


SARS-CoV-2 Infection and COVID-19 Vaccination In Lactating Individuals

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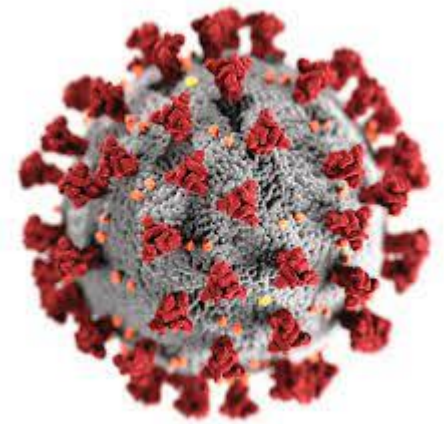
Disclosures

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SARS-CoV-2 Infection In Lactating Women

Background



- In December 2019, a disease outbreak, characterized by fever respiratory symptoms originated in China.
 - The pathogen was later identified as SARS-CoV-2 and the disease it causes was named COVID-19
- The United States reported it's first laboratory-confirmed case in Washington State in January 2020.
- Very little was known about the risk of spreading the illness through breastfeeding
- Early care reports from 24 SARS-CoV-2-infected women total
 - Detected viral RNA in ten breastmilk samples from four women.
 - In some but not all cases, environmental contamination as the source of the virus or retrograde flow from an infected infant could not be ruled out

SARS-COV-2 INFECTION IN LACTATION

- Mommy's Milk protocol was modified in March 2020, to capture COVID-19 symptoms, testing, treatment from all enrolled mothers, and to specifically recruit exposed, symptomatic, high risk
- As of June 2022, HMB has enrolled 650 lactating women across U.S. who met criteria
 - Tested positive
 - Symptomatic, not tested
 - Symptomatic, tested negative
 - High risk exposure, asymptomatic/not tested

Study Aims

- To examine the frequency and state of SARS-CoV-2 in the breast milk of women with recently documented infection

SARS-COV-2 INFECTION IN LACTATION

Research Letter

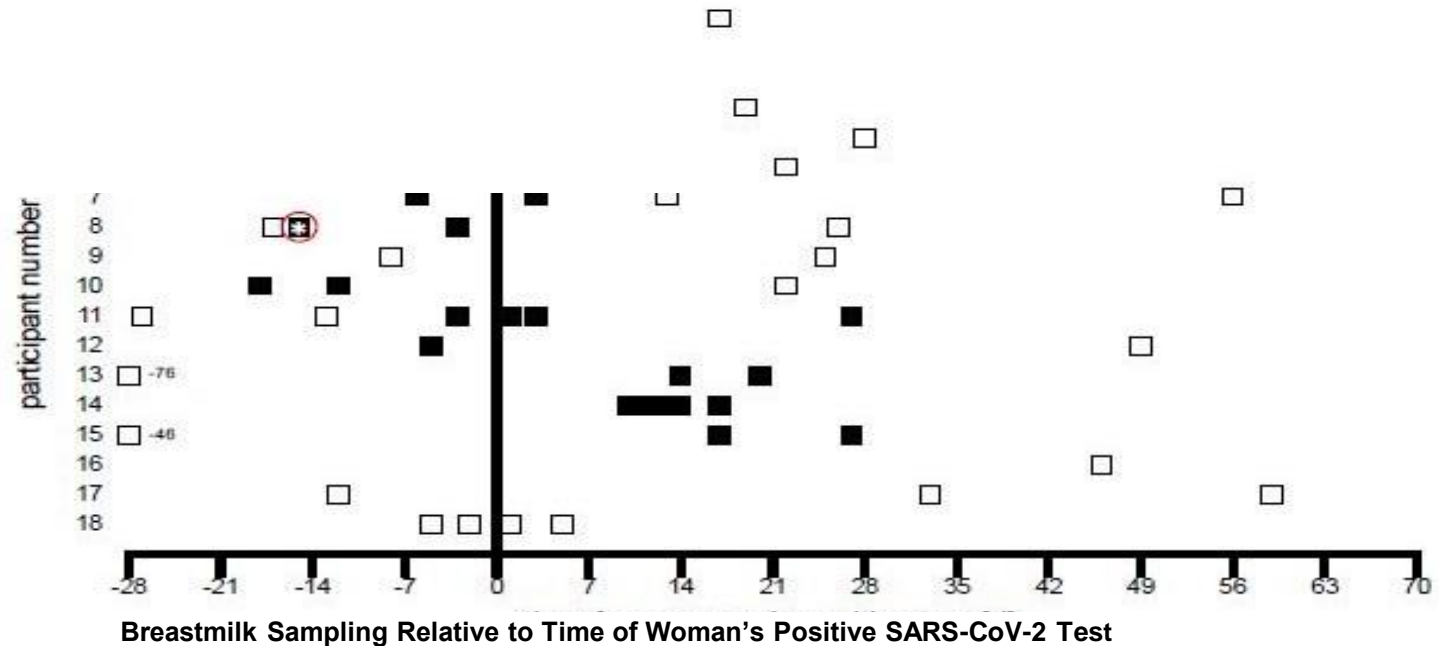
August 19, 2020

Evaluation for SARS-CoV-2 in Breast Milk From 18 Infected Women

Christina Chambers, PhD, MPH¹; Paul Krogstad, MD²; Kerri Bertrand, MPH¹; et al

[» Author Affiliations](#) | [Article Information](#)

JAMA. Published online August 19, 2020. doi:10.1001/jama.2020.15580



Filled and unfilled boxes indicate breastmilk samples that were collected when the woman was symptomatic and asymptomatic, respectively. All samples were tested for SARS-CoV-2 viral RNA by RT-PCR for infectivity. The sample highlighted by asterisk tested positive by RT-PCR, but negative by infectivity assay.

SARS-COV-2 INFECTION IN LACTATION

No infectious SARS-CoV-2 in breast milk from a cohort of 110 lactating women

[Paul Krogstad](#) , [Deisy Contreras](#), [Hwee Ng](#), [Nicole Tobin](#), [Christina D. Chambers](#), [Kerri Bertrand](#), [Lars Bode](#) & [Grace M. Aldrovandi](#)

[Pediatric Research](#) (2022) | [Cite this article](#)

Findings In a total study group of 110 women, SARS-CoV-2 RNA was detected in milk from 6 of 65 women (9.2%) with recent confirmed infection. Neither infectious virus nor subgenomic RNA (a marker of virus infectivity) were detected in any of the samples.

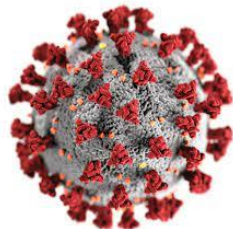
CONCLUSIONS

- SARS-CoV-2 RNA can be found infrequently in the breastmilk after recent infection
- We found no evidence that breastmilk contains an infectious virus or that breastfeeding represents a risk factor for transmission of infection to infants.

COVID-19 Vaccination In Lactating Women

Background

- In December 2020, two novel mRNA vaccines for SARS-CoV-2 received emergency use authorization from the FDA
 - Pfizer-BioNTech
 - Moderna
- Early clinical trial data demonstrated the vaccines ability to prevent infection and severe disease
- Breastfeeding women were excluded from the early trials
 - This led to many questions from healthcare providers and lactating women on the safety of the vaccines in this special population and their breastfed infants



Deployment of the Pfizer-BioNTech and Moderna mRNA Vaccines

The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020

Weekly / January 1, 2021 / 69(5152);1657-1660

On December 22, 2020, this report was posted online as an MMWR Early Release.

Kathleen Dooling, MD¹; Mona Marin, MD¹; Megan Wallace, DrPH^{1,2}; Nancy McClung, PhD¹; Mary Chamberland, MD^{1,3}; Grace M. Lee, MD⁴; H. Keipp Talbot, MD⁵; José R. Romero, MD⁶; Beth P. Bell, MD⁷; Sara E. Oliver, MD¹ ([View author affiliations](#))

[View suggested citation](#)

Summary

What is already known about this topic?

On December 1, the Advisory Committee on Immunization Practices (ACIP) recommended that health care personnel and long-term care facility residents be offered COVID-19 vaccination first (Phase 1a).

What is added by this report?

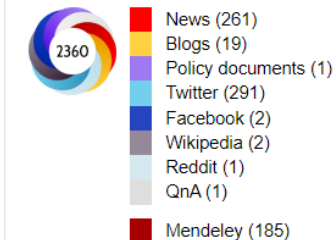
On December 20, ACIP updated interim vaccine allocation recommendations. In Phase 1b, COVID-19 vaccine should be offered to persons aged ≥75 years and non-health care frontline essential workers, and in Phase 1c, to persons aged 65–74 years, persons aged 16–64 years with high-risk medical conditions, and essential workers not included in Phase 1b.

What are the implications for public health practice?

Federal, state, and local jurisdictions should use this guidance for COVID-19 vaccination program planning and implementation.

Article Metrics

Altmetric:



Citations: 115

Views: 291,643

Views equals page views plus PDF downloads

Early Data from Lactation Studies

- Gray et al. → 31 breastfeeding women in the United States who received an mRNA vaccine
 - >60% reported vaccine-related side effects
 - No data on infant outcomes or impact of breastfeeding (milk supply, color changes, etc.)
- Perl et al. → 84 breastfeeding women in Israel who received the Pfizer-BioNTech vaccine
 - Reported similar frequencies of vaccine-related symptoms after both Dose 1 and Dose 2
 - This study did not report any infant adverse events following maternal COVID-19 vaccination

Early Data from Lactation Studies

- McLaurin-Jiang et al. → 4,455 breastfeeding women were enrolled in the United States who received one or more doses of either mRNA vaccine (Pfizer-BioNTech or Moderna) ≥ 2 days before the online survey were enrolled into the study through the InfantRisk Center, Facebook and Twitter
 - Injection site pain, fatigue, headache, muscle pain, chills and fever were significantly more common after the second dose for both vaccine brands
 - 303 (7.1%) of breastfed children had one or more symptoms following maternal vaccination
 - Mothers who received their 2nd dose were more likely to report increase fussiness in their breast child (2.8% versus 13.9%, $p < 0.05$)

COVID-19 VACCINATION IN LACTATION

- Mommy's Milk protocol was modified in December 2020, to capture COVID-19 vaccine dates, maternal and infant vaccine-related symptoms and any changes in milk supply from all enrolled mothers, and to specifically recruit for exposure to the vaccine
- As of June 2022, HMB has enrolled 700 lactating women across U.S. who were vaccinated or booster with a Pfizer, Moderna or Johnson & Johnson COVID-19 vaccine

Breastfeeding Medicine, Vol. 16, No. 9 | Clinical Research

 Full Access

Maternal and Child Outcomes Reported by Breastfeeding Women Following Messenger RNA COVID-19 Vaccination

Kerri Bertrand , Gordon Honerkamp-Smith, and Christina D. Chambers

Published Online: 16 Sep 2021 | <https://doi.org/10.1089/bfm.2021.0169>

Study Aims

- To evaluate a larger sample of vaccinated breastfeeding women for vaccine-related symptoms and their breastfed children for any non-serious and serious adverse events

Any maternal symptoms
Any local symptoms
 Pain at injection site
 Redness at injection site
 Swelling at injection site
 Itching at injection site
Any systemic symptoms
 Chills
 Headache
 Joint pain
 Muscle/body aches
 Fatigue or tiredness
 Fever
 Nausea
 Vomiting
 Diarrhea
 Abdominal pain
 Rash (body)
 Other
 Change in milk supply
 More milk
 Less milk
 Change in milk color
Child events
 Drowsiness
 Sedation
 Poor feeding
 Rash
 Bruising/bleeding
 Constipation
 Diarrhea
 Stools w/abnormal color
 Fever
 Low body temp
 Restlessness
 Irritability
 Poor sleep
 High-pitched crying
 Abnormal movements
 Abnormal skin color

Study Design

- Breastfeeding women residing in the United States who received both doses of either mRNA vaccine (Pfizer-BioNTech or Moderna) were enrolled into Mommy's Milk
- Participants completed a semi-structured telephone interview and questionnaire
 - Demographics, personal and family health history, child health history, breastfeeding habits, COVID-19 history, vaccine brand and maternal and child symptoms for 7 days following both doses of the vaccine
- Maternal and child characteristics and outcomes were compared by brand of vaccine for each dose using Student's *t* test for continuous and Fisher's exact test for categorical variables using R



Study Results

- Between December 14, 2020 through February 1, 2021, 180 women who received both doses of either mRNA vaccine were enrolled
- 128 (71.1%) of women received both doses of the Pfizer-BioNTech vaccine and 52 (28.9%) of women received both doses of the Moderna vaccine
- Child age at enrollment averaged 7.47 months (SD 5.44, range 0.09-27.45 months)
- 26.5% of children were exclusively breastfed (no formula supplementation or solid foods)
- 45.9% of children were breastfed 8 or more times per day

Study Results- Maternal Vaccine-Related Symptoms

- Dose 1
 - Similar proportions of women reported any vaccine symptom by brand (89.4% Pfizer; 98.1% Moderna)
 - Frequency by specific symptom did not differ between brands
- Dose 2
 - Women who received Moderna were significantly more likely to report both local (pain, redness, swelling or itching at the injection site) and systemic symptoms (chills, muscle/body aches, fever, and vomiting) compared to those who received Pfizer
 - All p's <0.05
 - Women who received Moderna were also significantly more likely to report a reduction in milk supply compared to those who received Pfizer
 - 8.0% versus 23.4%

Study Results- Infant Outcomes

- Infant Outcomes
 - Few events were reported with either brand or dose
 - None were serious adverse events
 - The most common events following Dose 2 were:
 - Irritability
 - Poor sleep
 - Drowsiness*

*Significantly more infants breastfed by women who received Moderna were reported to have this symptom (6.4% vs. 0%; p=0.02)

Study Limitations

- Symptoms were captured by self-report
- Volunteer sample which might not be generalizable to the population

Study Conclusions

- Breastfeeding women reported vaccine-related symptoms at similar frequencies to those previously reported
- Few non-serious events were reported in the breastfed children
- No serious adverse events were noted in the breastfed children

→ These data are reassuring regarding the safety of vaccination in breastfeeding women

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- Mommy's Milk Steering Committee
- Student Volunteers
- Our Participants!

TO LEARN MORE



<https://mothertobaby.org/pregnancy-studies/>



<https://MommysMilkResearch.org/>



<https://BetterBeginnings.org/>



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