COVID Vaccine updates and Perinatal Quality

Marjorie Meyer MD

Professor

Larner College of Medicine

University of Vermont

PERINATAL QUALITY COLLABORATIVE VERMONT

VERMONT DEPARTMENT OF HEALTH

VCHIP

COVID-19 Vaccine in Pregnancy

Short Story


00 × 1798


Get vaccinated.
Wear a mask.
>6 feet
Stay 6 feet from others, and avoid crowds.
Wash hands often.
1080 × 1081

Longer story

- Vaccines available
- Data available
- Recommendations for pregnancy and breastfeeding
- Recommendations for planning pregnancy

Vaccines

mRNA vaccines-2 shots

- Pfizer-3 weeks
- Moderna-4 weeks

Adenoviral vector vaccines-one shot

- Janssen Biotech: Johnson and Johnson

AstraZeneca

- Not in US

Vaccines

mRNA vaccines-2 shots

- Pfizer-3 weeks; 95% effective against illness
- Moderna-4 weeks; 94% effective against illness

Adenovirus vector vaccines-one shot

- Johnson and Johnson; 67% effective against moderate illness, 77% against critical illness, 93% against hospitalizations
- (not live virus, no preservatives, does not replicate)

AstraZeneca

- Not in US

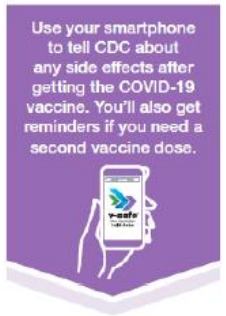
- *ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals.*
- *COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals*

"SMFM applauds ACIP's recent discussion, which will allow pregnant and lactating people access to the Janssen COVID vaccine"-SMFM March 1, 2021

COVID-19 vaccine safety update

Advisory Committee on Immunization Practices (ACIP)
March 1, 2021

Tom Shimabukuro, MD, MPH, MBA
CDC COVID-19 Vaccine Task Force
Vaccine Safety Team



1. text message check-ins from CDC (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.)

vaccine recipient completes web survey*

Vaccine recipients

v-safe℠ after vaccination health checker

2. clinically important health impact reported

✓ received medical care

Call center

3. **V-safe** call center conducts active telephone follow-up on a clinically important event and takes a VAERS report if appropriate

4. pregnancy registry team conducts outreach to assess eligibility for registry and obtain consent for enrollment and follow-up

Call center

* Selected web surveys capture information on pregnancy status

We have a LOT of real life data about the vaccine

v-safe after vaccination health checker

Summary of v-safe data as of February 16, 2021

	Pfizer-BioNTech	Moderna	Total
People receiving 1 or more doses in the United States*	28,374,410	26,738,383	55,220,364
Registrants completing at least 1 v-safe health check-in	1,776,960	2,121,022	3,897,982
Pregnancies reported to v-safe†	16,039	14,455	30,494

* COVID Data Tracker as of Feb 16, 2021 (107,571 doses with manufacturer not identified)
† Self-reported during a v-safe health check-in

The safety profile of vaccine is excellent

U.S. reports to VAERS after COVID-19 vaccines through February 16, 2021*

Vaccine	N	Non-serious AEs (%)	Serious AEs†§ (%)
Moderna	56,567	54,708 (97)	1,859 (3)
Pfizer-BioNTech	48,196	43,974 (91)	4,222 (9)
Total	**104,763**	**98,682 (94)**	**6,081 (6)**

* Total pre-processed reports (reports received and classified as serious or non-serious)
† Based on the Code of Federal Regulations if one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly or birth defect
§ Most commonly reported serious adverse events include: death (456 reports of death following Moderna vaccine and 510 following Pfizer-BioNTech vaccine), dyspnoea, pyrexia, SARS-CoV-2 test negative, nausea, headache, dizziness, fatigue, asthenia, pain

Most commonly reported adverse events to VAERS after COVID-19 vaccines through February 16, 2021*

Pfizer-BioNTech

Adverse event†	N (%)
Headache	2,322 (20.0)
Fatigue	1,801 (15.5)
Dizziness	1,659 (14.3)
Pyrexia	1,551 (13.4)
Chills	1,508 (13.0)
Nausea	1,482 (12.8)
Pain	1,464 (12.6)
SARS-CoV-2 Test Positive	1,002 (8.6)
Injection Site Pain	997 (8.6)
Pain in Extremity	923 (8.0)

Moderna

Adverse event†	N (%)
Headache	1,353 (23.4)
Pyrexia	1,093 (18.9)
Chills	1,056 (18.3)
Pain	945 (16.3)
Fatigue	888 (15.4)
Nausea	884 (15.3)
Dizziness	792 (13.7)
Injection Site Pain	671 (11.6)
Pain in Extremity	576 (10.0)
Dyspnoea	487 (8.4)

- No empirical Bayesian data mining alerts (EB05 ≥2) detected for any adverse event-COVID-19 vaccine pairs (most recent weekly results)

* For reports received and processed (coded, redacted, and quality assurance performed)
†Adverse events are not mutually exclusive

Anaphylaxis is RARE

Anaphylaxis following mRNA COVID-19 vaccines

Clinical Review & Education

JAMA Insights

Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021

Tom T. Shimabukuro, MD, MPH, MBA; Matthew Cole, MPH; John R. Su, MD, PhD, MPH

Shimabukuro TT, Cole M, Su JR. Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US-December 14, 2020-January 18, 2021. *JAMA*. 2021 Feb 12. doi: 10.1001/jama.2021.1967. Epub ahead of print.

	Pfizer-BioNTech	Moderna
Anaphylaxis reporting rate (cases per million doses administered)	4.7	2.5

Table. Characteristics of Reported Cases of Anaphylaxis Following Receipt of Pfizer-BioNTech (9 943 247 Doses) and Moderna (7 581 429 Doses) COVID-19 Vaccines—Vaccine Adverse Events Reporting System (VAERS), US, December 14, 2020-January 18, 2021

Characteristics	No. (%) of cases	
	Pfizer-BioNTech (n = 47)	Moderna (n = 19)
Age, median (range), y	39 (27-63)[a]	41 (24-63)
Female sex	44 (94)	19 (100)
Minutes to symptom onset, median (range)	10 (<1-1140 [19 h])[b]	10 (1-45)
Symptom onset, min		
≤15	34 (76)[b]	16 (84)
≤30	40 (89)[b]	17 (89)
Reported history[c]		
Allergies or allergic reactions	36 (77)	16 (84)
Prior anaphylaxis	16 (34)	5 (26)
Vaccine dose		
First	37	17
Second	4	1
Unknown	6	1
Brighton Collaboration case definition level[d]		
1	21 (45)	10 (52)
2	23 (49)	8 (43)
3	3 (6)	1 (5)
Anaphylaxis reporting rate (cases per million doses administered)	4.7	2.5

Vaccine Safety Datalink (CDC):
Comparative data of adverse health events in unvaccinated vs vaccinated people

Preliminary results of the VSD **unvaccinated concurrent comparator** analysis for COVID-19 vaccine safety after either dose of any mRNA vaccine as of February 13, 2021

VSD Rapid Cycle Analysis prespecified outcomes for COVID-19 vaccines	Concurrent comparator analysis	Risk interval	Events in vaccinated	Adjusted expected events in risk interval
Acute disseminated encephalomyelitis	Unvaccinated	1-21 days	0	0
Acute myocardial infarction	Unvaccinated	1-21 days	23	26.0
Acute respiratory distress syndrome	Unvaccinated	N/A	0	N/A
Anaphylaxis	Unvaccinated	0-1 days	20	N/A
Appendicitis	Unvaccinated	1-21 days	31	23.6
Bell's palsy	Unvaccinated	1-21 days	21	20.3
Convulsions/seizures	Unvaccinated	1-21 days	10	9.6
Disseminated intravascular coagulation	Unvaccinated	1-21 days	1	1.1
Encephalitis/myelitis/encephalomyelitis	Unvaccinated	1-21 days	1	.1
Guillain-Barré syndrome	Unvaccinated	1-21 days	1	.6
Thrombotic thrombocytopenic purpura	Unvaccinated	1-21 days	0	0
Immune thrombocytopenia	Unvaccinated	1-21 days	1	1
Kawasaki disease	Unvaccinated	1-21 days	0	0
MIS-C and MIS-A	Unvaccinated	N/A	0	N/A
Myocarditis/pericarditis	Unvaccinated	1-21 days	2	2.1
Narcolepsy and cataplexy	Unvaccinated	N/A	2	N/A
Stroke, hemorrhagic	Unvaccinated	1-21 days	8	10
Stroke, ischemic	Unvaccinated	1-21 days	41	38.8
Transverse myelitis	Unvaccinated	1-21 days	0	0
Venous thromboembolism	Unvaccinated	1-21 days	26	26.3
Pulmonary embolism (subset of VTE)	Unvaccinated	1-21 days	20	21.0

- No statistically significant increased risks detected for any prespecified outcomes

What about pregnancy data?

v-safe after vaccination health checker

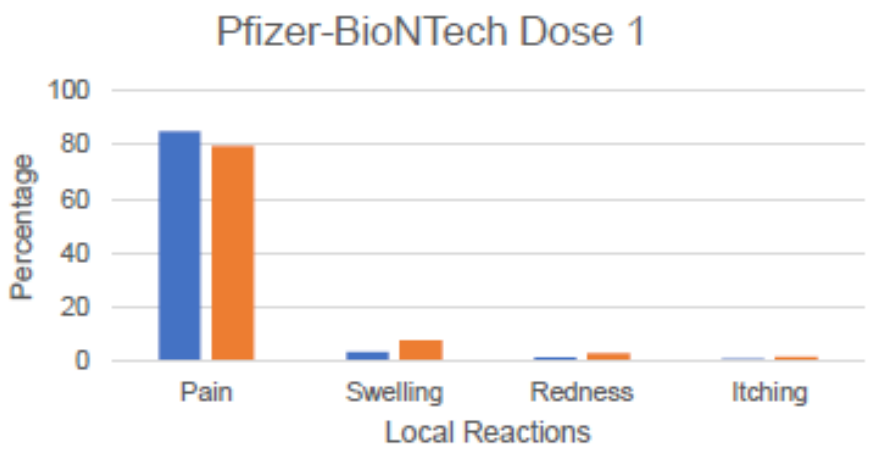
Summary of v-safe data as of February 16, 2021

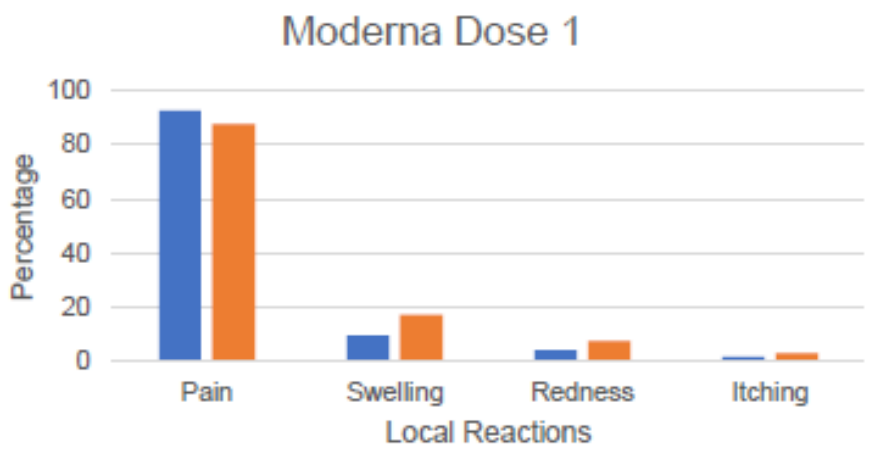
	Pfizer-BioNTech	Moderna	Total
People receiving 1 or more doses in the United States*	28,374,410	26,738,383	55,220,364
Registrants completing at least 1 v-safe health check-in	1,776,960	2,121,022	3,897,982
Pregnancies reported to v-safe†	16,039	14,455	30,494

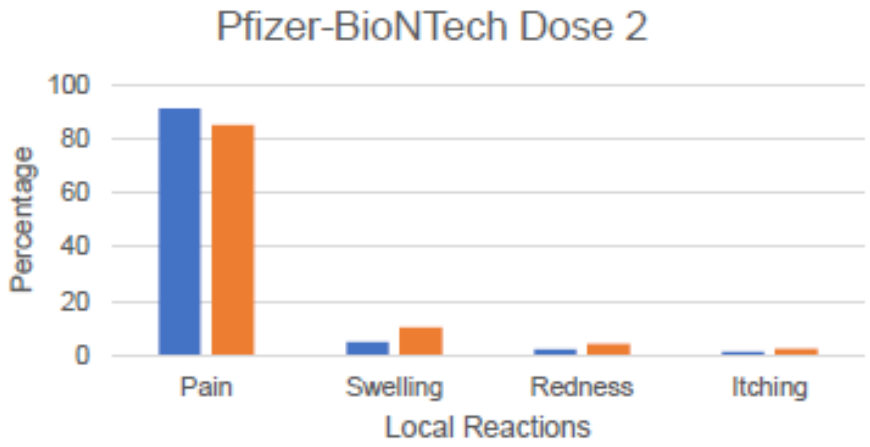
* COVID Data Tracker as of Feb 16, 2021 (107,571 doses with manufacturer not identified)
† Self-reported during a v-safe health check-in

Similar side effects: pregnant vs not pregnant

V-safe: Day 1 post-vaccination local reactions in pregnant and non-pregnant women aged 16-54 years*







Pregnant (self-report)
Not pregnant

v-safe℠
after vaccination
health checker

* Source: CDC unpublished v-safe data through January 13, 2021

V-safe pregnancy registry

- **V-safe** participants who report pregnancy following COVID-19 vaccination are actively contacted to enroll in pregnancy registry*
- Participants are contacted once per trimester, after delivery, and when the infant is 3 months old†
- Outcomes of interest include miscarriage and still birth, pregnancy complications, maternal intensive care unit admission, adverse birth outcomes, neonatal death, infant hospitalizations, and birth defects

* Must be registered in v-safe and have been pregnant at the time of COVID-19 vaccine receipt or within 30 days of vaccination; enrollment may discontinue when sufficient enrollment numbers are achieved

† Phone surveys are conducted along with maternal and infant medical record review

V-safe pregnancy registry enrollment as of February 19, 2021

Registry participants to date (N = 1,949)	
Enrolled	1,815
Not eligible*	103
Refused/declined†	31

- In the enrolled population, there have been 275 completed pregnancies, including 232 live births
  - Other outcomes include miscarriage, stillbirth, ectopic/tubal, other

*Eligibility assessment determines whether vaccination was during pregnancy or within 30 days of last menstrual period

†Refused indicates those for whom eligibility could not be fully assessed because participant chose not to engage with pregnancy registry team; declined indicates those who were eligible to participate but chose not to enroll

In these 2000 women, no change in pregnancy outcome compared to background rates:

V-safe pregnancy registry outcomes of interest in COVID-19 vaccinated pregnant women as of February 18, 2021*

Outcomes	Background rates*	V-safe pregnancy registry overall
Pregnancy outcome		
Miscarriage (<20 weeks)	26%	15%†
Stillbirth (≥ 20 weeks)	0.6%	1%
Pregnancy complications		
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension§	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
Neonatal		
Preterm birth	10.1%	10%
Congenital anomalies‡	3%	4%
Small for gestational age^	3-7%	4%
Neonatal death	0.38%	0%

* Sources listed on slide 33; † 93% of these were pregnancy losses <13 weeks of age; § Pre-eclampsia or gestational hypertension diagnosed during pregnancy and/or during delivery; ‡ Congenital anomalies (overall) diagnosed after delivery only; ^ Birthweight below the 10th percentile for gestational age and sex using INTERGROWTH-21st Century growth standards

Characteristics of COVID-19 vaccine pregnancy reports to VAERS through February 16, 2021* (N=154)

Characteristic	
Maternal age in years, median (range)	33 (16–51)
Gestational age in weeks at time of vaccination when reported, median (range)	13 (2–38)
Trimester of pregnancy at time of vaccination	**n (%)**
First (0-13 weeks)	60/118 (51)
Second (14-27 weeks)	36/118 (31)
Third (28+ weeks)	22/118 (19)
Vaccine	
Pfizer-BioNTech	97 (63)
Moderna	56 (36)
Unreported	1 (0.6)

* Reports received and processed through February 16, 2021

Adverse events in pregnant women following COVID-19 vaccine reported to VAERS through February 16, 2021* (N=154)

Adverse events	N (%)
Pregnancy/neonatal specific conditions	**42 (27)**
Spontaneous abortion/miscarriage†	29
Premature rupture of membranes	3
Fetal hydrops	2
Neonatal death in 22-week preterm birth	1
Premature delivery	1
Gestational diabetes	1
Vaginal bleeding	1
Stillbirth	1
Shortened cervix	1
Leakage amniotic fluid	1
Calcified placenta	1
Non-pregnancy specific adverse events (top 10) Headache (31), fatigue (29), chills (21), pain in extremity (17), nausea (15), dizziness (14), pain (14), pyrexia (13), injection site pain (13), injection site erythema (10)	**112 (73)**

* Reports received and processed through February 16, 2021

† Frequency of clinically recognized early pregnancy loss for women aged 20–30 years, 9–17%; age 30, 20%; age 40, 40%; age 45, 80%. ACOG Practice Bulletin No. 200: Early Pregnancy Loss. Obstet Gynecol. 2018132(5):e197-e207

Maternal vaccination safety summary

- Pregnant women were not specifically included in pre-authorization clinical trials of COVID-19 vaccines
  - Post-authorization safety monitoring and research are the primary ways to obtain safety data on COVID-19 vaccination during pregnancy
- **Substantial numbers of self-reported pregnant persons (>30,000) have registered in v-safe**
- The reactogenicity profile and adverse events observed among pregnant women **in v-safe did not indicate any safety problem**
- Most (73%) reports to VAERS among pregnant women involved non-pregnancy-specific adverse events (e.g., local and systemic reactions)
- Miscarriage was the most frequently reported pregnancy-specific adverse event to VAERS; numbers are within the known background rates based on presumed COVID-19 vaccine doses administered to pregnant women

Janssen data: all participants

Table 1. Mild Side Effects Among All Study Participants*

	Injection Site Reactions	Fatigue	Chills	Muscle Pain	Joint Pain	Headaches
Moderna	91.6%	68.5%	43.4%	59.6%	44.8%	63%
Pfizer-BioNTech	84.10%	62.90%	31.90%	38.30%	23.60%	55.10%
Janssen Biotech Inc.	48.6%	38.2%	N/A	33.2%	N/A	38.9%

**Fever was the least common side effect reported; see text above for data on frequency of fever*

…..based on data from ongoing and completed clinical trials of Ad26-vectored vaccines including COVID-19, HIV, and Ebola administered to pregnant individuals, overall, the Ad26-based vaccines have an acceptable safety and reactogenicity profile, without significant safety issues identified to date. In addition, the review of the available pregnancy data is not suggestive of a pregnancy-related safety concern (FDA 2021).

Lactating Individuals

ACOG recommends COVID-19 vaccines be offered to lactating individuals. While lactating individuals were not included in most clinical trials, COVID-19 vaccines should not be withheld from lactating individuals who otherwise meet criteria for vaccination. Theoretical concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving the vaccine. There is no need to avoid initiation or discontinue breastfeeding in patients who receive a COVID-19 vaccine (ABM 2020).

No change from prior recs

Individuals Contemplating Pregnancy

Vaccination is strongly encouraged for non-pregnant individuals. Further, ACOG recommends vaccination of individuals who are actively trying to become pregnant or are contemplating pregnancy and meet the criteria for vaccination based on ACIP prioritization recommendations. Additionally, it is not necessary to delay pregnancy after completing both doses of the COVID-19 vaccine.

Importantly, unfounded claims linking COVID-19 vaccines to infertility have been scientifically disproven. ACOG recommends vaccination for all eligible people who may consider future pregnancy. Given the mechanism of action and the safety profile of the mRNA vaccines in non-pregnant individuals, COVID-19 mRNA vaccines are not a cause of infertility. Adenovirus vector vaccines such as the Janssen COVID-19 vaccine cannot replicate following administration, and available data demonstrate that it is cleared from tissues following injection. Because it does not replicate in the cells, the vaccine cannot cause infection or alter the DNA of a vaccine recipient and is also not a cause of infertility (Evans, 2021).

No change from prior recs

If an individual becomes pregnant after the first dose of a COVID-19 vaccine requiring two doses (Pfizer-BioNtech or Moderna), the second dose should be administered as indicated. If an individual receives a COVID-19 vaccine and becomes pregnant within 30 days of receipt of the vaccine, participation in CDC's v-safe program should be encouraged (see below for more information on CDC's v-safe program).

Importantly, routine pregnancy testing is not recommended prior to receiving any EUA-approved COVID-19 vaccine.

COVID Vaccine, Pregnancy, and Lactation

We have a lot of evidence that if you are pregnant and get COVID illness there is a higher chance of severe illness requiring and intensive care unit, death, and risk to the baby by being born too early (premature).

We have a lot of evidence that all of the vaccines are effective in reducing the risk of severe illness and death from COVID. Although pregnant women were not enrolled in these trials, prevention of COVID infection will reduce the risk of severe disease.

There are no trials that have demonstrated the safety of COVID vaccine, but as of Feb 16, 2021, more than 30,000 pregnant women have been vaccinated with Pfizer or Moderna and participated in safety and outcome surveys. There is no evidence of harm in vaccinated pregnant women; pregnancy outcomes are similar to what is expected in the US in general.

Types of vaccine:

(1) Pfizer-BioNTech
(2) Moderna
(3) Johnson and Johnson Jassen

Summary of vaccine differences:

- No vaccine has been studied in pregnancy
- No vaccine will give you COVID (no live virus)
- We now have data on more than 30,000 women who received Pfizer or Moderna in pregnancy without evidence of harm

Pfizer: mRNA based vaccine (new method, tells the cells to make virus protein, not live virus, but does not interact with DNA), 90-95% effective in preventing infection, 2 shots 3-4 weeks apart. Some soreness, fever, and body aches especially after the second shot.

Moderna: mRNA based vaccine (new method, tells the cells to make virus protein, not live virus, but does not interact with DNA), 90-95% effective in preventing infection, 2 shots, 3-4 weeks apart. Some soreness, fever, and body aches especially after the second shot.

Johnson and Johnson: adenovirus vector vaccine (more established approach, tells the DNA to make virus proteins, not live virus), 66% effective in preventing infection but 85% effective in avoiding hospitalization and severe illness in non-pregnant patients. There appears to be less soreness, fever, and body aches compared to the mRNA vaccines.

Do I have to get a COVID vaccine?

No. The decision to receive a vaccine is your choice. COVID vaccine is offered to all pregnant and lactating women because overall the benefit is very likely to outweigh the risks.

How do I choose which vaccine?

Unfortunately, you may not have a choice: the vaccine clinics will be administering the type they have available. If you have a choice, you may use this information to choose. If you arrive for vaccination, you can decline that day but there will not be a guarantee of what type of vaccine might be available the next time. Most experts suggest you accept the vaccine that is offered because all approved vaccines have very similar ability to prevent severe disease and death.

What do the experts say?

The American College of Obstetricians and Gynecologists, the Society for Maternal Fetal Medicine, and the American Academy of Pediatrics all agree that although there are not clinical trial data, the opportunity of benefit in getting the vaccine (reduced chance or severity of disease in people that get the vaccine) is worth any risk: especially since we have a number of pregnant people that have received vaccine. The American College of Obstetricians and Gynecologists, the Society for Maternal Fetal Medicine, and the American Academy of Pediatrics all also recommend the vaccine for people that are breastfeeding. They also agree that if a person chooses not to be vaccinated, that choice is certainly supported. People choosing to not get the vaccine while pregnant can reconsider after birth.

Resources:

https://www.acog.org/womens-health/faqs/coronavirus-covid-19-pregnancy-and-breastfeeding

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

More information by the numbers:

While the side effects are not comfortable, severe illness is rare:

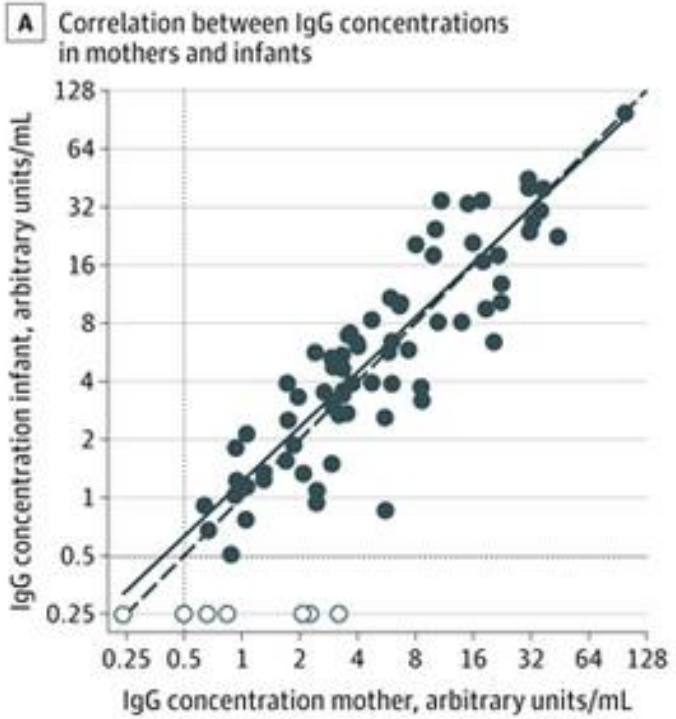
- The most common reason for severe complication from the vaccine is severe allergic reaction which happens 11 per 1,000,000 doses (0.011 per 1000). If nausea and vomiting occur, these are easily managed with commonly used medications and fluids if needed.
- COVID in pregnancy causes severe disease or death about 3 times more commonly in pregnant people. The chances are still low: about 10 per 1000 people need to be in the intensive care unit, 3 per 1000 on a ventilator and 1-2/1000 die.
- These data do not include the risk of early delivery, which is substantially increased with each of these. Of all people with COVID (not necessarily severe symptoms), 4% (40 per 1000) delivered less than 34 weeks-which is considered quite premature and almost always means the infant needs to be in a special care nursery for some time. All of these complications are significantly more likely and serious to the health of mother and baby than vaccine risk.

JAMA Pediatrics | Original Investigation

Assessment of Maternal and Neonatal Cord Blood SARS-CoV-2 Antibodies and Placental Transfer Ratios

Dustin D. Flannery, DO, MSCE; Sigrid Gouma, PhD; Miren B. Dhudasia, MBBS, MPH; Sagori Mukhopadhyay, MD, MMSc; Madeline R. Pfeifer, BS; Emily C. Woodford, BA; Jourdan E. Triebwasser, MD, MA; Jeffrey S. Gerber, MD, PhD; Jeffrey S. Morris, PhD; Madison E. Weirick, BS; Christopher M. McAllister, BS; Marcus J. Bolton, BS; Claudia P. Arevalo, BS; Elizabeth M. Anderson, PhD; Eileen C. Goodwin, BA; Scott E. Hensley, PhD; Karen M. Puopolo, MD, PhD

JAMA, 2021



Journal Pre-proof

COVID-19 vaccine response in pregnant and lactating women: a cohort study

Kathryn J. Gray, MD PhD, Evan A. Bordt, PhD, Caroline Atyeo, BS, Elizabeth Deriso, PhD, Babatunde Akinwunmi, MD MPH MMSc, Nicola Young, BA, Aranxta Medina Baez, BS, Lydia L. Shook, MD, Dana Cvrk, CNM, Kaitlyn James, PhD, MPH, Rose De Guzman, PhD, Sara Brigida, BA, Khady Diouf, MD, Ilona Goldfarb, MD MPH, Lisa M. Bebell, MD, Lael M. Yonker, MD, Alessio Fasano, MD, S. Alireza Rabi, MD, Michal A. Elovitz, MD, Galit Alter, PhD, Andrea G. Edlow, MD, MSc

March, 2021

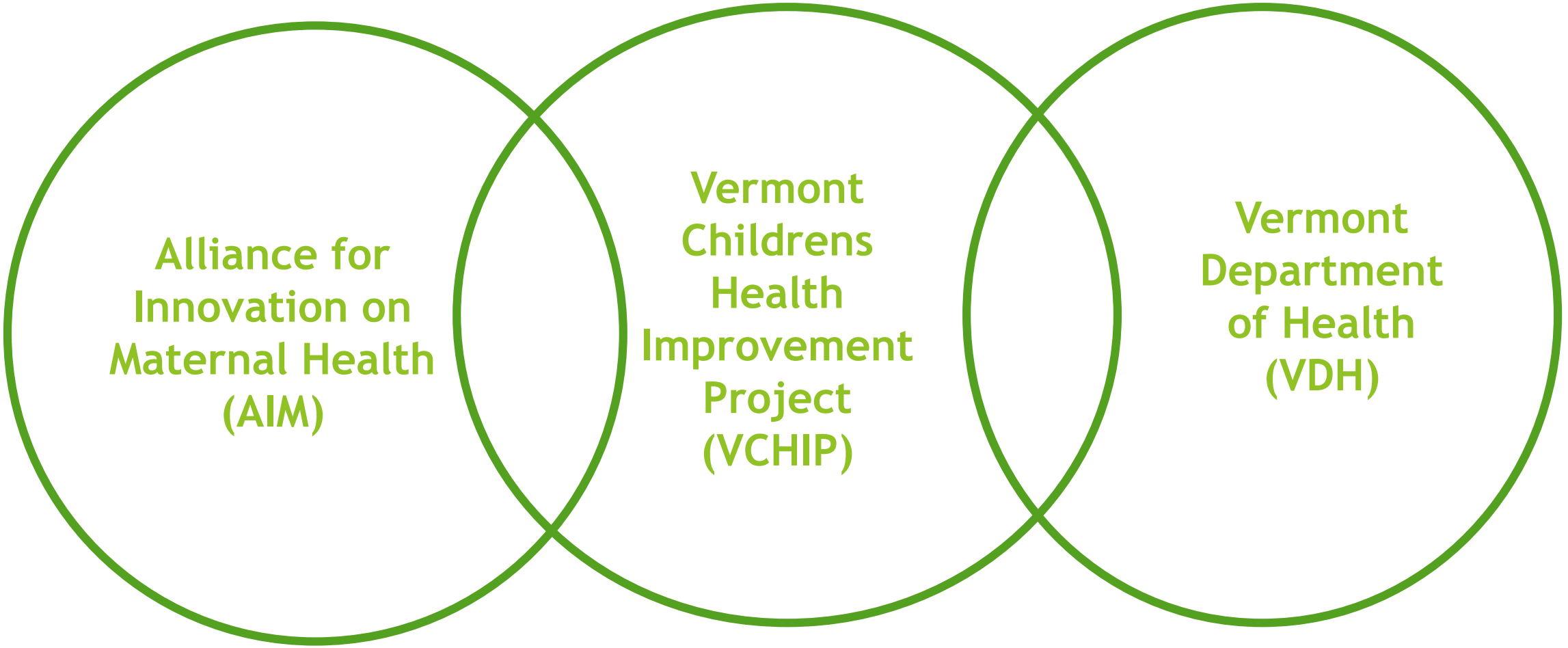
Conclusions: COVID-19 mRNA vaccines generated robust humoral immunity in pregnant and lactating women, with immunogenicity and reactogenicity similar to that observed in non-pregnant women. Vaccine-induced immune responses were significantly greater than the response to natural infection. Immune transfer to neonates occurred via placenta and breastmilk.

Short Story

Excellent safety profile in pregnancy
Excellent immune response
COVID Antibodies cross placenta

Statewide Collaboration

Multiple intersecting projects all with one priority: Perinatal Health and Quality Improvement



VCHIP
Vermont Child Health Improvement Program
UNIVERSITY OF VERMONT LARNER COLLEGE OF MEDICINE

PERINATAL QUALITY COLLABORATIVE VERMONT

Mission: optimizing care and health outcomes in pregnancy and infancy through collaboration and continuous quality improvement.

INTEGRATED DATA TEAM

VCHIP
Vermont Department of Health

Data Sets and Analytics:
All-Payer Database
Public Health Data
Electronic Hospital Record Datasets
VRPHP Community Hospital Data

SENIOR LEADERSHIP TEAM

VCHIP
Vermont Department of Health

Perinatal Clinical Team

Quality Specialist

STAKEHOLDER TEAM

VCHIP
Vermont Department of Health

Medical Community
VT Community Hospitals
Academic Medical Center Faculty

Community Based Care Organizations

Patients and Families

PREGNANCY, NEWBORN & INFANT INITIATIVES

OB Outreach Project

Goal: Improving the health of pregnant persons and neonates through outreach to statewide providers.

AIM: Alliance for Innovation in Maternal Health

Goal: Improving maternal care & reducing maternal morbidities by implementing a series of safety bundles.

STAMPP: Screening, Treatment & Access for Mothers/Perinatal Partners

Goal: Improving the mental health & wellbeing of pregnant/postpartum persons by increased screening for anxiety, depression, substance use & access to care.

ICON: Improving Care for Opioid-exposed Newborns

Goal: Improving health outcomes for opioid dependent pregnant and parenting individuals and opioid-exposed infants.

NSI-VT: Newborn Services Initiative Vermont

Goal: Improving the health of Vermont newborns, their mothers, & families through collaborative statewide initiatives on health care delivery during birth hospitalization.

VRPHP: Vermont Regional Perinatal Health Project

Goal: Provide high-quality academic health care resource for education, skills, competencies & quality improvement in perinatal health care in rural settings.

Cross-cutting elements include: substance use, social determinants of health, mental health, & health equity

Last Updated 2/10/2021

VCHIP
Vermont Child Health Improvement Program
UNIVERSITY OF VERMONT LARNER COLLEGE OF MEDICINE

PERINATAL QUALITY COLLABORATIVE VERMONT

Mission: optimizing care and health outcomes in pregnancy and infancy through collaboration and continuous quality improvement.

SENIOR LEADERSHIP TEAM

VCHIP
Vermont Department of Health

Perinatal Clinical Team

Quality Specialist

STAKEHOLDER TEAM

VCHIP
Vermont Department of Health

Medical Community
VT Community Hospitals
Academic Medical Center Faculty

Community Based Care Organizations

Patients and Families

- Coordinate efforts (and reduce duplication of efforts) re: perinatal quality and childhood health
- NNEPQIN is excellent for wide dissemination of data among rural hospitals
- PQC-VT will loop in state-specific issues and state (and hospital) level data

VCHIP
Vermont Child Health Improvement Program
UNIVERSITY OF VERMONT LARNER COLLEGE OF MEDICINE

PERINATAL QUALITY COLLABORATIVE VERMONT

Mission: optimizing care and health outcomes in pregnancy and infancy through collaboration and continuous quality improvement.

INTEGRATED DATA TEAM

VCHIP
Vermont Department of Health

Data Sets and Analytics:
All-Payer Database
Public Health Data
Electronic Hospital Record Datasets
VRPHP Community Hospital Data

Integrated data are the backbone of QAI efforts

- **Statistics Conferences**
- **AIM: Severe Maternal Morbidity**
- **Focus 1: PPH**
- **Focus 2: HTN**

Severe Maternal Morbidity, VUHDDS, 2015-2018 (n=21,123)
Statewide

Conditions / Procedures	# Codes	Conditions / Procedures	# Codes
Transfusion	149	Disseminated Intravascular Coagulation	48
Eclampsia	26	Renal Failure	20
Septicemia and Sepsis	17	Hysterectomy	16
Acute Myocardial Infarction	14	Ventilation	13
Severe Anesthesia Complications	12	Shock	9
Cerebrovascular Accidents / Stroke / Puerperal Cerebrovascular Disorders	8	Respiratory Distress	7
Pulmonary Edema	7	Thrombotic Embolism	4
Amniotic Fluid Embolism	0	Aneurysm	0
Cardiac Arrest / V Fib / General Heart Failure	0	Heart Failure during Procedure or Surgery	0
Sickle Cell Anemia with Crisis	0	Temporary Tracheostomy	0
Hemorrhage	**1576**		
Any SMM, including Transfusion (Total number of deliveries)	314	Any SMM, excluding Transfusion (Total number of deliveries)	177

- You will hopefully see hospital based statistics related to Severe Maternal Morbidity more frequently
- Coding is an issue nationally: the only way to get at that is to look at the coding data and work backwards
- We will continue to work on this together with the AIM initiative

Severe Maternal Morbidity, VUHDDS, 2015-2018
Rate per 10,000 deliveries, by hospital

Hospital Number	Total Deliveries	SMM including transfusions	SMM excluding transfusions	Influence of 1 case on rate
1	1506	93	27	7
2	811	247	148	12
3	829	133	48	12
4	786	76	13	13
5	8671	142	115	1
6	1288	101	39	8
8	1390	86	50	7
9	1396	79	50	7
10	725	110	14	14
15	1210	281	182	8
16	1852	259	49	5
Statewide	21,123	149	84	0.5

VCHIP
Vermont Child Health Improvement Program
UNIVERSITY OF VERMONT LARNER COLLEGE OF MEDICINE

PERINATAL QUALITY COLLABORATIVE VERMONT

Mission: optimizing care and health outcomes in pregnancy and infancy through collaboration and continuous quality improvement.

INTEGRATED DATA TEAM

VCHIP
Vermont Department of Health

Data Sets and Analytics:
All-Payer Database
Public Health Data
Electronic Hospital Record Datasets
VRPHP Community Hospital Data

SENIOR LEADERSHIP TEAM

VCHIP
Vermont Department of Health

Perinatal Clinical Team

Quality Specialist

STAKEHOLDER TEAM

VCHIP
Vermont Department of Health

Medical Community
VT Community Hospitals
Academic Medical Center Faculty

Community Based Care Organizations

Patients and Families

PREGNANCY, NEWBORN & INFANT INITIATIVES

OB Outreach Project

Goal: Improving the health of pregnant persons and neonates through outreach to statewide providers.

AIM: Alliance for Innovation in Maternal Health

Goal: Improving maternal care & reducing maternal morbidities by implementing a series of safety bundles.

STAMPP: Screening, Treatment & Access for Mothers/Perinatal Partners

Goal: Improving the mental health & wellbeing of pregnant/postpartum persons by increased screening for anxiety, depression, substance use & access to care.

ICON: Improving Care for Opioid-exposed Newborns

Goal: Improving health outcomes for opioid dependent pregnant and parenting individuals and opioid-exposed infants.

NSI-VT: Newborn Services Initiative Vermont

Goal: Improving the health of Vermont newborns, their mothers, & families through collaborative statewide initiatives on health care delivery during birth hospitalization.

VRPHP: Vermont Regional Perinatal Health Project

Goal: Provide high-quality academic health care resource for education, skills, competencies & quality improvement in perinatal health care in rural settings.

Cross-cutting elements include: substance use, social determinants of health, mental health, & health equity

Last Updated 2/10/2021

Thank you