

COVID-19 Region 7 Webinar for Critical Access Hospitals and Outpatient Facilities

Presented by Nebraska Medicine and the University of Nebraska Medical Center in collaboration with the Centers for Disease Control (CDC) through NICS (National Infection Control Strengthening for Small and Rural Hospitals)

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Today's topic: The COVID-19 Vaccine in Pregnancy and Lactation

Guidance and responses were provided based on information known on 1/19/2021 and may become out of date. Guidance is being updated rapidly, so users should look to CDC and jurisdictional guidance for updates.

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Acknowledgement:

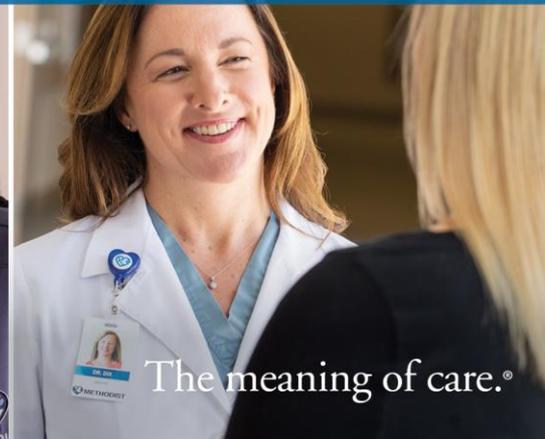
Today's presentation is produced in cooperation with Nebraska ICAP (Infection Control Assessment and Promotion Program)





mRNA COVID-19 Vaccine in Pregnancy and Lactation

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Background

- 12/11/2020: FDA EUA for Pfizer BioNTech COVID-19 vaccine
- Studied in >43,000 participants
- 16yo and older
- RCT
- People with stable chronic conditions WERE included (HIV, hepatitis, diabetes, cHTN)
- Pregnant and lactating women were excluded from the initial trial



Background

- 12/18/2020: FDA EUA for Moderna COVID-19 vaccine
- Studied in >30,000 participants
- 18yo and older
- RCT
- People with stable chronic conditions WERE included (HIV, hepatitis, diabetes, cHTN)
- Pregnant and lactating women were excluded from the initial trial



Administration

- 2-dose series, IM, 3-4 weeks apart
 - 4-day grace period
- If outside 4-day grace period, give dose ASAP, do not repeat doses.
- Can be given to those with hx of SARS-CoV-2 illness
 - Consider vaccination after 90 days from infection
- Administer **ALONE**
 - In pregnancy: do not administer within 14 days (before or after) of influenza or Tdap vaccines
 - If given within 14 days inadvertently, do not repeat doses of any of the vaccines.

Polack et al. Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine. NEJM: Dec 11, 2020

Baden et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine

Oliver et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine. MMWR: Dec 13, 2020

Oliver et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020



Pregnancy and COVID illness

- Increased risk of the following:
 - ICU admission (3-fold increase)
 - Mechanical ventilation (3-fold increase)
 - ECMO (2-fold increase)
 - Death (1.7-fold increase)
- Other critical risks:
 - Pneumonia, ARDS
 - Arrhythmias
 - VTE
 - Secondary infections
 - Acute kidney failure
 - Neurologic disorders – Headache, strokes, seizures
 - Gastrointestinal and liver disorders

Badr et.al. Are clinical outcomes worse for pregnant women at ≥ 20 weeks' gestation infected with coronavirus disease 2019? A multicenter case-control study with propensity score matching. *Am J Obstet Gynecol.* 2020;223(5):764.

Zambrano et.al. Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status - United States, January 22-October 3, 2020. *MMWR Morb Mortal Wkly Rep.* 2020;69(44):1641. Epub 2020 Nov 6.



mRNA Vaccine Pregnancy

- Population excluded in trial
 - Ongoing and planned human studies
- DART studies
 - Rats administered mRNA vaccine IM
 - 4 full human doses
 - Between pre-mating day 21 and gestational day 20
 - No direct or indirect harm
 - Antibody response noted in mothers, fetuses and offspring
 - No fertility effects
 - No adverse embryo/fetal development



mRNA Vaccine Pregnancy

- mRNA vaccines
 - 4 lipid nanoparticles encase the mRNA
 - NOT live or attenuated
 - Do NOT enter the nucleus of the cell
 - SE: fevers, muscle aches, fatigue, joint pain
 - Tylenol as needed for fevers in pregnancy

Polack et.al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. NEJM: Dec 11, 2020

Baden et.al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine



mRNA Vaccine Pregnancy

- Consider the following:
 - Level of COVID-19 transmission in community
 - Personal risk of contracting COVID-19
 - Risk of COVID-19 during pregnancy
 - Efficacy of vaccine
 - Side effects of vaccine
- It is **NOT** recommended that women have a pregnancy test prior to the receipt of the vaccine



mRNA Vaccine Lactation

- Lactating mothers were excluded
- Not live virus vaccine, not thought to be risk for the newborn
 - Consider we allow breastfeeding in COVID+ mother
- No need to avoid or discontinue breastfeeding or pumping during receipt of vaccine



mRNA Vaccine Preg/Lac

- “Should I get the vaccine if pregnant or lactating?”
 - The COVID-19 vaccine should not be withheld from pregnant or lactating women when they meet criteria for vaccination.
 - No safety signals noted from preliminary DART studies or from the phase 3 trial
 - Risk of COVID illness in pregnancy is higher than risks of vaccination
 - Pregnant women should be allowed to make an informed decision in conjunction with her healthcare team
 - Pregnant women should not be required to have “permission” from a doctor prior to receipt



mRNA Vaccine Preg/Lac

- Should I get the vaccine if I am trying to get pregnant?
 - Yes! You should not delay receipt of the vaccine if you are eligible
 - It is not necessary to delay pregnancy after receipt of the vaccine
 - It is not recommended that women of child bearing age have routine pregnancy testing prior to vaccination



mRNA Vaccine Myths

- Myths:

- ~~• The vaccine will alter fetal/newborn DNA~~

- mRNA does not enter nucleus and is degraded after production of the spike protein antigen

- ~~• The vaccine causes infertility~~

- Syncytin-1 shares 1 peptide (3 amino acids) in common with the spike protein.
- Syncytin-1 has a total of 538 aa and Spike protein has 510 aa
- “Mistaking a dog for a cat because they are wearing the same collar”
- Immune system does not recognize such small peptides as antigens to attack (<1% similar)



Ongoing monitoring

- V-SAFE
 - CDC surveillance, smart phone based
 - Pregnancy and lactation info to be collected
- Vaccine Adverse Event Reporting System (VAERS)
 - Early warning system for safety concerns
 - HCP to report significant adverse events



Ongoing Studies

- Mt. Sinai COVID vaccine during lactation study
 - covid19humanmilkstudy@gmail.com
- UC San Diego breast milk study
 - <https://betterbeginnings.org/what-we-do/research/breast-milk/>
 - <https://medschool.ucsd.edu/research/coe/momicore/research/Pages/COVID-19.aspx>
- RedCaps Univ of Washington Preg/Lac study
 - https://urlisolation.com/browser?c=3&clickId=5A4A7896-E786-40DA-A805-8C3486E8E8F4&traceToken=1611609461%3Bnmhs_hosted%3Bhttps%3A%2Ffredcap.iths.org%2Fsurveys%2F%3F&url=https%3A%2F%2Ffredcap.iths.org%2Fsurveys%2F%3Fs%3D87JFRCL8R8%26fbclid%3DIwAR225QthIHXuSPt06puoDIOB48ZhpTjETwblwVIYwPMfpdnGjLbfo0HFoc0



mRNA Vaccines and Anaphylaxis

- Reports of anaphylaxis outside the trial setting
 - Thought to be related to polyethylene glycol (PEG) nanoparticle
 - PEG is a component in other INJECTABLE medications
 - Those with allergy to injectable meds should be observed for 30m after vaccine receipt.



Vaccine confidence

- No steps were skipped in development and evaluation of the mRNA COVID-19 vaccine
- mRNA has been studied for over a decade for use as a vaccine and was a candidate vaccine for SARS-CoV-1 and MERS
- Can be produced in large quantity in vitro



Bottom line

- Women who are considering pregnancy, pregnant or lactating should be offered the mRNA COVID-19 vaccine when they meet criteria for receipt.
- Resources for providers: (SMFM, ACOG, CDC, ACIP)

[https://s3.amazonaws.com/cdn.smfm.org/media/2591/SMFM_Vaccine_Statement_12-1-20_\(final\).pdf](https://s3.amazonaws.com/cdn.smfm.org/media/2591/SMFM_Vaccine_Statement_12-1-20_(final).pdf)

[https://s3.amazonaws.com/cdn.smfm.org/media/2641/Provider_Considerations_for_Engaging_in_COVID_Vaccination_Considerations_12-15-20_\(final\).pdf](https://s3.amazonaws.com/cdn.smfm.org/media/2641/Provider_Considerations_for_Engaging_in_COVID_Vaccination_Considerations_12-15-20_(final).pdf)

[Vaccinating Pregnant and Lactating Patients Against COVID-19 | ACOG](#)

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2F covid-19%2Finfo-by-manufacturer%2Fpfizer%2Fclinical-considerations.html



mRNA COVID-19 Vaccine in Pregnancy and Lactation

- QUESTIONS?

Announcements and Updates

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Upcoming Webinars

2/16/2021- Live Question and Answer Webinar

- We want to know the hot topics and questions you would like us to discuss.

If you would like to pre-submit questions or topics for discussion

- Go to <https://forms.gle/4txREuvzsC2mfE3L8> and fill out the short Google form to submit questions



COVID-19 Tele-ICAR Assessments

- ICAP is offering COVID-19 focused virtual ICAR assessments to outpatient and acute care facilities
- The assessment will assess the status of COVID-19 policies and procedures and offer a summary of recommendations from ICAP
- Home Health Agencies fall under the outpatient umbrella and ICAP has developed a HH focused survey to support our HH partners
- Contact NE ICAP at 402.552.2881 to be connected with the IP responsible for the facility



Question and Answer Session

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Question and Answer session

Use the QA box in the webinar platform to type a question. Questions will be read aloud by the moderator; in the order they are received. A transcript of the discussion will be made available on the ICAP website

COVID-19 WEBINARS

Home / COVID-19 Webinars

Nebraska DHHS in association with the Nebraska ICAP team is hosting webinars on COVID-19 to address situation updates and essential information on COVID-19.

+	COVID-19 LTCF Webinar Slides
+	COVID-19 LTCF Webinar Recordings
+	COVID-19 Outpatient Webinar Slides
+	COVID-19 Outpatient Webinar Recordings
+	COVID-19 Update for Outpatient and Small & Rural Hospitals Webinar Slides
+	COVID-19 Update for Outpatient and Small & Rural Hospitals Webinar Recordings

COVID-19 RESOURCES –
HEALTHCARE FACILITIES

COVID-19 RESOURCES – PPE

COVID-19 RESOURCES –
SCHOOLS & BEHAVIORAL HEALTH

COVID-19 RESOURCES – EXPERT
INFORMATION

COVID-19 WEBINARS

COVID-19 TOOLS FOR LTCF

STAFFING RESOURCES



Infection Prevention and Control Office Hours

Monday – Friday

8:00 AM – 10:00 AM Central Time

2:00 PM -4:00 PM Central Time

Call 402-552-2881



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