COVID-19 Vaccine During Pregnancy & Lactation?

M. Lynn Yonekura, M.D.
Director, Community Health
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Dignity Health™
California Hospital Medical Center

To Vaccinate or Not To Vaccinate?

Risks

Benefits

Are Pregnant Women at Increased Risk for More Severe COVID-19 Illness?

- Jan. 22 - Oct.3, 2020
- 1,300,938 women aged 15-44 yr with laboratory-confirmed, SARS-CoV-2 acute infection in U.S.
  - 461,825 (35.5%) had pregnancy status; 409,462 (88.7%) symptomatic
  - Among symptomatic women, 23,434 (5.7%) were pregnant
- After adjusting for age, race/ethnicity, and underlying medical conditions, **pregnant women were significantly more likely than nonpregnant women to b**e:
  - **Admitted to ICU** (10.5 vs. 3.9/1,000 cases; aRR=2.9; 95% CI 2.6-3.4)
  - **Receive invasive ventilation** (2.9 vs. 1.1/1,000 cases; aRR=2.9; 95% CI 2.2-3.8)
  - **Receive ECMO** (0.7 vs. 0.3/1,000 cases; aRR=2.4; 95% CI1.5-4.0)
  - **Die** (1.5 vs. 1.2/1,000 cases; aRR=1.7; 95% CI 1.2-2.4)

MMWR 2020; 69:1641-1647

Are Pregnant Women at Increased Risk for More Severe COVID-19 Illness? (continued)

- **Pregnant women were more frequently Hispanic (29.7%)** and less frequently White (23.5%) compared with nonpregnant women (22.6% Hispanic and 31.7% White)
- Irrespective of pregnancy status, ICU admissions, receipt of invasive ventilation, and death occurred more often among women aged 35-44 yr. than among those aged 15-24 yr.
- Pregnant women were at **70% increased risk of death** compared to nonpregnant women.
- Whereas **Black women** made up 14.1% of women included in this analysis, they represented 36.6% of deaths overall, including 26.5% deaths among pregnant women and 37.4% deaths among nonpregnant women.
- Among **Hispanic women**, pregnancy was associated with 2.4 times the risk for death (95% CI=1.3-4.3)

MMWR 2020; 69:1641-1647

Are Pregnant Women at Increased Risk for More Severe COVID-19 Illness? (continued)

- Increased risk for ICU admission among pregnant women was particularly notable for **Asian** women (aRR=6.6; 95% CI=4.0-11.0) and **Native Hawaiian/Pacific Islander** women(aRR=3.7; 95% CI=1.3-10.1)
- Risk for receiving invasive ventilation among pregnant women aged 15-24 yr was 3.0 times that of nonpregnant women (95% CI=1.6-5.7) and among pregnant women aged 35-44 yr. was 3.6 times that of nonpregnant women (95% CI=2.4-5.4)

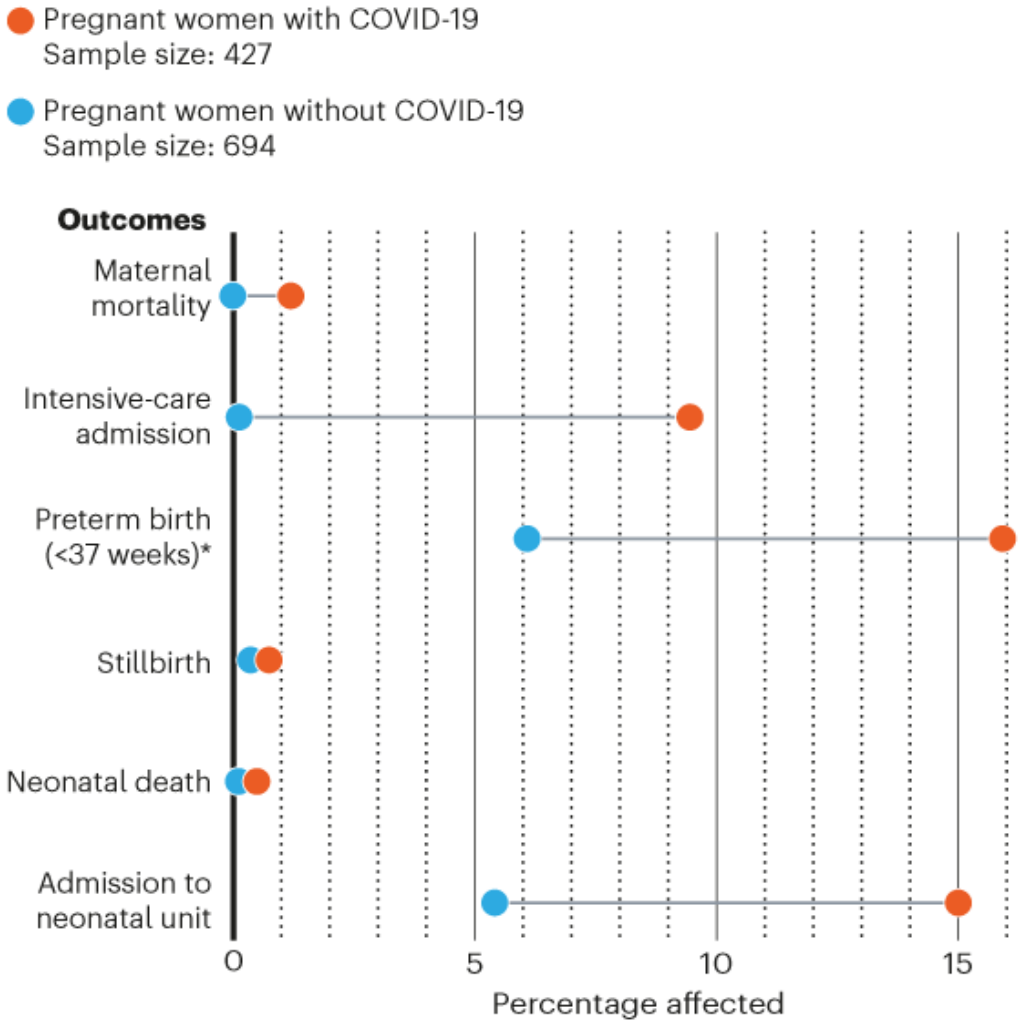
MMWR 2020; 69:1641-1647

Are Pregnant Women at Increased Risk for More Severe COVID-19 Illness? (continued)

- **Pregnant women with co-morbidities** such as obesity and diabetes may be at an even higher risk of severe illness, consistent with the general population with similar co-morbidities.

MMWR 2020; 69:669-775
MMWR 2020; 69:1355-1359
BMJ 2020; 369:m2107
MMWR 2020; 69:1641-1647

COVID Risks in Pregnancy



*Sample sizes: 44 pregnant women with COVID-19; 295 pregnant women without COVID-19

Nature **591**, 193-195 (2021)

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What is the impact of COVID-19 infection during pregnancy on the fetus and newborn? (continued)

- No increased risk of congenital anomalies
  - MMWR 2020; 69:1635-1640
- No increased risk of miscarriage
- COVID-19 infection during pregnancy is associated with an **increased risk for prematurity**
  - A study in Spain documented a 3 x increased risk for prematurity.
    - Pediatrics 2021; 147:e2020015065
  - A CDC study of 598 pregnant women with COVID-19 infection had a prematurity rate of 12.6% among live births, 25% higher than the rate of prematurity for the general population. Moreover, preterm births occurred 3 x more frequently in symptomatic pregnant women than in those who were asymptomatic.
    - MMWR 2020; 69:1347-1354
- The increased SB rate during the pandemic documented worldwide was not directly related to maternal COVID-19 infection.

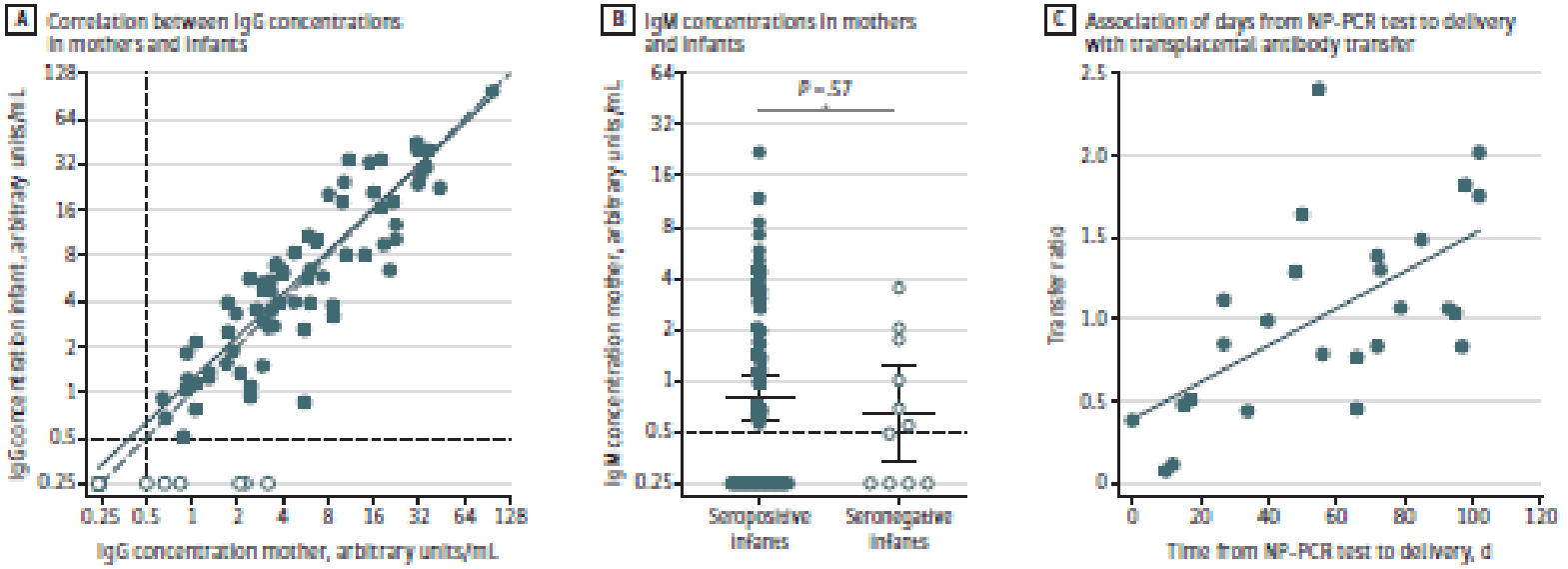
If the mother contracts COVID-19 infection during pregnancy, can she infect her fetus or newborn?

- 3 potential routes of maternal transfer of SARS-CoV-2 to the infant:
  - Intrauterine transmission through transplacental hematogenous spread or viral particles in amniotic fluid that are ingested or inhaled by the fetus.
  - Intrapartum transmission after exposure to maternal infected secretions or feces around the time of delivery
  - Postpartum transmission from an infected mother, family member, or health care worker or (theoretically) through breast milk
- A national, active surveillance study of neonatal SARS-CoV-2 infection in the UK found that neonatal infection is rare, with 5.6 cases/10,000 LB at the UK peak during March-April 2020.
  - 3% had possible vertical transmission; 12% nosocomial transmission
  - 42% had severe neonatal SARS-CoV-2 infection (2.4 cases/10,000 LB)
  - 24% prematurity rate

Lancet Child Adolesc Health 2021; 5:113-121

What is the Association Between Maternal and Neonatal SARS-CoV-2-Specific Antibody Concentrations?

Figure 2. Correlation Between Maternal and Neonatal Cord Sera Severe Acute Respiratory Syndrome Coronavirus 2-Specific Antibody Concentrations



A, Correlation between IgG concentrations in sera from seropositive women and matched cord blood from seropositive (n = 72; filled circles) and seronegative (n = 11; open circles) infants. IgG concentrations in cord blood positively correlate with maternal IgG concentrations ($r = 0.886$; $P < .001$). B, IgM concentrations in sera from seropositive women with seropositive (n = 72; filled circles) and seronegative (n = 11; open circle) infants. Horizontal lines represent geometric mean titers and error bars indicate the 95% CI ($P = .57$ using an unpaired t test on $\log_2$-transformed IgM concentrations). In panels A and B, the horizontal dashed line indicates 0.48 arbitrary units/mL, which was the cutoff used to distinguish positive vs negative samples. Samples that were below this cutoff were assigned an antibody concentration of 0.24 arbitrary units/mL. C, Association of duration in days from nasopharyngeal polymerase chain reaction (NP-PCR) test to delivery with transplacental antibody transfer. Transfer ratio of IgG antibodies from mother to infant (n = 26 matched mother-infant dyads) is positively correlated with days from NP-PCR test to delivery ($r = 0.620$; $P < .001$).

Efficient transplacental transfer of SARS-CoV-2 IgG antibodies supports the potential for maternally derived antibodies to provide neonatal protection from SARS-CoV-2 infection.

JAMA Pediatr. Doi:10.1001/jamapediatrics.2021.0038

If a mother with acute COVID-19 infection breastfeeds her newborn, can she transmit SARS-CoV-2 to him?

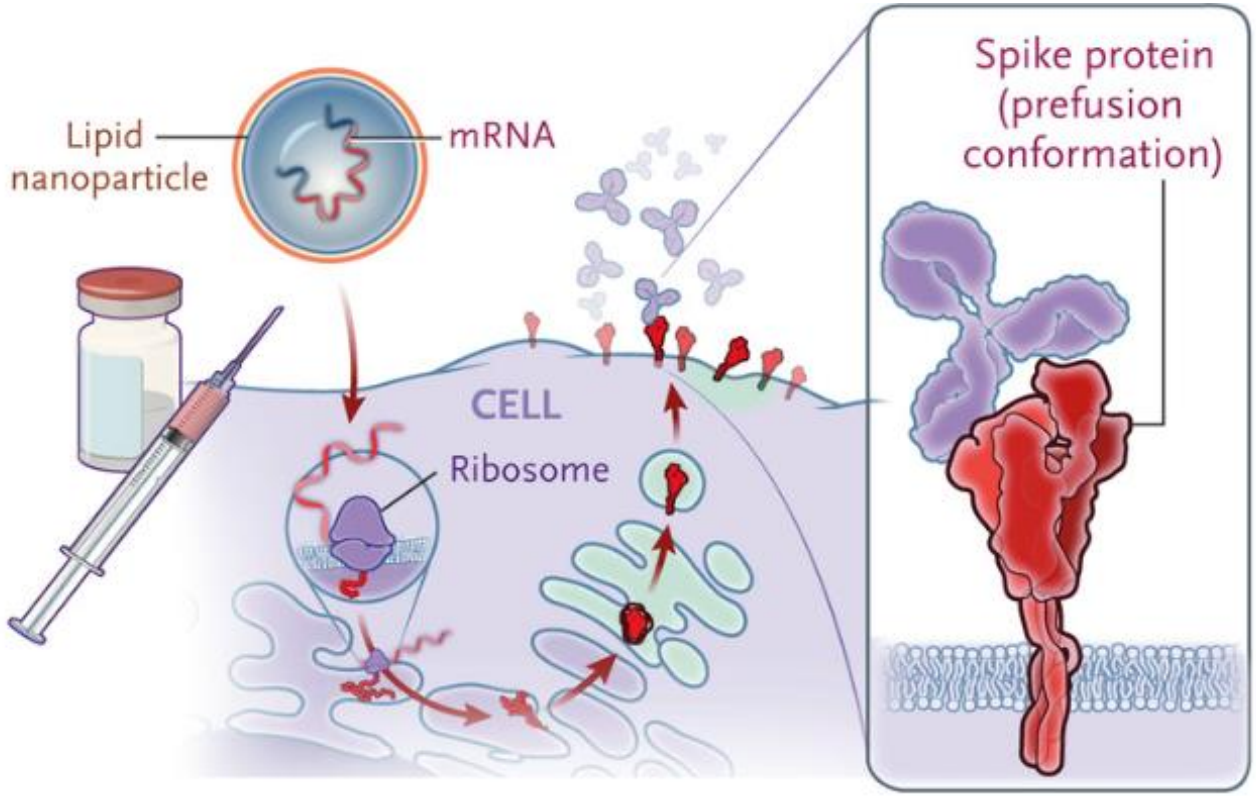
- As long as the mother wears a mask and washes her hands and breasts with soap and water before handling her newborn, there is no evidence that SARS-CoV-2 can be transmitted from the infected mother to her neonate via breast milk; rather, breast milk may be beneficial by providing protective antibodies against SARS-CoV-2 infection

- Breastfeed Med 2020; 15:351-352
- Am J Perinatol 2020;10.1055/s-0040-1714277
- NeoReviews 2021; 22(5).10.1542/neo.22-5-e1001

Vaccines for COVID-19

FDA issued EUA for Pfizer-BioNTech vaccine on 12/11/20 and for Moderna vaccine on 12/18/20

mRNA Vaccines for COVID-19

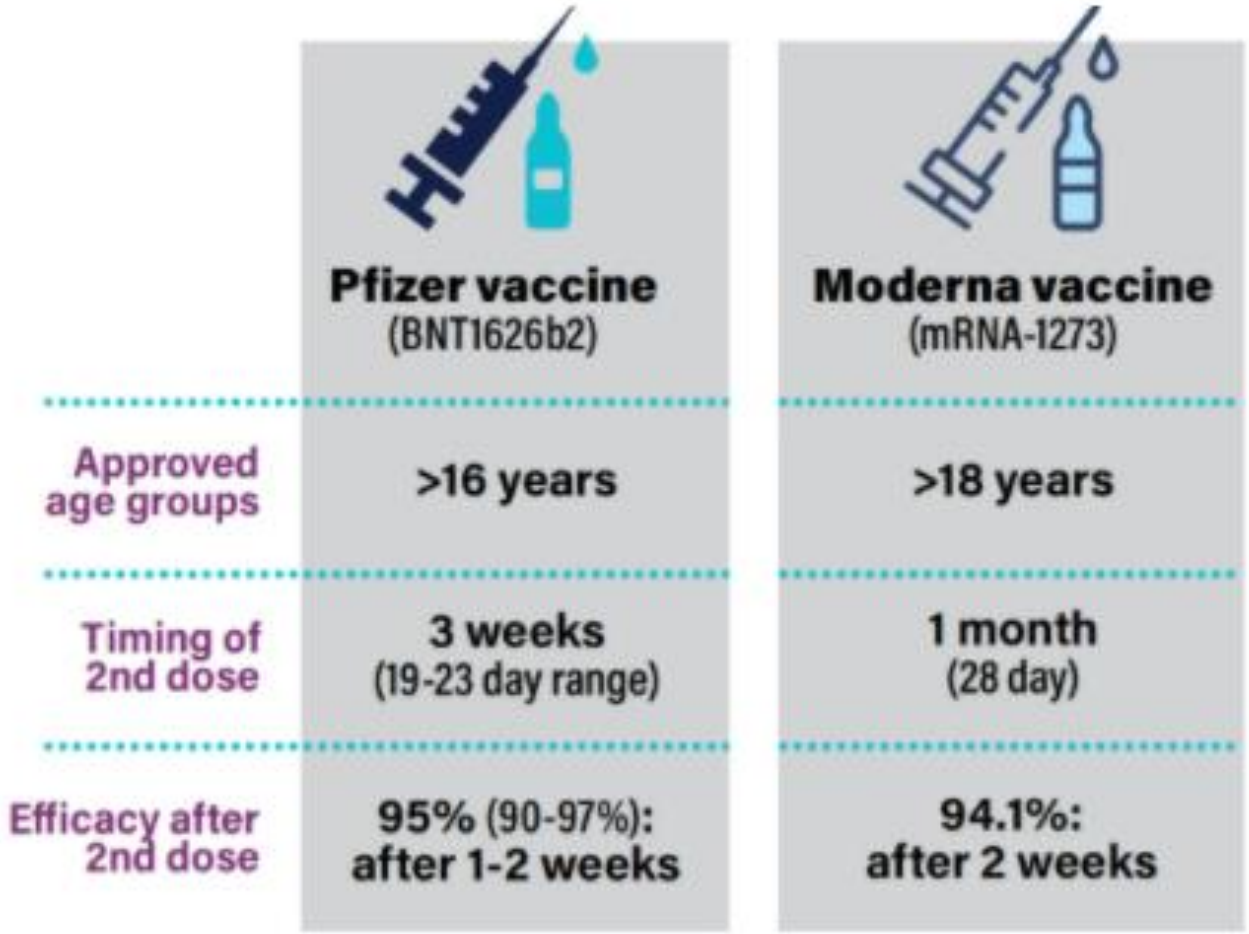


Ingredients of mRNA Vaccines for COVID-19

TABLE I. Ingredients of the Pfizer-BioNTech and Moderna COVID-19 vaccines

Ingredients	Pfizer-BioNTech	Moderna
Active	Nucleoside-modified mRNA encoding the viral spike glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike glycoprotein of SARS-CoV-2
Inactive—lipids	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102 (proprietary to Moderna)
	2[(PEG)-2000]-*N*,*N*-ditetradecylacetamide	PEG 2000 dimyristoyl glycerol
	1,2-Distearoyl-sn-glycero-3-phosphocholine	1,2-Distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
Inactive—salts, sugars, buffers	Potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dehydrate	Tromethamin, Tromethamin hydrocholoride, acetid acid, sodium acetate
	Sugar (sucrose)	Sugar (sucrose)
	Diluent (sodium chloride)	Diluent (none)

mRNA Vaccines for COVID-19



Side Effects Associated with mRNA Vaccines to COVID-19

- Fever greater than 38◦C occurred in:
  - 3.7% after first dose and 15.8% after second dose of Pfizer-BioNtech vaccine
  - 0.8% after first dose and 15.6% after second dose of Moderna vaccine
- Mild Side Effects Among Study Participants

	Injection site reaction	Fatigue	Chills	Muscle pain	Joint pain	Headaches
Pfizer-BioNtech	84.10%	62.90%	31.90%	38.30%	23.60%	55.10%
Moderna	91.6%	68.5%	43.4%	59.6%	44.8%	63%

- Allergic reactions including anaphylaxis have reported to be rare:
  - 5 cases/million doses administered for the Pfizer-BioNtech vaccine
  - 2.8 cases/million doses administered for the Moderna vaccine

Reactogenicity After Receiving mRNA-Based COVID-19 Vaccines

Table. Solicited Local and Systemic Reactions[a] to mRNA-Based COVID-19 Vaccines Reported 0 to 7 Days After Vaccination—Centers for Disease Control and Prevention V-safe Surveillance System, December 14, 2020, to February 28, 2021

	No. (%)					
	Dose 1			Dose 2		
Reaction	Both vaccines (N = 3 643 918)	Pfizer-BioNTech (n = 1 659 724)	Moderna (n = 1 984 194)	Both vaccines (N = 1 920 872)	Pfizer-BioNTech (n = 971 375)	Moderna (n = 949 497)
Any injection site reaction	2 550 710 (70.0)	1 085 242 (65.4)	1 465 468 (73.9)	1 443 899 (75.2)	666 635 (68.6)	777 264 (81.9)
Pain	2 472 373 (67.8)	1 055 604 (63.6)	1 416 769 (71.4)	1 389 629 (72.3)	645 917 (66.5)	743 712 (78.3)
Redness	204 097 (5.6)	56 780 (3.4)	147 317 (7.4)	240 265 (12.5)	57 956 (6.0)	182 309 (19.2)
Swelling	379 539 (10.4)	110 077 (6.6)	269 462 (13.6)	348 986 (18.2)	100 430 (10.3)	248 556 (26.2)
Itching	197 441 (5.4)	62 486 (3.8)	134 955 (6.8)	214 658 (11.2)	60 946 (6.3)	153 712 (16.2)
Any systemic reaction[a]	1 823 068 (50.0)	797 410 (48.0)	1 025 658 (51.7)	1 333 931 (69.4)	623 746 (64.2)	710 185 (74.8)
Fatigue	1 127 638 (30.9)	483 146 (29.1)	644 492 (32.5)	1 034 462 (53.9)	464 659 (47.8)	569 803 (60.0)
Headache	943 607 (25.9)	409 359 (24.7)	534 248 (26.9)	897 005 (46.7)	392 266 (40.4)	504 739 (53.2)
Myalgia	705 100 (19.4)	281 743 (17.0)	423 357 (21.3)	845 314 (44.0)	357 381 (36.8)	487 933 (51.4)
Chills	321 009 (8.8)	116 034 (7.0)	204 975 (10.3)	600 354 (31.3)	220 831 (22.7)	379 523 (40.0)
Fever	314 676 (8.6)	116 951 (7.0)	197 725 (10.0)	566 112 (29.5)	208 976 (21.5)	357 136 (37.6)
Joint pain	317 034 (8.7)	123 319 (7.4)	193 715 (9.8)	492 031 (25.6)	192 926 (19.9)	299 105 (31.5)
Nausea	275 423 (7.6)	114 087 (6.9)	161 336 (8.1)	319 248 (16.6)	127 454 (13.1)	191 794 (20.2)
Vomiting	25 425 (0.7)	9966 (0.6)	15 459 (0.8)	31 056 (1.6)	11 276 (1.2)	19 780 (2.1)
Diarrhea	189 878 (5.2)	83 016 (5.0)	106 862 (5.4)	133 877 (7.0)	60 641 (6.2)	73 236 (7.7)
Abdominal pain	111 044 (3.0)	47 096 (2.8)	63 948 (3.2)	117 494 (6.1)	48 129 (5.0)	69 365 (7.3)
Rash outside of injection site	42 409 (1.2)	17 765 (1.1)	24 644 (1.2)	32 686 (1.7)	13 132 (1.4)	19 554 (2.1)

[a] Systemic reactions do not include allergic reactions or anaphylaxis.

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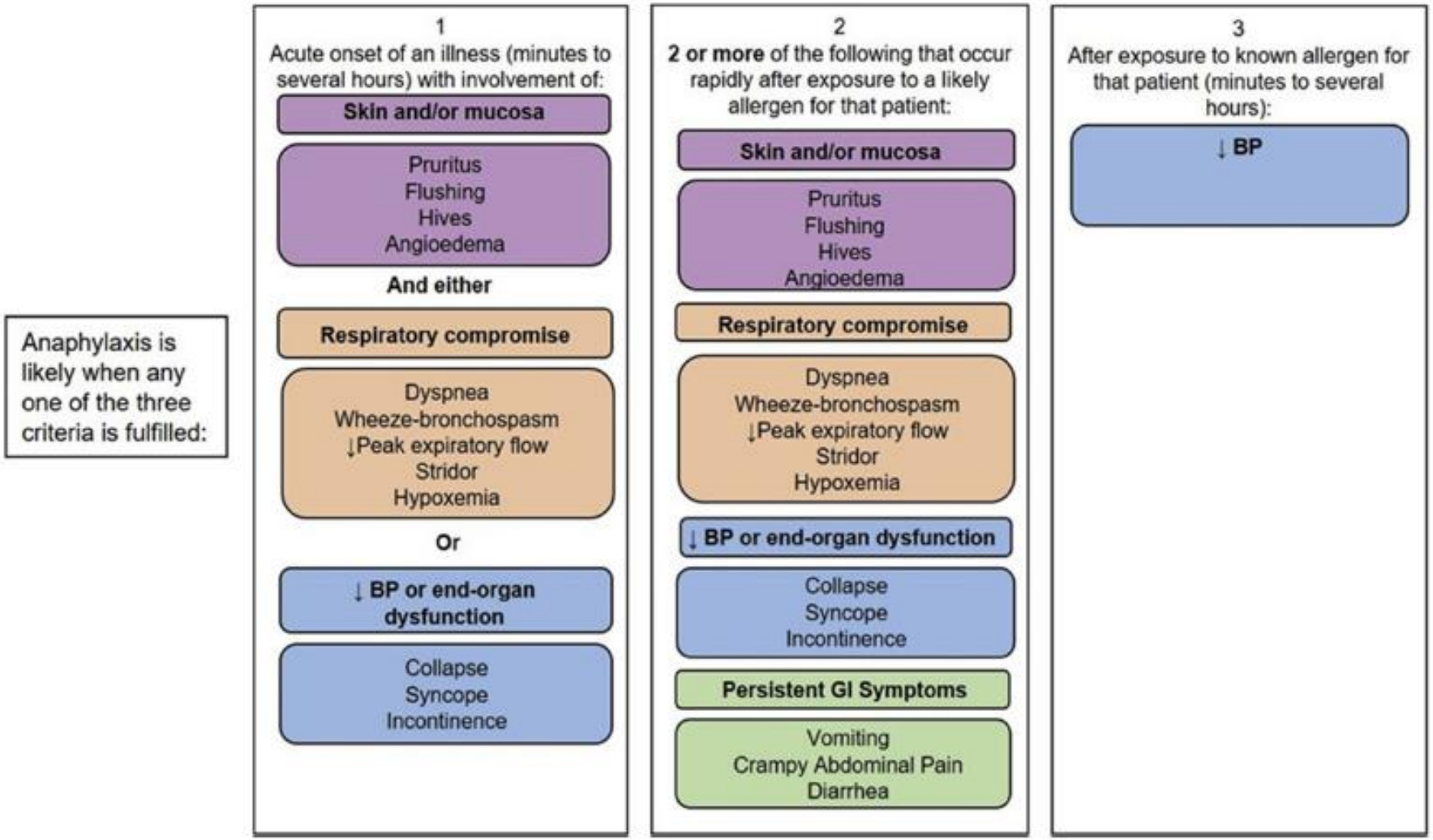
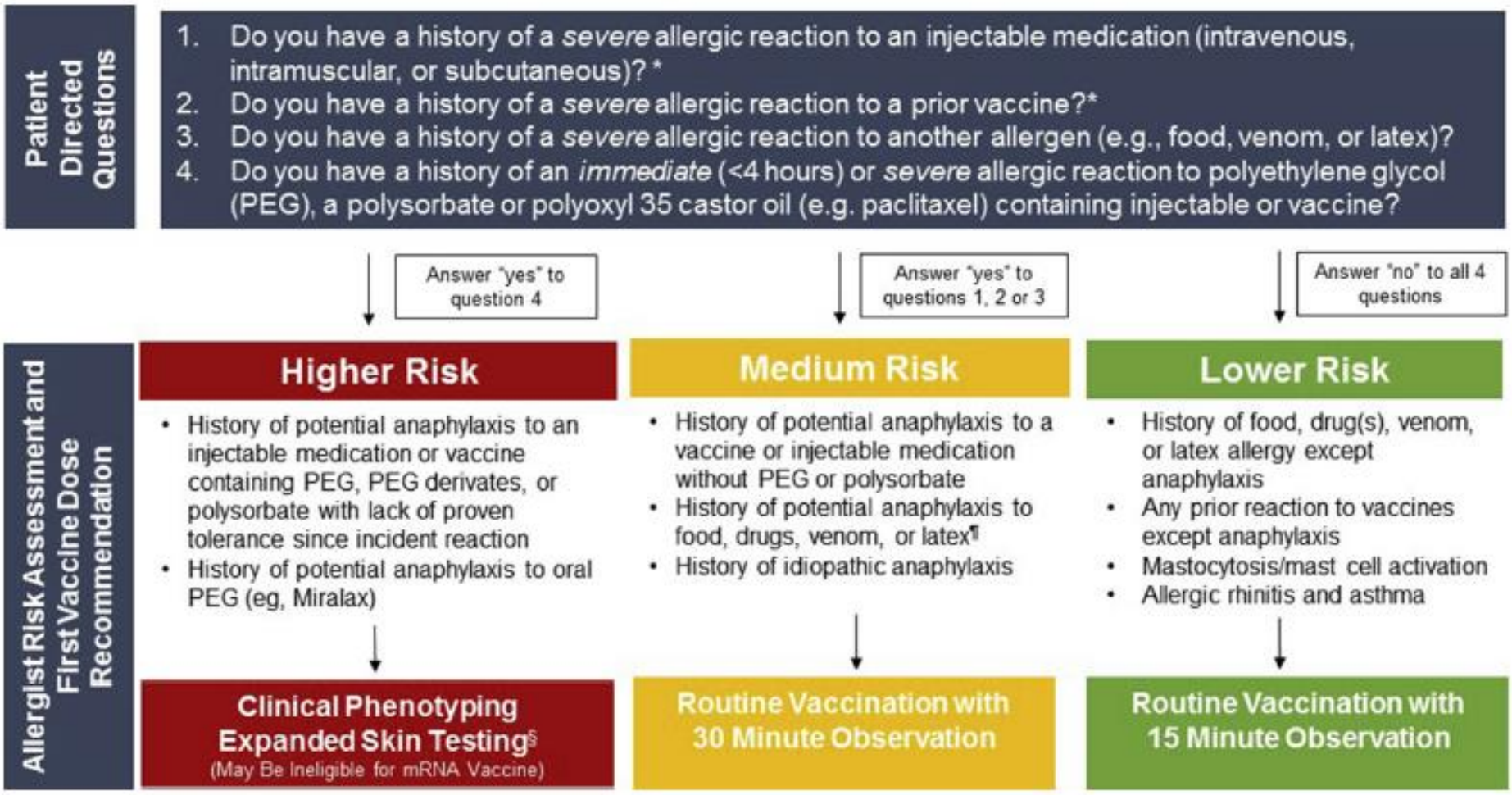
JAMA 2021;325:E1-2
doi:10.1001/jama.2021.5374

Anaphylaxis




Patient Directed Questions
1. Do you have a history of a *severe* allergic reaction to an injectable medication (intravenous, intramuscular, or subcutaneous)? *
2. Do you have a history of a *severe* allergic reaction to a prior vaccine?*
3. Do you have a history of a *severe* allergic reaction to another allergen (e.g., food, venom, or latex)?
4. Do you have a history of an *immediate* (<4 hours) or *severe* allergic reaction to polyethylene glycol (PEG), a polysorbate or polyoxyl 35 castor oil (e.g. paclitaxel) containing injectable or vaccine?
Answer "yes" to question 4
Answer "yes" to questions 1, 2 or 3
Answer "no" to all 4 questions
Allergist Risk Assessment and First Vaccine Dose Recommendation
Higher Risk
• History of potential anaphylaxis to an injectable medication or vaccine containing PEG, PEG derivates, or polysorbate with lack of proven tolerance since incident reaction
• History of potential anaphylaxis to oral PEG (eg, Miralax)
Clinical Phenotyping Expanded Skin Testing§
(May Be Ineligible for mRNA Vaccine)
Medium Risk
• History of potential anaphylaxis to a vaccine or injectable medication without PEG or polysorbate
• History of potential anaphylaxis to food, drugs, venom, or latex¶
• History of idiopathic anaphylaxis
Routine Vaccination with 30 Minute Observation
Lower Risk
• History of food, drug(s), venom, or latex allergy except anaphylaxis
• Any prior reaction to vaccines except anaphylaxis
• Mastocytosis/mast cell activation
• Allergic rhinitis and asthma
Routine Vaccination with 15 Minute Observation

Pfizer, BioNTech start testing COVID-19 vaccine in pregnant women

- In early February the NIH called for greater inclusion of pregnant and lactating women in COVID-19 vaccine research
- Pfizer Inc. and BioNTech SE have started an international study with 4,000 healthy pregnant volunteers to evaluate the safety and efficacy of their COVID-19 vaccine.
- The new study will test pregnant women aged 18 and older in the United States, Canada, Argentina, Brazil, Chile, Mozambique, South Africa, the UK and Spain.
- Women will receive the vaccine during weeks 24-34 of gestation, getting two shots 21 days apart - the same regimen used in the larger clinical trial
- Postpartum women who received placebo will be given an opportunity to receive the actual vaccine while remaining in the study.
- The study will also assess whether pregnant women transfer protective antibodies to their newborns.

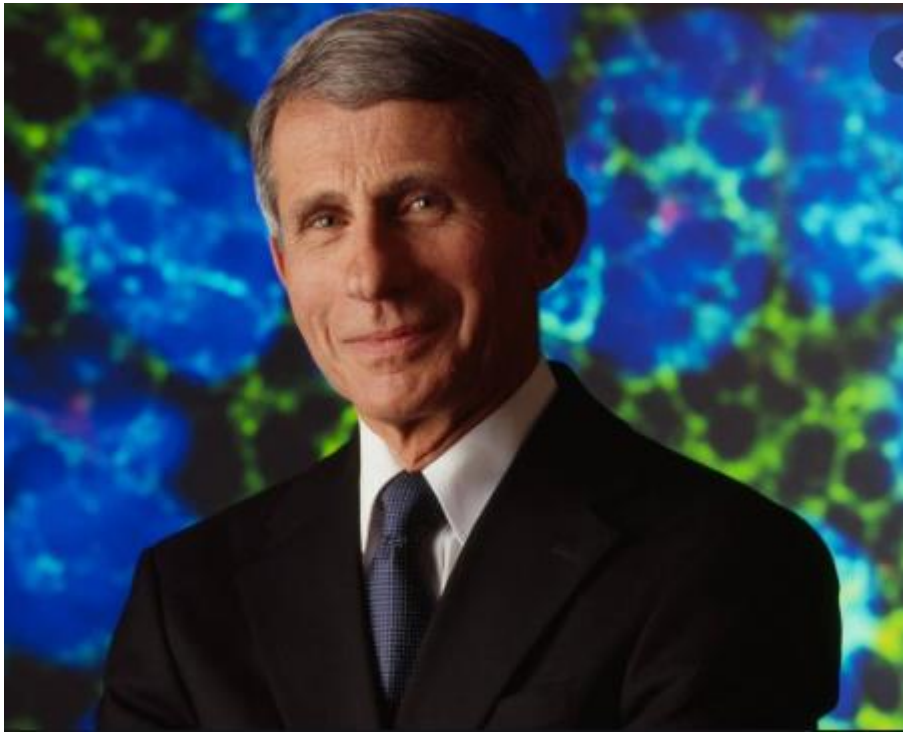
What is the impact of mRNA SARS-CoV-2 vaccines during pregnancy on the fetus and newborn?

- Data from Developmental and Reproductive Toxicity (DART) studies provide the first safety data to help inform the use of a vaccine in pregnancy until there is more data in humans.
  - Animal studies using both mRNA SARS-CoV-2 vaccines do not indicate direct or harmful effects with respect to female reproduction, pregnancy, embryo/fetal development, parturition, or post-natal development.
- As of Jan. 20, 2021, there have been over 15,000 pregnancies reported in CDC's V-SAFE post-vaccination health checker; CDC is also enrolling pregnant individuals in a pregnancy registry.
  - Evidence gathered through these systems will provide clinicians with critical needed data to inform future recommendations re COVID-19 vaccination during pregnancy.

Fauci says 20K pregnant women got COVID-19 vaccine with 'no red flags'

By Kenneth Garger

February 10, 2021 | 8:38pm | Updated



V-safe pregnancy registry outcomes of interest in COVID-19 vaccinated pregnant women as of February 18, 2021 (N=275 completed pregnancies)

Pregnancy Outcomes	Background Rate	V-safe Pregnancy Registry Overall
Miscarriage (<20 weeks)	26%	15%
Stillbirth (≥20 weeks)	0.6%	1%
Pregnancy Complications	**Background Rate**	**V-safe Pregnancy Registry Overall**
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
Neonatal	**Background Rate**	**V-safe Pregnancy Registry Overall**
Preterm birth	10.10%	10%
Congenital anomalies	3%	4%
Small for gestational age	3-7%	4%
Neonatal death	0.38%	0%

Source: Shimabukuro T. COVID-19 vaccine safety update. Advisory Committee on Immunization Practices

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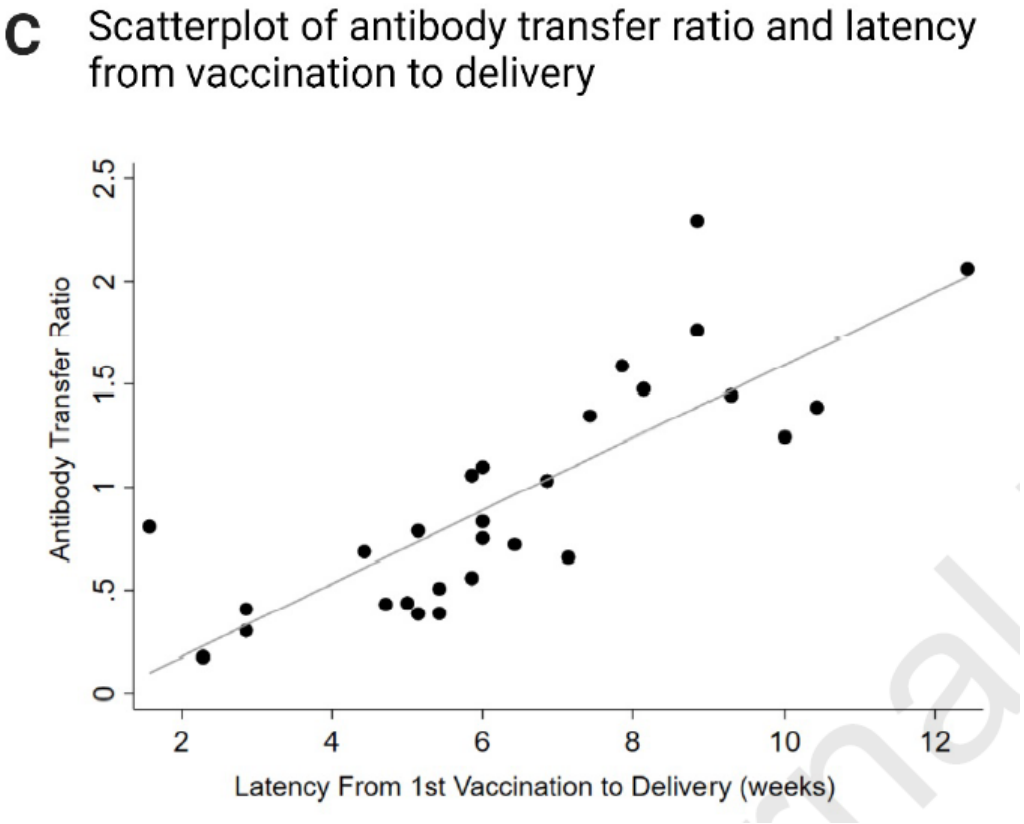
Association Between Latency from First Vaccine Dose and Antibody Transfer Ratio (Infant IgG/Maternal IgG)



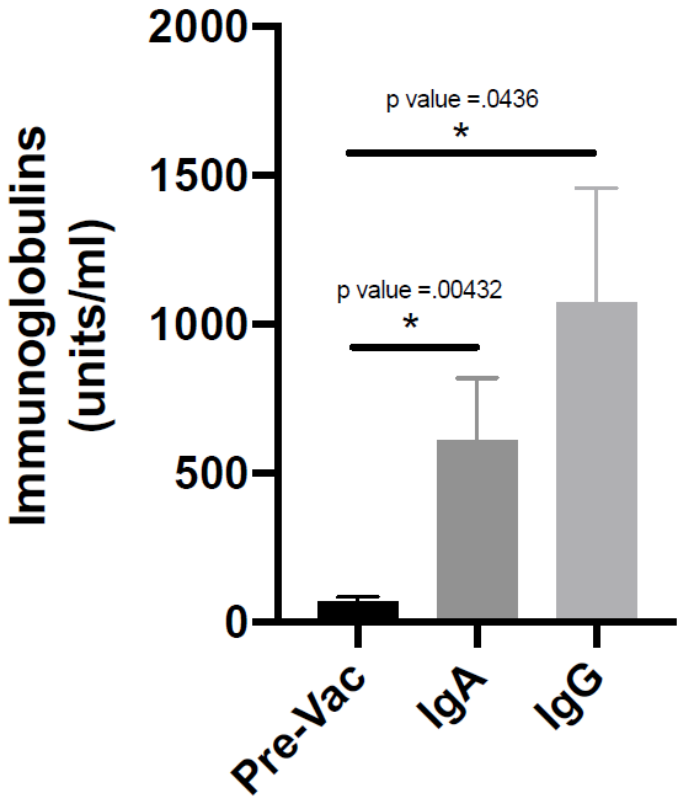
- Most pregnant women who had SARS-CoV-2 mRNA vaccine in 3rd trimester had transplacental transfer of IgG to infant
- The observed mean IgG transfer ratio was ~1
- The transfer ratio appears to increase with latency from vaccine

doi.org/10.1016/j.ajog.2021.03.035

SARS-CoV-2 antibodies detected in human breast milk postvaccination

Objective: To determine whether SARS-CoV-2 specific immunoglobins are found in breast milk post-vaccination, and to characterize the time course and types of immunoglobulins present.
Participants: Six lactating women who planned to receive both doses of the Pfizer-BioNTech or Moderna vaccine between December 2020 and January 2021. Breast milk samples were collected pre-vaccination and at 11 additional timepoints, with last sample at 14 days post 2nd dose of vaccine.
Exposure: Two doses of Pfizer-BioNTech or Moderna SARS-CoV-2 vaccine.
Main Outcome(s) and Measure(s): Levels of SARS-CoV-2 specific IgA and IgG immunoglobulins in breast milk.
Conclusions and Relevance: We are the first to show that maternal vaccination results in SARS-CoV-2 specific immunoglobulins in breast milk that may be protective for infants

Figure 1: Histogram of pre- and post- vaccination (Day 11 post-boost) levels (in ng/mL) of anti-SARS-CoV-2 spike IgG and IgA in breast milk (n=5).



medRxiv preprint doi: https://doi.org/10.1101/2021.02.23.21252328

“The Giving Tree?”
FDA issued EUA for J & J vaccine on 2/27/21

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COVID-19 Vaccine Information Chart

As of March 2021, the FDA has granted Emergency Use Authorization (EUA) for three COVID-19 vaccines, and has determined that while the vaccines have several differences, all three are very safe and highly effective at preventing hospitalization and death from COVID-19 disease. The table below summarizes important features of each vaccine.

Pfizer	Moderna	Janssen/Johnson & Johnson
2 doses	2 doses	1 dose
Approximately 21 days between doses	Approximately 28 days between doses	n/a
Newer technology (mRNA)*	Newer technology (mRNA)*	More traditional vaccine technology (viral vector)**
Contains no COVID-19 virus	Contains no COVID-19 virus	Contains no COVID-19 virus
95% effective at preventing symptomatic COVID-19 illness	94% effective at preventing symptomatic COVID-19 illness	66% effective at preventing symptomatic COVID-19 illness, 74% effective at preventing asymptomatic illness
No deaths during clinical trials	No deaths during clinical trials	No deaths during clinical trials
Authorized for age 16 and over	Authorized for age 18 and over	Authorized for age 18 and over
Possible side effects include mild to moderate flu-like symptoms (headache, body ache) and soreness at injection site	Possible side effects include mild to moderate flu-like symptoms (headache, [body ache) and soreness at injection site	Possible side effects include mild to moderate flu-like symptoms (headache, body ache) and soreness at injection site
Can be considered for pregnant and breastfeeding women, talk to your doctor about what is right for you	Can be considered for pregnant and breastfeeding women, talk to your doctor about what is right for you	Can be considered for pregnant and breastfeeding women, talk to your doctor about what is right for you
May require routine booster vaccines to manage variant strains. No boosters yet needed.	May require routine booster vaccines to manage variant strains. No boosters yet needed.	May require routine booster vaccines to manage variant strains. No boosters yet needed.

More to Know

* mRNA vaccines (Pfizer and Moderna) allow your body to quickly identify, remember, and respond to a virus even if it changes over time. Scientists have been studying mRNA vaccines for over 10 years.

** The Janssen/Johnson & Johnson vaccine utilizes an adenovirus to enter the cell and create proteins that trigger the immune system to react defensively against COVID-19.

- All available vaccines provide extremely strong protection against severe COVID-19 and significantly reduce the likelihood of hospitalization or death. The Janssen/Johnson & Johnson vaccine has been tested against variant strains not present during the Pfizer and Moderna clinical trials.
- If you are prone to severe allergic reactions, please speak with your doctor or provider before vaccination.

CDC HEALTH ALERT

Distributed via the CDC Health Alert Network
April 13, 2021, 1:00 PM ET
CDCHAN-00442

Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine

Summary
As of April 12, 2021, approximately 6.85 million doses of the Johnson & Johnson (J&J) COVID-19 vaccine (Janssen) have been administered in the United States. The Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) are reviewing data involving six U.S. cases of a rare type of blood clot in individuals after receiving the J&J COVID-19 vaccine that were reported to the Vaccine Adverse Event Reporting System (VAERS). In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). All six cases occurred among women aged 18–48 years. The interval from vaccine receipt to symptom onset ranged from 6–13 days. One patient died. Providers should maintain a high index of suspension for symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the J&J COVID-19 vaccine. When these specific types of blood clots are observed following J&J COVID-19 vaccination, treatment is different from the treatment that might typically be administered for blood clots. Based on studies conducted among the patients diagnosed with immune thrombotic thrombocytopenia after the AstraZeneca COVID-19 vaccine in Europe, the pathogenesis of these rare and unusual adverse events after vaccination may be associated with platelet-activating antibodies against platelet factor-4 (PF4), a type of protein. Usually, the anticoagulant drug called heparin is used to treat blood clots. In this setting, the use of heparin may be harmful, and alternative treatments need to be given.

LAHAN
Los Angeles County Health Alert Network

CDC/FDA Recommend that Providers Pause Administration of Johnson & Johnson COVID-19 Vaccine

April 13, 2021

All vaccine providers are asked to immediately pause administering the Johnson & Johnson (J&J) /Janssen vaccine out of an abundance of caution, per announcements from the CDC and the FDA this morning.

CDC and the FDA are reviewing data involving six U.S. cases of a rare type of blood clot in individuals after receiving the J&J COVID-19 vaccine that were reported to the Vaccine Adverse Events Reporting System (VAERS). More than 6.8 million doses of J&J COVID-19 vaccine administered in the U.S. to date. In these cases, cerebral venous sinus thrombosis (CVST) was seen in combination with thrombocytopenia. All six cases occurred among women aged 18–48 years. The interval from vaccine receipt to symptom onset ranged from 6–13 days. One patient died. The CDC is recommending this pause to further review these cases and to prepare the health care system to recognize and treat patients appropriately.

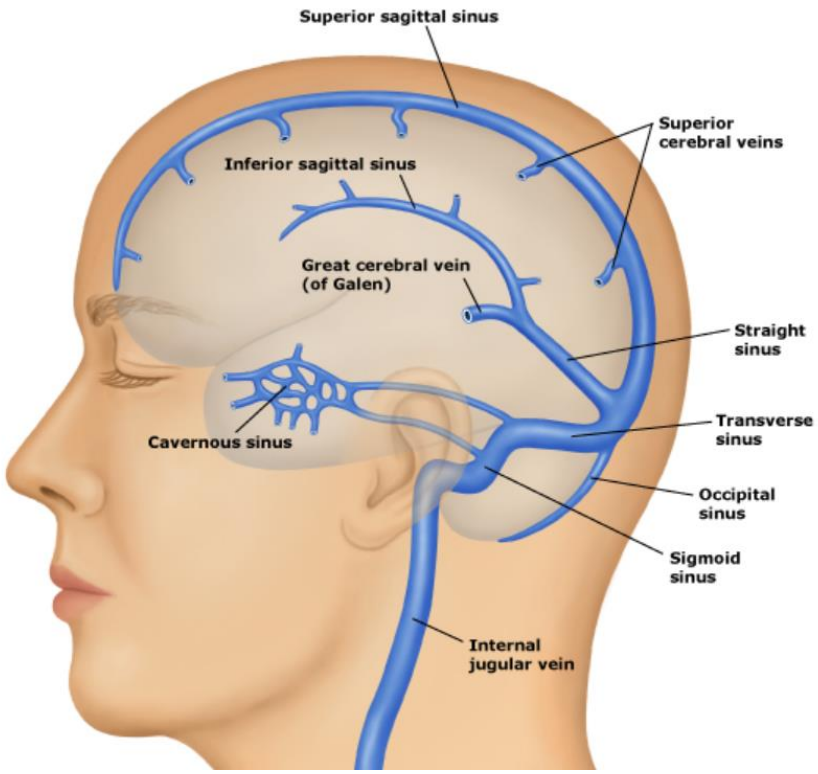
The CDC has released a Health Alert today, Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine that provides details on the cases as well as clinical recommendations for the recognition, management, and reporting of possible cases. The CDC advises that administration of heparin, normally used to treat blood clots, may be dangerous in the setting of vaccine-associated thrombotic thrombocytopenia and alternative treatments need to be given. Clinicians are asked to please review the full CDC alert that is included below.

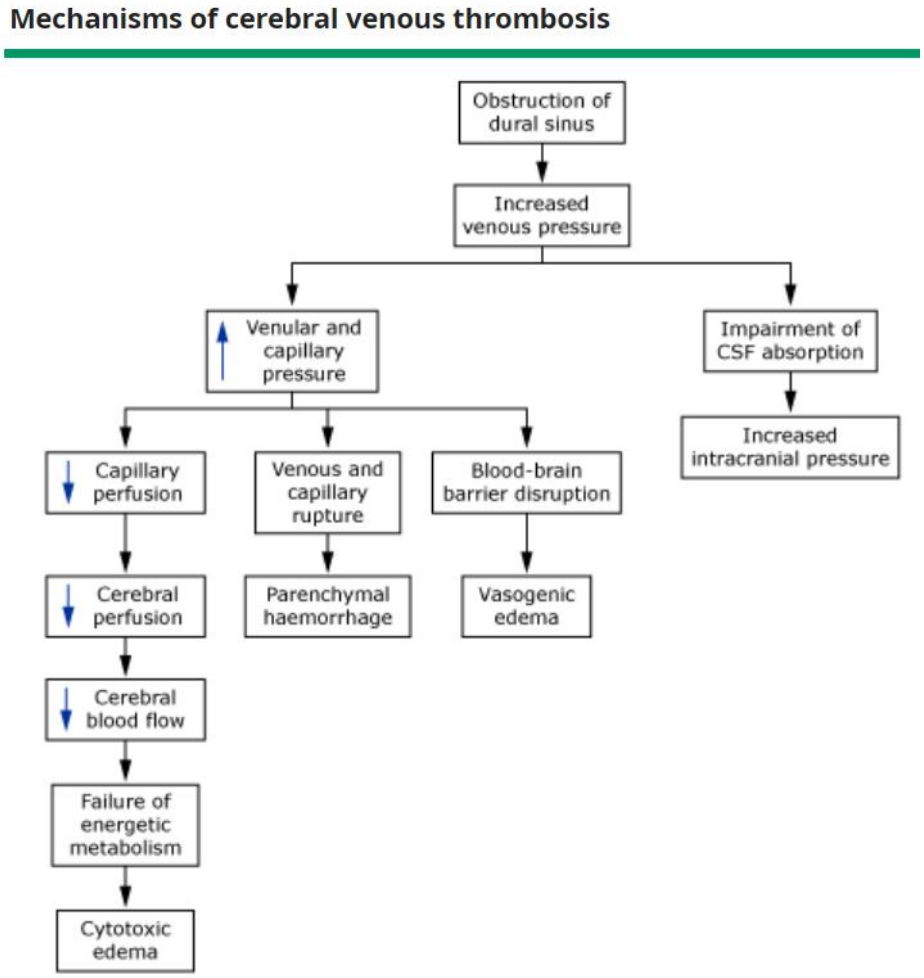
Cerebral Venous Sinus Thrombosis

- Annual incidence: 0.22-1.57/100,00
- Female:male ratio=3:1
- Median age: 34 yr. for women, 42 yr. for men
- Most frequent risk factors:
  - Prothrombotic conditions, either genetic or acquired
  - Oral contraceptives or HRT
  - Pregnancy and puerperium
  - Malignancy
  - Infection
  - Head injury & mechanical precipitants
  - Inflammatory diseases: SLE, Behcet disease, granulomatosis with polyangiitis, thromboangiitis obliterans, IBD, sarcoidosis; COVID-19

- Thrombophilias
  - Acquired
    - Pregnancy & puerperium
    - Oral contraceptives
    - Malignancy
  - Genetic
    - Antithrombin deficiency
    - Protein C or S deficiency
    - Factor V Leiden mutation (OR 3.1 for CVT)
    - G20210 A prothrombin gene mutation (OR 3.1)
    - Hyperhomocysteinemia (controversial)

Cerebral Venous Sinus Thrombosis





SARS-CoV-2 Vaccines

Vaccine	Manufacturer	Vaccine type	Antigen	Dose	Dosage	Storage conditions	Efficacy against severe COVID-19[a]	Overall efficacy	Current approvals
mRNA-1273	Moderna (US)	mRNA	Full-length spike (S) protein with proline substitutions	100 µg	2 Doses 28 d apart	−25° to −15 °C; 2-8 °C for 30 d; room temperature ≤12 h	100% 14 d After second dose (95% CI, not estimable to 1.00)	92.1% 14 d After 1 dose (95% CI, 68.8%-99.1%); 94.1% 14 d after second dose (95% CI, 89.3%-96.8%)	EUA: the US, EU, Canada, and UK
BNT162b2	Pfizer-BioNTech (US)	mRNA	Full-length S protein with proline substitutions	30 µg	2 Doses 21 d apart	−80° to −60 °C; 2-8 °C for 5 d; room temperature ≤2 h	88.9% After 1 dose (95% CI, 20.1%-99.7%)	52% After 1 dose (95% CI, 29.5%-68.4%); 94.6% 7 d after second dose (95% CI, 89.9%-97.3%)	EUA: the US, EU, Canada, and UK
Ad26.CoV2.S	Janssen/ Johnson & Johnson (US)	Viral vector	Recombinant, replication-incompetent human adenovirus serotype 26 vector encoding a full-length, stabilized SARS-CoV-2 S protein	5×10^{10} Viral particles	1 Dose	−20 °C; 2-8 °C for 3 mo	85% After 28 d; 100% after 49 d	72% in the US; 66% in Latin America; 57% in South Africa (at 28 d)	EUA: the US, EU, and Canada
ChAdOx1 (AZS1222)	AstraZeneca/ Oxford (UK)	Viral vector	Replication-deficient chimpanzee adenoviral vector with the SARS-CoV-2 S protein	5×10^{10} Viral particles (standard dose)	2 Doses 28 d apart (intervals >12 wk studied)	2-8 °C for 6 mo	100% 21 d After first dose	64.1% After 1 dose (95% CI, 50.5%-73.9%); 70.4% 14 d after second dose (95% CI, 54.8%-80.6%)	EUA: WHO/Covax, the UK, India, and Mexico
NVX-CoV2373	Novavax, Inc (US)	Protein subunit	Recombinant full-length, prefusion S protein	5 µg of protein and 50 µg of Matrix-M adjuvant	2 Doses	2-8 °C for 6 mo	Unknown	89.3% in the UK after 2 doses (95% CI, 75.2%-95.4%); 60% in South Africa (95% CI, 19.9%-80.1%)	EUA application planned
CVnCoV	CureVac/ GlaxoSmithKline (Germany)	mRNA	Prefusion stabilized full-length S protein of the SARS-CoV-2 virus	12 µg	2 Doses 28 d apart	2-8 °C for 3 mo; room temperature for 24 h	Unknown	Phase 3 trial ongoing	
Gam-COVID-Vac (Sputnik V)	Gamaleya National Research Center for Epidemiology and Microbiology (Russia)	Viral vector	Full-length SARS-CoV-2 glycoprotein S carried by adenoviral vectors	10^{11} Viral particles per dose for each recombinant adenovirus	2 Doses (first, rAd26; second, rAd5) 21 d apart	−18 °C (Liquid form); 2-8 °C (freeze dried) for up to 6 mo	100% 21 d After first dose (95% CI, 94.4%-100%)	87.6% 14 d After first dose (95% CI, 81.1%-91.8%); 91.1% 7 d after second dose (95% CI, 83.8%-95.1%)	EUA: Russia, Belarus, Argentina, Serbia, UAE, Algeria, Palestine, and Egypt
CoronaVac	Sinovac Biotech (China)	Inactivated virus	Inactivated CN02 strain of SARS-CoV-2 created from Vero cells	3 µg With aluminum hydroxide adjuvant	2 Doses 14 d apart	2-8 °C; Lifespan unknown	Unknown	Phase 3 data not published; reported efficacy 14 d after dose 2: 50.38% (mild) and 78% (mild to severe) in Brazil, 65% in Indonesia, and 91.25% in Turkey	EUA: China, Brazil, Columbia, Bolivia, Brazil, Chile, Uruguay, Turkey, Indonesia, and Azerbaijan
BBIBP-CorV	Sinopharm 1/2 (China)	Inactivated virus	Inactivated HB02 strain of SARS-CoV-2 created from Vero cells	4 µg With aluminum hydroxide adjuvant	2 Doses 21 d apart	2-8 °C; Lifespan unknown	Unknown	Phase 3 data not published; unpublished reports of 79% and 86% efficacy	EUA: China, UAE, Bahrain, Serbia, Peru, and Zimbabwe

Abbreviations: EUA, Emergency Use Authorization; UAE, United Arab Emirates; WHO, World Health Organization.

[a] Efficacy against severe disease, which includes COVID-19–related hospitalization, varies by age and by time after vaccination.

JAMA. 2021;325(13):1318-1320.

Dignity Health.
California Hospital Medical Center

Common Myths about the COVID-19 vaccines

Myth: I had COVID-19 so I don't need the vaccine.
There are severe health risks associated with COVID-19 and re-infection is possible. The vaccine offers additional benefit and the CDC recommends that you get the vaccine even if you have had a COVID-19 infection.

Myth: I will be protected against COVID-19 after the first dose, and I don't need a second dose.
For Pfizer and Moderna vaccines, it is important to get the second dose in order to have the most protection the vaccine can offer. You won't get the full duration of protection from the vaccines until one to two weeks after the second dose. For Janssen/Johnson & Johnson, only one dose is needed for immune protection to form in 28 days.

Myth: The vaccine isn't safe.
COVID-19 vaccines were tested in large clinical trials with a diverse group of individuals to make sure they meet safety standards. There were no significant safety concerns identified. We will not administer a COVID-19 vaccine unless the FDA has determined it is safe and effective.

Myth: I have allergies, I shouldn't get the vaccine.
People with severe allergies who have experienced anaphylaxis in the past or allergic reactions to vaccines should talk to their primary care doctor about whether they should get the COVID-19 vaccine.

Myth: I got the vaccine so I don't have to wear a mask.
While the vaccine will offer protection to the vaccinated person, you can still spread the virus to others. It is important to continue to wear a mask, wash your hands often, and stay at least 6 feet away from others.

Myth: The vaccine was rushed.
Years of science and innovation have paved the way for this vaccine to be delivered quickly. Two reasons the vaccines were developed quickly are because mRNA vaccines can be produced faster than other vaccines, and researchers used existing clinical trial networks to begin conducting COVID-19 vaccine trials as soon as possible.

Myth: The Janssen/Johnson & Johnson vaccine isn't as effective.
The Janssen/Johnson & Johnson vaccine significantly reduces the likelihood of hospitalization and death. Clinical trials for the Janssen/Johnson & Johnson COVID-19 vaccine occurred several months after previously developed vaccines, and therefore faced variants of the COVID-19 virus that were not present when the other vaccines were tested.

Myth: I'm planning to get pregnant, and pregnant women shouldn't get the vaccine.
Vaccinating against COVID-19 is important as pregnant women are at increased risk for severe illness if they are infected with the virus. Talk to your doctor about what's right for you.

Vaccinating Pregnant and Lactating Women Against COVID-19

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MATERNAL IMMUNIZATION

— TASK FORCE —

ACOG

AMERICAN ACADEMY OF FAMILY PHYSICIANS

AMERICAN COLLEGE of NURSE-MIDWIVES
With women, for a lifetime®

AWHONN
PROMOTING THE HEALTH OF WOMEN AND NEWBORNS

JOINED BY

AAPA

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

ACP
American College of Physicians
Leading Internal Medicine, Improving Lives

AMA
AMERICAN MEDICAL ASSOCIATION

APhA
AMERICAN PHARMACISTS ASSOCIATION

APHA
AMERICAN PUBLIC HEALTH ASSOCIATION
For science. For action. For health.

AIM
ASSOCIATION OF IMMUNIZATION MANAGERS

immunization action coalition
IAC
immunize.org

IDSA
Infectious Diseases Society of America

NACDS
NATIONAL ASSOCIATION OF CHAIN DRUG STORES

NACCHO
National Association of County & City Health Officials

National Foundation for Infectious Diseases®

NMA
National Medical Association

NPWH
NURSE PRACTITIONERS IN WOMEN'S HEALTH
Caring for Women

Society for Maternal-Fetal Medicine
High-risk pregnancy experts

VACCINATE YOUR FAMILY

Maternal Immunization Task Force & Partners Urge that COVID-19 Vaccine Be Available to Pregnant Individuals

- All pregnant individuals who choose to receive the COVID-19 vaccine must be allowed to do so in alignment with their state and local vaccination allocation plan, including health care workers.
- Pregnant individuals who otherwise meet criteria for COVID-19 vaccine should not be denied the opportunity to be vaccinated, should they choose to do so.
- Currently, available data demonstrate that pregnant individuals are at increased risk of more severe illness and death due to COVID-19 than their non-pregnant counterparts. Providing pregnant individuals with the opportunity to be vaccinated can be critical to allowing them to protect themselves, particularly if their occupation puts them at increased risk of contracting the virus or if they have underlying and co-morbid conditions.
- If pregnant individuals are excluded from the opportunity to decide whether to be vaccinated, it violates their bodily autonomy and puts them at risk of severe outcomes and death related to COVID-19 illness.

ACOG
The American College of Obstetricians and Gynecologists

Vaccinating Pregnant Individuals:

Eight Key Recommendations for COVID-19 Vaccination Sites

The American College of Obstetricians and Gynecologists (ACOG) recommends that pregnant individuals be free to make their own decision regarding COVID-19 vaccination. While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care team when feasible, documentation of such a discussion should not be required prior to receiving a COVID-19 vaccine. Further, pregnant individuals should not be denied COVID-19 vaccine(s) because of their pregnancy-status alone. COVID-19 vaccination sites should consider the recommendations below regarding vaccinating pregnant individuals.

1 COVID-19 vaccines should be available and administered to pregnant individuals who choose to be vaccinated.

2 While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care team when feasible, documentation of such a discussion should not be required prior to receiving a COVID-19 vaccine.

3 Pregnancy testing should not be a requirement prior to receiving any EUA-approved COVID-19 vaccine.

4 Similar to their non-pregnant peers, pregnant individuals can receive a COVID-19 mRNA vaccine in any setting authorized to administer these vaccines. This includes any clinical setting and non-clinical community-based vaccination sites such as schools, community centers, and other mass vaccination locations.

5 Precautions should be discussed with any individual who reports a history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate).

6 If anaphylaxis is suspected in a pregnant individual after receiving a COVID-19 vaccination, anaphylaxis should be managed the same as in non-pregnant individuals (CDC).

7 Pregnant individuals who experience fever following vaccination should be counseled to take acetaminophen. Acetaminophen has been proven to be safe for use in pregnancy and does not appear to impact antibody response to COVID-19 vaccines.

8 Pregnant individuals who receive a COVID-19 vaccine should be educated about and encouraged to participate in CDC's V-SAFE program (see below for more information on CDC's V-SAFE program).

For more information, please visit ACOG's Practice Advisory on Vaccinating Pregnant and Lactating Patients Against COVID-19 and CDC's Clinical Considerations.

‘I was so shocked:’ Health care worker denied Moderna vaccine because Kane County says it will not give it to pregnant or breastfeeding moms

By ALISON BOWEN
CHICAGO TRIBUNE | FEB 04, 2021 AT 9:54 AM

Because pregnant and lactating women **were not included in initial vaccine trials**, data is limited on how it might impact them. The Centers for Disease Control and Prevention (CDC) recommends they **be offered the vaccine**; maternal health groups such as the American College of Obstetricians and Gynecologists (ACOG) are urging data collection and conversations between patient and provider — and that the vaccine **should not be withheld** from pregnant women who are eligible for it.

“Pregnant individuals who otherwise meet the criteria for COVID-19 vaccines should not be denied the opportunity to be vaccinated,” the group said in a statement. “It not only violates their bodily autonomy, it also puts them at risk of severe outcomes and death related to COVID-19 illness. Excluding this critical population at increased risk of severe illness and death related to COVID-19 is unethical.”

All of this makes deciding whether to get a vaccine stressful for women who are pregnant, considering getting pregnant or breastfeeding. Pregnant women are **more at risk** of severe illness should they get COVID-19, **especially Black and Latina women**. Families are weighing factors like exposure risk, personal health factors and potential benefits.

As a therapist, Raess will eventually be working in schools and is sometimes called to assist a 24-hour crisis line. She wanted to feel she was protecting herself and her family, which includes a 22-month-old daughter and 11-week-old son.

Underlying Medical Conditions Associated with High Risk for Severe COVID-19, CDC, March 29,2021

- Cancer
- Chronic kidney disease
- Chronic lung disease, including COPD, asthma (moderate-to-severe), interstitial lung disease, cystic fibrosis, pulmonary HTN
- Dementia or other neurologic conditions
- Diabetes
- Down syndrome
- Heart conditions (heart failure, coronary artery disease, cardiomyopathies, or HTN)
- HIV
- Immunocompromised state
- Liver disease
- Overweight or obese
- PREGNANCY
- Sickle cell disease or thalassemia
- Smoking, current or former
- Solid organ or blood stem cell transplant
- Stroke or cerebrovascular disease
- Substance use disorders

Medical Experts Continue to Assert that COVID-19 Vaccines Do Not Impact Fertility

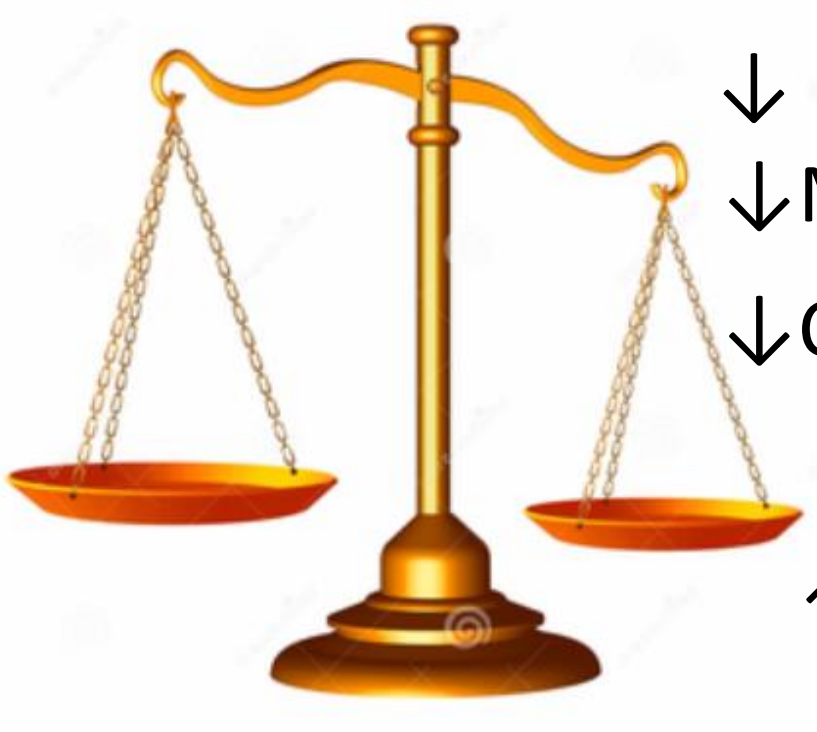
- American College of Obstetrics and Gynecology, American Society of Reproductive Medicine, and the Society of Maternal-Fetal Medicine made the following statement:

"We assure patients that there is no evidence that the vaccine can lead to loss of fertility. While fertility was not specifically studies in the clinical trials of the vaccine, no loss of fertility has been reported among trial participants or among the millions who have received the vaccines since their authorization, and no signs of infertility appeared in animal studies. Loss of fertility is scientifically unlikely."

To Vaccinate or Not To Vaccinate?

Risks

Safety



Benefits

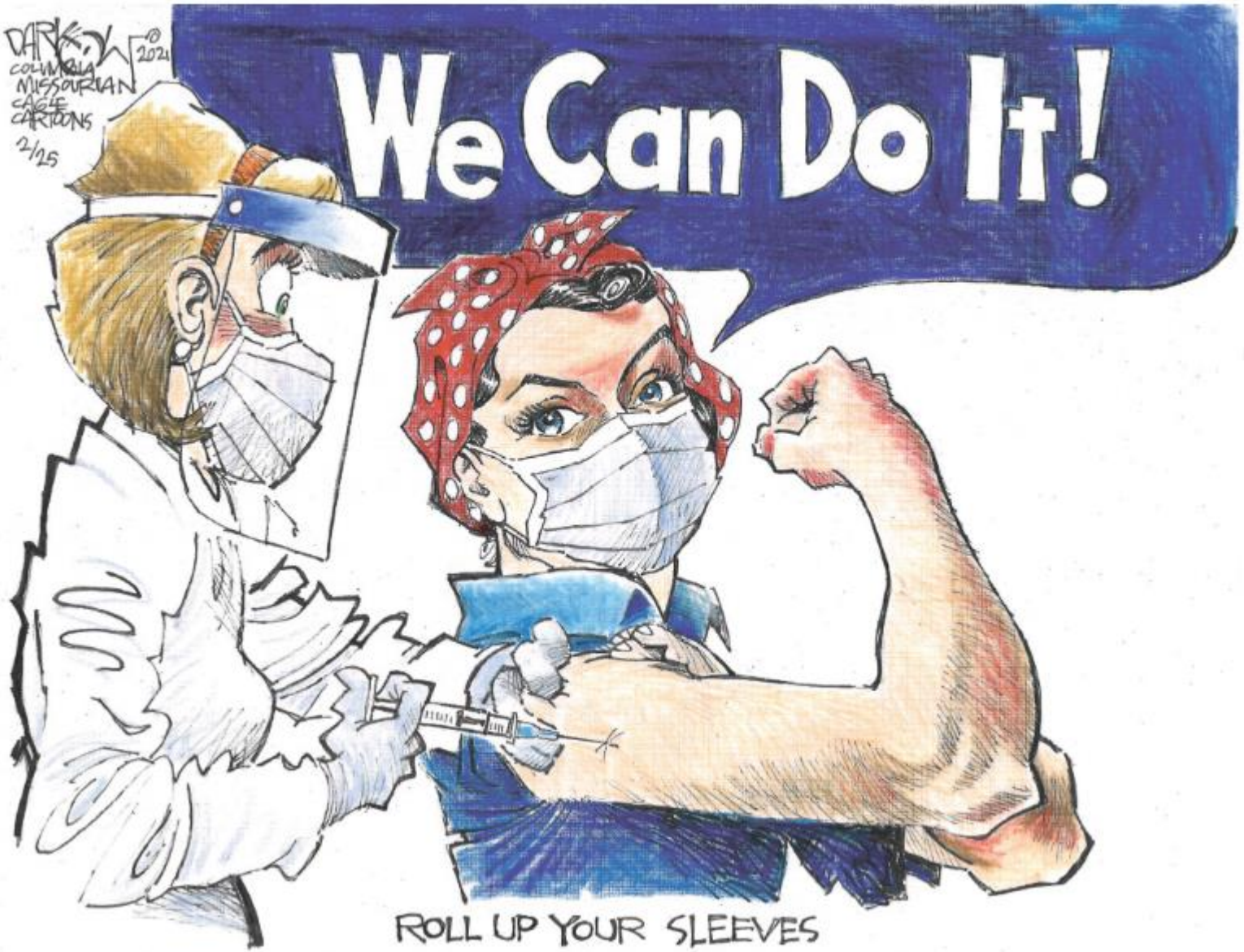
↓ Mortality

↓Morbidity

↓Complications

Prevention

↑Equity


We Can Do It!
ROLL UP YOUR SLEEVES

Thank You

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