



OB/GYN Webinar Series 2020-2021

COVID-19 Vaccine in Pregnancy & CDC LOCATE

*Tuesday, February 16, 2021
12:00pm- 1pm*



The University of Vermont
LARNER COLLEGE OF MEDICINE



THE
University of Vermont
MEDICAL CENTER

VCHIP Webinar:
LOCATe: Levels of Care
Covid Vaccine: how to counsel
pregnant patients

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CDC Levels of Care Assessment Tool (CDC LOCATe)



Risk-Appropriate Care

Risk-appropriate care is a strategy developed to improve health outcomes for pregnant women and infants. States may develop coordinated regional systems to help ensure that pregnant women and infants at high risk of complications receive care at a birth facility that is best prepared to meet their health needs. For example, pregnant women with severe heart conditions need care at facilities that have a full range of specialists available to help care for complex medical conditions. Infants born before 32 weeks gestation should be cared for at facilities with specialized health care providers and equipment to care for infants who are born too early or who are critically ill.

Goal of Levels of Maternal Care (ACOG, SMFM):

- Reduce maternal morbidity by encouraging the growth and maturation of systems for the provision of risk-appropriate care specific to maternal health needs.
- Development of collaborative relationships between hospitals of differing levels of care in proximate regions, which ensures every maternity hospital has the personnel and resources to care for unexpected emergencies.



CDC Levels of Care Assessment Tool

Definitions and monitoring of levels of care vary widely among states. To address this issue, CDC developed the CDC Levels of Care Assessment Tool (LOCATe). This web-based tool helps states and other jurisdictions create standardized assessments of levels of maternal and neonatal care. CDC LOCATe is based on the most recent guidelines and policy statements issued by the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the Society for Maternal-Fetal Medicine. [Review Frequently Asked Questions about CDC LOCATe.](#)

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



FROM THE AMERICAN ACADEMY OF PEDIATRICS

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

POLICY STATEMENT

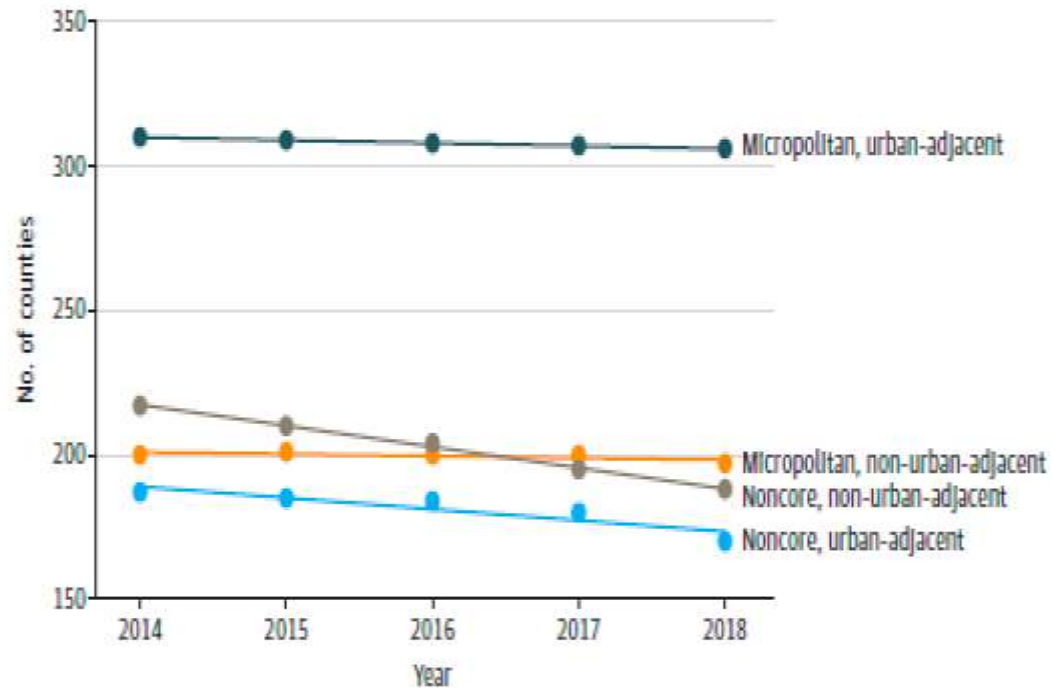
Levels of Neonatal Care

Rural Hospital Based OB services are critical to Maternal (and child) Health:
These hospitals are at risk nationally

Changes in Hospital-Based Obstetric Services in Rural US Counties, 2014-2018

JAMA July 14, 2020 Volume 324, Number 2

Figure. Number of Rural US Counties With Hospital Obstetric Care, 2014-2018



Original Investigation

FREE

March 27, 2018

Association Between Loss of Hospital-Based Obstetric Services and Birth Outcomes in Rural Counties in the United States

Katy B. Kozhimannil, PhD, MPA¹; Peiyin Hung, PhD, MSPH²; Carrie Henning-Smith, PhD, MPH, MSW¹; et al

Conclusions and Relevance In rural US counties not adjacent to urban areas, loss of hospital-based obstetric services, compared with counties with continual services, was associated with increases in out-of-hospital and preterm births and births in hospitals without obstetric units in the following year; the latter also occurred in urban-adjacent counties. These findings may inform planning and policy regarding rural obstetric services.

(nonmetropolitan) counties were placed into 4 categories based on county population (micropolitan, with a town of 10000-50000, and noncore, without a town >10 000) and urban adjacency.

PATIENT CARE

NEONATAL CARE

The next 11 questions relate to services and staff available at your facility that involve the care of newborns.

N1. Does your facility provide congenital cardiac surgery for neonates onsite?	<input type="radio"/> Yes <input type="radio"/> No (If "No" skip to N2.)
N1.1. In the last 12 months, did your facility provide 10 or more congenital cardiac surgeries for neonates?	<input type="radio"/> Yes <input type="radio"/> No
N2. Does your facility provide complex pediatric subspecialty surgery for neonates other than cardiac surgery onsite? (Capable of surgical repair of complex congenital or acquired conditions)	<input type="radio"/> Yes <input type="radio"/> No (If "No" skip to N3.)



CDC Maternal & Neonatal Levels of Care Assessment Tool (CDC LOCATe V 0.8.0)

N10.1 What is your neonatal level of care designation? (Choose one) Specify other: _____	<input type="radio"/> I <input type="radio"/> II <input type="radio"/> III <input type="radio"/> IV <input type="radio"/> Other
N10.2 How is this neonatal level of care designated? (Mark all that apply) Specify other: _____	<input type="checkbox"/> State regulatory based <input type="checkbox"/> State voluntary based <input type="checkbox"/> AAP based <input type="checkbox"/> Self-designated <input type="checkbox"/> Unknown (not sure) <input type="checkbox"/> Other
N11. Based on the 2012 AAP guidelines for neonatal levels of care, what do you consider your neonatal level of care to be? (Choose one)	<input type="radio"/> I <input type="radio"/> II <input type="radio"/> III <input type="radio"/> IV <input type="radio"/> Unknown (not sure)



CDC Maternal & Neonatal Levels of Care Assessment Tool (CDC LOCATe V 0.8.0)

MATERNAL CARE

The next 14 questions relate to services and staff available at your facility that involve the care of obstetric (maternal) patients.

<p>W1. Does your facility staff an OB Unit (Labor and Delivery, LDR, LDRP)?</p> <p>NOTE: If "No" is selected for this option, the survey assumes that you do not provide obstetric services other than emergency care; and you should skip to the NEONATAL STATISTICS section on the last page of this survey.</p> <p>This answer is appropriate for most children's hospitals, many small rural hospitals, and other hospitals that do not specifically staff an obstetric unit.</p>	<input type="radio"/> Yes <input type="radio"/> No (If "No" skip to STATISTICS section on the last page.)
<p>W2. What type of obstetric/maternal care patients does your facility accept? (High risk, complicated examples include: placenta previa and severe preeclampsia) (Mark all that apply)</p>	<input type="checkbox"/> Uncomplicated <input type="checkbox"/> High risk, complicated
<p>W3. Does your facility have a formal written plan for transport of complicated obstetric/maternal patients?</p>	<input type="radio"/> Yes <input type="radio"/> No (If "No" skip to W4.)
<p>W3.1 Does this formal written plan include... (Mark all that apply)</p>	<input type="checkbox"/> Transport out to a higher level of care facility <input type="checkbox"/> Receipt from a lower level of care facility
<p>W4. Does your facility have an intensive care unit onsite that is available to accept obstetric/maternal care patients?</p>	<input type="radio"/> Yes <input type="radio"/> No

Level II Special care nursery	<p>Level I capabilities plus:</p> <ul style="list-style-type: none"> • Provide care for infants born ≥ 32 wk gestation and weighing ≥ 1500 g who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis • Provide care for infants convalescing after intensive care • Provide mechanical ventilation for brief duration (< 24 h) or continuous positive airway pressure or both • Stabilize infants born before 32 wk gestation and weighing less than 1500 g until transfer to a neonatal intensive care facility 	<p>Level I health care providers plus:</p> <p>Pediatric hospitalists, neonatologist, and neonatal nurse practitioners.</p>
Level III NICU	<p>Level II capabilities plus:</p> <ul style="list-style-type: none"> • Provide sustained life support • Provide comprehensive care for infants born < 32 wks gestation and weighing < 1500 g and infants born at all gestational ages and birth weights with critical illness • Provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric ophthalmologists • Provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide • Perform advanced imaging, with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography 	<p>Level II health care providers plus:</p> <p>Pediatric medical subspecialists^a, pediatric anesthesiologists^a, pediatric surgeons, and pediatric ophthalmologists^a.</p>
Level IV Regional NICU	<p>Level III capabilities plus:</p> <ul style="list-style-type: none"> • Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions • Maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site • Facilitate transport and provide outreach education 	<p>Level III health care providers plus:</p> <p>Pediatric surgical subspecialists</p>

CDC Assessment of our data:

Neonatal Care

All community hospitals level 1
UVMHC Level 3

Note:

The self assessment each hospital performed in the survey was consistent with the CDC assessment in every hospital

TABLE 1 Definitions, Capabilities, and Provider Types: Neonatal Levels of Care

Level of Care	Capabilities	Provider Types ^a
Level I Well newborn nursery	<ul style="list-style-type: none"> • Provide neonatal resuscitation at every delivery • Evaluate and provide postnatal care to stable term newborn infants • Stabilize and provide care for infants born 35–37 wk gestation who remain physiologically stable • Stabilize newborn infants who are ill and those born at < 35 wk gestation until transfer to a higher level of care 	<p>Pediatricians, family physicians, nurse practitioners, and other advanced practice registered nurses</p>

Table 1. Levels of Maternal Care: Definitions, Capabilities, and Health Care Providers*

Accredited Birth Center

Definition	Care for low-risk women with uncomplicated singleton term vertex pregnancies who are expected to have an uncomplicated birth
Capabilities and health care providers	<ul style="list-style-type: none"> Refer to birthcenters.org for American Association of Birth Centers' Standards for Birth Centers.

Level I (Basic Care)

Definition	Care of low- to moderate-risk pregnancies with ability to detect, stabilize, and initiate management of unanticipated maternal-fetal or neonatal problems that occur during the antepartum, intrapartum, or postpartum period until the patient can be transferred to a facility at which specialty maternal care is available
Capabilities	<ul style="list-style-type: none"> Capability and equipment to provide low-risk and appropriate moderate-risk maternal care and a readiness at all times to initiate emergency procedures to meet unexpected needs of women and newborns within the center. This includes <ul style="list-style-type: none"> ability to begin emergency cesarean delivery within a time interval that best incorporates maternal and fetal risks and benefits. limited obstetric ultrasonography with interpretation readily available at all times.² support services readily available at all times², including laboratory testing and blood bank. capability to implement patient safety bundles² for common causes of preventable maternal morbidity, such as management of maternal venous thromboembolism, obstetric hemorrhage, and maternal severe hypertension in pregnancy.⁵ ability at all times⁴ to initiate massive transfusion protocol, with process to obtain more blood and component therapy as needed. Stabilization and the ability to facilitate transport to a higher-level hospital when necessary. This includes <ul style="list-style-type: none"> risk identification and determination of conditions necessitating consultation, referral, and transfer. a mechanism and procedure for transfer/transport to a higher-level hospital available at all times.¹ a reliable, accurate, and comprehensive communication system between participating hospitals, hospital personnel, and transport teams. Ability, in collaboration with higher-level facility partners, to initiate and sustain education and quality improvement programs to maximize patient safety.
Health care providers	<ul style="list-style-type: none"> Every birth attended by at least one qualified birthing professional (midwife⁶, family physician, or ob-gyn) and an appropriately trained and qualified RN with level-appropriate competencies as demonstrated by nursing competency documentation. Physician with privileges to perform emergency cesarean delivery readily available at all times.⁴ Primary maternal care providers, including midwives⁶, family physicians, or ob-gyns readily available at all times.⁷ Appropriately trained and qualified RNs with level-appropriate competencies as demonstrated by nursing competency documentation readily available at all times.⁷ Nursing leadership has level-appropriate formal training and experience in maternal care. Anesthesia providers, such as anesthesiologists, nurse anesthetists, or anesthesiologist assistants working with an anesthesiologist,⁸ for labor analgesia and surgical anesthesia readily available at all times.⁹

(continued)

Maternal Level of Care:

Must meet ALL criteria for the level

Way more complicated than the neonatal care

Maternal Level of Care	Hospital Self Assessment	CDC Assessment
Level <1	0	4
Level 1	8	6
Level 2	2	0
Level 4	1	1

Why the discrepancy?

- CDC Survey with multiple questions about what providers were available
- Self-assessment was by the hospital when survey was performed
- CDC took the answers and matched to the Level of Maternal Care for CDC assessment

W1-Has OB unit and type of obstetric patients	W2-Transport plan for OB patients	W3-ICU for OB patients	W4-Hospital services for OB patients	W5-Policies and procedures for SMM	W6-OB providers on staff	W7-Physician provider for emergency C-sections	W8-Anesthesia providers for OB	W9-Has general surgeon available for OB	W10-Has other specialist/sub specialists available for OB	W11-Current maternal level of care designation	W12-ACOG-based self-assessed maternal level of care	Survey assessed maternal level of care
2	<1	<3	1	1+	2	1+	2	2+	<3	ND	I	I
1	1	<3	1	1+	2	1+	<1	2+	<3	ND	I	<I
2	2+	<3	1	<1	2	1+		<2	<3	ND	I	<I
3+	<1	3+	4	1+	3+	1+	3+	2+	3+	IV	IV	IV
2	<1	<3	1	<1	2	1+	2	2+	<3	ND	I	I
1	1	<3	1	1+	2	1+	<1	2+	<3	ND	II	<I
2	<1	<3	1	<1	2	1+	2	2+	<3	ND	I	I
2	1	<3	1	1+	2	1+	2	2+	<3	I	I	I
2	<1	<3	1	1+	2	1+	2	2+	<3	ND	I	I
2	1	<3	1	1+	2	1+	2	2+	<3	ND	II	I
2	<1	<3	1	<1	2	1+	<1	<2	<3	ND	I	<I

Level 1:
24/7 coverage with both CRNA and anesthesiologists accounts for <1

Health care providers

- Every birth attended by at least 1 qualified birthing professional (midwife¹, family physician, or ob-gyn) and an appropriately trained and qualified RN with level-appropriate competencies as demonstrated by nursing competency documentation
- Physician with privileges to perform emergency cesarean delivery readily available at all times[†]
- Primary maternal care providers, including midwives¹, family physicians, or ob-gyns readily available at all times[†]
- Appropriately trained and qualified RNs with level-appropriate competencies as demonstrated by nursing competency documentation readily available at all times[†]
- Nursing leadership has level-appropriate formal training and experience in maternal care
- Anesthesia providers, such as anesthesiologists, nurse anesthetists, or anesthesiologist assistants, working with an anesthesiologist¹ for labor analgesia and surgical anesthesia readily available at all times[†]

	W1-Has OB	W2-Transport	W3-Physician	W4-Hospital	W5-Policies and	W6-OB	W7-Physician provider	W8-Anesthesia providers for OB	W9-Has general surgeon available for OB	W10-Has other specialist/sub specialists available for OB	W11-Current maternal level of care designation	W12-ACOG-based self-assessed maternal level of care	Survey assessed maternal level of care
								2	2+	<3	ND	I	I
								<1	2+	<3	ND	I	<I
								MM: <1	<2	<3	ND	I	<I
								3+	2+	3+	IV	IV	IV
								2	2+	<3	ND	I	I
								<1	2+	<3	ND	II	<I
								2	2+	<3	ND	I	I
								2	2+	<3	I	I	I
	2	<1	<3	1	1+	2	1+	2	2+	<3	ND	I	I
								2	2+	<3	ND	II	I
								<1	<2	<3	ND	I	<I

1: Readily available at all times: the specific person should be available 24 hours a day, 7 days a week, for consultation and assistance, and able to be physically present onsite within a time frame that incorporates maternal and fetal or neonatal risks and benefits with the provision of care. Further defining this time frame should be individualized by facilities and regions, with input from their obstetric care providers. If referring to the availability of a service, the service should be available 24 hours a day, 7 days a week, unless otherwise specified;

¹Scope of practice for nurse anesthetists and anesthesiologist assistants may vary by state.

LOCATe Summary

- Overall doing well
- There are no consequences to level of care: just use as a reference in assessment of the types of patients to keep locally electively
- Vermont rural hospitals are essential, especially for OB care
- Goal is to keep patients local and ensure rural hospital viability

Vermont's Hospitals

Number of Vermont Hospitals

15

Number of Not-for-Profit Community Hospitals
- includes 8 Critical Access Hospitals

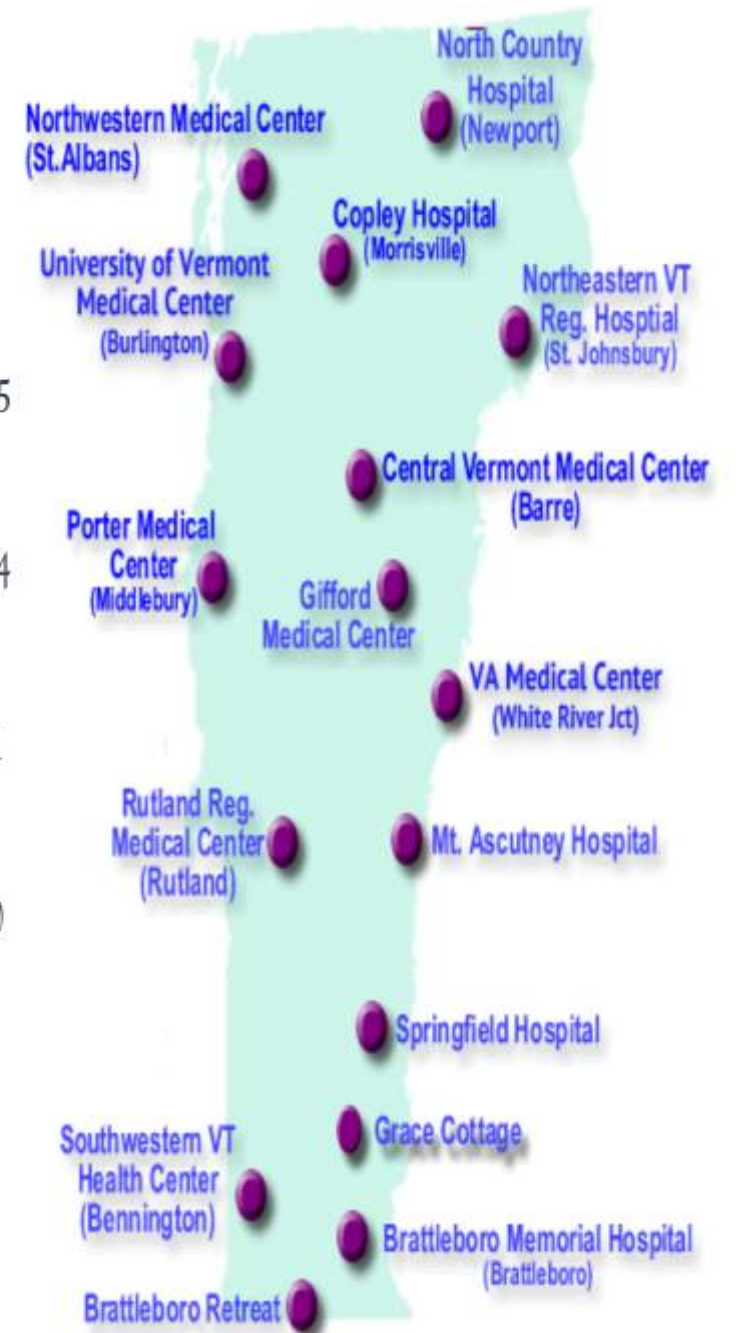
14

Number of Federal Government Hospitals

1

Number of Investor-Owned (For-Profit)
Community Hospitals

0



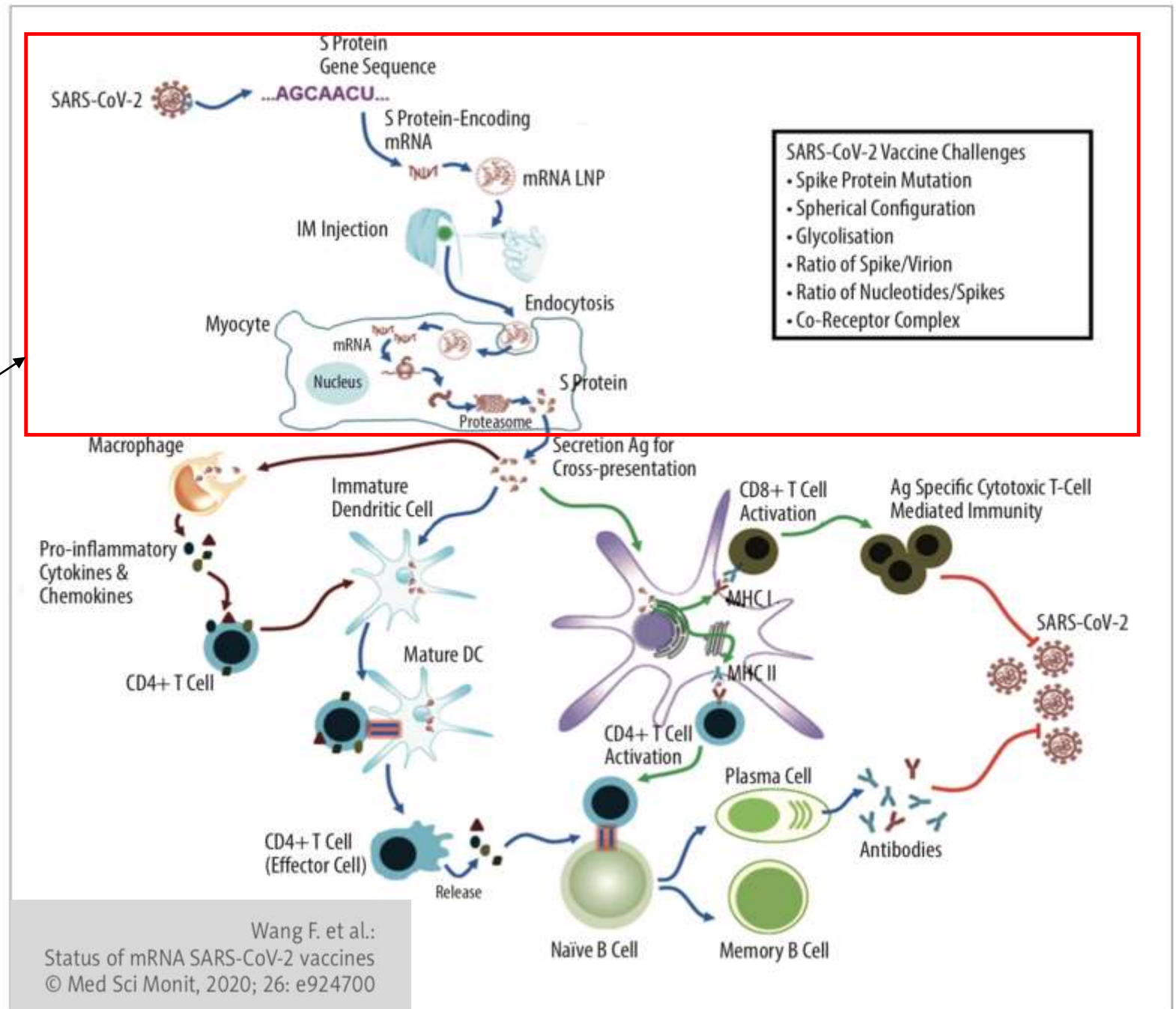
COVID Vaccines in Pregnancy and Lactation



mRNA vaccines:

Biologic Plausibility of placental interaction and effect of immune activation to COVID

- (1) mRNA is not stable and is a large molecule with a negative charge: even if it makes it to the placental interface, the biochemical characteristics suggest it would not cross the placental interface
- (2) Even if a lipid nanoparticle made the way to placenta, it might make Spike antigen and then stop just as the myocytes
- (3) The immune response to pregnant pts with covid and the vaccine are very similar: Ab and T cell response to the Spike protein. We know pregnant infected women are sick but no evidence that the immune response is harmful to mom or baby (and potential passive immunity). No biologic reason to think the antigen would be worse than the viral effects-which are largely related to maternal disease not the virus per se
- (4) We DO know preterm birth and maternal illness are bad



Pre-pregnancy/Planning



AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE (ASRM)
PATIENT MANAGEMENT AND CLINICAL RECOMMENDATIONS DURING THE
CORONAVIRUS (COVID-19) PANDEMIC

UPDATE No. 11 – COVID-19 Vaccination
December 16, 2020

Summary:

Non-pregnant women WERE in the trials
Take prenatal vitamins (folic acid)
Get COVID vaccine

- **Because COVID-19 mRNA vaccines are not composed of live virus, they are not thought to cause an increased risk of infertility, first or second trimester loss, stillbirth, or congenital anomalies.** It should be noted that pregnant and lactating women were excluded from the initial phase III trials of these two vaccines, so specific safety data in these populations are not yet available and further studies are planned. However, the mechanism of action of mRNA vaccines and existing safety data provide reassurance regarding the safety of COVID-19 mRNA vaccines during pregnancy. The FDA EUA letter permits the vaccination of pregnant and breastfeeding individuals with a requirement that the company engage in post-authorization observational studies in pregnancy (9).
- **While COVID-19 vaccination can cause fever in some patients (up to 16% of those vaccinated and mostly after the second dose), this risk should not be a concern when deciding whether to vaccinate a pregnant individual or a patient desiring pregnancy.** While fever in pregnancy (particularly the 1st trimester) has been associated with an increased risk of neural tube defects, a recent study demonstrated the association no longer remained significant if the patient is taking >400 mcg of folic acid daily (10). Another large Danish cohort study did not demonstrate any increased risk of congenital anomalies of those who reported fever in the first trimester (11). Additionally, the most common symptom of COVID-19 infection itself is fever (83-99% of affected patients). Patients who experience fever following vaccination should take an antipyretic medication, like acetaminophen (12).
- **Patients who conceive in the window between the first and second dose of the vaccine should be offered the second dose of the vaccine at the appropriate interval.**
- **Physicians should promote vaccination to patients, their communities, and to the public.** Preliminary data suggests that those populations at greatest risk of severe disease from COVID-19 may also be the most hesitant to be vaccinated, and specific efforts to increase vaccine uptake in these communities should be undertaken.

CDC ACIP Recommendations about Pfizer Vaccine in Pregnancy

- If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated.
- A conversation between the patient and their clinical team may assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19.
- While a conversation with a healthcare provider may be helpful, it is not required prior to vaccination.
- There is no recommendation for routine (MM: pregnancy) testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after Pfizer-BioNTech COVID-19 vaccination.

Vaccinating Pregnant and Lactating Patients Against COVID-19

Last updated January 27, 2021

Practice Advisory | December 2020

ACOG and SMFM both recommend offering vaccine to pregnant women



Leaders in Women's Health Encourage Health Workers to Receive the COVID-19 Vaccine
Vaccination is the Key to Preventing New Infections

Summary of Key Information and Recommendations

COVID-19 vaccine development and regulatory approval are rapidly progressing. Thus, information and recommendations will evolve as more data are collected about these vaccines and their use in specific populations. This Practice Advisory is intended to be an overview of currently available COVID-19 vaccines and guidance for their use in pregnant and lactating patients.

- The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the following vaccines:
 - Pfizer-BioNTech mRNA vaccine (BNT162b2): for use in individuals age 16 years and older as a 2-dose regimen given 3 weeks (21 days) apart.
 - Moderna mRNA-1273 vaccine: for use in individuals age 18 and older as a 2-dose regimen given 1 month (28 days) apart.
- After an explicit, evidence-based review of all available data, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥ 16 years for the prevention of COVID-19 (CDC 2020) and the use of the Moderna-1273 COVID-19 vaccine in persons aged ≥ 18 years (CDC 2020).
- ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups.
- COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP.

Vaccinating Pregnant and Lactating Patients Against COVID-19

Practice Advisory ⓘ | December 2020

Last updated January 27, 2021

- Individuals considering a COVID-19 vaccine should have access to available information about the safety and efficacy of the vaccine, including information about data that are not available. A conversation between the patient and their clinical team may assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19 by pregnant patients. Important considerations include:
 - the level of activity of the virus in the community
 - the potential efficacy of the vaccine
 - the risk and potential severity of maternal disease, including the effects of disease on the fetus and newborn
 - the safety of the vaccine for the pregnant patient and the fetus.
- While a conversation with a clinician may be helpful, it should not be required prior to vaccination, as this may cause unnecessary barriers to access.
- Vaccines currently available under EUA have not been tested in pregnant women. Therefore, there are no safety data specific to use in pregnancy. See details about the Food and Drug Administration's (FDA) EUA process below.
- Similar to their non-pregnant peers, vaccination of pregnant individuals with a COVID-19 mRNA vaccine may occur 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.
- Pregnancy testing should not be a requirement prior to receiving any EUA-approved COVID-19 vaccine.

- Pregnant patients who decline vaccination should be supported in their decision. Regardless of their decision to receive or not receive the vaccine, these conversations provide an opportunity to remind patients about the importance of other prevention measures such as hand washing, physical distancing, and wearing a mask.
- Expected side effects should be explained as part of counseling patients, including that they are a normal part of the body's reaction to the vaccine and developing antibodies to protect against COVID-19 illness.
- The mRNA vaccines are not live virus vaccines, nor do they use an adjuvant to enhance vaccine efficacy. These vaccines do not enter the nucleus and do not alter human DNA in vaccine recipients. As a result, mRNA vaccines cannot cause any genetic changes.

- No need for specific counseling before women get vaccine (but it should be available if they want)
- No need for pregnancy testing
- No need to wait through first trimester (but OK if they want to delay)

Vaccinating Pregnant and Lactating Patients Against COVID-19

Practice Advisory ⓘ | December 2020

Last updated January 27, 2021

Lactating Individuals

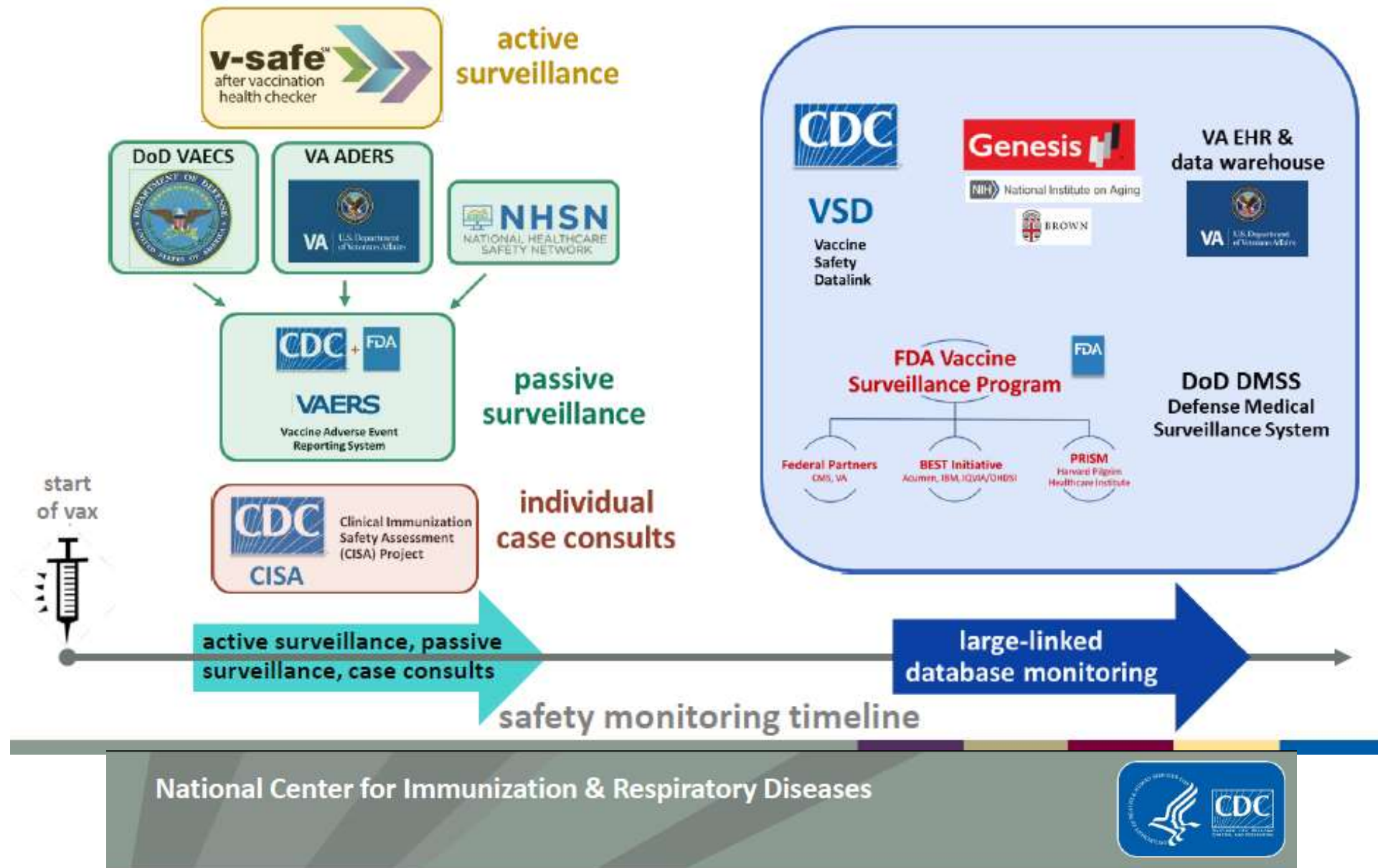
ACOG recommends COVID-19 vaccines be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP. While lactating individuals were not included in most clinical trials, COVID-19 vaccines should 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](#)).

Individuals Contemplating Pregnancy

Vaccination is strongly encouraged for non-pregnant individuals within the ACIP prioritization group(s). 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.

Post-Vaccination follow-up:

There is substantial pre-existing infrastructure through the CDC to track vaccine safety



CDC asks that:

- Vaccination providers help CDC get the word out to vaccine recipients:
 - Give a one-page **info sheet** to patients at the time of vaccination.
 - Counsel patients on the importance of enrolling in **v-safe**.

Questions are asked about pregnancy at the time of the COVID-19 vaccine and a registry will be created

Hi Olivia, It's time for your first health check-in.

<https://vsafe.cdc.gov/xyz123>

Click the text link to start v-safe check-in



**Get vaccinated.
Get your smartphone.
Get started with v-safe.**

What is v-safe?
v-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And **v-safe** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's **v-safe** makes a difference — it helps keep COVID-19 vaccines safe.

How can I participate?
Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from **v-safe** around 2pm local time. To opt out, simply text "STOP" when **v-safe** sends you a text message. You can also start **v-safe** again by texting "START."

How long do v-safe check-ins last?
During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **v-safe** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?
Yes. Your personal information in **v-safe** is protected so that it stays confidential and private.*

*To the extent v-safe uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

12/01/20

v-safeSM
after vaccination
health checker

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.



Sign up with your smartphone's browser at vsafe.cdc.gov
OR
Aim your smartphone's camera at this code



<https://www.cdc.gov/vsafe>

Report an Adverse Event to VAERS

VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences. Anyone can submit a report to VAERS, including parents and patients.

Healthcare providers are **required by law** to report to VAERS:

- Any adverse event listed in the [VAERS Table of Reportable Events Following Vaccination](#) that occurs within the specified time period after vaccinations
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

Healthcare providers are strongly **encouraged** to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
- Vaccine administration errors

Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention.



[Click here for guidance to healthcare providers on reporting adverse events to VAERS after COVID-19 vaccination](#)

Dr. Fauci says (2/3/21):

..... There have been “no red flags” seen in the more than 10,000 pregnant women who have received Covid-19 vaccine shots so far....

Since the authorization of the [Moderna](#) and [Pfizer-BioNTech](#) vaccines in December, over 10,000 pregnant women, many of whom were health-care workers, have gotten the shots, Fauci said. He noted that there is evidence that a coronavirus infection can lead to heightened risk of an adverse outcome in pregnancy, which might be why many pregnant health-care workers decided to get the vaccine.



Decision Tool (not validated but pretty good)



I'm pregnant. Should I get the COVID vaccine?

For most people, getting the COVID vaccine as soon as possible is the safest choice.

However, trials testing the vaccine in pregnant and breastfeeding women have not been completed.

The information below will help you make an informed choice about whether to get the COVID vaccine while you are pregnant or trying to get pregnant.

Your options:



Get the COVID vaccine as soon as it is available



Wait for more information about the vaccine in pregnancy

What are the benefits of getting the COVID Vaccine?

1. COVID is dangerous. It is more dangerous for pregnant women.

- COVID patients who are pregnant are 5 times more likely to end up in the intensive care unit (ICU) or on a ventilator than COVID patients who are not pregnant.¹
- Preterm birth may be more common for pregnant women with severe COVID, but other obstetric complications such as stillbirth do not appear to be increased.²
- Pregnant women are more likely to die of COVID than non-pregnant women with COVID who are the same age.^{3,4}



2. The COVID vaccine will prevent 95% of COVID infections.

- As COVID infections go up in our communities, your risk of getting COVID goes up too.
- Getting the vaccine will prevent you from getting COVID and will help keep you from giving COVID to people around you.

3. The COVID vaccine cannot give you COVID.

- The COVID vaccine has no live virus.⁵
- The COVID vaccine does NOT contain ingredients that are known to be harmful to pregnant women or to the fetus.
- Many vaccines are routinely given in pregnancy and are safe (for example: tetanus, diphtheria, and flu).

More details about how the vaccine works can be found on page 5.

What are the risks of getting the COVID vaccine?

1. The COVID vaccine has not yet been tested in pregnant women.

- The vaccine was tested in over 20,000 people, and there were no serious side effects. However, it was not tested in pregnant women.
- We do not have data on whether the vaccine works as well in pregnancy as it did in the study of non-pregnant individuals.
- We do not have data on whether there are unique downsides in pregnancy, like different side effects or an increased risk of miscarriage or fetal abnormalities.



2. People getting the vaccine will probably have some side effects.

- Although there were no serious side effects reported, many people had some side effects. The side effects of the vaccine were:
 - injection site reactions like sore arm (84%)
 - fatigue (62%)
 - headache (55%)
 - muscle pain (38%)
 - chills (32%)
 - joint pain (24%)
 - fever (14%)
- About 1% of people will get a high fever (over 102°F). A persistent high fever during the first trimester of pregnancy might increase the risk of congenital defects or miscarriage. For those reasons, you may choose to delay your COVID vaccine until after the first trimester.
- The CDC recommends using Tylenol (acetaminophen) during pregnancy if you have a high fever.

What do the experts recommend?

COVID is very dangerous and can spread very easily. Because of this, **"the Pfizer-COVID vaccine is recommended for persons 16 years of age and older in the U.S. population under the FDA's Emergency Use Authorization."**(CDC)⁶

However, because there are no studies of pregnant women yet, there are no clear recommendations for pregnant women. This is standard for a new drug and is not due to any particular concern with this vaccine.

The **Society for Maternal-Fetal Medicine** **strongly recommends** that pregnant individuals have access to COVID vaccines. They recommend that each person have a discussion with their healthcare professional about their own personal choice.⁷

The **American College of Obstetricians and Gynecologists** recommends that the COVID vaccine should **not** be withheld from pregnant individuals who meet criteria for vaccination.⁸

What else should I think about to help me decide?

1

Make sure you understand as much as you can about COVID and about the vaccine. Ask a trusted source, like your midwife or doctor. Page 5 has more information about the vaccine.

2

Think about your own personal risk. Look at the columns below and think about your risk of getting COVID (Left). Think about your safety - are you able to stay safe (Right)?

The risks of getting sick from COVID are higher if...

- You have contact with people outside your household who do not wear masks
- You are 35 years old or older
- You are overweight
- You have other medical problems such as diabetes, high blood pressure, or heart disease
- You are a smoker
- You are a racial or ethnic minority, or your community has a high rate of COVID infections
- You are a healthcare worker⁹

If you are not at higher risk for COVID and...

- ...you are always able to wear a mask
- ...you and the people you live with can socially distance from others for your whole pregnancy
- ...your community does NOT have high or increasing COVID cases
- ...you think the vaccine itself will make you very nervous (you are more worried about the unknown risks than about getting COVID)
- ...you have had a severe allergic reaction to a vaccine

If you are at a higher risk of getting COVID, it probably makes sense to get the vaccine.

... it might make sense for you to wait for more information.



Baystate Health



University of Massachusetts Medical School

If patients want counseling about reproduction (pregnant, planning, breastfeeding) and you want UVMMC to discuss with them:

- Schedule consult with MFM as usual (mostly Meyer and Brown)
- We can do counselling by telemedicine consult
- Only people that are candidates for vaccine now
- (we should change from shot to jab)



Thank you!



Upcoming Webinars

In collaboration with UVMHC, Vermont Dept. of Health, VCHIP

Upcoming Webinars:

- **2/26/21**– 11am-12noon EST – Improving Care for New Americans
- **03/16/21** – 12-1pm EST – Alliance for Innovation on Maternal Health (AIM) & Perinatal Mood and Anxiety Disorders (PMADs)