1) 34-39.



A New Face in Clinical Trials: Expecting Mothers

In a seismic shift, medical ethics now call for pregnant women to be included in drug trials.

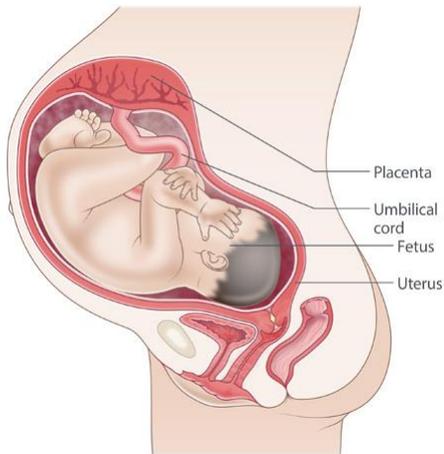
A tipping point?

- Anne Drapkin Lyerly, MD, MA, professor of social medicine and associate director of Center for Bioethics at Uni N. Carolina, Chapel Hill and research professor in O &G
- *Scientific American* 2020



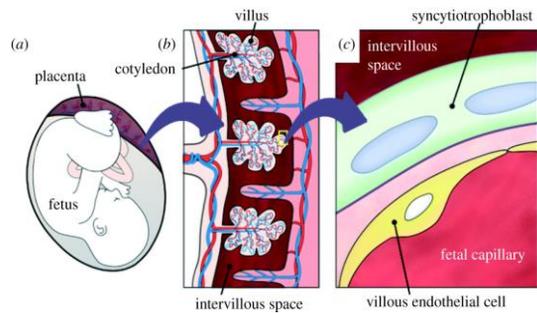
Pregnancy and breastfeeding tend to be grouped together . . .
Yet they are not the same

Pregnancy



Raising Children Network: 38 weeks pregnant

- Placenta is a permeable “barrier” between maternal medications/vaccines and the fetus
- Medications in early pregnancy can cause birth defects, e.g. thalidomide (in 1960s)

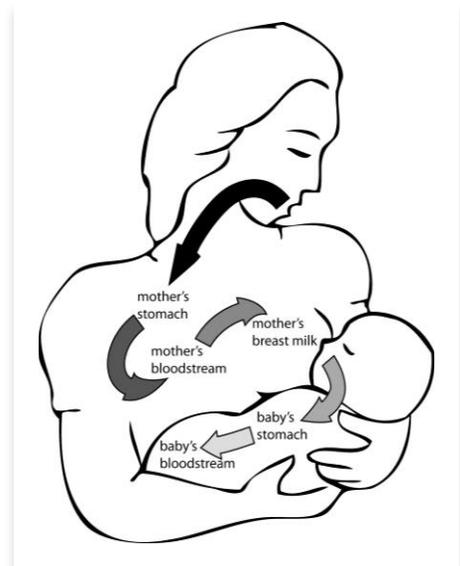


<https://doi.org/10.1098/rfsf.2019.0031>



Lactation

We need to follow the path of medicine/vaccine through the mother's body to the baby's circulatory system.





Breastfeeding vs pregnancy

- The risk of maternal medicines/vaccines for the breastfed infant are much *lower* than potential risks of medicines during pregnancy.
 - Medicines/vaccines taken during lactation *cannot* lead to teratogenesis.
 - In pregnancy the fetus receives five to ten-fold *higher* levels of medicines than the breastfed infant receives.
- (Hale *Medications and Mothers Milk* 2007)
- 



Breastfeeding: risk vs benefit

“For most medications, the potential for harming the breastfed infant is minimal; small amounts of medication are transferred into human milk and absorbed by the child (Rowe et al., 2013).”

The importance of breastfeeding and human milk for infants, their families, and society is widely recognized (Victora et al., 2016), and authors usually conclude their reviews with the recommendation that the benefits of medication use during lactation outweigh the risks (Newmark et al., 2019; Versteegen & Ito, 2019).”

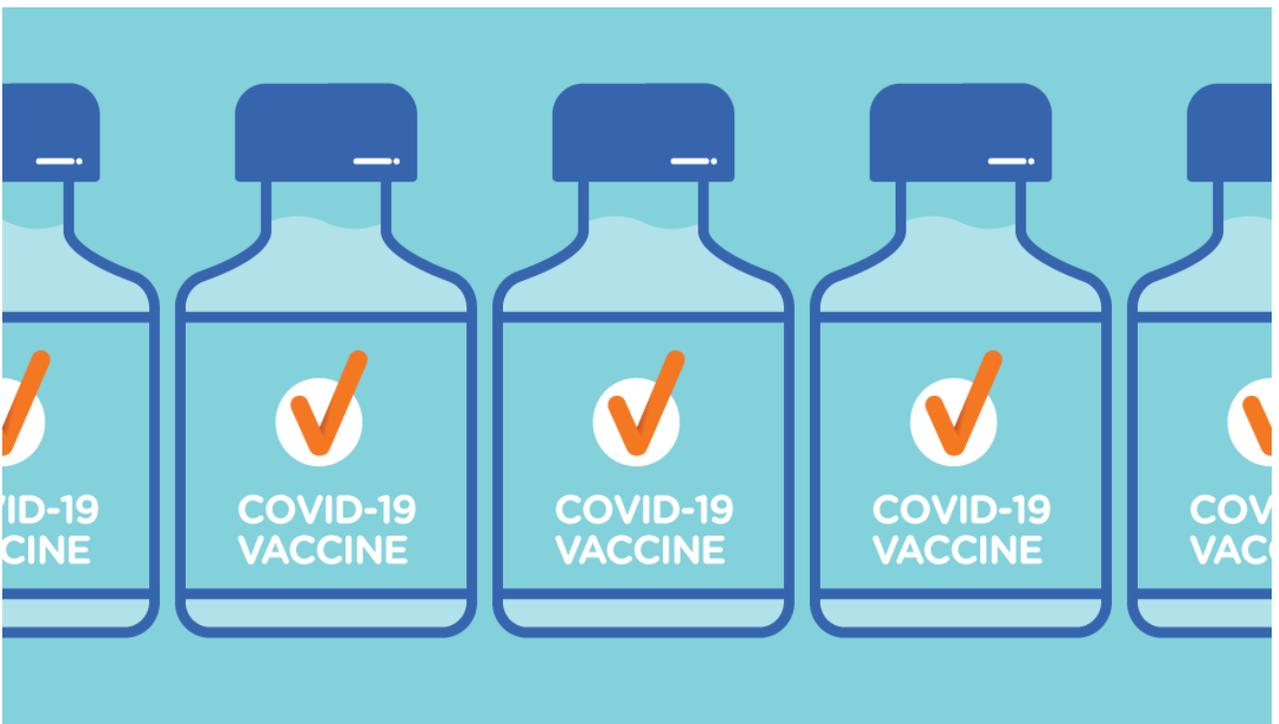
Amir LH, Grzeskowiak LE, Kam LR. Ethical issues in use of medications during lactation. *J Hum Lact* 2020; 36(1) 34-39.





Risk society

- ““Good” mothers should manage and avoid any risks, thereby protecting their babies from harm and put their children's needs before their own – they should not allow toxins to enter the body . . .
 - The increased complexity involved when one body's actions impact the body of another – as in the pregnant and lactating body - has received little acknowledgment. ‘
 - McDonald K, Amir LH, Davey M-A. Maternal bodies and medicines: a commentary on risk and decision-making of pregnant and breastfeeding women and health professionals. *BMC Public Health* 2011; 11 (Suppl 5): S5.
- 





TIME
magazine
18 Jan 2021

How the vaccines compare

Company	UK Approved	Type	Doses	Storage
Oxford Uni-AstraZeneca	✓	Viral vector (genetically modified virus)	x2	Regular fridge temperature
Pfizer-BioNTech	✓	RNA (part of virus genetic code)	x2	-70C
Moderna	✓	RNA	x2	-20C
Novavax	Pending	Protein-based	x2	Regular fridge temperature
Janssen	Pending	Viral vector	x1	Regular fridge temperature

Source: Respective companies, WHO



AUSTRALIA	
TGA approval	Manufactured
Pending	In Australia by CSL
✓ COMIRNATY provisionally approved; ≥16 yrs age (25 Jan 2021)	In Europe
Pending	
Pending	

TGA Provisional determinations: these companies can apply for approval

Effective date	Sponsor	Name	Type
19 January 2021	Bioclect Pty Ltd (on behalf of Novavax Inc.)	NVX-CoV2373	Protein sub-unit
16 November 2020	Janssen-Cilag Pty Ltd	Ad26.COVS.S	Viral vector
14 October 2020	Pfizer Australia Pty Ltd	BNT162b2 [mRNA]	mRNA
9 October 2020	AstraZeneca Pty Ltd	ChAdOx1-S [recombinant]	Viral vector

- Have included women, but exclusion criteria typically say:
- “Female participants of childbearing potential were not to be pregnant or breastfeeding and had to agree to use protocol-approved forms of contraception until 6 months after the first vaccination.”
- “Pregnant women were excluded from early COVID-19 vaccine research, resulting in a missed opportunity to generate safety and efficacy data, and potentially affecting whether pregnant women will receive the benefits of COVID-19 vaccines.”

Bardají A et al. Lancet 2021

COVID-19 Vaccine trials

Comment

The need for a global COVID-19 maternal immunisation research plan



There is evidence that COVID-19 threatens maternal and perinatal health. Pregnant women, especially in the second half of pregnancy, are at increased risk of complications—eg, severe pneumonia, hospitalisations,

risk-benefit analyses to inform COVID-19 vaccine trials in pregnancy and the use of COVID-19 vaccines in pregnant women before and after regulatory approvals. The use of an approved vaccine in pregnant women needs to be

Published Online
January 25, 2021
[https://doi.org/10.1016/S0140-6736\(21\)00148-X](https://doi.org/10.1016/S0140-6736(21)00148-X)

Consumer Product Information (CMI)

COMIRNATY™ COVID-19 VACCINE

Active ingredient: BNT162b2 [mRNA]

This vaccine has **provisional approval** in Australia to prevent COVID-19 disease caused by SARS-CoV-2 virus in adults and adolescents from 16 years of age and older. This approval has been granted on the basis of short term safety and efficacy data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed.



Breastfeeding included
with pregnancy

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you receive this vaccine.

Pfizer January 2021



Who can take the Pfizer-BioNTech COVID-19 vaccine?

8 January 2021

8 Jan 2021

Pregnant and breastfeeding women

Pregnant women are at higher risk of severe COVID-19 than non-pregnant women, and COVID-19 has been associated with an increased risk of pre-term birth.

However due to insufficient data, WHO does not recommend the vaccination of pregnant women at this time.

In case a pregnant woman has an unavoidable risk high of exposure (e.g. a health worker), vaccination may be considered in discussion with their healthcare provider.

If a breastfeeding woman is part of a group (e.g. health workers) recommended for vaccination, vaccination can be offered. WHO does not recommend discontinuing breastfeeding after vaccination.

WHO Advice

Conflicting advice re breastfeeding!

Singapore:

The Ministry of Health recommends that women who are breastfeeding can receive the Pfizer-BioNTech vaccine but are advised to stop breastfeeding for 5 to 7 days after as a cautionary measure.

India:

Outlook

THE NEWS SCROLL

19 JANUARY 2021 Last Updated at 11:29 AM | SOURCE: PTI

People with fever, pregnant and breastfeeding women avoid

Initially in Dec 2020, Public Health England said “that until more information is available, pregnant women should not routinely have these vaccines.”

thebmjopinion

Latest

Authors ▾

Topics ▾

Healthcare workers who breastfeed should be offered the covid-19 vaccine

December 21, 2020



Breastfeeding

There are no data on the safety of COVID-19 vaccines in breastfeeding or on the breastfed infant. Despite this, COVID-19 vaccines are not thought to be a risk to the breastfeeding infant, and the benefits of breast-feeding are well known. Because of this, the JCVI has recommended that the vaccine can be received whilst breastfeeding. This is in line with recommendations in the USA and from the World Health Organisation.

Public Health England NHS

A guide to COVID-19 vaccination

All women of childbearing age, those currently pregnant or breastfeeding

You must read this before you go for vaccination

“What does this mean for me?”

- Here are the key points you should consider:
 - • •
 - If you are breastfeeding, you may **decide to wait** until you have finished breastfeeding and then have the vaccination.”

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/951758/PHE_COVID-19_vaccination_guide_on_pregnancy_English_v2.pdf (28 Jan 2021)

In the USA



- [COVID-19 Vaccines in Pregnant and Breastfeeding People | University of Utah Health](#)
- COVID-19 VACCINES
- Under the Emergency Use Authorization (EUA) for the Pfizer/BioNTech vaccine, there are **no restrictions based on pregnancy or breastfeeding status**. Patients are recommended to have a discussion with their health care providers.



COVID-19 Vaccination in Pregnant and Breastfeeding Women

Updated Tuesday 26 January 2021

Breastfeeding

There are no data on the safety of COVID-19 vaccines in lactating women or on the effects of inactivated vector-based vaccines or mRNA vaccines on the breastfed infant or on milk production/excretion. These vaccines are not thought to be a risk to the breastfeeding infant.

...

RAZCOG emphasises the importance of inclusion of pregnant and breastfeeding women in clinical trials of COVID-19 vaccines to develop evidence-based advice regarding safety and efficacy.



COVID-19 Vaccine pregnancy vs breastfeeding



Pregnancy

- Teratogenicity unlikely
- Could immune response to the vaccine in early pregnancy led to miscarriage? Currently unknown.



What do we know about COVID-19 vaccines in lactation?

- 
- 
- Very unlikely that vaccine fluid would enter blood stream and reach breast tissue
 - In the unlikely event that nanoparticles or mRNA are present in milk, it would be digested by the child and unlikely to have any biological effects.
 - Physiology is reassuring; but need data on outcomes once the vaccine is used in lactating individuals and their children.
 - Currently the only vaccines not recommended during lactation are smallpox and yellow fever.
- 

Academy of Breastfeeding Medicine, 14 Dec 2020

ABM STATEMENT

Considerations for COVID-19 Vaccination in Lactation

- Currently **no clinical data** on use of COVID-19 mRNA vaccines in lactation.
- However, there is **little biological plausibility** that the vaccine will cause harm, and antibodies to SARS-CoV-2 in milk may protect the breastfeeding child.
- Health care providers should use **shared decision-making** in discussing the benefits of the vaccine for preventing COVID-19 and its complications, the risks to mother and child of cessation of breastfeeding, and the biological plausibility of vaccine risks and benefits to the breastfed child.

