Advocacy Brief

“The role of Midwives and Nurses in Protecting, Promoting and Supporting Breastfeeding”

Presented by:

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USAID, GHSI-III Contract

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A survey was conducted to understand the health worker experiences and perspectives (which include doctors, nurses, neonatal nurses and midwives) in the area of breastfeeding.

The purpose was help inform the advocacy brief drafted by the Year of the Nurse and Midwife (YNM) Working Group as part of the Global Breastfeeding Collective.

The brief was created by the Global Breastfeeding Collective, COINN, ICM, and BEST Services of Ireland.
Advocacy Brief “The Role of midwives and nurses in protecting, promoting and Supporting Breastfeeding”

WHY:
• When breastfeeding mothers and newborns are not supported and protected, childhood infections and mortality increase, cognitive development is compromised, rates of obesity, diabetes and maternal and child cancers increase

• Health care providers must be prepared to protect, promote and support the breastfeeding dyad and work in multidisciplinary teams

HOW:
• All midwives and nurses including neonatal nurses who care for the small and sick newborn must endorse the importance of breastfeeding, be competent in providing support as well as protect mothers and newborns from barriers to breastfeeding

• Breastfeeding support is a component of respectful maternal care as well as quality of care and must be tailored to meet the needs of well and small and sick newborns

• Specialized training is needed for neonatal nurses, midwives, mental health providers, & community nurses to meet the unique needs of mothers and newborns
Survey responses ignite the global CALL to ACTION

1. Invest in midwives
2. Full integrate critical competencies
3. Fund and develop comprehensive specialized training for midwives, neonatal nurses and nurses
4. Fully integrate quality and respectful maternal and newborn care
5. Establish and enforce legislation to protect breastfeeding
6. Allocate adequate staffing levels
7. Strengthen the leadership role of midwives and nurses at the national, local, and facility levels
Vaccine safety and efficacy in pregnancy and lactation

Data from the v-safe surveillance system and pregnancy registry and the VAERS demonstrated no obvious safety signals among pregnant persons. Injection site pain was reported more frequently and headache, myalgia, chills, fever reported less frequently among pregnant than nonpregnant women.

Post-vaccination milk samples collected 4-48 hours after Pfizer or Moderna vaccination revealed no detectable levels of vaccine mRNA in any component of the milk.

Kachikis A et al. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2783112
Vaccines are well-tolerated among pregnant and lactating women. Reactions were increased after second, as compared to first dose, but odds of several reactions (among them, fever) were significantly decreased among individuals who were pregnant, compared with those who were neither pregnant nor lactating.

BNT162b2mRNA vaccination was associated with a significantly lower risk fo SARS-CoV-2 infection among pregnant women. There were no severe vaccine-related adverse events.
Impact of COVID-19 on pregnant women and newborns

In a meta-analysis of 40 studies from LMIC, there was a significant increase in stillbirth and maternal death during vs. before the pandemic. Preterm births were not significantly changed overall, but were decreased in some high-income countries. Depression scores were higher as were surgically managed ectopic pregnancies during the pandemic. Global maternal and fetal outcomes show considerable disparity between high- and low-resource settings.

In a multinational cohort study of 2130 pregnant women in 18 countries, women with COVID-19 had increased risk for a composite maternal morbidity and mortality index. Newborns of women with COVID-19 had significantly higher severe neonatal and perinatal morbidity and mortality as compared to newborns of women without COVID-19.
Thank You

Protecting Human Milk & Breastfeeding in Pediatric Primary Care

Presenters

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Disclosures

• Dr. Kawan reports no Conflicts of Interest related to this presentation
• Dr. Spatz reports current research funding from National Association of Neonatal Nurses, honorarium from Association of Women’s Health Obstetric & Neonatal Nurses, honorarium from Medela. These relationships have not influenced content of this presentation

The Pandemic has Negatively Impacted Birth & Breastfeeding


  –Interviews with first time mothers during the start of the pandemic in USA
Five Key Areas Identified

• Recommendations changing every day
• Guilt/concern/stress
• In-person versus telehealth visits
• Missing time with family and friends
• Silver linings

Skin to Skin Prevalence Remains Low

[Image of a research article from PLOS ONE]
The Pandemic has Negatively Impacted Skin to Skin Contact

- 14% of hospitals discouraged skin to skin contact
- 6.5% of hospitals prohibited skin to skin contact
Ten Steps for Promoting & Protecting Breastfeeding in the Vulnerable Infant

• Step 1: Informed decision
• Step 2: Establishment & maintenance of milk supply
• Step 3: Human milk management
• Step 4: Feeding the infant the milk
• Step 5: Skin-to-skin care
• Step 6: Non-nutritive sucking
• Step 7: Transition to breast
• Step 8: Measuring milk transfer
• Step 9: Preparation for discharge
• Step 10: Appropriate follow-up
National & Global Outcomes

Why It Works

• Each of the step has associated evidence with published manuscripts with outcomes
• Plus Power of Pumping & Skin to Skin-Transfer of Intubated Infant DVDs

Breastfeeding Resource Nurses

EXEMPLARY SERVICE

Report of a Staff Program to Promote and Support Breastfeeding in the Care of Vulnerable Infants at a Children’s Hospital

Diane L. Spatz, PhD, RNC

ABSTRACT

Despite premature infants do not have the opportunity to begin breastfeeding in an optimal manner, yet, these infants may benefit most from human milk. Health-care providers’ knowledge of breastfeeding is both limited and infrequent, due to deficits in training. This article outlines a multifaceted approach to develop a comprehensive, hospital-wide system to support and promote breastfeeding for vulnerable infants. This approach was designed for the staff of the Children’s Hospital of Philadelphia.

• Over 900 Breastfeeding Resource Nurses (BRNs) at CHOP
• Two day-16 hour course
• Nurse receives continuing education credit for course and are paid to take course
Outcomes of BRN Model

• Mixed methodology
  - Survey sent to all BRNs with active CHOP emails
    • 425/600 BRNs responded to 21 question survey
  - Qualitative interviews with 18 key informant BRNs


BRN Study-Qualitative Outcomes

- Four themes emerged from the data
  - Empowering through evidence
  - Advocacy
  - Going the Extra Mile
  - Personal connections to breastfeeding
  - “And here’s the funny thing, when I first started working, I would always talk about my job with my husband. At the time he was a teacher at a school and we didn’t have kids or anything like that. Well, he got to learn so much about breastfeeding ... actually, the teachers went out to lunch, and all of the ladies were talking about like sore nipples and all of that. And [my husband], they were like, what do you even know about this? He said, actually, this is what you should have done for it… And he was spot on! He knew it. And you know what, all of our friends know that if I am not available for some reason, ask my husband… he will probably know the answer!”

CHOP Care Network-Karabots

- Large Primary Care site in West Philadelphia serving approximately 40,000 patients
- Average newborn volume approximately 125-140 newborns/month
- 86% of patients covered by Medicaid
- Approximately 82% of patients identify as African-American
- Staffing model includes Breastfeeding Resource Nurses and several providers with lactation consultant certification (but no full-time IBCLC)
AAP: Current Recommendations, last updated May 2021

FAQs: Management of Infants Born to Mothers with COVID-19;

“The AAP strongly supports breastfeeding as the best choice for infant feeding.”

• "Mothers and newborns may room-in, according to usual center practice."
• "During the birth hospitalization, the mother should maintain a reasonable distance from her infant when possible. When a mother provides hands-on care to her newborn, she should wear a mask and perform hand-hygiene."

Karen M. Puopolo, M.D. Ph.D., Mark L. Hudak, M.D., David W. Kimberlin, M.D., James Cummings, M.D.
American Academy of Pediatrics Committee on Fetus and Newborn, Section on Neonatal Perinatal Medicine, and Committee on Infectious Diseases; FAQs: Management of Infants Born to Mothers with Suspected or Confirmed COVID-19, Critical Updates on COVID-19, Clinical Guidance, May 4, 2021

Practice QI Data

Exclusive breastfeeding at newborn visit July 2019-through July 2021
Practice QI Data

Exclusive Breastfeeding 1 month (July 2019-July 2021)

Proposed Reasons for Decreased Breastfeeding Rates

- Lack of skilled breastfeeding support
- Early hospital discharge
- Minimized/shortened office visits
- Stress
- Other children not in school, increased burden on breastfeeding parents
- Lack of family support/visits
- Concern about illness
Office Interventions

- Aggressive promotion of Philadelphia Health Department free lactation consultant virtual service (Pacify)
- Active promotion of existing community support groups (virtual)
- Nurse telephone outreach – referred by practice physicians and nurse practitioners
- Renewed staff education efforts

UK Breastfeeding Experiences during COVID-19 Pandemic

“The results highlighted two very different experiences: 41.8% of mothers felt that breastfeeding was protected due to lockdown, but 27.0% of mothers struggled to get support and had numerous barriers stemming from lockdown with some stopped breastfeeding before they were ready.”

Call to Action!

Promoting and Protecting Human Milk and Breastfeeding in a COVID-19 World

Call to Action!

- Acknowledge and address disparities
- Understand the role of human milk and breastfeeding in mitigating toxic stress
- Change the current prenatal care paradigm
- Engage and empower family members on the lactating person's journey to breastfeed/chest feed or provide milk for their child
- Create a sense of urgency about milk supply
- Increase access to PDHM (not as a replacement to parent’s own milk) but as a bridge
Call to Action

• Why don’t is there not increased funding and access for things we know that work?

New Resource to Educate Nurses & Midwives

• The Association of Women’s Health Obstetric & Neonatal Nurses Evidence Based Practice Guideline
  – The Use of Human Milk During Parent–Newborn Separation - Journal of Obstetric, Gynecologic & Neonatal Nursing (jognn.org)
Thank you

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Detection of SARS-CoV-2-Specific IgA in the Human Milk of COVID-19 Vaccinated Lactating Health Care Workers

Vivian Valcarce, MD
CIF-RIG 9/10/2021

Vivian Valcarce, Lauren Stewart Stafford, Josef Neu, Nicole Cacho, Leslie Parker, Martina Mueller, David J. Burchfield, Nan Li, and Joseph Larkin III
FUNDING SOURCE DISCLOSURE

Children’s Miracle Network
Background

• In 2019, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged

• Two mRNA vaccines, the BNT162b2 Pfizer/BioNTech and mRNA-1273 Moderna/NIH were approved for emergency use in US in December 2020

• Vaccinating pregnant or lactating mothers is a strategy to protect young infants from disease

• Milk produced by mothers, previously infected by COVID-19 is a source of neutralizing anti-SARS-CoV-2 IgA and IgG antibodies
Objective

- Determine the presence of specific SARS-CoV-2 IgA in the human milk of lactating women after the COVID-19 vaccine administration
Study Design

• Prospective observational study
• Single center, University of Florida
Inclusion Criteria

- Breastfeeding women
- ≥18 years old, able to provide informed consent
- No known history of COVID-19 infection
- Planning on receiving the COVID-19 vaccine
Exclusion Criteria

• History of COVID-19 infection
• Vaccinated with no pre-vaccination breastmilk stored
Study Protocol

• Health care workers were approached through University of Florida institutional e-mail, and flyers posted at Shands Hospital

• Upon agreement to participate, a questionnaire was administered to collect maternal demographics information, lactation duration, and the infant's sex

• After study completion, Qualtrics survey to assess the type of COVID-19 vaccine received, milk supply change with vaccination, as well as participants' medical and family history, allergies, and medications

• Blood and human milk samples were collected at three time points: prevaccination (TP1), 16–30 days post the first dose of vaccine (TP2), and 7–10 days post-second dose of vaccine (TP3)
**Study Protocol**

**Blood samples collection by finger prick in EDTA coated tubes**
- Centrifugation at 2000g for 10 min at 4°C
- Plasma separated and stored at -20°C
- ELISA for total IgG using validated kit Human IgG ELISA Kit (ab195215)
- Plasma diluted 1:1,000,000 and 1:10,000,000 using Sample Diluent NS and Wash Buffer.

**ELISA for SARS-CoV-2 specific IgG and IgA in plasma** (RayBiotech COVID-19 Human IgG ELISA Kit)

**Human milk samples collected and stored at -20°C**
- Aliquotted into 2mL centrifuge tubes
- Centrifugation at 500g for 15 min at 4°C
- Using a 21G needle, the aqueous layer was separated from the fat layer, and placed in a clean tube
- Aqueous layer centrifuged at 3000g for 15 min at 4°C
- Human milk diluted 1:200,000 using Sample Diluent NS
- Final aqueous layer removed and stored undiluted at -20°C

**ELISA for total IgA** Abcam Human IgA ELISA Kit (ab196263)

**ELISA for SARS-CoV-2 specific IgA and IgG in human milk** (RayBiotech COVID-19 Human IgA ELISA Kit)
- Human milk diluted 1:3, 1:9, 1:27, 1:81, and 1:243
Analytical Methods

- The focus of this analysis was change in titer levels over time and differences in changes between vaccine types.
- Log(10)-transformed antibody titer for SARS-CoV-2-specific and total IgG/IgA in plasma and human milk over time (at prevaccination, post-first, and post-second dose).
- In addition, change over time in log(10)-transformed antibody titers was modeled by vaccine type (Moderna versus Pfizer/BioNTech).


DEMOGRAPHICS

- 22 Lactating health care workers with no known history of COVID-19 infection are enrolled in the study

- 21 completed the three-time sample collection for human milk: pre-vaccination (TP1), post 1st vaccine (TP2), and post 2nd vaccine (TP3)

- The study population consists primarily of White, non-Hispanic women in their mid-30s working in the healthcare setting

- 7 participants received the Moderna vaccine and 14 received the Pfizer/BioNTech vaccine

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**TABLE 1 Study participants characteristics (n= 21)**

<table>
<thead>
<tr>
<th>Maternal characteristics (n=21)</th>
<th>N (%) or Mean ± Standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>34 ± 3.9</td>
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<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>20 (95)</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
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<tr>
<td>Non-Hispanic</td>
<td>18 (85)</td>
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<tr>
<td>Hispanic</td>
<td>3 (15)</td>
</tr>
<tr>
<td>Profession</td>
<td></td>
</tr>
<tr>
<td>Healthcare worker</td>
<td>19 (90)</td>
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<tr>
<td>Body mass index (kg/m²)**</td>
<td>24.8 ± 3.4</td>
</tr>
<tr>
<td>Normal/Healthy weight</td>
<td>11 (55)</td>
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<tr>
<td>Overweight</td>
<td>7 (35)</td>
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<tr>
<td>Obese</td>
<td>2 (10)</td>
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<tr>
<td>History of allergies*</td>
<td>6 (30)</td>
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<tr>
<td>History of asthma*</td>
<td>1 (5)</td>
</tr>
<tr>
<td>History of inadequate immune response to vaccine*</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Family history of Cancer*</td>
<td>13 (65)</td>
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<tr>
<td>Family history of autoimmune disorder*</td>
<td>1 (5)</td>
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<tr>
<td>Antibiotic use last 6 mo*</td>
<td>5 (25)</td>
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<tr>
<td>Parity (no.)</td>
<td>1.9 ± 0.9</td>
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<tr>
<td>Time postpartum (mo)</td>
<td>6.8 ± 4.8</td>
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<td>Infant sex</td>
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<tr>
<td>Female</td>
<td>12 (57)</td>
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<tr>
<td>Male</td>
<td>9 (43)</td>
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<tr>
<td>Tandem breastfeeding</td>
<td>1 (5)</td>
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<tr>
<td>Vaccine brand</td>
<td></td>
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<tr>
<td>Moderna</td>
<td>7 (33.3)</td>
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<tr>
<td>Pfizer</td>
<td>14 (66.7)</td>
</tr>
<tr>
<td>Developed decreased human milk supply after COVID vaccine*</td>
<td>3 (15)</td>
</tr>
</tbody>
</table>

*Categorical data are given as number of participants and, in parentheses, percentage of total. Continuous data are provided as means ± standard deviations. *Definitions put forth by the U.S. Centers for disease Control and Prevention were used for body mass index categories. †, missing data from 1 subject.
Outcomes

1. SARS-CoV-2 **IgA** is secreted in human milk after COVID-19 vaccination

- IgA statistically significantly increased from TP1 to TP2 \( (p < 0.0007) \) and from TP1 to TP3 \( (p < 0.0001) \)
Outcomes

2. SARS-CoV-2 IgG is secreted in human milk after COVID-19 vaccination

- There was a statistically significant increase of IgG in human milk from TP1 to TP2 (p < 0.0006) and TP1 to TP3 (p < 0.0001)

- Concentration of SARS-CoV-2 IgA was higher than those of IgG in the human milk, with a predominance of SARS-CoV-2 IgA, as found in natural infection

Box and whisker plots.
*** p < 0.01; **** p < 0.0001
Outcomes

3. SARS-CoV-2 IgA is present in plasma after COVID-19 vaccination

- IgA statistically significantly increased from TP1 to TP2 (p < 0.0001) and from TP1 to TP3 (p < 0.0001)
Outcomes

4. Plasma samples are positive for SARS-CoV-2 IgG after COVID-19 vaccination

- There was a statistically significant increase of IgG in plasma from TP1 to TP2 (p = 0.005) and TP1 to TP3 (p < 0.0001)

Box and whisker plots.

*** p < 0.01; **** p < 0.0001
Outcomes

5. There is a positive correlation between plasma and human milk SARS-CoV-2 antibodies.
Outcomes

6. Similar antibody response to Pfizer/BioNtech and Moderna vaccines was detected

- Both mRNA vaccines generated statistically significant SARS-CoV-2 specific IgA and IgG in human milk and plasma by TP3

- There is a significantly higher mean of SARS-CoV-2 IgG in plasma at TP3 in Pfizer vs. Moderna vaccinated mothers ($p = 0.005$)
Outcomes

- 85% of human milk and plasma samples were positive for SARS-CoV-2 IgA by TP3 based on the established cut off value

- 100% human milk and plasma samples tested for SARS-CoV-2 IgG were positive by TP3

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>IgA Human milk</th>
<th>IgG Human milk</th>
<th>IgA Plasma</th>
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<tr>
<td>C-001</td>
<td>+</td>
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<td>C-002</td>
<td>-</td>
<td>+</td>
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<td>+</td>
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Conclusions

mRNA-based COVID-19 vaccines, Pfizer/BioNtech and Moderna, induce SARS-CoV-2 IgA and IgG secretion in human milk and plasma, with statistically significant increases from TP1 to TP3.

There is a predominant IgA response in human milk.

The peak of SARS-CoV-2 IgA and IgG in human milk and plasma occurs 7-10 days after receiving the second dose of the COVID-19 vaccine.

The samples analyzed represent a one-time point of what is likely a dynamic immune response. Samples collected in the first 2 weeks after the second vaccine administration may not reflect the maximal immune response.
Conclusions

Higher SARS-CoV-2 IgG in plasma among mothers who received the Pfizer vaccine. However, statistical significance does not imply clinical relevance.

Interestingly, the participant with the highest concentration of SARS-CoV-2 IgA in the human milk (12 times higher than the mean of IgA post-vaccination) was the only participant tandem breastfeeding her two children.

These novel results suggest the potential transfer of protective antibodies to nursing infants after maternal COVID-19 vaccination and may show a promising influence in vaccination strategy for lactating mothers.
SARS-CoV-2 IgA and IgG in human milk

SARS-CoV-2-IgA

SARS-CoV-2-IgG
SARS-CoV-2 IgG in plasma
THANK YOU!