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A Continuation of COVID-19 Vaccines and Infant Feeding

Webinar Transcript

Jennifer Yourkavitch

Thanks for joining us today, we have a great agenda for this meeting. We're talking about the same theme as last time: A continuation of COVID-19 Vaccines and Infant Feeding and all the issues around that. I'm Jennifer Yourkavitch, I'm a perinatal epidemiologist and a lactation consultant and I serve as the Director of Monitoring Evaluation and Learning for USAID Advancing Nutrition. My colleagues Victoria Anders, Erin Berkazen, Alyssa Klein and I have been hosting these meetings of the COVID-19 Infant Feeding Research Interest Group over the past few months. Today is the last scheduled meeting that USAID Advancing Nutrition will be hosting. We're not sure what this convening will look like going forward but we will let you know as soon as we do and, in the meantime, the website that we've established will remain active and we'll keep that updated. And the list serve that was established will be active so you can continue to post to that. We have one announcement before we get started. Please join us at the Global Nutrition Coordination Plan Meeting on September 16th at 8:00 a.m. Eastern U.S. Time. The topic is "Infections and Infant Feeding Practices, Lessons learned from response to recent crises including HIV, Ebola and COVID-19". And I think we'll put the link for registration in the chat. So, you've got that, great, thanks Victoria. Okay, so we have an exciting lineup of speakers today and we'll get right to that.

I'm just going to pull up my other information here, great. So, first we have Dr. Vivian Valcarce from the University of Florida and the title of her presentation is "Immune Response and Breast milk after Maternal COVID-19 Vaccination". Dr. Valcarce is a neonatology fellow at the University of Florida, she's passionate about human milk research and infant nutrition. She completed her medical degree at the University of Zaragoza, Spain and her pediatric residency at the University of Miami Jackson Memorial Hospital. She's currently leading a study that aims to characterize the immune response in human milk after COVID-19 vaccination. So over to you Dr. Valcarce, thank you so much for joining us.

Dr. Vivian Valcarce

Thanks everyone and thanks for that introduction, really nice. I'm going to share my screens if that's okay. Can you see it? I'm going to put a speaker. So, thanks everyone and I'm going to discuss the study that I have been working on in this call. You will also see Lauren Stafford and we both are called first authors on this paper that was recently published at Breastfeeding Medicine. The title is "The Detection of SARS-CoV-2-Specific IgA in the human milk of COVID-19 Vaccinated Lactating Healthcare Workers. The funding source for this study was Children's Miracle Network. We all know this but I'm going to talk a little bit about background. So, in 2019, the Severe Acute Respiratory Syndrome Coronavirus 2 emerged and it caused such a big pandemic. In December 2020, two mRNA vaccines were approved: the Pfizer and Moderna were immediately approved in the United States. We knew at that time that vaccinating pregnant or lactating mothers have been used as a strategy to protect young infants from disease for example with flu and also proteoses with the Tdap that mothers get during the third trimester of pregnancy and we knew that milk that was produced by mothers that were previously infected by COVID-19 was the source

of neutralizing antibodies specific for COVID-19, IgA and IgG. So, our main objective was to determine if there was a specific SARS-CoV-2-IgA in the human milk of lactating women after a COVID-19 vaccination.

Our design of the study was a prospective observational study that was conducted at the University of Florida. Inclusion criteria: we included a breastfeeding woman that was above 18 years old and able to provide informed consent. When they didn't have history of COVID-19 infections, so we basically wanted to only study the effect of vaccination in the antibody production in breast milk, and in mothers that were planning to receive a COVID-19 vaccine.

Exclusion criteria was history of COVID-19 infection and if mothers were vaccinated at the time of the enrollment, if they had breast milk stored in the last seven days after vaccination, we were enrolling them. If they did not have a breast milk store, they were not qualified. So, what we did, we thought about this idea soon after the vaccines were approved so we got IRB approval really fast. We worked hard for a week and we got approval in December 24th and so we sent an institutional email to the healthcare workers at the University of Florida that at that time were the first to be vaccinated. And we also posted some flyers at Chance Hospital. Upon agreement to participate, we administered a questionnaire and we collected maternal demographics, lactation duration and also infant sex. Once we completed the study, we sent a Qualtrics survey where we collected vaccine information, which type of vaccine the mom received, also if there was a change in meal supply after vaccination and also some further maternal and family history. We collected blood and human milk at three different time points. Pre-vaccination, 16 to 30 days after the first vaccine or between vaccines and up to seven days after the second vaccine. So basically, three time points before vaccination in between vaccines and after the second dose. This is a little bit of the work that was done in the lab mostly by Lauren Stafford that is in the call. So, we collected as I mentioned blood samples, these were collected by finger prick and they were collected in an EDTA tube, they were centrifuged and they were stored at -20 and eventually ELISA was done for total IgG and also for specific IgG and IgA, this was in the blood.

In the human milk, we collected the milk and we stored at -20 and then we did several centrifugations until we were able to separate the aqueous layer and stored at -20 and again we performed the ELISA in this case for total IgA in the breast milk and then for specific IgA and IgG. And this we performed at different dilutions. A little bit about the statistics that we performed. So, the focus was to analyze the change in titer levels of antibodies over time and also difference in changes between the vaccine type. We used a Log (10) transformed antibody titer for specific and also for total antibodies in blood and in milk. And again we used the same Log (10) transformed method for a vaccine type.

This is our demographic table. Totally we enrolled 22 lactating healthcare workers with no known history of COVID-19 infection. However, 21 completed the three-time sample collection and this was the data that we included in our results. As I mentioned three time points: pre-vaccine, in between vaccines and post-second dose. In our demographics, the majority of women were in the mid-30s as we see here at a median age of 34. Majority were white, so 20 participants were white and one was Asian and non-Hispanic with 18 of 21 were non-Hispanic and three were Hispanic. Majority of the participants were healthcare workers, they were all working in the healthcare setting but 19 of them identified themselves as physicians or nurses and the rest were [.....] or working in research coordination - things like that. 7 of the participants received Moderna and 14 received Pfizer.

These are our outcomes. This is the representation of IgA in human milk and this is specific for COVID-19. So, in this table we see the three time points: pre-vaccination, post first dose and post second dose, and these are the levels of IgA. And we see how they steadily increased and there was a significant increase. And here we see the concentration of IgA in unit per ml. So, we see that there is IgA secreted in human

milk after COVID-19 vaccination and then we see that there is a significant increase from a Time Point 1; that was pre-vaccination, to Time Point 2 that was in between vaccines and we set P value below 0.0007. Then we see from pre-vaccination to post second dose a significant increase with P value below 0.0001. The peak level of IgA was observed at up to 10 days after the second dose with levels going up to 10 000 units per ml of IgA in the breast milk.

This is the IgG in human milk and again we see that there is specific IgG secreted in human milk after COVID-19 vaccination with a significant increase again from pre-vaccination to after the first dose and again from pre-vaccination to after the second dose with significant P values below 0.0001. In this case, the IgG concentration that we see goes up to a 1000, I mean a little bit lower than 1000. So, we can see that in the human milk, there is a predominant IgA. In the prior slide we saw that IgA went up to 10 000 while IgG is up to 1000. And this half stands and knowing that 90 percent of the antibody that we find in the breast milk is IgA and only 2 percent is IgG.

Here we see specific IgA in plasma so we also collect blood pre-vaccination, post the first dose and post the second dose and we see that there is also a presence of specific IgA in response to a COVID-19 vaccination with statistically significant increase. And again, with IgG, this was expected knowing that the studies that were performed with the vaccines were evaluating the response of IgG specific for COVID-19 in plasma. So we do see a significant increase in IgG after vaccination. We also established a comparison of levels in plasma with levels of antibodies in breast milk and we saw that there was a correlation discount. There was a correlation of antibody specific for COVID-19 in plasma and in human milk.

So we have two graphs here. This one is specific IgA and we see here plasma levels and here are human milk levels and these are from the same participants. So here are the participants by colors. So, we see that the higher the level in plasma as we see here, the higher the level in the human milk of IgA and the same happened with IgG. They higher the level in plasma the higher the level in the breast milk. We also found that there was a similar response between Pfizer and Moderna vaccine detected in blood and in breast milk, and both vaccines generated a statistically significant increase of specific IgA and IgG in human milk and in plasma after vaccination. We do see that there is also a significant higher mean of IgG in plasma after vaccination in Pfizer versus Moderna. So we do see higher mean levels of igg in plasma in a participant that receives Pfizer.

This is a table where we see the outcome based on positive or negative. So, I forgot to mention that we actually established a line that divided negative or positive based on a control. So we tested all the pre-vaccination values and established a positivity level basically. So based on that pre-vaccination established level, we have this table where we that. Here we have IgA in human milk and IgG in human milk. These are all specific for COVID-19 and here IgA and IgG in plasma specifically for COVID-19. And we see that in human milk about 80 percent of the samples were positive in human milk and also in plasma for IgA based on our established cutoff value that was determined with the pre-vaccination samples. And we see that there is 100% of the levels that we tested of IgG in human milk were 100 percent positive. This that we have here that says 'Non-Applies' was just based on the amount of founding that we had, we couldn't test all the samples for IgG in human milk. But 100% of the ones that we tested were positive for specific IgG and also 100% of the samples were positive for IgG in plasma.

So, our conclusions, the mRNA based COVID-19 vaccines and Pfizer and Moderna induce SARS Cov-2 to IgA and IgG secretion in human milk and plasma with statistically significant increase from Time Point 1 or pre-vaccination to Time point 3 post second dose. We see that there is a predominant IgA response in human milk and this is a logical base on the amount of IgA level that is usually in breast milk compared with IgG. We do see a peak of SARS-CoV-2 IgA and IgG in human milk and plasma and this peak occurs

seven to ten days after receiving the second dose of COVID-19 vaccine. However, these samples represent a one-time point of what could be a dynamic immune response. So, the samples that were collected in the first two weeks after the second vaccine administration may not reflect the maximal immune response; so it may even go higher 10 days after vaccination.

We see higher SARS-CoV-2 IgG in plasma among mothers who received the Pfizer vaccine. However, statistical significance does not imply clinical relevance. This is an interesting point but the participant that had the highest concentration of SARS-CoV-2 IgA in human milk that was actually 12 times higher than the mean of IgA post vaccination and was the only participant that was doing tandem breastfeeding - so the baby she was breastfeeding at the time was a three months old baby and two-year-old taller. So, these results suggests the potential transfer of protective antibodies to nursing infants after maternal COVID-19 vaccination and maybe a promising influence in vaccination strategy for lactating mothers or pregnant mothers.

So, this graph that I'm to show now is our current work. So after we finished this initial pilot study, we had continued working and our new goals are to determine for how long these antibodies are present in breast milk and in plasma, and we are also studying a neutralization capability - so we want to know if actually these antibodies are able to neutralize the virus and lastly, we are also analyzing infants' stools to know if we see these specific antibodies present in the stool of infants. Basically, knowing that there is antibodies in the stool would give us further information that these antibodies are passed to the infants. So, here we see and this result hasn't been published yet so you guys are one of the new and few people who know about these results. These are the graphs that represent SARS-CoV-2 IgA. This one is in human milk. So we have here the graph for IgA in human milk and we see a pre-vaccination value. These are the concentrations again in unit per ml and here are the time points so we have re-vaccination, in between vaccines, and up to 10 days after vaccination, and then we see three months after vaccination completion, and six months after vaccination completion. And we see how the levels of IgA had the peak that we saw 10 days after the second dose, and we see how this level is trending down gradually up to six months after vaccination completion.

And here we see the IgG specific for COVID-19, the time points up to six months after vaccination and the levels, and we have the pre-vaccination values and in between vaccines up to 10 days and then again a gradual decline up to six months. However, based on our cutoff of positivity at six months after vaccination completion, majority of the mothers that we have been able to test are still positive for IgG in the human milk. While based on our cutoff of positivity, around 50 of the mothers still have IgA in the breast milk, while 50 have become negative for IgA in the breast milk. So, it could be because of the long duration. We know that IgG is a memory antibody so it should stay in the body for a longer time.

Here we also have the IgG specific for CoV-2 in plasma and again these are the time points and the concentration in unit per ml of IgG in plasma and we see that our peak level was around 10 days after vaccination and we do see a decline however again. 100% of our samples for now at six months post-vaccination are still positive based on our cut-off of positivity. So that's our good news; the level trend down, but they are still considered to have antibodies protecting towards COVID-19. This is my presentation, so I know at the end there's going to be questions if anyone has any, thank you so much.

Jennifer Yourkavitch

Thank you so much for that great presentation. We do have a couple of questions I'd like to get to now if possible. So you see them in the chat there, there's a question about the biology, the mechanism, IgA and IgG are found in breast milk and then ingested and what happens next? Do they pass through the gut

lining into the bloodstream, do they get destroyed in the gut, by what mechanism do they confer protection to the child that's breastfeeding?

Dr. Vivian Valcarce

Yes, so that's a great question. We do know based on prior science study and research that the main immunoglobulin in the breast milk is IgA and that what it usually does ... the IgA is actually a dimer and this dimer is able to resist the acid content in the stomach and this IgA will go and coat the GI tract. And we have seen this through the history where babies that are breastfeeding are at a lower risk of developing gastroenteritis like rotavirus for example. So, it protects the baby towards bacterial and viral gastroenteritis and also, we have seen that babies that are breastfeeding and breastfed get protected from bacterial towards respiratory infections like RSV. So the exact mechanism is postulated to be coating the GI tract. It is not clear if any of these antibodies would go and pass that barrier of the GI tract. It is believed that it does not cross the barrier and that's what is in the research that have been done.

However, one of the our interest is to actually test and get some blood from the babies and be able to see if by any chance any of these antibodies are able to translocate and get into the baby's system. But I would say our idea is that these antibodies may protect and they actually may not only coat the GI tract, there is evidence also that this antibodies can coat the nasopharynx of babies either by reflux or just being in the mouth, the milk can coat the nasopharynx and actually protect the entry of the virus into the system. For the IgG it is not as clear. So that's one of our purposes because we actually see that the IgG stays for a longer time. So we see that the IgG is in lower levels but it stays for a longer time in breast milk as well as plasma. So it may have an important role that we don't know yet.

Jennifer Yourkavitch

Great, thank you and one other question, do you think the gestational age of the newborn would impact the levels of antibodies pre-term in terms of pre-term versus full-term milk?

Dr. Vivian Valcarce

So, you mean pre-term versus full term, you mean in the milk.

Jennifer Yourkavitch

Yes.

Dr. Vivian Valcarce

So, unfortunately, we don't have enough data, that's why we are trying to enroll and gather more data so in our next paper hopefully we can have some further information because we have some pre-term mothers of infants that were born preterm that we may be able to enroll. In one study that was recently published from Spain in Jama, they found that the levels of IgA were actually increasing with age and they were significantly higher after 22 months breastfeeding. So I am not sure about a pre-term and full-term but they have been seeing actually an increase in these antibodies with time of duration of breastfeeding. And we kind of gather for similar information if our values was not significant but that may be because we didn't have enough patients enrolled but we do see that there is actually an increase in these levels with times that moms breastfeed.

Jennifer Yourkavitch

Age of the child too. I was thinking that with the tandem breastfeeding example that older child might be triggering a different response.

Dr. Vivian Valcarce

Yeah, that might be the reason because the mom was breastfeeding while she was pregnant because I actually asked her that question.

Jennifer Yourkavitch

Interesting! Thank you, Dr. Valcarce, I appreciate that. And we may have time to come back for more discussion but right now we're going to move to our second presentation from Theresa Shaver and Leah Greenspan. Theresa Shaver is a globally recognized nurse midwife with more than 35 years of experience in international health program management and implementation, focused primarily on maternal newborn and reproductive health. She's a Skill Technical Advisor and Leader in Global Partnerships, non-profit organizations strategic planning and program design, community mobilization, capacity building, advocacy campaign development and evaluation. She's worked extensively in Southeast Asia, Central Asia, Africa and South America. She serves as the Senior Maternal and Newborn Health Advisor in the office of Maternal Child Health and Nutrition at USAID. And Dr. Leah Greenspan is a board-certified pediatrician and neonatologist. She's worked clinically in the Washington DC area for almost 20 years. Dr. Greenspan has extensive experience working in Global Health with a focus on newborn health in sub-Saharan Africa and Asia. And prior to joining the team at USAID as a Senior Newborn Advisor in March of 2020, she worked with multiple NGOs as a newborn consultant developing and implementing programs in both the rural and urban settings to build the capacity of medical professionals and strengthen health systems around the continuum of maternal newborn care. Their presentation is The Role of Midwives and Nurses in Protecting, Promoting and Supporting Breastfeeding, thank you and over to you Theresa and Leah.

Dr. Leah Greenspan

Thank you so much. Good morning, good afternoon and good evening to all of you. Thank you for giving us the opportunity to present the advocacy brief. I need to give a disclaimer that Theresa and I are here on behalf of USAID but our remarks are in service to the US government and are not being made by the US government. So, I will so kick us off talking about the advocacy brief, the role of the midwives and nurses in protecting, promoting and supporting breastfeeding. So, next slide please.

The advocacy brief is based on information and input from a survey that was conducted by the Year of the Nurse and Midwife Working Group as part of the Global Breastfeeding Collective. The survey was conducted to understand health workers' experiences and perspectives in the area of breastfeeding. The health workers included doctors, nurses, neonatal nurses and midwives. The survey informed the advocacy brief that again was drafted by the Year of the Nurse and Midwife Working Group as part of the Global Breastfeeding Collective and the brief itself was created by the Global Breastfeeding Collective, COINN which is the Council of International Neonatal Nurses, ICM and the BEST services of Ireland. Next slide please.

So, why did we do the advocacy brief?

When breastfeeding mothers and newborns are not supported and protected, we all know childhood infections and mortality increases, cognitive development is compromised and rates of obesity, diabetes and maternal and child cancers increase. Healthcare providers must be prepared to protect, promote and support the breastfeeding dyad and work as a multi-disciplinary team. How? All midwives and nurses including neonatal nurses who care for small and sick newborns must endorse the importance of breastfeeding. And to do this they must be competent in providing support as well as protecting mothers and newborns from barriers to breastfeeding. Breastfeeding support is a component of respectful maternal care as well as a quality of care, and must be tailored to meet the needs of well and small sick newborns.

Specialized training is needed for neonatal nurses, midwives, mental health providers and community nurses to meet the unique needs of mothers and newborns. I will turn it over to Theresa who will speak on behalf of the Call to Action that was ignited by the survey and the advocacy brief. Over to you Theresa.

Dr. Theresa Shaver

Hi everyone, we're speaking to the choir here. We know you all are experts on this but what was very interesting in (next slide please) what we found is that even at the front line workers, and this is predominantly, the survey was conducted in low and middle income countries. These messages came from them but what Leah and I have also found in our discussions with the various commissions that USAID works in, there's still a tremendous amount of misinformation especially around COVID-19, vaccinating pregnant women and separating moms from babies. So, what we would really like to do is ask all of you to be a part of this. This call of action is available on the Breastfeeding Collective website at UNICEF, but really could include midwives, nurses, neonatal nurses and physicians that are working on counseling and supporting breastfeeding in your research. We really ask you to really make a conscious and important effort to do that. There needs to be more competencies even though there's lots of trainings out there, we found in the survey there wasn't these competencies available and nor had there been training for these healthcare providers. There needs to be specialized training, especially for the collaboration that we continue to reinforce around midwives, nurses, physicians working together. There needs to be really respectful care both for the mother and baby. We heard in the survey, many responded, they simply were overwhelmed and they didn't have the time and legislation. It may be there but it wasn't a policy and it wasn't reinforced.

Staffing levels as I'm sure many of you have heard especially in the current situation of COVID-19 are pretty bleak. And strengthening the role of midwives and nurses at a national local facility but I would also plead to all of you, please include them in the research that you're doing and help them to be involved and be advocates in their country settings.

Next slide please.

Dr. Leah Greenspan

So, the next two slides list current research on vaccine safety and efficacy in pregnant, and pregnancy and lactation, and the impact of COVID-19 on pregnant women and newborns. You all are the experts and are probably even more up-to-date on current research as there is a massive amount of information coming in on a daily basis. On this slide, we have the evaluation of messenger RNA from COVID-19, short-term reactions among pregnant and lactating individuals in the first wave of COVID-19. And also, as after we even created these slides, New England Journal published an article with the findings suggesting that there is no risk of spontaneous abortions after mRNA COVID-19 vaccination. Either before conception or during pregnancy. And this is consistent with the expected risk of spontaneous abortions. These findings add to the accumulating evidence about the safety of mRNA COVID-19 vaccinations in pregnancy and COVID-19 vaccinations.

On the next slide, please, I have two articles listed that look at the effects of the COVID-19 pandemic on maternal and perinatal outcomes with a systematic review and meta-analysis. One launched in June and another one launched in April both of 2021. So, at this time I encourage and do engage you in conversation as I mentioned, you all are the experts in what's hot off the press around these topics and maybe share that information if you don't have any questions. And I do want to thank all the authors whose names are listed on this slide for their incredible contributions to the advocacy brief that was recently launched.

Over to you all for further discussion on what is current in the literature on COVID-19 vaccines in breast milk and COVID-19, over.

Jennifer Yourkavitch

Thanks so much Theresa and Leah. Important call to action there. Let's see in the chat, I see a note from Dr. Spatz about a new resource for educating nurses and midwives. Thanks for sharing that. Are there any questions for Theresa and Leah at this time? Okay, well, you may think of some as we go along. Feel free to put them in the chat at any time and we can return to discussions after the next presentation. Okay, and our next presentation is from doctors Diane Spatz and Meg Kawan. It's called "Protecting human milk and breastfeeding in pediatric primary care during COVID-19 pandemic and beyond". Dr. Spatz is a professor of perinatal nursing and the Helen M. Shearer professor of nutrition at the University Of Pennsylvania School Of Nursing. Sharing a joint appointment as a nurse scientist in lactation at the Children's Hospital of Philadelphia (CHOP) and founder of the CHOP lactation program and mother's milk bank. Dr. Spatz is an active researcher, clinician and educator who's internationally recognized for her work surrounding the use of human milk and breastfeeding, particularly in vulnerable populations. She has been the principal investigator or co-investigator on over 60 research grants and has authored and co-authored over 200 peer-reviewed applications and numerous book chapters related to human milk and breastfeeding. Dr. Meg Kawan is a general pediatrician in West Philadelphia and practices at the Karabot's Pediatric Care Center with the Children's Hospital Of Philadelphia. In addition to practicing primary care, she's been an international board certified lactation consultant since 2008. Dr. Kawan is involved in medical and resident education and serves as a clinical assistant professor of pediatrics in the clinical track at the Pearlman School of Medicine of the University of Pennsylvania in Philadelphia. She currently serves as a chapter breastfeeding coordinator for the Pennsylvania chapter of the American academy of pediatrics East region. Okay, so over to you Dr. Spatz and Kawan, thank you for joining us.

Dr. Diane Spatz

Thank you very much. I will share my screen for both Meg and I if you give me just one moment. All right, fabulous, thank you for that kind introduction and Meg and I are very happy to be here and I actually think it was really perfect that we followed Leah and Theresa because it really builds on what they presented. So, we both are in West Philadelphia serving a vulnerable community. These are our disclosures and I'm going to start with what we've already talked about all through this research affinity group. Early in the pandemic in Philadelphia, we interviewed first-time mothers and really found that it had a profound negative impact on them. And this still seems to be holding true even all this time after we're into the pandemic. We heard this in the prior presentation about people getting conflicting information and we're still seeing that. The parents reported guilt, concern and stress. They also didn't feel like their needs as a lactating person were as important as for example people who were suffering from COVID-19. The participants talked about the fact that while a telehealth visit may be helpful to troubleshoot an easy problem, it did not replace the need for tangible in-person support like helping someone to latch a baby to the breast. And again this is something that we're seeing persistently; that people are not getting access to in-person services. It was very difficult not to have the family and friends support network after having a child, as they were following the social distancing guidelines. It was quite challenging for them.

And then, the only silver lining was for those mothers who were able to work from home. Breastfeeding actually became easier and Dr. Kawan will talk about that from a study in the UK. Things that I continue to be worried about is that even before the pandemic, we know that early exclusive breastfeeding and skin-to-skin contact still does not occur in so many settings. It's not prioritized and we know all the benefits of early exclusive breastfeeding and skin-to-skin contact, yet it's not done with both vaginal and

caesarean births. And then, in the US with the CDC, they actually found that one in five hospitals were either discouraging or prohibiting skin to skin. So, we all know how concerning that is for the establishment of effective breastfeeding.

For my career, I have really focused on looking kind of beyond BFHI. I think BFHI is a fabulous foundation when we're working with healthy term infants. We have 28 percent of our hospitals in the US that are BFHI but that means the majority of them still are not, and then we have to think about that critical role of human milk and of how we can get the most information to the most families. So I'm again very happy that we're following Leah and Theresa because that role of the nurse and the midwife is absolutely critical. When I was recruited to Children's Hospital Of Philadelphia, I knew that there was no possible way we could really use the BFHI model at a children's hospital that includes not only a 545 bed hospital but also 29 primary care sites that are providing pediatric primary care. We've also seen during this pandemic that this process, these 10 steps, have been really important because of what has happened with birth hospitals who have separated parents from their children and not allowed skin to skin, and for all the information that is not really true, that has erupted with COVID-19. So, the first two steps: informed decision and establishment and maintenance of milk supply, if we don't have families be able to do those two things, we're not going to have a long-term breastfeeding family. And what's really critical is how do we get that informed decision making to all families and then how do we ensure all families come to [.....].

We have data and publications both in the US and in developing countries and developed countries. So, US, Thailand, Japan and we also have educational materials to go with it. Now, partnered with that is this concept of the nurse and the critical role of the nurse. And so again, in the US, we don't have a lot of midwives. Only about five percent of people get to have a midwifery birth. But we have 3.2 million nurses and if our nurses are not equipped with the appropriate education to be able to support the lactating family, we're not going to have good clinical outcome. So, again, knowing when I came to CHOP that we were talking about a pediatric practice not a typical birth hospital, we needed a different type of education for these nurses to help families. So, it is a two-day course which has continuing education associated with it and nurses are paid to take the course. This has also been replicated in other hospitals besides Children's Hospital Of Philadelphia. It is important to note that we have these breastfeeding resource nurses both in our inpatient area as well as in our primary care areas, okay. So where Meg Kawan works, okay. We published some of the outcomes of this model and I think one of the things that is really important is that we know that nurses don't receive adequate education about this in their programs of study, which means then they don't provide support. But you can see in this sample 90% reported providing direct breastfeeding assistance on a regular basis. And furthermore, and this is a goal of the program is, the nurses were also mentoring people who had not had the education and training. And in the qualitative part of the research, the nurses talked about how critical it was to understand the evidence and the science of human milk and lactation so that they could empower their families and that idea of empowering through evidence or research. It allowed nurses to be really good patient advocates, to want to go the extra mile to help families in their breastfeeding journeys, and it also impacted them on a personal level. So, all of our primary care centers at CHOP have breastfeeding resource nurses at them, all the 29 sites, and they are responsible for doing a lot of tangible assistance in the community. So, I'm now going to turn it over to my colleague Dr. Meg Kawan.

Dr. Meg Kawan

Hi everybody, thank you so much Diane. I apologize, my camera is not working. It worked yesterday so I'm not sure what's going on but I'm happy to be here. As Dianna mentioned, I'm a primary care pediatrician so I work exclusively in the ambulatory setting. I work at our largest site known as Karabots which is extremely large. I've been told we're the largest primary care site in the United States; we serve

approximately 40,000 patients and we see an average newborn volume somewhere between 125 and 140 newborns per month. So, we see a lot of babies. 86% of our patients are covered by Medicaid and about 82% identify as African American. And our staffing model does include the breastfeeding resource nurses, and I'll talk about that in a little bit in their role. We also are fortunate to have several providers with lactation consultant certification. Our office does not have a full-time IBCLC or lactation consultant doing full-time breastfeeding work so it's integrated into our primary care practice.

Next slide please.

I wanted to just mention the AAP recommendations as other presenters have mentioned, our office like primary care pediatricians really looks to the AAP for guidance. And the AAP has strongly endorsed breastfeeding as the optimal choice for infant feeding throughout the pandemic, but I'm sure everyone in this group is aware initially as the pandemic began, there was the recommendation to separate newborns from their breastfeeding parent. And even when that recommendation had changed, which we know now that it is recommended that breastfeeding parents can room in with their infant with distancing and precautions to minimize transmission. That information was sometimes late to disseminate in our community and it was still even after the recommendation had changed, many health care workers and parents perceived that rooming-in with a COVID-19 infected parent was a less safe option. So we saw separation continue.

Next slide.

I wanted to share some of our quality improvement data from our office. About three years ago, our office started tracking our breastfeeding outcomes which when I started at my office six years ago, I thought that would be very easy information to get. We use a pretty sophisticated electronic medical record system known as "Epic". But, when I started, I found that we were not consistent at all in the way that we documented breastfeeding status, particularly exclusivity. So it was a lot of work with a team in our office and we had institutional support to now be able to track breastfeeding rates in our very large practice just through six months at this point. About 80 percent of our providers do use this tracking method so it's kind of rough data but we do have 80 percent of our providers consistently tracking breastfeeding status. So, this shows our breastfeeding rates at the newborn visit July of 2019 through 2021 and our overall breastfeeding rates have been fairly consistent at about 73%, our exclusive breastfeeding rates had hovered between 40 and 45% prior to the pandemic which certainly is an area where we need to work in our community. But what you can see here is really a dramatic decrease in breastfeeding exclusivity rates. They went to kind of the 30% right in the April, May, June and July and they still have not rebounded to the pre-pandemic levels.

Next slide please

And not surprising if you have very low newborn exclusive breastfeeding rates, your one-month breastfeeding rates will not be much higher. I think this is still the newborn, if you can go to the next slide Diane. At one month that was where our team saw a huge decrease, pretty shortly after the pandemic. So this is again the same time period July 2019 through July 2021, our exclusive breastfeeding rates and they really dropped dramatic dramatically. At the one-month point in May of 2020, our exclusive breastfeeding rate was 7.5% for the infants in our practice which was just devastating for those of us that do this work. So, that was really an urgent call to action for we have an interdisciplinary group that meets regularly. We had an urgent meeting and talked about what we can do to try to address this. Diane had mentioned some formal data that she was able to do through her qualitative studies. This is just what we were asking parents and what they were telling us, they really were not getting that skilled breastfeeding support in person, and many parents were choosing early hospital discharge. It was not necessarily

something that was encouraged by the healthcare team but families were terrified and just wanted to get out of the hospital as quickly as possible.

On our end, we were actually shortening office visits in the early days of the pandemic. We were doing phone calls the day in advance of the visit and just kind of bringing the baby in, examining the baby and sending families out as quickly as possible. And that minimized the amount of time that our team was able to spend supporting breastfeeding in the office. I don't have to tell all of you that the stress that parents were experiencing at that time was unprecedented. A huge issue we found is parents that had other children now had all their children home who weren't in school and they just found it incredibly difficult to try to breastfeed, and homeschool, and it was very overwhelming. Family support typically if the aunt or the grandparent would come and help a new parent. That was not happening. And concern about illness; we heard from some parents even who weren't experiencing symptoms of COVID-19 they just perceived formula as a safer option.

Next slide please.

So, we tried to look at our existing resources to see what we were capable of doing in the office and it was really challenging because we were experiencing staff shortages and staff was being kind of redeployed; we were one of the first sites in the city to have drive-through testing available for children. So, that was a big office outreach but it did de-prioritize the support parents were getting for breastfeeding in the office. So, the things that we tried to do ... we were fortunate in Philadelphia that the health department was paying for Pacify which was a lactation consultant virtual service that was available to families 24 hours a day, seven days a week. So it was a great service and it was available anytime with a very quick response rate, of course this was virtual and not hands-on. We also have a very active breastfeeding support group in West Philadelphia that was in existence before the pandemic and very well attended. That group had increased the frequency of their groups to weekly and so we really tried to highlight their work and partner with them. One of our nurses had a grant that she was situated in a high school to do family planning work and since the high school was closed she started doing breastfeeding kind of telephone outreach. So families we felt like were at high risk for needing more support were referred and she would do phone calls, just one day a week though so it wasn't a ton of time. And really we tried to aggressively renew our staff education and discuss where we were and how we really needed to prioritize that as an office.

Next slide.

I think that's back to Diane.

Dr. Diane Spatz

Nope, one more for you.

Dr. Meg Kawan

I did want to mention there was this study that was published from the UK that I think really spoke true to what we were experiencing within our network and that they were able to look at breastfeeding experiences of parents during the pandemic, and I really found two very different experiences and that about 40 percent of mothers felt breastfeeding was protected during the lockdown. But a significant 27 percent really struggled to get support and had many barriers and that led to earlier breastfeeding cessation. And what I found out was exactly what we were seeing for a certain percentage of parents, they're breastfeeding longer, it was easier, the parents that were able to work from home. But for the majority of our families, and I work in a marginalized community, that was just not the experience that we

were seeing. We're the only office in our primary care network that does track our breastfeeding rates regularly. I don't have data from the other offices but my colleagues that work in more affluent communities have said that they've noticed an improvement in breastfeeding. So, it really is an unfortunate story of widening already existing disparities. Thank you.

Dr. Diane Spatz

Thank you Meg and so, back to me, I think one of the reasons Victoria was like please come and present was because at the last meeting that we had, there was that discussion about what else do we need to discuss, like, what else, we have this research now, we know about antibodies, we know about vaccines, we know all this good stuff but, my point was, we know this but what's happening is that we are seeing a real increase in that disparity. And so, for people who are well resourced and well educated, and have privilege and can work from home, yes, breastfeeding has become easier for some of our families. But then for many of our families who are at risk for not making informed decisions about infant feeding and who aren't able to pay for private services, and don't have any in-person support for breastfeeding, then we're seeing these big dips in breastfeeding rates. And we've seen this throughout our primary care sites. Like I said CHOP has 29 of them. So there's a whole variety of what we're seeing in the pediatric office but the burden has increased on pediatric practices because of what's happening or not happening in birth hospitals and because of the fact that people aren't getting the same amount of care and intervention as before the pandemic. I think I shared this paper earlier when this first came out, this was an international effort of both clinicians, midwives and Bench researchers. There is a lot of interventions that we actually know do work so why aren't we doing them. And so in our call to action, we really talk about the fact that there are huge disparities that are getting worse and we have to acknowledge them, we have to acknowledge structural racism, we have to change how we think about human milk and think about it as a proactive management strategy to mitigate toxic stress, which so many of our families are at risk for, we need to change the current prenatal care paradigm because it's not working. We know that we should be actually talking to families at every point of contact about human milk and breastfeeding yet this isn't happening. And I was lecturing earlier this week to our midwifery students at Penn and they said the real challenge is if you only have seven minutes with a pregnant person and her family or the family, how are you going to really go in depth about the science of human milk and the physiology of lactation? The importance of empowering the family, right? One of the things I'm very proud that we did at CHOP with our special delivery unit is we had families quarantined together prior to birth so that they had support people. And how do we help families set up that breastfeeding support team prior to giving birth? Something that I'm very concerned about with the pandemic and even before is that sense of urgency about milk supply. We have something at CHOP called our ambulatory breastfeeding consortium where we really push knowledge out to all of our primary care sites but one of the things about intervening in primary care is we now have really missed that critical window of opportunity for milk supply because we have all this data; about the first three to five days in lactation biomarkers, and if we don't do a good job of establishing milk supply in the first three to five days, we're not going to have milk supply long term. And this is not being prioritized in birth hospitals. Then, thinking about PDHM not ever as a replacement to parents own milk but as a bridge and we know most hospitals have very restrictive PDHM policies and only about half of hospitals in the US actually even have PDHM. So, there are a lot of things that we do know that work and are effective in improving breastfeeding outcomes, nurses and midwives. The critical role of nurses and midwives in changing breastfeeding outcomes. The use of Doula services. We know that Doulas in particular working with low-income families can increase breastfeeding initiation. However, in the US, only 6 percent of families use Doula services. So, why is there not increased funding and access for Doula services? Peer counseling we know works but again with a pandemic, in-person peer counseling has been halted by WIC offices, by community supports and so, while it's great we have online peer

counseling, again that doesn't replace the need for tangible support. And in this paper down in the middle we used a peer counselor model to educate high risk low-income families who had high-risk pregnancy and who were taking medications and they were at great risk for not breastfeeding. And we were able to statistically significantly increase both intention to breastfeed, breastfeeding knowledge and also then what they did in terms of actually breastfeeding. So again, why don't we have mandatory peer counseling for example in the WIC program. Why isn't there increased funding and access of peer counselors?

And then, lastly, home visiting. We know that nurse family partnership, you see better rates of breastfeeding in NFP. In our work that we used a community health nurse and peer counselor model working in East Baltimore, a low income primarily African American community for just four home visits, we were able to statistically significantly increase breastfeeding rates at 6, 12 and 24 months. So it doesn't take much to make a difference. This is the resource that I dropped into the chat box. This is an evidence-based practice guideline focused on parent infant separation. Every part of it has tables of evidence and a rating of the evidence available and you can find that on PubMed. That is Meg and I's contact information and we thank you for your time and attention.

Jennifer Yourkavitch

Thank you so much Diane and Meg. Wow, that's a powerful call to action and you spanned the prenatal, the postnatal, all the opportunities that there are to improve breastfeeding support across providers, across systems in those times. Thanks so much for that. You have questions or comments, this is our discussion time. Together, we have a few minutes here, I saw a comment there from Bindi that parents perceive formula as a safer option demonstrates that we need to change the messaging from the benefits of breastfeeding to the risks of not breastfeeding or the risks of artificial feeding. Any comments on that from the presenters, how we communicate about benefits and risks.

Dr. Diane Spatz

I can comment on that. I am aware of some hospitals that have people sign consent for formula and their consent say things like your baby will be more likely to be obese or have diabetes or whatever if you feed your baby formula. My concern with that is that you can't go to a grocery store and buy pasteurized dinner human milk and in the US, informal milk sharing is discouraged by the FDA. So, what if you are a lactating parent and you have glandular hypoplasia and you actually can't make a sufficient quantity of milk? What if you've had a breast reduction surgery and you can't make a sufficient amount of milk, right? So, what are your other options? So, I 100% agree that we need to change how we message and educate families but my approach would be that informed decision making where we actually teach about the science of human milk, the way in which the components of human milk work to protect the baby, how the milk impacts every single organ of the body, and then also emphasize that even if a parent could not make a hundred percent milk for their baby, any amount of milk actually matters, right? So that like we have a different messaging that is really about empowering that person to be able to effectively make milk. And then I guess it also then just goes into me for me, the fact that no one in birth hospitals is really having a sense of urgency about milk supply and so then we have people who actually want to breastfeed but they end up not being able to make them enough milk because they haven't had good management in the critical window.

Jennifer Yourkavitch

Thanks Diane, I think I'll follow up there from Ben, oh sorry, go ahead Leah.

Dr. Leah Greenspan

Yeah, I just wanted to underscore what Diane said because I think it's very important that we don't shame mothers and there are circumstances where formula is necessary, and when we create messaging, we need to keep that in mind. Some premature babies need supplements, there's definitely circumstances where mothers can't breastfeed and shaming mothers in any circumstances is for me a big conflict, over.

Jennifer Yourkavitch

Thanks Leah. Dan, I see your hand, please go ahead.

Dan Raiten

Hi everybody, this is a great series of presentations and I am very much in favor of the last two comments. I would like to throw out a comment, a question, in terms of reorientation of the discussion. It's really a choice issue and we use that term in certain contexts but we don't use it in the context of human milk at a great extent and I'm wondering if there is value in repositioning this discussion in terms of a parent's choice and be able to be informed about how, what they need to know about that choice.

Dr. Diane Spatz

Not all people are given equal information, that's the problem. Because of structural racism or because of the type of care that people get. I mean, we have a publication that came out this past year, even though we have really high-risk people delivering at our birth hospital which is only babies with congenital anomalies, we do ascertain a manner of care. So like our parents get very different information about human milk and lactation and they all initiate lactation, a hundred percent of them do, but we've given them the right information. But not all people are getting good evidence-based information and that to me is a real problem because that's gotten worse with the pandemic as well. Sorry, I get a little upset about it because there are things that work and there are ways to give information to people that we know are effective, but not everyone is getting equal access and that's a huge problem.

Dan Raiten

Agreed a hundred percent and just the FYI, some of you may be aware of the project that we've initiated called "BEGIN". It's really intended to develop that effort space and part of that process is breast milk ecology and genesis of infant nutrition. One of the working groups involved in that project is focused specifically on a translational framework to help develop the information, and distribute and disseminate the information to support the implementation of safe and effective infiltrating practices and equitable information resources. So, we couldn't agree more and stay tuned for those reports. They'll be coming out shortly.

Jennifer Yourkavitch

Thanks Dan, so that's NIH's Begin program. So, you can probably find that on the website or contact Dan Raiten. Okay thanks. I want to note a comment here from Tanika about the shaming effect for particularly young or adolescent mothers who already are shamed for being mothers early and may have a history of childhood sexual trauma that can complicate the breastfeeding relationship. So, another particularly vulnerable population. And then Laura has a question, I was wondering how much effort is focused on partners of lactating women and providing them with information on the importance of breastfeeding. Would someone like to address that?

Dr. Diane Spatz

We do that in our programming at our institution both through the prenatal and postpartum period. We have a resource community support that it's not just mothers, it's actually all family members are welcome. I think in the US back 10 years ago with the surgeon general in her call to action, she said the need to educate fathers and grandmothers but I think with COVID-19, if people were following social distancing recommendations, remember some of those people were missing from the equation.

Jennifer Yourkavitch

Right, meaning they weren't allowed in the birth space, they weren't allowed in the provider space, right, because of COVID-19 precautions. So, that complicates their ability to advocate for their partner and support their partner in breastfeeding. Any other comments on that partner involvement? We have just a few more minutes for questions for any of the presenters.

Dan Raiten

I don't know if you had this conversation at the beginning, I'm sorry I was late. Was there a discussion about the transition from USAID Advancing Nutrition?

Jennifer Yourkavitch

No, just mentioned that this would be the last one and we'd let them know what's happening going forward. So, please feel free.

Dan Raiten

Okay, but first, I want to thank all of you for your continuing involvement and support of the CIF RIG. We started this in March of 2020 and there's been a tremendous enthusiasm although I know the enthusiasm may be waiting just a bit given the number of attendees to today's workshop. That's probably due to a lot of different things. NICHC which initiated this project as the original secretariat will assume the role of the secretary moving forward. I've received approval for that from my leadership so we will continue this. What I'd really like to know from the community here is whether or not you still see value in continuing the CIF RIG. We're happy to do this but if the participation is going to continue to win, we all have lots to do and there's certainly plenty of issues that we're dealing with in our own individual venues. We don't want to take up time, if you got it, this is not a value due so what I'd like to ask is if you could send your thoughts with regard to the value of the CIF RIG and the value of continuing it.

We'll follow up this meeting today with a message to everybody that we have on our mailing list to see if we can get a larger reflection from the community. But for those of you that are still on the call today, this is where we're going, this is what we'd like to hear from you. If you think it's valuable, we will continue to do it. There's still a lot of work to be done clearly. I'd also like to just remind everybody that next week on the 16th there's a webinar that's being conducted under the auspices of the Global Nutrition Coordination Plan. It is focused on how do we come up with better responses. All the things we've heard today, all the challenges that we've heard that have accrued as a result of this pandemic? We've experienced them before, we experienced them with HIV, we're experiencing them with COVID-19, we experienced them with Zika and we'll experience them again with future challenges. How do we develop a framework for not just sustaining safe and effective infant practices but being more resilient and more effective in our response to these challenges? So, that's what the focus of that webinar is going to be on the 16th and you're all invited. You should have all received invitations to it. Hopefully you registered for it and we'll look forward to seeing you then. So, back to you Jennifer, thank you.

Jennifer Yourkavitch

Great! Thank you, Dan, for the announcements. Let's see, just seeing something in the chat, great, thanks Tanika. Any other announcements from anyone, comments, questions before we close?

Dan Raiten

I should have said this right up front, I want to thank USAID Advancing Nutrition for all the support that you guys have given. You guys have a lot on your plate, you have plenty of things to do and you took this on in the middle of all that you're doing, you've done a tremendous job, you've been great partners and we're looking forward to working with you moving forward. So, thank you Jennifer and your whole team.

Jennifer Yourkavitch

Thanks Dan, thanks so much. We're looking forward to continuing this journey. On behalf of USAID Advancing Nutrition I want to thank all of you for your participation over these many months. It's been a really valuable journey together and we're looking forward to seeing you all again and hearing about your great work in the next forum that Dan described. So, thanks everybody, we'll see you soon.

Dr. Vivian Valcarce

Thank you.

Dr. Leah Greenspan

Thank you so much.



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