Welcome & Introduction
Dana Wollins, DrPH, MGC
Vice President, Clinical Affairs & Guidelines
IDSA

- 61st in a series of weekly calls, initiated by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19

- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.

- This webinar is being recorded and can be found online at www.idsoociety.org/cliniciancalls.
TODAY’S CALL:

COVID-19 in Pregnant Individuals; Vaccine Q&A

Hosted in partnership with the American College of Obstetricians & Gynecologists (ACOG)

COVID-19 in Pregnant Individuals

Titilope Oduyebo, MD, MPH, FACOG
Medical Officer
v-safe Pregnancy Registry
Maternal COVID-19 Immunization
U.S. Centers for Disease Control and Prevention

Sarah Mbaeyi, MD, MPH
Chief Medical Officer, COVID-19 Vaccine Task Force
U.S. Centers for Disease Control and Prevention

Vaccine Q&A

Linda O. Eckert, MD
Professor, Obstetrics & Gynecology
Adjunct Professor, Global Health
University of Washington
ACOG Liaison, Advisory Committee on Immunization Practices (ACIP)
Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button
COVID-19 During Pregnancy

Titilope Oduyebo MD, MPH, FACOG
Medical Officer
v-safe Pregnancy Registry
Maternal COVID-19 Immunization

Infectious Diseases Society of America
April 10, 2021

cdc.gov/coronavirus
Disclosure

▪ I have no potential conflicts of interest to disclose.

▪ The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention (CDC).
COVID-19 during pregnancy
US Data on COVID-19 during Pregnancy

Pregnant women with COVID-19 by age

Pregnant women with COVID-19 by race/ethnicity

https://covid.cdc.gov/covid-data-tracker/#pregnant-population
What Do We Know So Far?

- Susceptibility to infection and disease severity among pregnant women
- Mother-to-child transmission
- Effects on the embryo, fetus, and neonate
COVID-19 in Pregnancy Living Systematic Review

- Pregnant and recently pregnant people with COVID-19 diagnosed in a hospital
  - May be less likely to show symptoms of fever and myalgia
  - Fever and cough most common, among ~40% of pregnant people with COVID-19

- Risk factors for severe COVID-19 in pregnancy
  - Older maternal age (≥ 35)
  - High body mass index (≥ 30)
  - Underlying medical conditions
Severity of COVID-19 during Pregnancy: Living Systematic Review and Meta-Analysis

- Illness severity: pregnant women with COVID-19 vs. nonpregnant women with COVID-19

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>No of studies</th>
<th>Women (No with event/No in group (%))</th>
<th>Odds ratio (95% CI)</th>
<th>I² (%)</th>
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<tr>
<td></td>
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<td>Pregnant women with covid-19</td>
<td>Comparison group</td>
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<tr>
<td>All cause mortality</td>
<td>8</td>
<td>103/34 047 (0.3)</td>
<td>3388/567 075 (0.6)</td>
<td>0.96 (0.79 to 1.18)</td>
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<tr>
<td>ICU admission</td>
<td>7</td>
<td>616/34 035 (1.8)</td>
<td>9568/567 073 (1.7)</td>
<td>2.13 (1.54 to 2.95)</td>
</tr>
<tr>
<td>Invasive ventilation</td>
<td>6</td>
<td>270/34 001 (0.8)</td>
<td>3280/567 043 (0.6)</td>
<td>2.59 (2.28 to 2.94)</td>
</tr>
<tr>
<td>ECMO</td>
<td>2</td>
<td>17/30 446 (0.1)</td>
<td>120/431 490 (0.0)</td>
<td>2.02 (1.22 to 3.34)</td>
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Birth outcomes among Pregnant People with COVID-19
Living Systematic Review and Meta-Analysis

- Birth outcomes: pregnant women *with* COVID-19 vs. pregnant women *without* COVID-19

<table>
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<th>Odds ratio (95% CI)</th>
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<td>Comparison group</td>
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<tr>
<td>Perinatal outcomes:</td>
<td></td>
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<tr>
<td>Stillbirth</td>
<td>9*</td>
<td>9/1039 (0.9)</td>
<td>26/4755 (0.5)</td>
<td>2.84 (1.25 to 6.45)</td>
</tr>
<tr>
<td>Neonatal death</td>
<td>8*</td>
<td>4/970 (0.4)</td>
<td>5/3316 (0.2)</td>
<td>2.77 (0.92 to 8.37)</td>
</tr>
<tr>
<td>Admission to neonatal unit</td>
<td>10*</td>
<td>329/1285 (25.6)</td>
<td>519/4588 (11.3)</td>
<td>4.89 (1.87 to 12.81)</td>
</tr>
<tr>
<td>Preterm birth &lt;37 weeks</td>
<td>18</td>
<td>147/1184 (12.4)</td>
<td>572/7365 (7.8)</td>
<td>1.47 (1.14 to 1.91)</td>
</tr>
</tbody>
</table>

Mother-to-Child Vertical Transmission of SARS-CoV-2 and Disease Severity among Infants

- A small number of newborns tested positive shortly after birth despite no contact with their mother post-delivery.

- SARS-CoV-2 infections in neonates (≤ 28 days) are uncommon.
  - Majority of these infections are either asymptomatic or result in mild disease

2. CDC. MMWR. Coronavirus Disease 2019 in Children — United States, February 12–April 2, 2020
3. Walker et al. Maternal transmission of SARS-COV-2 to the neonate, and possible routes for such transmission: a systematic review and critical analysis
COVID-19 vaccination during pregnancy
Clinical Considerations: COVID-19 Vaccination during Pregnancy

- Pregnant persons may choose to be vaccinated.

- A discussion with a healthcare provider can help make an informed decision; however, it is not required prior to vaccination.
Limited Safety Data for COVID-19 Vaccines in Pregnancy

- No safety concerns in animal developmental and reproductive toxicity (DART) studies on Pfizer-BioNTech, Moderna, or Janssen COVID-19 vaccines

- Pregnant persons excluded from Pfizer, Moderna, and Janssen COVID-19 vaccine clinical trials
  - No safety concerns noted among those inadvertently vaccinated with Pfizer, Moderna, or Janssen COVID-19 vaccines

- mRNA and adenovirus vaccines
  - mRNA degrades quickly by normal cellular processes and doesn’t enter the nucleus of the cell
  - Data available on use of Ebola adenovirus vaccine during pregnancy

CDC Activities: Monitoring COVID-19 Vaccine Safety During Pregnancy
Vaccine safety monitoring systems
Vaccine safety monitoring systems

VAERS

Immunization Safety Office

CISA

VSD

v-safe pregnancy registry
v-safe After-Vaccination Health Checker

Text message check-ins from CDC (daily 1st week; weekly through 6 weeks; then at 3, 6, and 12 months) and vaccine recipients choose to complete web survey

✓ Received medical care

v-safe call center follows up and takes a VAERS report if appropriate.

✓ Reported pregnancy

Pregnancy registry team calls to assess eligibility, and for those eligible, obtains consent for enrollment and follow-up.†

†Participants are contacted once per trimester, after delivery, and when the infant is 3 months old.

Outcomes of interest include miscarriage and stillbirth, pregnancy complications, maternal intensive care unit admission, adverse birth outcomes, neonatal death, infant hospitalizations, and birth defects.
Preliminary Data from v-safe: Pregnant and Non-pregnant Persons

<table>
<thead>
<tr>
<th></th>
<th>Pfizer-BioNTech</th>
<th>Moderna</th>
<th>Total</th>
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<tbody>
<tr>
<td>Pregnancies reported to v-safe†</td>
<td>16,039</td>
<td>14,455</td>
<td>30,494</td>
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* † Self-reported during a v-safe health check-in

Preliminary v-safe data as of Feb 16, 2021 from Day 1 check-ins indicate similar rates of:

– Health impacts
– Local reactions
– Systemic reactions

UPDATE: 77,960 pregnant people reported to v-safe (as of April 5, 2021)

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf
v-safe Pregnancy Registry

Smartphone-based platform that initiates active outreach among those who report medically attended events or pregnancy following COVID-19 vaccination and links to pregnancy registry

If a women reports:
✓ Pregnant at time of vaccination (initial survey for each dose)
✓ Had a positive pregnancy test since vaccination (Day 21, 42 of each dose and monthly surveys)

COVID-19 Vaccine Pregnancy Registry:
• Once each trimester during pregnancy
• Once after delivery
• Once after the infant is 3 months old

Medical records requested:
• At conclusion of pregnancy
• After first 3 months of infant’s life
v-safe Pregnancy Registry: Preliminary Reports

- 275 completed pregnancies as of Feb 19, 2021
  - Most are live births, based on self-report data
  - Most first dose vaccination in third trimester
  - No pregnancy or neonatal outcomes above the background rate

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### All Vaccines

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<tr>
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<tbody>
<tr>
<td>Enrolled</td>
<td>1,815</td>
</tr>
<tr>
<td>Not Eligible&lt;sup&gt;a&lt;/sup&gt;</td>
<td>103</td>
</tr>
<tr>
<td>Refused/Declined&lt;sup&gt;b&lt;/sup&gt;</td>
<td>31</td>
</tr>
</tbody>
</table>

<sup>a</sup> Eligibility assessment determines whether vaccination was during pregnancy or within 30 days of last menstrual period
<sup>b</sup> 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

UPDATE: 4,218 pregnant people enrolled in pregnancy registry (as of April 5, 2021)

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf
Summary

- Although the overall risk of severe illness is low, pregnant people are at an increased risk for severe illness from COVID-19 when compared to non-pregnant people.

- Pregnant people with COVID-19 are at increased risk for poor birth outcomes including preterm birth.

- Pregnant women were not included in preauthorization clinical trials of COVID-19 vaccines.

- Post-authorization safety monitoring and research are important to obtain safety and effectiveness data on COVID-19 vaccination during pregnancy.

- Substantial numbers of self-reported pregnant persons (>75,000) have registered in v-safe.
  - The reactogenicity profile and adverse events observed among pregnant persons in v-safe have not indicated any safety problem.

- Preliminary safety data on COVID-19 vaccine in pregnancy have not identified any safety signal; however, most data so far are from people vaccinated late in pregnancy.

One-stop Shop Toolkit for Pregnant People and New Parents

Web Resources
- Pregnancy, Breastfeeding, and Caring for Newborns
- COVID-19 Vaccination Considerations for People Who Are Pregnant
- V-safe After Vaccination Health Checker

Clinical Care Guidance
- Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States
- Guidance on Care for Breastfeeding Women
- Considerations for Inpatient Obstetric Healthcare Settings

Pregnant People & New Parents

Pregnancy, Breastfeeding, and Caring for Newborns

Vaccination Considerations for People who are Pregnant or Breastfeeding

What You Can Do If You Are at Higher Risk of Severe Illness from COVID-19

Thank you
COVID-19 in Pregnant Individuals; Plus Vaccine Q&A
Hosted in partnership with the American College of Obstetricians and Gynecologists
Saturday, April 10, 3-4 p.m. ET

Linda O Eckert, MD
Professor, Obstetrics & Gynecology
Adjunct Professor, Global Health
ACOG Liaison to ACIP
@drlindaeckert
DISCLOSURES

• No financial conflicts of interests

• Receive no financial renumeration from manufacturers
ACOG Recommendations
Pregnant Individuals

- ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups.

- ACOG recommends that in the interest of patient autonomy, pregnant individuals should 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.
WHAT FACTORS SHOULD I CONSIDER?

- 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
  - Medical/ethnic risk factors
  - Living situation factors
- the safety of the vaccine for the pregnant patient and the fetus

Additional Considerations for Pregnant Individuals

• Similar to their non-pregnant peers, vaccination of pregnant individuals with a COVID-19 mRNA vaccine or with a viral vector 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.

• Pregnant women who experience fever following vaccination should be counseled to take acetaminophen.

• There is currently no preference for the use of one COVID-19 vaccine over another except for 16-17 year olds who are only eligible for the Pfizer-BioNtech vaccine.
Additional Considerations for Pregnant Individuals Cont.

- Individuals should complete their 2-dose series with the same vaccine product if receiving a mRNA vaccine.

- COVID-19 vaccines should not be administered within 14 days of receipt of another vaccine. For pregnant individuals, vaccines including Tdap and influenza should be deferred for 14 days after the administration of COVID-19 vaccines.

- Anti-D immunoglobulin (i.e. Rhogam) should not be withheld from an individual who is planning or has recently received a COVID-19 vaccine as it will not interfere with the immune response to the vaccine.
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.

• 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.
Individuals Contemplating Pregnancy

• **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.

• Given the mechanism of action and the safety profile of the vaccine in non-pregnant individuals, COVID-19 mRNA vaccines and viral vector vaccines are not thought to cause an increased risk of infertility. It is not necessary to delay pregnancy after completing both doses of the COVID-19 vaccine.

• If an individual becomes pregnant after the first dose of the COVID-19 vaccine series, the second dose should be administered as indicated.

• Pregnancy testing should not be a requirement prior to receiving any COVID-19 vaccine.
RECENT GOOD NEWS
Several Studies Demonstrate Antibody Transfer from Vaccinated Pregnant Individual to Fetus

Research Letter

Cord Blood Antibodies following Maternal COVID-19 Vaccination During Pregnancy

Leena B. MITHAL MD MSCI 1,2,3, Sebastian OTERO BA 1, Elisheva D. SHANES MD 2, Jeffery A. GOLDSTEIN MD PhD 2, Emily S. MILLER MD MPH 3

N=27 pregnancies: 25/27 infants with IgG, concentration IgG increases with time since first vaccine dose
Several Studies Demonstrate Antibody Transfer from Vaccinated Pregnant Individual to Fetus

Original Research: Obstetrics

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

Kathryn J. Gray MD PhD 1, *, Evan A. Bordt PhD 2, *, Caroline Atyeo BS 3,4, *, Elizabeth Deriso PhD 3, Babatunde Akinwunmi MD MPH MMSc 1, Nicola Young BA 5, Aranxta Medina Baez BS 5, Lydia L. Shook MD 5,6, Dana Cvrl CNM 5, Kaitlyn James PhD, MPH 5, Rose De Guzman PhD 5, Sara Brigida BA 5, Khady Diouf MD 1, Ilona Goldfarb MD MPH 5, Lisa M. Bebell MD 7, Lael M. Yonker MD 8, Alessio Fasano MD 8, S. Alireza Rabi MD 9, ... Andrea G. Edlow MD, MSc 5,6,..

N=10 cord blood samples from vaccinated individuals
• 10/10 had IgG to spike protein present in cord blood
• IgA also present in breast milk
Several Studies Demonstrate Antibody Transfer from Vaccinated Pregnant Individual to Fetus

Antibody response to SARS-CoV-2 mRNA vaccines in pregnant women and their neonates

Malavika Prabhu, M.D.¹; Elisabeth A. Murphy, Ph.D.²; Ashley C. Sukhu, B.S.³; Jim Yee, B.S.⁴; Sunidhi Singh, B.A.¹; Dorothy Eng, B.A., B.S.⁴; Zhen Zhao, Ph.D.³,⁴; Laura E. Riley, M.D.¹; Yawei J. Yang, M.D., Ph.D.³,⁴

122 pregnant individuals
N=55: 1 dose, 24/55 (43.6%) infants with IgG
N=67: 2 doses, 65/57 (98.5%) infants with IgG

bioRxiv preprint doi: https://doi.org/10.1101/2021.04.05.438524; this version posted April 6, 2021
BENEFITS TO CONSIDER

• Protecting fetus
  • HEALTHY mom better for fetus!
  • may be associated with preterm birth

• Protecting Infant
  • Maternal antibody passed via cord blood and breast milk to baby

• Protecting Post partum Mom
  • May decrease her need for isolation, and increase options for support
Patient: “I am planning to get pregnant, should I get the COVID-19 Vaccine?”

Me: “Yes!”

- No mixing of DNA
- No persistence of vaccine materials in the body
- No adjuvants or preservatives in the vaccines
- No chance to get COVID-19 from vaccines
- No increased risk of miscarriage in data thus far

COVID-19 in pregnancy is a KNOWN risk

ACOG RESOURCES
ACOG Practice Advisory

Comprehensive clinical guidance for ACOG members regarding COVID-19 Vaccination for Pregnant and Lactating Individuals.

Conversation Guide for Clinicians

Highlights the main conversation points for clinicians from ACOG’s Practice Advisory to help discuss COVID-19 vaccines with pregnant individuals.

➢ Intended to help guide risk/benefit conversations

Vaccinating Pregnant Individuals: Eight Key Recommendations for COVID-19 Vaccination Sites

➢ Brand new resource from ACOG intended for all variations of COVID-19 vaccination sites

➢ Provides key recommendations from ACOG regarding COVID-19 vaccines and pregnancy

➢ Not intended to be a guide for risk/benefit conversations

https://www.acog.org/covid-19/vaccination-site-recommendations-pregnant-individuals
In response to reports of pregnant individuals being denied COVID-19 vaccines simply because of their pregnancy status, ACOG leveraged the *Maternal Immunization Task Force* to publish a joint statement with 17 partner organizations, further advocating for pregnant individuals to be free to make their own decision regarding their health, in conjunction with their clinical care team when appropriate.
COVID-19 resources on ACOG’s Patient Education Portal include:

➢ Expert columns

➢ Frequently Asked Questions
Coding for COVID-19 Immunizations

Brand new practice management resource outlining coding specifics for COVID-19 vaccines
THANK YOU!!

• Co-authors of the ACOG Practice Advisory: Laura E. Riley, MD; Richard Beigi, MD; Denise J. Jamieson, MD, MPH; Brenna L. Hughes, MD, MSc; Geeta Swamy, MD; Linda O’Neal Eckert, MD; Mark Turrentine, MD; and Sarah Carroll, MPH.

• ACOG- Expert Immunization and Emergency Preparedness Workgroup

• QUESTIONS?

@drlindaeckert
Q&A and Discussion
Vaccine Q&A

Sarah Mbaeyi, MD, MPH
Chief Medical Officer
CDC COVID-19 Vaccine Task Force

Dr. Mbaeyi has no disclosures to report.
Links from Today’s call

Slide 7- https://covid.cdc.gov/covid-data-tracker/#pregnant-population


Slide 44- https://www.acog.org/covid-19/vaccination-site-recommendations-pregnant-individuals
Attend, Learn & Collaborate.
Advancing Science, Improving Care

idweek.org
Virtual Conference

Save the Date
Sept. 29 – Oct. 3, 2021

Important Dates:
• Registration Opens – mid-May
• Abstract Submission Deadline – June 9
• Case Submission Deadline – June 9
An online community bringing together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.

Specialty Society Collaborators

- American Academy of Family Physicians
- American Academy of Pediatrics
- American College of Emergency Physicians
- American College of Physicians
- American Geriatrics Society
- American Thoracic Society
- Pediatric Infectious Diseases Society
- Society for Critical Care Medicine
- Society for Healthcare Epidemiology of America
- Society of Hospital Medicine
- Society of Infectious Diseases Pharmacists

www.COVID19LearningNetwork.org
@RealTimeCOVID19
#RealTimeCOVID19
CDC-IDSA Partnership: Clinical Management Call Support

FOR WHOM?
-Clinicians who have questions about the clinical management of COVID-19

WHAT?
- Calls from clinicians will be triaged by CDC to a group of IDSA volunteer clinicians for peer-to-peer support

HOW?
- Clinicians may call the main CDC information line at 800-CDC-INFO (800-232-4636)
- To submit your question in writing, go to www.cdc.gov/cdc-info and click on Contact Form
Continue the conversation on Twitter
@RealTimeCOVID19
#RealTimeCOVID19

We want to hear from you!
Please complete the post-call survey.

Next Call: Saturday, April 17th

A recording of this call will be posted at
www.idsociety.org/cliniciancalls
-- library of all past calls now available --

Contact Us:
Dana Wollins (dwollins@idsociety.org)
Deirdre Lewis (dlewis@idsociety.org)