

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



Karen Crowley, DNP, APRN-BC, WHNP, ANP, CNE

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.





COVID VACCINE

Facts 4 Nurses

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.

COVID VACCINE
Facts for Nurses

“The risk of getting COVID-19, particularly for our community, is greater than any harm of taking the vaccine.”

SANDRA LINDSAY
DIRECTOR OF NURSING FOR CRITICAL CARE
Long Island Jewish Medical Center | Northwell Health

COVIDVaccineFacts4Nurses.org
Source: Association of peri-Operative Registered Nurses

ANA AMERICAN NURSES ASSOCIATION
Registered Nurse

AMERICAN NURSES FOUNDATION

This advertisement features a portrait of Sandra Lindsay, a Black woman wearing a white lab coat and a blue surgical mask. The background is a light blue with faint white circular patterns. The text is primarily in white and blue, with the quote in a larger font. Logos for the American Nurses Association and American Nurses Foundation are visible in the bottom right corner.

COVID VACCINE
Facts for Nurses

More than **145 million** doses of COVID-19 vaccine have been administered in the U.S. since December.

ANA AMERICAN NURSES ASSOCIATION
AMERICAN NURSES FOUNDATION
AMERICAN ASSOCIATION OF CRITICAL CARE NURSES
AACN
AONL
ashp
NBNA
APIC
AORN
AWHONN
ASV
National Association of Pediatric Nurse Practitioners
Sigma

COVIDVaccineFacts4Nurses.org
Source: Centers for Disease Control and Prevention

This advertisement features a portrait of a healthcare worker in full PPE, including a face shield and gloves. The background is a light blue with faint white circular patterns. The text is primarily in white and blue. A large number '145 million' is highlighted in blue. Logos for various nursing organizations are displayed in two rows at the bottom.



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)

COVID VACCINE
Facts for
Nurses

The likelihood of a severe side effect after receiving any COVID-19 vaccination is
less than 0.5%

COVIDVaccineFacts4Nurses.org
Source: American Nurses Association

ANA
AMERICAN NURSES ASSOCIATION

AMERICAN NURSES FOUNDATION

COVID VACCINE
Facts for
Nurses

50%
of unvaccinated
American nurses still
have questions about
COVID-19 vaccines.
We can help!

COVIDVaccineFacts4Nurses.org
Source: American Nurses Foundation Impact Survey

ANA
AMERICAN NURSES ASSOCIATION

AMERICAN NURSES FOUNDATION

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.



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
- 12/2020-3/2021 (Collier, A.Y., McMahan, K., Yu, J., et al. 2021)
 - 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
- 1/28/2021-3/31/2021 (Prabhu, M., Murphy, E.A., Sukhu, A.C. et al. 2021)
 - 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>
 - <https://www.cdc.gov/vaccinesafety/pdf/vsafe-pregnancy-surveillance-protocol-508.pdf>
- [Mother to Baby Ask an Expert](#)



References

- Advisory Committee on Immunization Practices. (2021). The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine- United States, December 2020. Morbidity and Mortality Weekly Report, 69(5125), 1657-1660. https://www.cdc.gov/mmwr/volumes69wr/mm695152e2.htm7s_cid=mm695152e_w
- American College of Obstetricians and Gynecologists. (2020). Vaccinating pregnant and lactating patients against COVID-19 (Practice Advisory). Vaccinating Pregnant and Lactating Patients Against COVID-19, ACOG.
- Bervieller, P., Guerby, P., Garabedian, C. (2020). COVID -19 and Breastfeeding: Not That Simple. Journal of Human Lactation, 00(0), 1-2.
- Collier, A.Y., McMahan, K., Yu, J., et al. (2021). Immunogenicity of COVID-19 mRNA Vaccines in Pregnant and Lactating Women. Journal of American Medical Association, May 13, E1-11. DOI: 10.1001/jama.2021.7563
- Center for Disease Control and Prevention. (2021). COVID-19: Pregnant or Breastfeeding. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html>
- Dumitiriu, D, & Gyamfi-Bannerman, C. (2021). Understanding Risks of Newborns Born to SARS-CoC-2 Positive Mothers. Journal of American Medical Association. April 29. DOI: 10.1001/jama.2021.6210
- 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
- Gee, J., Marquez, P., Su, J., et al. First Month of COVID 19 Vaccine Safety Monitoring-United States, December 14, 2020-January 13,2021.(2021). MMWR Morb Mortal Wkly Rpt; 70, 283-288. DOI: <http://dx.doi.org/10.15585/mmwr.mm7008e3>



References

- Mithal, L.B., Otero, S., Shanes, E.D., Goldstein, J.A., & Miller, E.S. (2021). Cord Blood Antibodies following Maternal COVID-19 Vaccination During Pregnancy. *American Journal of Obstetrics and Gynecology*, doi:<https://doi.org/10.1016/j.ajog.2021.03.035>.
- Prabhu, M., Murphy, E.A., Sukhu, A.C., Yee, J., Singh, S., Eng, D., Zhao, Z., Riley, L.E., Yang, Y.L. (2021). Antibody Response to Coronavirus Disease 2019 (COVID-19) Messenger RNA Vaccination in Pregnant Women and Transplacental Passage into Cord Blood. *Obstetrics and Gynecology*, 00(00), 1-3. DOI: 10.1097/AOG.0000000000004438.
- Rasmussen, S.A., Kelley, C.F., Horton, J.P., Jamieson, D.J. (2021). *Obstetrics and Gynecology*, 137(3), 408-414.
- Shay, D.K., Gee, J., Su, J.R., Myers, T.R., Marquez, P., Liu, R., Zhang, B., Licata, C., Clark, T.A., & Shimabukuro, T. T. (2021). Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine-United States, March-April 2021. *MMWR Morb Mortal Wkly Rpt*; 70(18), 680-694.
- Shimabukuro, T. T., Kim, S.Y., Myers, T.R., et al. (2021). Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. *New England Journal of Medicine*. April. DOI: 10.1056/NEJMoa2104983.



References

- Society for Maternal-Fetal Medicine. (2020). SARS-CoV-2 vaccination in pregnancy (Statement). [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)
- Villar, J., Artiff, S., Gunier, R.B. et al. (2021). Maternal and Neonatal Morbidity and Mortality Among Pregnant Women With and Without COVID-19 Infection: The INTERCOVID Multinational Cohort Study. *Journal of American Medical Association Pediatrics*, April. DOI: 10:1001/jamapediatrics.2021.1050
- Wallace M, Woodworth KR, Gargano JW, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 Years — United States, May 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:749–752. DOI: http://dx.doi.org/10.15585/mmwr.mm7020e1external_icon
- Woodworth, K.R., O'Malley-Olsen, E., Neelam V., et al. Birth and Infant Outcomes Following Laboratory-Confirmed SARS-CoV-2 Infection in Pregnancy-SET-NET, 16 Jurisdictions, March 29-October 14, 2020. *MMWR Morb Mortal Wkly Rep* 2020; 69(44), 1635-1640.



Questions

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

Clinical Inquiries: Practicereferenceline@awhonn.org

