COVID-19 Vaccination and Reproductive Health

Town Hall Webinar
May 27, 2021

AWHONN
PROMOTING THE HEALTH OF WOMEN AND NEWBORNS
Housekeeping Notes:

• All attendees are on mute.
• We will leave time at the end of the presentation for questions. Please submit questions via the Q&A section on your webinar application throughout the presentation.
• If you have technical difficulties, please try to log in using a different browser.
• We will be recording this presentation and will make the recording available on the AWHONN website.
• There are no nursing contact hours available with this presentation.
Open Forum

Ben Scheich, Vice President of Analytics, Operations, Policy, Strategic Initiatives will moderate the open forum.

Please add your questions or comments to the Q & A chat.

We will be sending out the slides and a link to this recording after the call is completed.

For more information, email practicereferenceline@awhonn.org or visit https://www.awhonn.org/education/obstetric-triage-orientation-education/
Presenter

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Vice President of Nursing, Education, Research, and Practice

Association of Women’s Health, Obstetrics and Neonatal Nursing
Disclosure

The COVID Vaccine Facts for Nurses campaign is proudly sponsored by:

Johnson & Johnson

The American Nurses Association and its collaborating organizations are solely responsible for the data and related content associated with this campaign. The campaign’s commercial sponsor was not involved in development of this content.
**LISTEN**
Use surveys, town hall meetings, and other mechanisms to actively identify and rapidly address concerns from the nursing community.

**EDUCATE**
Provide materials for nurses to use in educating themselves, their patients, and their communities on the COVID-19 vaccines. Particular attention to addressing the needs of at-risk communities.

**SHARE**
Collaboratively provide key open-source resources with nurses and organizations in user-friendly environment.

**AMPLIFY**
Exponentially increase the reach of educational materials related to the vaccines. Build reach and engagement across the nursing community.
Confirmed 23, Direct reach = more than 750,000:

- American Nurses Association
- American Nurses Foundation
- American Association of Critical Care Nurses (AACN-Critical Care)
- American Association of Occupational Health Nurses (AAOHN)
- American Organization for Nursing Leadership (AONL)
- American Society of Health-System Pharmacists (ASHP)
- Asian American / Pacific Islander Nurses Association (AAPINA)
- Association for Professionals in Infection Control and Epidemiology (APIC)
- Association of periOperative Registered Nurses (AORN)
- **Association of Women, Health Obstetric and Neonatal Nurses (AWHONN)**
- Chi Eta Phi Sorority, Inc.
- National Association of Hispanic Nurses (NAHN)
- National Association of Indian Nurses of America (NAINA)
- National Association of Neonatal Nurses & National Association of Neonatal Nurse Practitioners
- National Association of Pediatric Nurse Practitioners (NAPNAP)
- National Association of School Nurses
- National Black Nurses Association (NBNA)
- National Coalition of Ethnic Minority Nurse Associations (NCEMNA)
- Nurses Who Vaccinate
- Orthodox Jewish Nurses Association (OJNA)
- Philippine Nurses Association of America (PNAA)
- Sigma Theta Tau International Honor Society of Nursing (Sigma)
- Transcultural Nursing Society (TCNS)
Town Hall Agenda

• COVID-19 Risks in Pregnancy and Breastfeeding
• Emergency Authorization Use and COVID-19 Vaccine Types
• General COVID-19 Vaccine Safety
• Immunogenicity in Pregnancy and Lactation
• Preliminary Pregnancy Safety Data
• Professional Organization Recommendation
• Vaccine Considerations and Education
• Resources
COVID-19 Risks in Pregnancy/Breastfeeding

• Higher risk of severe illness in pregnant individuals than non-pregnant people
  • Severe illness includes hospitalization, ICU admission, breathing assistance and death
• Higher risk of preterm labor, Hypertension, Preeclampsia/Eclampsia
• Higher risk of NICU admission, Neonatal Respiratory Disease, severe neonatal morbidity index, and hyperbilirubinemia.
  • limited data indicating that placental transmission of the disease occurs (0.9%)
• Approximately 13 % of neonates born to patients with COVID 19 during pregnancy tested positive, with cesarean delivery increasing risk of positive neonate results.
• Breastfeeding was not found to increase infant positivity rate.

Villar, J., Artiff, S., Gunier, R.B. et al. (2021)
COVID 19 Vaccine Types & EUA

• Emergency Use Authorization (EUA)
  • Emergency Use Authorization Pathway

• mRNA- 2 currently released
  • require 2 doses
  • Age approved: 12 or 16
  • No live virus
  • Other mRNA vaccines used safely in pregnancy: Flu
  • No catch up if missed second dose

• Viral Vector- 1 currently released (1 in clinical trial)
  • Requires 1 dose
  • Age Approved: 16
  • Viral Vector- modified version
  • Other Viral Vector vaccines used safely in pregnancy: Ebola and Flu

• Recombinant Protein subunits (2 in clinical trial)
  • Other Recombinant protein vaccines used safely in pregnancy: Influenza
Safety Profile

• Intense monitoring through Vaccine Adverse Events Reporting System (VAERS) and v-safe

• December 14, 2020- January 2021 VAERS
  • 6,994 adverse events reported of 13,794,904 doses administered (.0005%)
    • headache, fatigue, and dizziness, myalgia, fever
  • 90.8% non-serious in nature and 9.2% as serious
    • Anaphylaxis 4.5 per million doses
    • Death 113 (65% LTCF patients)
    • Review of medical records, autopsy and death certificates indicated no association of death and the vaccine

• December 14, 2020-January 2021 v-safe
  • 10,825 of the 1.6 million vaccine recipients reported pregnancy at time of vaccine
  • 262 reported pregnancy after vaccination at the 3- or 6-week check-in
  • Non serious side effects that include injection site pain, headache, fatigue and myalgia

• Viral Vector Vaccine Pause
  • Thrombosis with thrombocytopenia syndrome (TTS) is a rare but serious condition if not diagnosed in early stages. Occurs within 3 weeks of vaccination and presents with s/s of blood clots or bleeding disorder.
    • Seen more in women less than 50
    • Pause lifted after review of records confirmed benefits outweigh the risk

Vaccine Immunogenicity in Pregnancy and Breastfeeding

- Preliminary data indicates placental transmission
  - Antibody response present in pregnant, lactating and non-pregnant women after receiving full vaccination
  - Antibodies present in infant cord blood and in breastmilk
  - 103 total 18-45, 66% white HS (30 pregnancy/16 lactation and 57 non-pregnant-vaccinated and 22 pregnant and 6 non-pregnant with previous infection
  - antibody response higher with vaccination than with infection for both maternal, cord blood and breast milk
  - All (n=122) participants had a negative SARS-CoV-2 Nasopharyngeal test upon admission for delivery and all dyads were symptom free through discharge
  - All received a mRNA vaccine- 55 (45%) received 1 dose; 67 (55 %) received 2 doses
  - Maternal antibody response: 87 (71 %) + IGG, 19 (16 %) + IGM and IGG, 16 (13 %) no antibody response.
  - Cord Blood IGG were found in 44% of those that received 1 dose and 99% in those that received 2 doses
  - IGG levels increase week by week, starting with 2 weeks after 1st dose (P=0.005 week 2-3, and P=0.019 weeks 3-4) as well as first and second week after second dose (P=2e-07)
  - Positive correlation with Maternal IGG levels, cord blood IGG levels (R=0.89, P=2.2e-16) and the placental transfer ratio with each elapsed week from receipt of the 2nd dose (R=0.8, P=2.6e-15).
  - Initial maternal antibody response as soon as 5 days after 1st vaccine and presence of IGG in cord blood samples as soon as 16 days after 1st vaccination.
  - All delivered healthy infants
Immunogenicity 2

• mRNA vaccines
• Maternal and cord blood samples for SARS-CoV-2 IGM and IGG antibodies
• Antibody transfer ratio (Cord blood IGG value/Maternal IGG value)
• 27 participants – delivered 28 infants
  • Maternal age mean of 33 (SD 3y)
  • Gestational age of first vaccination 33 weeks (SD2w)
  • 75% non-Hispanic white, 11% Hispanic
  • 74% received both doses
  • Mean latency from vaccination to delivery 6 weeks (SD 3w)
  • 50% maternal blood samples had + IGM at time of delivery, 0% of infants had +IGM
  • 96% maternal blood samples had +IGG at time of delivery
  • 25 of the 28 infants born had + IGG antibodies in cord blood
  • Increase time between vaccination and delivery correlated with higher transmission to infant ($\beta=0.2$, 95% CI 0.1-0.2), as did receiving the second dose ($\beta=19.0$, 95% CI 7.1-30.8) and latency from full vaccination to delivery ($\beta=2.9$, 95% CI 0.7-5.1)
Preliminary Safety Data 12/14/2020-2/28/2021

• v-safe self-reporting, v-safe pregnancy registry and VAERS
• 35,691 v-safe + pregnancy at time of and after vaccination
• Side effects consistent with non-pregnant—pain at injection site and nausea/vomiting seen more frequently in pregnancy
• 3,958 v-safe pregnancy registry referrals
  • 827 completed pregnancy
    • 712 (86%) delivery of live term baby
      • 9% preterm birth
      • 3% small for gestational age
      • 2% congenital abnormalities
      • Zero neonatal deaths
    • 115 (13.8%) pregnancy loss
      • SAB 12.6%
      • Stillbirth 0.1%
      • Other –TAB or ectopic 1.2%

• VAERS reports:
  • 221- SAB 16% 1st trimester, 1% second trimester SAB, PROM, stillbirth and vaginal bleeding

Safety Data in Pregnancy and Breastfeeding

• Manufacturers collecting data on clinical trial participants who have since become pregnant
• VAERS and V-safe programs
• Animal studies for all three available vaccines showed no adverse outcome to pregnancy, fetus or babies.

• Limited data on safety of vaccine in pregnancy, effects on fetus, milk production or fertility are becoming available

• Standardized pregnancy testing prior to vaccination is not recommended

• No guidance for breastfeeding after + COVID 19 test after delivery
  • Limited data on presence of COVID 19 in breast milk transmission, However, a small study conducted on 6 breastfeeding individuals showed no presence of SARS-CoV-2 in breastmilk
Professional Organization Recommendation

- **ACOG**
  - recommends offering COVID 19 Vaccine to Pregnant individuals
  - recommends all lactating individuals receive the COVID 19 Vaccine
  - Recommends those considering pregnancy to receive the COVID 19 Vaccine without delay in seeking pregnancy

- **AWHONN**
  - recommends a shared decision-making model between pregnant or lactating individual and their HCP

- **ACNM**
  - recommends a shared decision-making model between pregnant or lactating individual and their HCP

- **NPWH**
  - recommends a shared decision-making model between pregnant or lactating individual and their HCP

- **SMFM**
  - recommends that all pregnant individuals have access to the COVID 19 vaccine in consultation with HCP
  - Recommends vaccination for lactating individuals

- **American Academy of Breastfeeding**
  - identifies the potential benefit of passive immunity to infants

- **CDC**
  - recommends offering COVID-19 Vaccination to pregnant and breastfeeding patients
Vaccine Consideration

• Discussions with Healthcare provider
  • Consider personal health risks
    • obesity, diabetes, hypertension, asthma, cardiac disease, preterm risk
  • Risk of exposure to COVID-19
  • Timing of Vaccination regarding reactogenicity of vaccine
  • Benefits of vaccination
  • Safety evidence in pregnancy and lactation
  • Age of patient

• Racial and ethnic disparities
  • Black People are 3 times more likely to be diagnosed with COVID 19 than White People, usually as a result of comorbidities
  • Black People are 6 times more likely to die from COVID 19 than White People
  • Indigenous People are 4 times more likely to die from COVID 19 than White People

• Previous Vaccine allergic reactions
Education

• Fever- manage with antipyretic, not prophylactically
• Signs and symptoms of adverse events
  • Shortness of breath, difficulty breathing, feeling as if throat is closing
  • Pruritis, redness
  • Severe headache with or without visual changes
  • Swelling in legs
  • Change in mental status
  • Easy bruising
  • Epitaxis/Epipulsis
• Pump breastmilk if needed
• Strictly recommend all preventative measures that include face mask, frequent handwashing, social distancing, and vaccination.
Resources

- AWHONN Maternal Immunization Website
- AWHONN COVID 19 Website
- ANA Microsite
- VAERS
- CDC V-safe

CDC Sites:
- https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

- Mother to Baby Ask an Expert
References


- Dyer, O. (2020). Covid-19: Black People and Other Minorities are Hardest Hit in US. British Medical Journal, April 14, 369:m1483. DOI: 10.1136/bmj.m1483

References


References


Questions

Questions we are unable to address during this webinar may be submitted to:

Clinical Inquiries: Practicereferenceline@awhonn.org