

COVID-19 Vaccine Considerations Related to Pregnancy

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Docket No. FDA-2021-N-0173
Vaccines and Related Biological
Products; Notice of Meeting;
Establishment of a Public Docket;
Request for Comments

Qualifications

- Board Certified pediatrician
- 25+ years clinical experience
- Specialize in preconception, pregnancy, infant, and childhood health
- Patient vaccine consultant
- Ongoing COVID-19 vaccine data analysis



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Pregnancy Considerations

- To date, such women have not been well-studied.
- Hopefully Pfizer's recently announced pregnancy study will provide more data so women can make better informed decisions.

Graphic created by:

- Institute of Obstetricians & Gynecologists
- The Rotunda Hospital
- National Immunisation Advisory Committee (NIAC)
- National Women & Infants Health Programme

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I am pregnant
Should I get a COVID-19 vaccine?

Get a COVID-19 vaccine as soon as it is available to you VS **Wait until more information is available about the vaccines in pregnancy**

What are the positives of this option?

- A vaccine will reduce your risk of getting infected with COVID-19
- You will not experience any side effects or other adverse effects from the vaccines
- Other vaccines are recommended in pregnancy with good safety information
- Available data do not suggest there are safety concerns about the COVID-19 vaccines in pregnant and non-pregnant people

What are the negatives of this option?

- COVID-19 vaccines have not been studied in pregnancy and breastfeeding
- You will still be at risk of getting COVID-19
- You may get some side-effects from getting the vaccine.
- You will still be at risk of getting sick from COVID-19; this may lead to hospital admission or pre-term birth.

You might consider this option if you:

- Have a medical condition
- Are a health or social care worker
- Have regular contact with people who don't wear masks
- Are 35 years or older
- Are overweight
- Are a smoker
- Are from a Black, Asian or other ethnic minority
- Live in crowded housing or an area with a high rate of COVID-19 infection
- Are not at higher risk of getting COVID-19
- Think getting a vaccine will make you very nervous
- Are more worried about the unknown risks of a vaccine compared with the risks of getting COVID-19
- Have had a severe allergic reaction to previous injected medicines

If you chose this option:

- Get the vaccine when you are between **14 WEEKS** and **33 WEEKS** pregnant.
- Take paracetamol if you develop a fever
- Continue to follow public health advice
- Only choose this option if you and the people you live with can follow current public health advice on:
 - wearing a mask
 - social distancing
 - working from home where possible

Think about your own personal risk of getting COVID-19
If your personal risk is high it might make sense for you to get the vaccine when you are pregnant

It is your choice whether or not you get the COVID-19 vaccine before, during or after pregnancy

This decision aid was produced by the Irish Medicines in Pregnancy Service (IMPS) at the Rotunda Hospital and The Institute of Obstetricians and Gynaecologists (IOG), and endorsed by the National Immunisation Advisory Committee (NIAC) and the National Women and Infants Health Programme (NWIHP). Version 2, Updated 15/02/21

Morbidity Associated with COVID-19 and Pregnancy Outcomes

Women infected with COVID-19 during pregnancy vs. women not infected during pregnancy

- Increased odds ratio of being admitted to an ICU, having a preterm birth, and having her baby admitted to a neonatal ICU
- No differences seen in maternal mortality, need for C-section, stillbirth, neonatal death, or fetal distress.

<https://www.bmj.com/content/370/bmj.m3320>



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Ongoing COVID-19 Vaccine Hesitancy

- 28% of people age 18-29 and 36% of people age 30-49 would “probably” or “definitely not” get a COVID-19 vaccine, even if determined to be safe by scientists and available for free-of-charge
<https://www.kff.org/coronavirus-covid-19/report/kff-covid-19-vaccine-monitor-december-2020/>
- **Multiple polls show women 6-18% more likely than men to have hesitancy** https://www.washingtonpost.com/lifestyle/style/women-covid-vaccine-skeptical/2020/12/15/63551cac-3a61-11eb-9276-ae0ca72729be_story.html



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Conflicting Guidance for Pregnant Women

- **World Health Organization (WHO)**
Initial recommendation, not get mRNA-containing vaccine unless high risk (e.g, work exposures or chronic conditions)
- **Centers for Disease Control (CDC)/American College of Obstetricians & Gynecologists (ACOG)**
Urged consultation with doctors. Didn't make a recommendation; kept decision-making with patient.
- **WHO changed stance to align with CDC/ACOG** → added to confusion/hesitancy

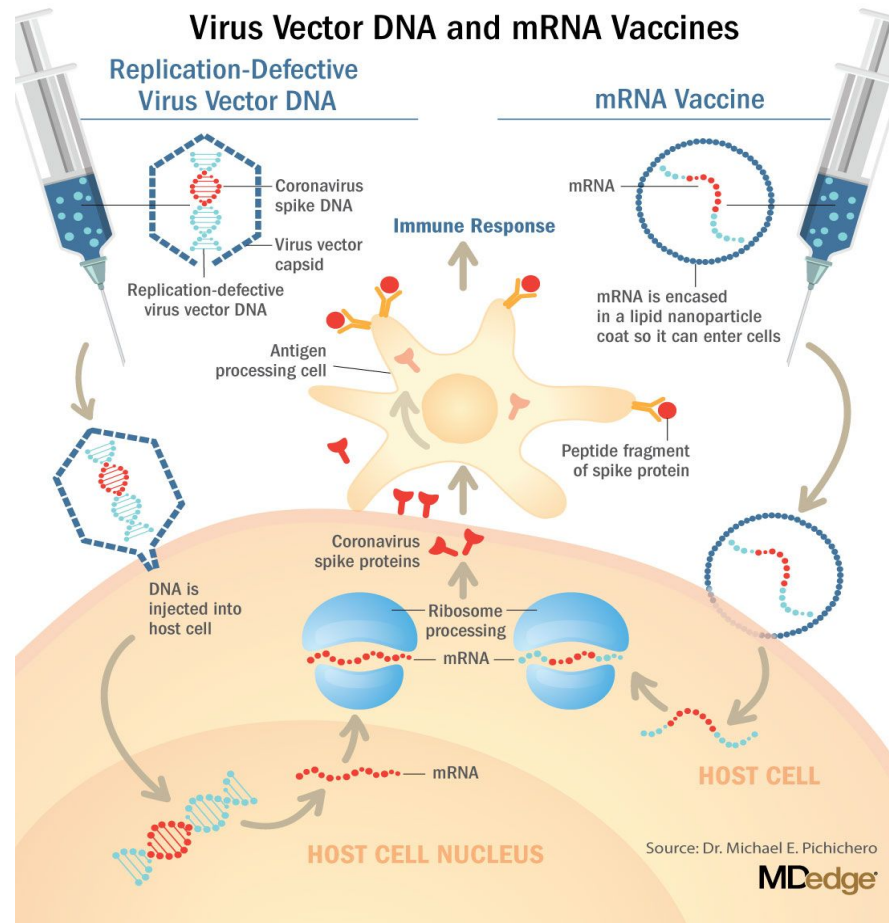


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DNA and mRNA Vaccines: Different Mechanisms of Action



Questions Remain About Vaccine DNA Incorporating Into Human Genome

- Does replication-defective vector ensure integration impossible?
- Can genetic material injected arm come in contact with developing zygote/embryo/fetus?
- Do we have adequate research to answer these questions?



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Can DNA from Johnson & Johnson Vaccine Affect Spermatogenesis?

- Adenovirus can enter sperm

<https://wwwnc.cdc.gov/eid/article/23/11/pdfs/17-1049.pdf>

- Mice research indicates adenovirus vector DNA does not integrate into offspring DNA

<https://www.sciencedirect.com/science/article/pii/S2213671118301322>

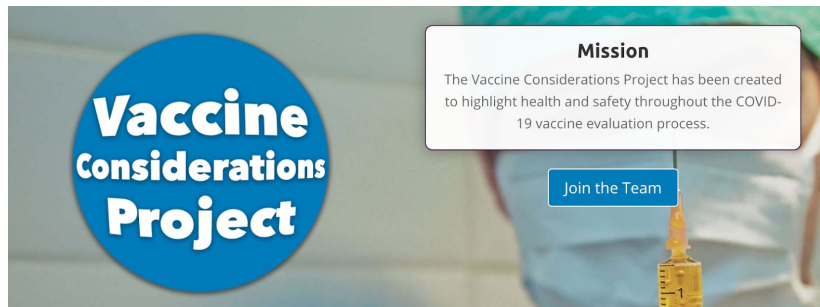


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Vaccine Considerations Project



Vaccine Considerations Project

Mission
The Vaccine Considerations Project has been created to highlight health and safety throughout the COVID-19 vaccine evaluation process.

[Join the Team](#)

www.VaccineConsiderations.com

Dec. 17th FDA Advisory Council (VRBPAC) Meeting

Our Senior Medical Advisor, Dr. David Berger, again, provided an oral presentation at the FDA Vaccines and Related Biological Products Advisory Committee meeting at on December 17th – [see the video](#).

Dec. 10th FDA Advisory Council (VRBPAC) Meeting

Both Jared Krupnick, the Founder of the Vaccine Considerations Project, as well as Board Certified Pediatrician, and the project's Senior Medical Advisor, Dr. David Berger, were pleased to provide separate oral presentations (**Jared's presentation**) (**Dr. Berger's presentation**) to the FDA Vaccines and Related Biological Products Advisory Committee meeting on December 10th.

- Oral Presentation Request Package
- Dec. 10th Meeting Information
- Processed Transcript (of Oct. 22nd VRBPAC meeting)
- Matrix of Concerns (of Oct. 22nd VRBPAC meeting)
- Oct. 22nd VRBPAC meeting video

Leading the 6pm News in Miami / Ft. Lauderdale

See the very supportive **news coverage we received of our presentations to the FDA Advisory Committee** December 10th.



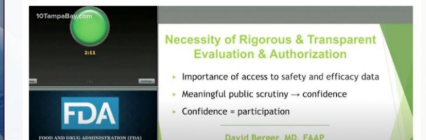
[View Matrix of Concerns](#)

Dr. Berger Prominently Featured in Tampa Media

See the excellent news coverage our Senior Medical Advisor, Dr. Berger, received of his presentations to the FDA Advisory Committee December 10th (**WFLA coverage**) (**WTSP coverage**).



Tampa pediatrician urges FDA to build COVID-19 vaccine confidence through transparency



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Summary

TRANSPARENCY IS CRITICAL

- Transparency needed to reduce COVID-19 vaccine hesitancy

IMPORTANT CONSIDERATIONS

- Is medical/research community confident DNA from Johnson & Johnson vaccine will not incorporate into human genome, especially of zygote/embryo/fetus?
- Current public education, guidance, and informed consent does not adequately address pregnancy.



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