

CIF-RIG Vaccine-related Issues

Webinar Transcript

Victoria Anders

Hello everyone. Good morning, good afternoon, good evening, depending on where you are. Thank you so much for joining us today for our July 2021 COVID-19 and Infant Feeding Research Interest Group or CIF-RIG meeting. We are very happy to have you. I'm very happy to begin our discussion on the topic vaccine-related issues for lactating people including vaccine hesitancy, messaging, confusion around vaccines and current and past research. My name is Victoria Anders, I am a project officer with USAID Advancing Nutrition and we have been supporting these monthly CIF-RIG meetings for a couple of months now. So we are very happy today to be welcoming two colleagues who will be giving brief presentations related to this topic - Vaccine related issues for lactating people. Following which, the two speakers are Tina Chambers from the University of California at San Diego in the United States and Michael Ceulemans from KU Leuven in Belgium. We will follow their two presentations with a Q&A session. And finally, hoping that we have time for that as well, an open discussion on outstanding research and programmatic needs related to COVID-19 and breastfeeding. And our colleague Mija Ververs from Johns Hopkins University and the CDC will be leading that.

We will also give you a reminder at the end of our call so that you are aware. In place of a CIF-RIG meeting in August, we ask that you please join the US government's Global Nutrition Coordinating Plan or US GNCP meeting which will be held on August 18th. Everyone who is invited to this call will receive the call-in details and agenda within the next couple of weeks. Our next CIF-RIG meeting will be on September 10, 2021.

All right, so we will move on to our first speaker at this point who again is Dr. Tina Chambers from the University of California at San Diego. She will be discussing vaccines side effects in lactating vaccinated people and adverse reactions in their breastfed infants. Dr. Chambers is a professor in the Department of Pediatrics and Family and Preventative Medicine at the University of California - San Diego School of Medicine. She is also the co-director of the Center for Better Beginnings. She is a clinical professor in the Skaggs School of Pharmacy and Pharmaceutical Sciences at UCSD, vice-chair of clinical research in the UCSD Department of Pediatrics, director of the UCSD CTRI Center for Life Course Research and also director of clinical research at Rady Children's Hospital, San Diego. Dr. Chambers is a perinatal epidemiologist specializing in the area of environmental causes of adverse pregnancy outcomes, birth defects and childhood disabilities, with a special focus on human teratogens; environmental agents that cause birth defects. She is currently conducting research on the prevention of alcohol related birth defects, the safety and pregnancy of several medications and the safety vaccines during pregnancy. She also serves as an advisor to various US government institutes and agencies as well as the World Health Organization. So I will pass it on to you Tina at this point for your presentation. Thank you very much.

Dr. Tina Chambers

Thank you and it's nice to be on the meeting with Michael Ceulemans who is a colleague and friend. So, we share a lot of common interests. So, hopefully you can see the screen all right, everything good, okay. I'm going to give a quick update on COVID-19 vaccination and lactation work that we've been doing through the UC San Diego Human Milk Biorepository. The project director is Kerry Bertrand who would be on today but she is on a much needed vacation and our biostatistician Gordon Honor Kamp Smith.

So, funding and conflict of interest. First, Victoria asked me to say in terms of vaccination and lactation, if this research I'm going to talk about, if I am a person who is would potentially be a subject of that research and No. Although I have breastfed all three of my kids. They are in their 30s and I certainly was not vaccinated for COVID-19 while breastfeeding but very much a person who would have benefited from this research, should I be in that age range. So for the overall work that we've been doing on COVID-19 and the vaccination, Larssen Rosenquist Foundation has helped us with some staff support, the Donor Milk Bank Network particularly, the Austin Donor Milk Bank has helped us with shipping costs, Medela Corporation has provided us with in kind donations of breast pump and milk collection bags, we have an NICHD funded project looking at the use of the humano-biorepository home collection protocol versus clinic collection, and we've gotten some supplemental funds to help fund this work today. And I received research funding from pharmaceutical companies that do manufacture vaccines but none of it is for vaccine work in lactation.

So as you know, the issue of side effects of these vaccines has been of interest in the population in general and in a publication that just came out in the New England Journal Medicine, a couple months ago, some of the data were reported from the V-Safe program in the U.S that looked at pregnant women, not lactating women but pregnant persons, for the two mRNA vaccines. And so, these large numbers here are people who reported to through V-Safe to the CDC, the symptoms and side effects. In these V-Safe participants 16 to 54 years of age who identified as pregnant and entered their symptoms. And so, they compared dose one to dose two and each of the two doses, and just to put it in a nutshell, you know some of the side effects or reactions were more common than others. They seem to be more frequent often times with a second dose and seem to be more frequent often times with the Moderna versus the J&J brand. When they compared local and systemic reactions in women who reported through V-Safe who were pregnant versus those in the same age range who didn't identify as pregnant. They saw that they were quite similar in terms of the frequency of these reported reactions in these data, at least for people who reported the first day after they received their vaccine.

There's been a paper that was published also this year by Catherine Gray et al that looked at a small sample of women, a subset of women who were lactating and were vaccinated. And they also reported on side effects after the first and second dose. These are all mRNA vaccines but they didn't differentiate between the two brands. And as you can see the side effects, local injection site soreness were quite commonly reported after the first or second dose, more side effects reported after the second dose, and some of them quite frequent occurring in up to 50 percent of individuals who were lactating; these 31 women who were lactating. So, the Human Milk Biorepository we talked about last time we spoke at this meeting was established in 2014. The geographic area it covers is all of US and Canada. So we recruit individuals who are lactating, who are willing to participate. And the participation involves providing one or more breast milk samples, completing some interviews, providing some online data, releasing medical records and then they also agreed to participate in neurodevelopmental questionnaires and sometimes face-to-face testing. And this has, as we said, been going on for a number of years for the broad purpose of developing a resource where multiple research questions could be asked. And obviously this was a nice place to be at the beginning of the pandemic, to be able to use this resource to look at infection and lactation and now to be looking at it with the vaccine.

In our pregnancy studies we've been asking women if they would voluntarily be willing to answer some questions about vaccine hesitancy. And certainly there are other data out there that suggests the same thing. But in these women who are motivated to be enrolled in a study are already pregnant, when asked about their willingness to receive a COVID-19 vaccine, the highest level of has hesitancy in these 279 women when answering the question about willingness to receive it during pregnancy, only 37% said YES. Willingness to receive a COVID-19 vaccination while breastfeeding, 54% said YES, but still 46% said they would not or were not sure whether they would. So when we started introducing vaccine into the human milk biorepository study, we were able to do this pretty quickly in December when the first ones received

emergency authorization, and we had a huge influx of referrals from women who wanted to participate. We didn't have sufficient resources to respond to all of those but we have been able to enroll 1200 women who have consented and are in the process of sending samples and they're pretty evenly divided between the two micro mRNA vaccines in terms of enrolment. And then since it became available in the US, we've consented about 200 J&J vaccinated women. They get the same standard HMB interviews, medical records release and so on, but the additional thing that they participate in is a seven-day questionnaire following each vaccine dose. So it is different from what the other studies I showed might be capturing in terms of asking about symptoms and reactions in those full seven days following each dose. And then we also asked a standard checklist of infant events and this is from a checklist that was developed by Phil Anderson who runs Blackmed here at UCSD and the mother's report in the seven day period following each dose. Any of those events that they noted in the infant. Then of course the mothers are sending milk samples, a serial set, up to eight pre-first dose, between doses, and up to 90 days post last dose. Although we have some people who saved milk, who were part of the clinical trials, so we have some longer term samples as well. And working with Lawrence Bode here at UCSD and others to look at antibody responses and other characteristics of the milk sample. So far, as others have shown, for the mRNA vaccines, their responses seem robust and looking at J&J now.

So I'm going to talk now about those subset of data from that sample of vaccinated women regarding these side effects or reactions or whatever you want to call them. So, this is the first 356 lactating participants who are fully vaccinated and who completed these questionnaires. And 221 received the Pfizer vaccine, 117 Moderna, 16 so far we have the full data on for J&J. And they look pretty similar in terms of the distribution of maternal age, they tend to be white, highly educated, partly influenced by who were early adopters of this vaccination, a small percentage had a prior COVID-19 (Sars-CoV-2) infection, the average age of the breast-fed child in these moms when they enrolled was somewhere between about five and seven months. In the mRNA vaccines, predominantly or close to half female, a little bit fewer female in the J&J, and the majority three quarters or more were being exclusively breastfed.

So here's the checklist of the symptoms or reactions broken down by brand and by dose. And a lot of data in the next few slides but the bottom line is that local reactions such as pain at the injection site were quite common and did differ by dose, and then ones that were reported less frequently also did differ by brand and by dose. Maybe more commonly after the second dose, and for some of these we see differential reporting by brand. The systemic reactions have kind of the same pattern, chills, headache, joint pain, body ache and fatigue, being reported in the small sample of J&J vaccinated much more commonly than in the first dose of either the mRNA vaccines. And then as we saw in the other population data and the small sample from Gray, after the second dose, more commonly reported systemic reactions and more common in some cases in the Moderna vaccine than the Pfizer vaccine. And then, same picture here with fever for example not frequently reported with Pfizer and Moderna after first dose was frequently reported with J&J, much more frequently reported with the second dose of Pfizer or Moderna and more much more frequent in Moderna versus Pfizer. We kind of looked at combinations of any local or any systemic and again we see pretty much the same pattern that it seems to be specific to this type of reaction and then J&J is a different animal.

We did ask a question about change in milk supply and about any change in the characteristics of the milk. And what you're seeing here in these bars is percentages. So on the left panel it's the percent within seven days of dose 1 who reported more milk, less milk production or a reduction in milk supply or a change in milk, some sort of characteristic of the milk, which was reported as a change in milk color. So you can see a small proportion of Pfizer participants had two percent for example said that they had more milk, but about seven and a half percent said they had a reduction in milk supply, six and a half percent said they noticed a change in color. Similarly with Moderna first dose a little over eight percent reported a reduction in milk supply and seven percent a change in milk color. With J&J, nobody reported a change in milk color but about six percent reduction in milk supply. And after dose two, if these are certainly not on this same

visual scale here. These are percentages again. But you can see with Pfizer more after dose two about eleven percent reduction in milk supply, eight percent change in milk color and after Moderna close to fourteen percent reduction in milk supply and about seven percent change in milk color. So I should say that for the women who reported a reduction in milk supply they were asked when and if that resolved and uniformly within 72 hours women said that it returned to normal.

The infant symptom checklist is shown here so mothers of course are responding to what they note in their infant, irrespective of whether it's just incidental or not. So you can see that the reported number of these events or symptoms is quite small across the board. Very few are being reported at all. We have some numbers that the percentages look higher for J&J but the numbers are quite small again. When we look at the ones that are the most common going down to the end of the checklist, the two that were reported most frequently are irritability and poor sleep. So this would be a change from what they had experienced with the infant prior to being vaccinated. And you can see that this is occurring after first dose in maybe two to five percent of mRNA vaccinated mom's babies and a little bit higher but small numbers with J&J and then occurring more frequently after second dose with Pfizer and Moderna both. We looked at is there anything about the mom or the infant that was associated with reduction in milk supply particularly after dose two when the numbers were higher. And so, adjusting for these multiple comparisons we did see that local swelling at the injection site was associated with a reduction in milk supply after dose 2 and more systemic symptoms or reactions, Diarrhea and abdominal pain, were also significantly associated with reduction in milk supply. So whether that's causally related we don't know. And the two infant symptoms that were borderline associated with reduction in milk supply are drowsiness and irritability which certainly could make a case for why that might be a result of reduction in milk supply.

So I'll end there and happy to answer any questions or leave it to the end. Whatever everyone prefers.

Victoria Anders

Thank you Tina. I think we will wait until the end since we only have two speakers today. Thank you so much for that and please everyone else keep adding your questions to the chat or otherwise keep them ready. All right so we will pass on now to Michael Ceulemans who's coming to us from K.U Leuven in Belgium. Let me get my notes back. He will be discussing vaccine willingness and the impact of the COVID-19 pandemic on women's perinatal experiences and practices through showing data from a multinational cross-sectional study covering the first weight of the pandemic. Dr. Ceulemans is a PharmD PhD and a post-doctoral researcher at the research group Clinical Pharmacology and Pharmacotherapy within the department of pharmaceutical and pharmacological sciences of KU Leuven in Belgium, and is also a lecturer in the masters of pharmaceutical care and midwifery of the same university. He is currently also affiliated as a teratogen information specialist at the teratology information service of Lareb, the Pharmacovigilance Center in the Netherlands. Dr. Ceulemans has a master's in pharmaceutical sciences and also holds a PhD in perinatal medication use and the role of the community pharmacist. His research interests are drug safety and pregnancy and lactation, drug information, fetal maternal pharmacotherapy, pharmacoepidemiology and pharmaceutical care. He was the coordinator of a European COVID-19 research project on pregnancy and lactation, studying women's mental well-being, medication use, vaccine willingness, perinatal experiences, access to health services, and breastfeeding practices during the pandemic. Several publications following this project have been published in peer-reviewed international journals. Welcome Dr. Ceulemans, thank you very much and I will be passing it over to you.

Dr. Michael Ceulemans

Okay thank you very much for the nice introduction and the invitation. Indeed Tina it's nice to see you again during this meeting. I will mainly talk about our results of our international study on vaccine willingness; that was one of the outcomes we measured, but I will also talk about some counselling perspectives that I have had in the last couple of weeks and months at the Dutch Test in the Netherlands

later up, which I think represent nicely the questions patients have surrounding this topic at the moment. Now my disclosures, no specific conflicts of interest and on the slides you can also see the sources that supported our research activities during the study last year and at this time in 2021.

So let's start with this nice overview. It's a nice illustration I downloaded two days ago and actually shows the different vaccine policies on lactation worldwide. So as you can see policies differ quite substantially and if you are just wondering where you can find Belgium well it's very, very tiny but it's somewhere here in Western Europe. So the reason that I'm here to day is I think because of this publication. We published the manuscript a few months ago in the international journal of environmental research and public health and together with our international colleagues and it's on behalf of all of them that I'll present some of the results today. Here, just kind of a map of western Europe where you can see the countries where we distributed the survey and collected some data, and all the colleagues involved are affiliated to the European Network of Teratology Information Services. So it was in Belgium, Ireland, Norway, Switzerland, the Netherlands and the UK.

And importantly ... okay yes ... first this slide maybe as I was introduced at the start of the presentation, we did not only look at vaccine willingness honestly. So we had some different research interests and research questions that we wanted to get addressed and one of them was the mental health status as well of pregnant and breastfeeding women. The results were published a few months ago in the Scandinavian Obstetrics Journal and the information or the data on the medication use, and this paper actually is currently under review. Today I will talk about vaccine willingness of course. And just a few words on the methods; a cross-sectional study, and it was just a one-time point that we measured actually women's vaccine willingness and it's important to know that it was one year ago. So that was why I was a bit hesitant let's say to present the results today because they are not really new anymore and I think time has changed in the meantime so it's one year later but we will have a look at the results but they were collected somewhere in June-July last year, and the data in Belgium were actually even collected in April-May at the peak of the first wave of the pandemic. All breastfeeding women could participate and also women who breastfeed in the last three months. And in Belgium we only ... let's say all breastfeeding women but also women who breastfeed in the last four weeks only could participate. And of course the survey was available in the different languages.

Now about the survey questions, what we asked was actually the vaccine willingness and it was assessed on a four-point liquor scale ranging from strongly agree, agree to disagree and strongly disagree. And we dichotomized the results of the statement and we calculated the percentages for each country. So that was actually what we did and we also performed the regression analysis to identify factors that were associated with vaccine willingness in this cohort.

So let's have a look at the results. We were let's say able to include more than 9400 breastfeeding women and most of them were collected in Belgium, but also in Norway and Netherlands, followed by Switzerland, Ireland and only few women in the UK. And what is important to note I think is that more than 90% of the breastfeeding respondents were still breastfeeding at the time of the survey completion. Only say 18% of women were within the first six weeks postpartum; less than one percent had tested positive for SARS-CoV-2 and as you can see, and that's not so surprising I think, it was a highly educated cohort with many women who were employed at the time of the survey. Now if you look at the results overall about, 70 % was willing to get a vaccine during breastfeeding. But if we exclude Belgium, because these data were collected let's say earlier on in the pandemic, and if we exclude Belgium, the percentage was about 59%. I think a recent paper showed 55% among breastfeeding women. So let's say it was not that different from estimates observed in the general population at that time. It might be a bit lower yes but its difference is not that much I must say in the pregnant population. It was even lower but what you can see that's important to take home today as well is that there are differences across countries. As you can see for example the percentages in Switzerland were much lower and there are also differences within countries. I'm not really sure how familiar you are with Belgium but we have a part that speaks Dutch. I speak Dutch

from the northern part of Belgium where we have a very high vaccine willingness also in the breastfeeding population at that time. But the southern part of Belgium, where they speak French, was a much lower percentage. So we have differences even within a country or within a community. That's important to take home.

If we look at factors that were associated with vaccine willingness, we found that women living in Belgium were more likely to get a vaccine but this might be due to the timing of the survey. Another point was that women who delivered in the last six months, and even more who delivered in the last six weeks, were more willing to get the vaccine. And also women who were highly educated and professionally active or employed were more likely to get a vaccine. And I don't think that these characteristics are that surprising.

Some considerations. Let's say it was a large sample with the uniform data collection instrument but with only few UK residents participated and the limitations I think, they need to be emphasized once again is that the results were not collected at the same time in these countries, and about one year ago, and at that time there were no publications on the vaccine efficacy, there were also no vaccine available, there were no data on COVID-19 vaccine and breastfeeding so it is really a different time than we are today. And of course there was some selection but of course we had a highly educated cohort, a lot of women were employed, and these were actually factors that were associated with vaccine willingness. So it is possible that it was a kind of over estimation of the vaccine willingness in this population. But as it is, more than one year ago, we thought it's a good idea to have a new initiative and that's why currently we are doing another study, a new survey, in five of these six countries as you can see on the slide. So it's still ongoing and all women who delivered in the last three months are eligible. And what we did is actually that we have more interest in finding the predictors of vaccine hesitancy in this population and that's why we have added additional questions on perceptions towards vaccine safety, vaccine efficacy. And the study is ongoing but I thought let's have a look at some results. So yesterday I looked at the Belgian data and I will show you preliminary data. Just only a few things but might be relevant to share with you. The sample is not that huge I must say; it's 226 postpartum Belgian actually Dutch-speaking women. About 80% was breastfeeding at the time of the survey and, fourth point is important, I think about 60% of the breastfeeding women were already vaccinated. We have a very high vaccine uptake in the Dutch speaking part in Belgium. At this moment let's say about 80% of Belgian inhabitants older than 18 years old have got their first shot. So we think we are doing a good job. And at the time of the survey, 60% of the breastfeeding women were already affected in this cohort. It might be a bit higher than the general population but, as you can see, as of those not yet vaccinated, I think we found that 66% would do this as a breastfeeding woman. But there was kind of 40% that was ... 35% was not sure or doesn't want it. So there is absolutely a group of breastfeeding women that are not in favor of the vaccine. And we asked some other questions and what we found was that 14% of the women answered that the vaccines during breastfeeding are not effective and not safe for themselves and for their nursing infants. So again whether this is 10, 20, or 30%, there is absolutely a group of women who are still uncertain and are not willing to get a vaccine and this is something we should consider in our counselling activities as well.

Okay, I would like to share some ideas on our counselling activities and that's why I brought some questions that we've got over the last couple of weeks, and you can think about potential solutions or answers, but let's go through them one by one. The first one was a woman who called us saying that her nursing infant was suffering from fever and red spots on the skin since two days, and then we asked okay "when did you get the vaccine?" it was actually two days ago. So it was about the same time period she asked us, is this related, should I continue breastfeeding or not. And she did not experience any side effects herself after the vaccination so this one is actually a first example. Another one was that a woman said "I know that my infant will receive antibodies against COVID-19 through breast milk but how long do I still need to breastfeed my infants and I will receive my second shot within a few weeks"? So women ask us "how long should I still breastfeed to get these protective antibodies for the passage of these

antibodies to the nursing infant”? So this is a question we also get from time to time. Another one is a woman who said “I’ve already contacted different healthcare professionals and organizations but no one can really answer my question and answer me whether is it safe to get the vaccine while breastfeeding and are there any risks associated for the infant”? There was another one and then the fourth one, and this is an interesting one I think Tina will like this for sure. It was a woman, actually a husband, a man who calls and said “my wife got her Moderna last week and since then her milk production has substantially declined”. And they were worried and they found the publication on the internet stating that it's indeed possible. So I asked them which publication are you talking about and it's not a surprise but they found this one Tina mentioned a few minutes ago. And some people find these preprint articles of course on the internet and then they start reading it and this couple was really worried about the findings. I have a few slides on the findings but of course Tina already mentioned them. So let's go directly to this one. So they were worried about the reduction in milk production. With the Moderna it was the first vaccine and they said well if you see the results of the publication then it will be even worse maybe after the second vaccine. And of course in the publication it was written that in all cases milk production returned to be normal within 72 hours. But people have these questions, people find this on the internet and then call us for these things. Okay, so this is something that Tina mentioned; the side effects. And very recently a new publication came out by Thomas Hale and colleagues and I’m also focusing here on the impact of the vaccination on the potential reduction of milk production. In this paper, they found it was about 6% of the women and 7% of the women reported one or more symptoms in their child following maternal vaccinations; this is a low percentage. I think that could reassure patients to some extent at least.

This is already my conclusion. Policies regarding COVID-19 vaccination and lactation differ across countries and I think this is for patients not always easy to understand because they ask us and say well in another country you can get a vaccine or you can't get a vaccine and here it's the opposite so people find this very strange I must say. And the second point is that providing this balanced and evidence-based information and very up-to-date information to patients and also to professionals is vital as there are some misunderstandings or misperceptions among patients. So this information is very vital to make sure that they have the good information to do this shared decision making in a proper way. And then the third point in the conclusion is that vaccine hesitancy in breastfeeding women, I don't think it can be excluded. It might be the case at least in some women so it might be a bit more let's say present compared to the general population but less among the pregnant population. So it's good that studies are ongoing to show that there are antibodies in milk and that they go to the infant. And studies that show that you didn't find any mRNA of the vaccine in the breast milk. So these studies are important because patients do have these questions. But if we look at vaccine willingness, I think it's important to make sure that we need evidence and insight in country specific estimates, but also time specific estimates, because that can vary substantially, and it's important to provide insight in the drivers of the vaccine hesitancy. And this data we are collecting at the moment, because if we know what scares patients, then it's vital information in the counselling to tackle these barriers. With these words I think I would like to end my talk. I would like of course to thank my international colleagues with whom we collaborated on this project and yes this is a nice picture of our university in Belgium. Thank you very much and I’m open to your questions.

Victoria Anders

Excellent. Thank you so much Michael and Tina for these great presentations. We obviously see some overlap already in the research that is going on. We have a couple of questions from the chat. Please we welcome all other participants to include any other questions you have in the chat as we continue. Our first question in the chat was for Tina and it was from Borg Bindi. She asks “how was the reduction in milk supply interpreted or reported. Is it possible that this was impaired milk ejection reflex rather than reduced production, even if it was interpreted as the latter, given that pain, diarrhea, etc., impaired milk ejection reflex is possible.

Dr. Tina Chambers

That is a great comment and it makes complete sense that that could be the mechanism. And given the maternal reactions that seem to be most associated with it, the question was asked very generically: did you note any change in milk supply? And then they indicated 'no' or 'more' or 'less' but not the potential mechanism. But it's absolutely a question we can go back and ask of those mothers if what exactly were the characteristics of when this happened and how it happened. That makes complete sense. It's a great comment.

Victoria Anders

And then Sarah Comstock has also asked you a question Tina. Do you collect any information or measures of dehydration in the vaccinated mothers?

Dr. Tina Chambers

No, and that could be another mechanism as well for reduction in milk supply and that is not asked. We wouldn't pick it up this way but the questions that are asked about exposures over the previous 14 days wouldn't pick that up. We do a brief food frequency questionnaire but I don't think that would pick it up. That is a great suggestion of potentially a question we could add if they experienced anything or thought they did. That could be another mechanism.

Victoria Anders

Thank you and I will pass it over to Bindi to respond regarding her question.

Bindi Borg

Thank you for that response. That's so interesting that you're considering going back and asking for some more details. In my experience counselling breastfeeding women, although women often report reduced supply when actually it's not reduced supply, or they have a perception of reduced supply but no actual evidence. So the best evidence for reduced supply would be a reduced number of wet nappies but very seldom do you actually hear that as actual evidence of reduced supply. So women perceive reduced supply for a whole bunch of reasons. Some related to milk ejection reflex, some are related to baby fussiness, but my hunch would be that reduced supply is over reported with inadequate evidence or mother's not knowing what evidence to give just a perception.

Mija Ververs

If you have a follow-up question I would love to hear what it was. Sorry.

Dr. Tina Chambers

Yeah so I and maybe Bindi offline we could talk about how to frame that question because we certainly have permission to re-contact and get additional information. And in the case where we are asking about whether it persisted, they maybe are less motivated to or don't have information that would help support that if it's only short term. But you are right, it's absolutely subjectively reported and you know there may be different motivations or perceptions of why that occurred or why they thought that occurred. And going back to the fluid intake thing, maybe if the nausea or diarrhea are associated with it as well maybe either compounded by or influenced by some level of dehydration.

Victoria Anders

Thank you both for those comments and questions. So turning to Michael, there was a question about any future plans to repeat the survey including outside of Europe possibly.

Dr. Michael Ceulemans

Well that's a very relevant question of course but at this point not yet I think so. Actually it's been a really challenge to have this second study in Europe on going I must say. It was even a challenge to be here

today. So I think we're all busy I'm afraid and we need to find time. I'm really happy that we could manage this to have a second round in Europe at least and to ask more about, and that's the second question I think, ask more about the drivers of the vaccine hesitancy and what makes women hesitant to get a vaccine; so are they afraid of something in specific. So these are questions that we included this time in the survey. So I'm really happy that we'll have at least this evidence. In Belgium we only have 225 postpartum women. But for example, in Norway, [...] Northring had more than 2000 patients or respondents; pregnant and postpartum, so she will have more data at least on the drivers of the vaccine hesitancy.

Dr. Tina Chambers

Michael I think it's fabulous that you guys did that. If I could add to this, we did this exact thing with the flu vaccine after the pandemic H1N1 and did a survey of a vaccine hesitancy for flu vaccine in breastfeeding and it was there, it was high. And what the drivers of that were ... I think it would be so interesting to see. I know there is this unique thing about people saying 'this is a new vaccine type product' and that worry that the mRNA fragments themselves might be harmful. But is it really generic drivers of vaccine hesitancy in breastfeeding that would indicate that a more broad-based education program would be necessary across the board for the flu vaccine. Anything that you might get while breastfeeding or are there unique drivers for this vaccine.

Dr. Michael Ceulemans

Well, in this ongoing survey we also asked whether women got their flu shot last winter so to see whether this kind of ... is associated with how they ... so that was I think an important question. I showed some primary Belgian data and I don't think I spoke it out loud but it was mentioned on the slide: if I looked at the data yesterday, the main driver in this cohort was actually being afraid of the long-term effects of the COVID-19 vaccine and say we don't know what will happen within 20 years. So this was actually the most common one in at least our cohort.

Dr. Tina Chambers

Yeah and you could apply that to pretty much anything, right. We don't know what will happen in 20 years.

Dr. Michael Ceulemans

Yes, and that is the difficult one if we get this question when we're counselling. What do you answer to patients because I don't know what's going to happen with 20 years. We don't expect anything specific but I don't have the hard evidence to over it, so.

Victoria Anders

Great thank you. We had another question for Michael from Sarah Comstock "Do you know if the mothers are hesitant due to concerns about their infant or due to concerns about themselves?"

Dr. Michael Ceulemans

Well, the most important one that they reported was the long-term. Questions on the lack of information on long-term effects and then we should look into more in detail but I don't think there's a specific preference at this stage to say that they were mainly ... I didn't see any kind of trends to make a decision between those two at this stage in the day. But it's too early so, you asked me to come back in September, I'm not sure it's going to make that but that's why I tried to at least show some preliminary results today. So yeah, I will check that out as well.

Victoria Anders

Great, we will look forward to that. Feel free everyone, all participants, to continue adding questions to the chat. You can also ask to speak up and ask your question, spoken.

Dr. Michael Ceulemans

Can I also ask a question, maybe Tina knows the answer. The problem we are suffering from is that we got some people call us or just tell us that after the vaccine of the breastfeeding mom, the infant indeed has some fever, some irritability, and we were thinking about a biological mechanism because the vaccine is not in the milk, so we are thinking about what causes this kind of immune-active things in cytokines or something.

Dr. Tina Chambers

Yeah, we've talked about that too. I don't see any, maybe others have comments on how they think that could happen, but the reaction is that it's incidental and or coincidental. And one of the ways I think we can look at that is that we ask these same questions of everybody in the breastmilk biorepository who hasn't been vaccinated as well, and I suspect that the prevalence of reported fever in two to three percent of kids just happens naturally. So we can look at this as similar to the baseline incidence of that occurring coincidentally in mothers who are responding to these questions.

Victoria Anders

Then we had one general question for both of you to comment on. Given the rate of hesitancy worldwide for the lactating population, what do you two believe or, based on your own research or other research that you have read and interacted with, what will influence vaccine acceptance? More information, specific influencers, any other factors?

Dr. Tina Chambers

I'll say, I think a huge driver would be although the common message is we think that providing protection to the mom protects the baby and that the antibodies that are clearly present in breast milk are probably providing some protection for the baby, but if we could demonstrate evidence that they are and how, I think that would go a long way towards reducing vaccine hesitancy if the mother thought that this actually was leading to concrete protection for the baby beyond the global protection that the baby is getting from being breastfed, period.

Dr. Michael Ceulemans

Well, we try to highlight those ways, the risk benefits saying that there are no obvious risks associated for the mom and the infant. But on the other hand, we do know to some extent what the risks are of getting COVID-19. That was something I would want to bring in the discussion. And with regard to the antibodies, well we asked also in our previous study that had been published. We asked about the impact of COVID-19 pandemic on breastfeeding practices. At least in the cohort that participated in our study, we could not find a huge negative impact of the pandemic on the breastfeeding practices. So, they reported that because of the pandemic, they even felt stronger to give the breastfeeding because it might protect the nursing infant to some extent by giving it already some antibodies. So, I think we had a quite large sample but of course it could be some bias because of the sampled women online, and they were highly educated. But, in our cohort, at least in general, we did not find the very negative impact of the pandemic on the breastfeeding practices on the contrary actually. But I don't know, Tina, that's also your impression?

But of course, if it was reduced support, we have some cases of course if there was reduced support, there were no lactation consultants and so on. Then of course and there were mysteries that could have affected the breastfeeding in a negative way. But generally spoken, we are still waiting for the breastfeeding numbers in Belgium during the pandemic and then we can compare it to prior to the pandemic. But at this stage we don't think that it has a real huge negative impact in general.

Yarden Golan

Hi, I am sorry I joined late, but I wanted to add the two things. First of all, my name is Yarden, I'm doing the COVID power study at UCSF and we have 50 lactating participants in the study that got the vaccine.

And I wanted to first of all say that we also see the same thing about the pandemic and most of the mothers report that it helped them to breastfeeding longer because they were at home; they could breastfeed for longer than they expected, that's one thing. And regarding your comment about the fever, I wanted to say that we also had one report about an infant that got fever after the second shot and it ended up being a natural infection. So the mother reported about fever but actually the infant and the mother were infected by COVID and it took us a while because the mother didn't report about infection so it took us a while to understand it but at the end we detected antibodies again, the N-protein. So it ended up as a natural infection and not related to the vaccine. So it's also something to consider because they are not hundred percent protected from other illnesses same as other viruses and also from COVID. So, that's something to remember.

Victoria Anders

Thank you very much for that additional comment and Bindi had also left one comment in the chat regarding taking a positive spin to help with framing of public health messaging as well.

Dr. Tina Chambers

I think that's so important to find what are the reasons why people did do it and disseminate those.

Bindi Borg

If I could just add there, I think Michael kind of responded to that intentionally or not, you know I'm always looking for opportunities to promote breastfeeding right and I would love, Tina, I'm banking on you to find that evidence of protection. It would be such a forgive the pun shot in the arm for breastfeeding, if we could say very clearly your baby is protected. Even though people should know that breastfeeding will protect your baby from a whole bunch of other things as well. It would just be a fantastic boost, so please find that.

Yarden Golan

I just thought about it yesterday. It's really hard because in general, infants are much less sick than adults, so we have a very small number of infants at the U.S. And also globally that are sick and I think it should be like a joint work to get the data maybe about the infants that got infected and see if they were breastfed or not, and to get conclusions about the effect of the vaccine or antibodies in the milk on the infants. It's really hard from a single study of 100 or 50 patients or even a thousand to get babies that really get sick or something like that. The percentages are so low that it's very hard to conclude anything.

Dr. Tina Chambers

I agree, I do think it would take thousands and it's really a discussion we had with CDC about vaccine efficacy and pregnancy and lactation, that you need to have a platform where you are able to follow lots and lots of people. It could be done through health systems, if breastfeeding practices were routinely and accurately recorded, there would be a possibility. And if babies got tested, then you could do it but I agree with you totally, you need large numbers. If you could demonstrate at something proximal though, you guys are more expert than I am on this but the question about if the antibodies themselves are too large a molecule to get through digestive tract, is there some level of systemic antibody response in the baby that can be measured with this vaccine, or is there some way of demonstrating that antibodies protect, if they're only present in the GI (gastro-intestinal) tract or the mouth, I don't know.

Victoria Anders

Veronica, yes, please feel free to ask your question.

Veronica Valdes

We're doing this study in Chile of IGG, unfortunately because we didn't have the means to do the IGA. With the Sinovac vaccine, we have more than 100 women and it's now in the ethic department to allow

it. So probably in September, we will have the results so we can share with you. And Tina, we had a couple of women that did have reported a rash after the first nursing and one was big enough to be hospitalized. The baby yeah, but we didn't know if she had eaten something.

Dr. Tina Chambers

Yeah, I'm just thinking off the top of my head. I don't think we had anybody enrolled that reported that but we had anecdotal report of somebody who just e-mailed and asked that question, so yeah, I don't know.

Veronica Valdes

It can't be antibodies but as Michael said, maybe something that goes with that.

Dr. Tina Chambers

Yeah, who knows?

Dr. Michael Ceulemans

In our case, we figured out that actually the child was also going to kindergarten, how was I to be sure that the rash was not coming from a kind of other viral infection that the child was having.

Victoria Anders

Any remaining questions for our two speakers or other comments?

Great, thank you Tina and Michael once again and to everyone else, for your questions, comments as well and a reminder that all of the presentations, both presentations from today, as well as the recordings, will be posted online. The link has been shared in the chat several times. At this point, we will pass on to our next agenda item which is a discussion on remaining research topics related to COVID-19 and breastfeeding. So, I will pass it over to Mija Ververs who is at Johns Hopkins University and the CDC to lead us through that discussion.

Mija Ververs

Hi there, thanks and just a quick reminder now for everybody. The next week normally would have been in August but we're combining it with other platforms and it will be on lessons learned about HIV, Ebola and COVID in regard to infant feeding and breastfeeding. And I'm sorry I want to switch on my video but I only get a very exotic place here so I can't show my face unfortunately. So, that will be about what were the biggest challenges in these outbreaks with regard to infant feeding and breastfeeding, what were the lessons learned but also what would have helped us to do better? So that's on the 18th of August and that is eastern standard time from 8:00 to 9:30. So hopefully you can block it already in your agenda and we will provide you with more information in two or three weeks later.

That said, we have a few minutes left to discuss a few issues which I think might be of interest to all of us and perhaps Victoria, would you be able to share one slide. What I would like to ask the audience, all the 17 participants we have still on is, what are the outstanding issues related to infant feeding and COVID, and what do we still need to do more research on and whether that's related to today's sessions, more on vaccine but also others issues can be raised, anything. And the other question is, what to do, what do field and also programmatic staff and all researchers still perceive as the main difficulties and challenges concerning breastfeeding and COVID-19. So, it doesn't matter, you can respond to any question, one or two, but I would like to give you the floor to come up with some issues which you would say, hey, this we should address more or this is more a challenge we might need to do more research on that or tackle that, so the floor is open.

Diane Spatz

Hi everyone, this is Diane Spatz, I'm a Ph.D. nurse. I'm a professor at the University of Pennsylvania School of Nursing and I'm a nurse scientist at Children's Hospital Philadelphia. Related to these two questions, one of my biggest concerns is the disparities that have been reported in some of the past presentations that we've heard and what I'm observing in my clinical practice and my research is that, and we heard this in the presentations today, I mean, well-educated white women are getting vaccinated, they are breastfeeding, they're having better breastfeeding outcomes, but we heard an earlier presentation this summer where the total reduction and variation in breastfeeding rates was in low-income, latino women from New York city where the rates dropped significantly. Children's Hospital Philadelphia has 30 primary care sites that provide pediatric primary care and we are seeing that people of color and low-income families are coming in and their breastfeeding outcomes are, they're not getting the help they need in the birth hospitals, and so my biggest concern and area where I feel like we have to address the research is what are we going to do about this widening disparity and how can we get that to change.

Mija Ververs

Thank you, Diane, meaning also perhaps the long-term effect on the health of these population groups being less breastfed, having less breastfed children. So thank you for that. Bindi, would you like to speak out what you wrote?

Bindi Borg

I mean, it's just because I've now gotten vaccinations in a couple of different countries and of course I'm paying attention to the advice and the decisions around vaccinating pregnant and lactating women in different countries. And I am quite amazed that different countries apply very different advice and it would be so interesting to know why or how they make their decisions. So, that would be a very much policy type of piece of research and why the advice, which I think was fairly clear, about vaccinating pregnant and lactating women that came, that has come from who has or hasn't been applied

Mija Ververs

And you mean a difference in advice recommendations from the ministries of health, mostly?

Bindi Borg

Yes, that's right. I mean, it's a whole other layer isn't it, to health providers, doctors or hospitals but I'm thinking ministries of health.

Mija Ververs

Yeah, which we obviously saw as well with breastfeeding continuation or not during COVID times, with suspected or not suspected or confirmed cases, there were similar issues. More ideas.

Sarah Comstock

This is Sarah Comstock, I just put a message in the chat but I want to echo what was brought up earlier about the disparities. I think, in fact, during COVID we may have seen increases in these disparities because a lot of the lower income individuals were working those jobs at the grocery stores, the gas stations, the custodians at the hospitals, and had to be outside of the home and they also additionally didn't have necessarily in-home help, maybe their parents would have come to visit or sisters would have come to visit and help them with their infants, couldn't get any lactation help so. I think that the disparities that were already present might have been even greater during the pandemic. And I'm not sure that any data exists yet on that but I think that would be helpful in highlighting sort of the issues with working women and breastfeeding in general, also even in a non-pandemic time.

Mija Ververs

Thank you, Sarah. What would be then needed to correct this for both Diane and Sarah, for all of you because of disparities.

Sarah Comstock

I think the real issue is that women aren't really given the time to put into lactation and breastfeeding. And of course, with the affordable care act, that improved especially for white-collar workers but I don't know how well it truly improved for individuals working fast food or convenience stores or things like that; I mean, public policies that give women the time to do this important practice without negatively impacting their career trajectories or their jobs because a lot of lower income individuals, the types of jobs they have, they just basically get let go or not given any hours by their employers.

Mija Ververs

So, we comeback to labor laws as usual?

Diane Spatz

This is Diane Scott again. I agree that the employment piece of it is important. However, the disparities are starting way before employment. Okay, so we already know strategies that work to increase breastfeeding and low-income women, for example, peer-to-peer support, doula, home visits, I mean. I have published about this, other people have published about it. We know that there are intervention strategies that do work, however, those intervention strategies haven't been made standard of care. So, for example, in WIC while WIC may provide peer counseling services, it's not universal, it's not standard what happens from state to state and even county to county is not consistent. And so what I am seeing and we have some data on this that we are working on a manuscript right now, is that it's at the first pediatric visit, the low-income person's breastfeeding journey has already been sometimes irreparably damaged, because at the birth hospital, and in Philadelphia, all of our hospitals are baby friendly. But despite them being baby-friendly at the birth hospitals, all these low-income women haven't gotten seen by an IBCLC provider, have had their babies gotten copious amounts of formula even before discharge and didn't get any type of support. So, when they're coming now to primary care, the primary care center is really having to try to work very hard to restore or keep that person to even have a milk supply. And so we have data where we have seen these tremendous depths with COVID and just how the women present at that very first pediatric practice. We have published our call to action about this but if we can't effectively have people establish a milk supply in the first 7 to 14 days, like that return to work doesn't matter because they already are ineffectively established and so the information that our low-income women and our people of color are getting before they even give birth, they're not getting the information they need and then they're having these negative consequences in the birth hospital. And in pediatric primary care, I don't know if anyone works in that area, but it's a fee for service. It's all about billable hours. So providing breastfeeding assistance when you're talking about billable hours is really kind of hard to do. I mean we do it as a nurse driven model but there's ... I am so concerned for our families.

Mija Ververs

Thank you. I think many of us share this this concern. I would like to ask also people outside the U.S. who are on the call to respond maybe to Diana's concerns and challenges. Anyone? Michael from Belgium perhaps.

Dr. Michael Ceulemans

Well, I'm not sure if am very well placed to add something to this.

Mija Ververs

OK, anyone else who would like to comment on one of the questions.

Dr. Tina Chambers

I think Veronica has her hand up.

Mija Ververs

Yes oh sorry yeah.

Veronica Valdes

One of the things that we did in Chile was to ... we do have postnatal leave but during COVID we extended that postnatal leave because there were no schools, the mothers had all these challenges. So if women were nursing they could extend the postnatal leave up to one year. But we are really concerned that the practices in the NICUs, on the premature infants, the sick infants that are in the hospital, are back to the not safe 50s, 40s. Because the mothers are not considered part of the treatment, they put all kinds of restrictions that they can go one hour every other day or like horrible things. So I think that for us is a key issue of research and we are like accessing a questionnaire to all the NICUs in the country to see what the practices are now and the impact of COVID on that. But I would like to hear from other countries related to that too.

Mija Ververs

Anyone else on that? Thank you Veronica.

Dr. Tina Chambers

I was going to add to Diane's comment and I know it's not the perfect solution but it does seem, and this is true of pregnancy as well - that the pandemic as always some emergency raises or puts us in a position of giving attention to something that has not been paid attention to before. And so the opportunity I think is here to say (a) to demonstrate what we think is true which is that there are health disparities in what happened with continuation or uptake of breastfeeding and the support reasons why, in the pandemic. And in terms of preparing for the next one, and there's lots of places in the world where this is happening where people are preparing for the next pandemic, inclusion of pregnant and breastfeeding women in that formulation. So they were left out entirely in the early response to this now and we can be better prepared for this in the future. And then having that data on what the losses were, during the pandemic, in these disparities on breastfeeding and what the responses would be. Maybe that's a step in the direction of making that the standard of care in normal life.

Mija Ververs

Excellent. Thank you for that. Anyone else still from an experience outside of the U.S or maybe inside. Any more. Erica, are you online? I see you are working with CDC, is there anything you would like to share on this? Erica? No. Okay.

Erica

I see Dr. Spatz has her hand up. Go ahead.

Dr. Diane Spatz

I think that it's really interesting that Tina brought up about including the pregnant and lactating women. Because we just went through Preglac, the task force on research specific to pregnant and lactating women, and that was published well before the pandemic with 20 key recommendations about the importance of including pregnant women and lactating women in research about the need to increase the number of scientists in the field, about registries, about all this stuff. That happened well before the pandemic that was published. Yet we collectively, whatever, people chose to like ignore it and not even think about any of those recommendations. The thing is about breastfeeding and interventions that work. We already know many interventions that are effective improving breastfeeding, especially for low-income and people of color, but we are not investing the money to have those things be standard of care.

Mija Ververs

Bindi, you want to comment on that? I see your hand is up.

Bindi Borg

I think we are all sort of talking around similar subjects. For me I would call it lack of trust in women's bodies and medicalization of birth and infant feeding. And I'm kind of following up on what Tina said. I think one way and I should say that we even are guilty of that ourselves sometimes because as researchers and as academics and as public health professionals, we tend to try and be cautious and balanced and that's great when we are talking to each other. But it's not so great when we are talking to the public and dealing with real people. So, following up a little bit especially on what Tina said, there was ... a study using the list tool wasn't there or am I just fantasizing about it; about the lives lost due to separation during COVID. And I think that those kinds of tools that we need to use more of them to really say breastfeeding is the norm. The mother-child-infant diet is the norm. The precautionary principle should be applied to doing anything that interrupts breastfeeding and the mother-child diet rather than the opposite. And the kinds of studies like using the list tool or the cost of not breastfeeding or to really put norm to make breastfeeding and mother-child diet the norm as opposed to something that we study as a comparator.

Mija Ververs

Yeah. Correctors still, we actually had a large research group where we did a modelling on this how many children we would lose by not having been breastfed as opposed to being infected by COVID and die. And these modelling tools are very important. On that note, that's exactly also what the next webinar on the 18th of August. We would like to see a framework being drafted, "when will you divert from the standard practice - standard good practices? When do you separate a child from a mother and say you don't get the breast milk, what framework you would need for an infectious disease outbreak to make that decision before you do too much damage? So that was the aim of the webinar on the 18th of August as well.

We are heading towards the last few minutes of this webinar. I'm not sure whether anyone still would like to add something. And feel free to do so. We are interested in your voice, your opinion, whether it's still in question one or two. If not we all like to have a five minutes break somehow before all the other next meetings start or some of you have the end of the working day, working week. Victoria, you would like to do a closure? Some closing comments?

Victoria Anders

Yes, thank you Mija and thank you again everyone, and especially to Michael, Tina and Mija for taking the time to share your presentations and comments as well as lead a discussion today. So just a couple of reminders, I'm trying to pull up my notes excuse me. As we have mentioned, in place of the CIF-RIG poll in August, we ask that you please join the USG Global Nutrition Coordinating Plan meeting to be held on August 18th from 8:00 to 9:30 a.m. Eastern Time in the USA. And we welcome you to join in for the discussion on lessons learned regarding breastfeeding and HIV, Ebola and COVID-19. The call details will be sent to everyone who is currently on the CIF-RIG meeting invitation.

Our next CIF-RIG meeting will be on September 10th which is also a Friday and at the same time 10:00 a.m. Eastern. Please reach out to me, my email has been shared in the chat, should you be interested in presenting or know of a colleague who might be. Also a reminder to sign up for the CIF-RIG list serve, the link for which has also been sent in the chat. That is where we send updates on CIF-RIG meetings and where any colleagues in the list serve can share relevant resources, new publications, etc. Finally the PowerPoint slides and recording from this session will be posted on the CIF-RIG web page, the link for which is also in the chat. We will send a reminder or a note once those power points and recording have been posted. Other than that, thank you so much for attending today. Thank you again to our speakers and we hope you have a lovely weekend.

All

Thank you, thank you everyone, thank you.



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