



USAID
FROM THE AMERICAN PEOPLE

COVID and Infant Feeding Research Interest Group

Webinar Transcript

Dan Raiten

So, but, welcome, everybody. This is for those of you just to make sure you're on the right call, this is the COVID Infant Feeding Research Interest Group. We meet more to (]. We want to welcome everybody and thank you for your connection to this program. We'll start off by going with a quick report from the CIF, the Committee for Feeding Working Group, which, as you recall, is linked to the WHO, Maternal Newborn Child and Adolescent Health COVID Research Network. We'll start with the president. Well, let me start with introductions from Nigel.

Nigel Rollins

Well, good afternoon, everyone. I work for WHO Maternal, newborn child and adolescent health. I'm delighted to be working with Dan and others on this. It's snowing outside, by the way. So nice snow of the season. So.

Dan Raiten

Beautiful. So there isn't any global warming, though, that's we're told by President ... Shelly, you want to start off with the report from the technical group.

Shelley McGuire

Sure, I would love to just have a couple of slides to share and we'll see what I can do this. You're seeing the slide?

Victoria Anders

Yes, we are. OK, great.

Shelley McGuire

So this is I'm Shelley McGuire. For those of you who don't know me, I'm a maternal infant nutritionist with the expertise in milk human milk composition. And I've been working with a group that's part of part of this group. And then others brought in and we had work on a paper regarding how to best practices related to the collection and handling. And I'm very happy to report today and get this going

that this paper has been accepted in its interest. So those of you who aren't familiar with this, I just want to really quickly go through why we wrote this paper and what to look for in this paper so that when it comes out, we'll shoot it out to everybody and and you'll know what's there. But this group and others recognized really, really early in the pandemic that that this the issue of maternal to infant transmission for breast feeding was going to be a topic, a really important topic. And we needed to figure out whether this bacteria could be transmitted in that ...in that fashion. And we also recognized early that human milk collection and analysis is tricky. And so we wanted to make sure that the research done in this area was going to be accurate and usable. So that's the first paper started coming out back in March, March and April. It was immediately noticeable that many of them did not report how the milk was collected, handled or analyzed. And so we really realized that this was going to be an issue. So for this paper, our goal was to delineate best practice framework related to human collection, handling and storage for COVID-19, for SARSs-COV-2, but with also with the idea that this that these best practices could be used for future pandemics when they will happen. Our target audience for this paper was actually researchers who typically don't study human milk microbiome and immunology. And we just wanted to give them some assistance in thinking through what they needed to think through in order to do their study correctly. So the paper will be published in *Breast Feeding Medicine*, and we just got the proofs this week. So I suspect it's going to be published pretty soon. And I just wanted to point out the author team here, many of whom are on this call and many of whom had never worked together before. So this is quite a feat to pull this off. So myself and Anti Seppo, Amenia Goga, Danilo Buonsenso, Maeia Carmen Colladon Sharon Donovan, Janice Mueller, Gastón Ofman, Michele Monroy- Valle, Deborah Conner, Ryan M. Pace and Philippe Van de Perre, who is going to be one of our speakers today. So that's wonderful. And I'm just going to show you three tables there. Too much to go into. But I just wanted to give you a sense of what's in this paper, because this paper was really written for non-human lactation researchers.

We actually started by in table one, we define some of the really important terms and concepts that people need to think about when delving into human milk research. For example, what is for milk versus hind's milk, what is a complete breast expression, et cetera? Because these concepts are really important when determining how milk should be collected for a particular outcome variable. We also provided the table outlining the sources of variation in human milk composition, because these two are important when trying to look at DNA, RNA, microbial viability, antibodies in milk, cytokines and immune cells, which are the milk constituents, which are of particular interest in this regard.

And then finally there is table three, which outlines metadata that should be considered when we're collecting milk or at least should be reported. And that's a big issue here. We can't control for everything in a study, but certainly we should report some of these things. For example, how is the milk collected? The mode of collection, was it collected from one breast or both breasts, what kind of storage containers was preservative added, etc. So that is my little presentation for today. And I really, really appreciate this team that worked on this paper. We're hoping to write a second paper, but I think we're just all too tired right now to do it. So hopefully we'll get started on that in the spring and that is going to be best practices related to milk analysis. So with that over back over to Dan.

Dan Raiten

Thank you Shelly, that was great. At some point we should have a conversation about long term plans from this technical group and get some feedback from this ... from the interest group about what the needs are. But let's turn now to be smiling, cheerful Mija Ververs, reporting on the repository.

Mija Ververs

Yeah. Very briefly, maybe another time will be a bit more in detail because we working on one big repository for the MYCH, including breast. And in an Excel format, we hope to have it finalized within one, two weeks. So researchers, clinicians, and policy makers can use it a little bit easier and actually use it also for a systematic review and analysis, et cetera, et cetera. So it will be excel over three 1/2 thousand records. So that would be...what is different from this data. That repository will be different from math or other search engine. Is that the condensed? It is dense with everything related to MCH, so you don't have to go through PubMed anymore and do the search and de-duplicate. So that's a quick fix then. So that will be useful, will give more information when that's relevant. And then within one or two hours we will have to update of the breastfeeding infant feeding COVID repository again. We will add 17 new papers published over the last two weeks and the excerpts will be ready online in one two hours. I think that's it for now. Thank you.

Dan Raiten

Wonderful, thank you. Tremendously valuable resource for all of us, and we're grateful to my team's efforts. Let's turn now to Jennifer Jenice from our communications group.

Fatmata Sesay

Hi, Fatmata here, I would like to give some quick highlights on behalf of the communication group. One is just to note that Beth is on behalf of the communications group, is working on a brief on misconceptions surrounding COVID and breast feeding. This is currently being reviewed by the [PACK] team and will be coming out in the next few weeks or days for the team to review as well. And the findings of this will help develop informational brief to basically address core misconceptions on breastfeeding and COVID. Then secondly, the group is also working on a blog to look around the lack of research and awareness and the impacts of COVID, and infant feeding and generally viral infections and nutrition. And this is also under review, and once ready will be widely disseminated then. Then, we are also very pleased to note that USAID Advancing Nutrition is taking over the coordination of the meetings in a very special way, basically sending out invitations. And this is a very welcome idea. And lastly, the group has also worked on an explanatory document on what the CIF Week entails, that we are doing. Well, the meetings and the key topics that have been discussed, basically, that's all from us. Thank you.

Dan Raiten

Thank you for that, Fatmata. I was derelict in not acknowledging Advancing Nutrition in their new role here. We're very grateful to have them and their leadership involved here. I'm going to now turn to the presentations to ... and I need to talk to Nigel, if that's ok Nigel.

Nigel Rollins

Delighted to. So I have known Philippe for quite a long time, probably done a similar amount of time as we have known each other, which we won't we won't try to say how long either of those go back. But I was working in South Africa at the time and Philippe came to work with our group. We were doing a large study on infant feeding and HIV transmission, and Philippe came in as this sort of tall, sort of commanding, and he had a presence about him to really help us think through some of the virology. I didn't really know much about Philippe at that time, but I have come to both enjoy him as a as a really

excellent scientist, as very thoughtful and quiet and assured and ... and also a very good cook, amongst other things. So, Philippe, we have been sort of doing bits and pieces of work along the way. And he... we talked a little bit about the Koch's postulates and then just it was a through almost like a throwaway comment.

And then a little while later, Philippe came up and said, I've done this work. So I thought it would be fantastic because I think it is a real challenge to us in public health that we sometimes make certain jumps of faith or maybe not faith, but we make jumps in our thinking and our recommendations and without really applying good science. I think that's what Philippe is going to really share some thoughts with us today, but very much in the context of COVID. So, Philippe, we're absolutely delighted. Thank you for joining us. And we look forward to the presentation or...

Philippe Vande Perre

Thank you, it's a pleasure.

Nigel Rollins

So I think over to you for have you got a yield to share from your screen?

Philippe Vande Perre

Are we...? Yes, I will try to share the screen. Can you....

Nigel Rollins

We've got it, we've got the second slide, Philippe. We're on the second slide, not the first. So I should just say, well, Philippe doing that, is that Philip is ... he had both the first, laboratory... the health facility service in Montpellier for the hospital, as well as running a research lab there. So Philippe, if you can tell us a little bit more about where you come from...

Philippe Vande Perre

Can you see the first slide now?

Nigel Rollins

Yep!

Philippe Vande Perre

OK, great. So thank you very much, Nigel, for the introduction. So my name is Philippe Van de Perre. I'm a molecular biologist based in Montpellier, and I've been involved since almost ... almost three and a half decades in risk making with many studies in transmission of human viruses, mostly HIV, with not only HIV and since... sometimes we have been thinking with different colleagues and friends about and the question of the plausibility of oral transmission by human milk, and then the debate was that there

was no ... there is no very clear and non-subjective criteria to determine if a given human virus can or cannot be transmitted by ... by human milk. And we have tried to think about this and tried to delineate some ... some criteria that that would help evaluating the plausibility of a transmission of a given virus by human beings. So, of course, I will not go into details about the importance of the feeding, but also the fact that one of the very few difficulties with the breastfeeding, and especially breastfeeding promotion, is the idea that sometimes breastfeeding and breast milk can be routes of transmission for a human viruses or human infections. And that we need you to think about the criteria to urge to identify it. The idea here was to clearly distinguish breast milk transmission that means transmission of a different virus due to the ingestion effect of breast milk by the breast of a baby ... from breastfeeding transmission that includes all different modes of transmission, including close contacts, genic transmission, droplets, similar environments with the vectors, etc., which are much more ...much more complex. And as a first principle, the idea was to...to base our thinking on the principle of the Koch's postulate. Just to refresh the memory, Robert Koch, his picture is the right hand corner of the slide, this is not me. This is Robert Koch and the director, Robert Koch was really in the second half of the 19th century pioneering the principle of evidence based medicine by trying to establish causality, relationships between a microbe, for instance, a bacteria that can be cultured in pure culture and any given disease. And in the first version of the Koch's postulates, he had established four criteria that had to be fulfilled to... to establish this causality and I'll just rapidly read it for you.

The macrocosm must be found in abundance in all organisms, uh, with, uh, suffering from the disease, but should not be found in healthy organism. Uh, the organism. The microorganism must be isolated from the disease organism in pure culture. The culture micro-organism should be it should cause disease when introducing healthier and micro-organism must be really isolated from the inoculated disease experiments and hosts and identified as being identical to the original specific causative agent. So we took this kind of principle of having criteria that each of them, taken separately, is not sufficient to infer causality, but that taken together could give an idea of ... of the possible causal relationship between ... between an agent and transmission.

For instance, here transmission by breast milk. So we have delineated four criteria. The first is that there is evidence for a viral infection in infants receiving breast meat from infected mothers, with the human virus that we have chosen to study, that the virus... viral antigen or viral genome are present in the breast milk of infected mothers. The third criteria is that this virus in breast milk is, in fact, is in fact infectious, is able to replicate.

Fourth criteria is that there is reasonable, reasonable attempts have been made to rule out other relevant transmission routes, potentially associated with breast feeding transmission, and finding that transmission by breast milk can be reproduced by oral inoculation in an animal model. So those were the five criteria that we used and that we have tried to challenge on a series of candidate viruses. So we have chosen 16 human viruses that have somehow ... some have been suspected of being possibly transmitted by breastmilk. And we made an extensive review of the literature. And I think the paper we have approximately 130 articles that have been selected, and we decided to... enter ... interpret for each of the viruses those five criteria.... Sorry. Five criteria are satisfied and fulfilled, and we can comfortably infer that transmission is proven for those viruses. If only four criteria are fulfilled, the breast milk transmission is probable. If three criteria are fulfilled, breast milk transmission is possible, and if they are fewer than three criteria fulfilled, breast milk transmission is very unlikely.

And if at least two criteria, we don't report it, viral transmission by breastmilk was considered as insufficiently documented. As I know that you are all interested in in SARS-COV-2 transmission and in COVID, in fact I took this analytical framework, and especially for the SARS-COV-2 criteria and the transmission by breast milk. The first criteria four for SARS-COV-2 evidence of infection in infants receiving breast feeding from infected mothers, we have at least two reports. So this criteria is fulfilled. The second criteria, that the virus antigen overall genome is present in breast milk samples. We have

also a couple of reports showing that SARS-COV-2 were on... may... in some situations may be presenting in breast milk of infected mothers. The third criteria, that the virus in breast milk is infectious. We have one study by Chambers to try to culture SARS-COV-2 from breast milk of infected mothers without success. It means that so far, not satisfied, not fulfilled. There was no, as far as I know, very convincing attempt to rule out other transmission modalities than direct breast milk transmission. And there is one paper interesting for this by [] and co-authors. And the fifth criteria on the transmission can be reproduced by a correlation in an animal model. So far, there have been animal models for other coronavirus, other highly pathogenic corona viruses like Mers-COV by [Simon ... and Marmozet]. And those models can be infected by early inoculation, but as far as I know, there is no similar report for SARS-COV-2 that means this criteria is not fulfilled for the moment. That means that for SARS-COV-2, we have two of the five criteria that are satisfied. But, other... other criteria that have not been documented so far. And we have classified SARS-COV-2 as unlikely with insufficiently documented evidence. So if we take a look at the list of the 16 human viruses, I will not get into details of course, for all 16 viruses. For 11 out of the 16 viruses fulfil some but not all criteria, and were classified, categorized as follow. Five viruses, were considered as satisfying the five criteria and was suggested to be of proven evidence of transmission by breast milk. Those are HTLV1, HIV, and cytomegalovirus, which are the three, which is not surprising, those are the three prototypes breast milk transmits the viruses, but also dengue virus and a Zika virus satisfying all five criteria. With four criteria satisfied and the probable transmission, we have Ebola virus, West Nile virus and more recently suspected to be transmitted by a virus and this virus, I don't know if you are familiar with this virus. It's the hantavirus, that is extremely transmissible by person to person contact. And there have been a couple of papers suggesting transmission by breastfeeding. And, for instance, a very nice paper in the New England Journal of Medicine of this week on this virus outbreak in Argentina, a very excellent paper. So those three viruses are classified as probably... transmissible by breast milk. Three criteria out of the five classified as possible. We have the yellow fever vaccine strain, Epstein Barr virus and hepatitis E virus and likely transmitted as the criteria fulfilled with the chikungunya virus, an unlikely but insufficiently documented SARS-COV-2, herpes simplex virus, and hepatitis B and hepatitis C virus. Of course, the exercise could have been done on a much larger group of viruses and that that is something that we should probably contemplate.

So in conclusion, of course, this is not a formal evaluation of transmissibility of the respiratory viruses, because we lack a gold standard to compare with. But I think it's... it's an analytical framework that I think is interesting in order to demonstrate or not the breast milk transmission of a given virus, that could be important in terms of first information to the public and to the mothers in particular, in alleviating some anxiety when ... when it is possible. Also avoiding the unjustified and inadequate practice of infant feeding when it is absolutely not necessary and maybe also guiding further public health recommendations regarding infant feeding and the prevention of some of those viruses.

I think it's maybe also useful for identifying knowledge gaps on breastfeeding and breast milk transmission of viruses, and maybe stimulate research and lab experiments on them and on those viruses in order to... to fill those knowledge gaps and. And finally, I think this typical framework would be useful to evaluate transmissibility by other rules for human viruses. There are some controversies for some for some viruses about, for example, sexual transmission. And I think it could be probably it... may be useful to try to use the similar analytical framework to just where the 1950s is and if goes in the causal relationship between a virus and the mode of transmission is.

So that was it for them to fill some knowledge gaps.

Nigel Rollins

Thank you, Philippe. And again, I think Philippe would be... he would immediately agree that transmission is only one part of the public health framing in that you've got to understand the consequences of infection and the consequence of other preventive strategies. But I think as a critical step in terms of determining transmissibility, this is a very nice framework. But I think we can open up to questions. I'm not sure who's seeing the questions. I'm not sure. If people want to raise their kind of hands by there, there is the facility all the same just to raise your hand to ask questions. Any questions at all?

Shelley McGuire

Philippe I have a probably a just a really simple question, do you have any reason to believe that this framework wouldn't also be useful for bacterial pathogens?

Philippe Vande Perre

Good question. Yes, I think maybe interesting show for bacterial pathogens as well. I think you're perfectly right. Especially since those ... those bacteria are probably easier to study with the culture, another means that are much more easily accessible.

Shelley McGuire

We've been trying to study the potential for leprosy, for Mycobacterium Lecrae transmitted. And it just strikes me that this is a wonderful framework for that as well.

Dan Raiten

So I have a question. Most of the data that we have is around the early stages of lactation, I'm assuming we can apply these principles to later stages of lactation. □ any thoughts about the particular later stages of lactation, the period of introduction of complementary feeding, etc. presents a certain level of risk as we work through HIV, I'm just wondering. Should we be thinking about that?

Philippe Vande Perre

In fact, the idea here was really to ascertain if the transmission is plausible, not really to evaluate the risk of transmission or to quantify the risk of transmission. If I understood your question correctly.

Dan Raiten

I guess the question is...is your focus has been on early stages of lactation in the newborn period. Should we should be continuing of doing this kind of analysis around later stages of lactation because things change? I don't think we have much knowledge with regard to the ...you know, what happens when mom gets infected about four or five points. It is like training and what the implications might be. I don't know if we have data on that, but should we?

Philippe Vande Perre

I think you're perfectly right, of course. I think the example of HIV, for example, where we have evidence of ... of very large transmission. Even from some women with prevalent infections, with infection present since the very beginning of the lactation and transmission occurring 24 months later, we have also the very infection in that stage of breast feeding during... this stage of breast feeding and a high risk of transmission in that circumstances. So I think you're perfectly right. We should continue evaluating this even well after the neonatal period.

Kimberly Mansen

Great thank you. This is very fascinating and so helpful to have something organized to think through this, and I think my question relates a little bit to Dan's, and so you've answered it already. But in addition to that, just thinking that who we're thinking that this may transmit a virus to, that who is very different in infant, not just the stages of lactation, but the infant it's whether it's a newborn, neonate, preterm and low birth weight and the neonate versus a older term infant in the community. And so just wondering how to ... what would be your recommendation for considering that side of it as well, especially knowing the differences and that health in the microbiome? And are there other factors going on here. How is that related to this model or how would you recommend we think through that.

Philippe Vande Perre

Again, the principle of this framework is really to ascertain that the causal relationship in terms of transmission and to know that that virus is transmissible by breastmilk. It's a very first step. I mean, the next is, of course, to study the determinant of transmission and the risk factors, and eventually the cofactors of transmission for those viruses. For example, the example of the [] virus, which recently identifies as a potentially transmissible virus by breast milk, in my view, the first step would be to... to have to confirm that we know good confidence that this virus is transmissible by breast milk, and then to study the determinants and try to understand in which conditions the virus is transmitted. And that, of course, needs cohort studies or case control studies comparing, transmitting versus not transmitting mothers, et cetera, to identify risk factors and potentially biological determinants of transmission for those viruses. But the idea was here ... to have the very first level of understanding is to confirm that a virus is effectively transmissible by breast milk.

Kimberly Mansen

That's really helpful. Thank you.

Nigel Rollins

Thank you, Philippe, and I think everybody appreciates that, you know, it's a very elegant being, Koch's work was very elegant and this kind of just it's an extrapolation of that. But I think it is in days when there are many so many pieces of evidence flying around... is very helpful just to help organize where does this piece of evidence fit within that chain? And recognizing that the issue of whether something is transmissible can be transmitted or not is the first is the first consideration in the public health chain. The magnitude of that risk, the consequences of that infection need to follow on. But this is the first step and it's difficult within sort of a pandemic to accumulate this type of evidence very rapidly. But I

think with hindsight, this is very useful. There was a very similar set of discussions all around Zika whenever that emerged. And we're going to move on. And thank you very much for being there.

Sharon Donovan

Can I just ask the questions? So, Philippe, were you planning to publish this?

Philippe Vande Perre

Yes

Sharon Donovan

So but in the meantime, would you be willing to share the references that you viewed as part of this?

Philippe Vande Perre

Yes, of course, I could even share the manuscript if you want.

Sharon Donovan

Just to educate ... the broader context is, since you look at so many viruses, I think it would be useful as a resource.

Philippe Vande Perre

Yes, that would be very... if Nigel agrees, that would be very...

Nigel Rollins

I think... I think it's fine, I think just we would ask it just not that it doesn't get in until it kicks it in any way, jeopardizes the publication possibility. We'll share the manuscript with you and then hopefully it will get accepted and it's been there. But I think I think as Philippe is very happy to share it with you for the references, which is very valuable work, and then hopefully fingers crossed, the next time around, we'll hear some good news about it, but maybe we just don't share with any further, Okay? And so maybe Philippe ... I'm happy for you to put in the box or send it to Sharon or send it to me, and then we can we can pass it on anybody who particularly wants the manuscript itself. I think it might be better to do it by invitation. So Alicia or anybody, if you could just if anybody could just get into the chat box, if you're interested to receive the paper and an email address and then we can get that sent out to you. Okay.

Philippe Vande Perre

Right.

Nigel Rollins

So the second presentation is a little bit different. It really brings from a transmission question to real life practices and outcomes. And Melissa Bartick is with us today, together with a couple of others from her team. I think Veronica had been in touch with this. We weren't expecting we thought maybe you were going to be on a plane. But Melissa is going to be sharing with us some experiences from an international data collection exercise on maternal newborn practices and some around COVID, and what that translates to in terms of the infant feeding questions. So, Melissa, thank you for joining us. Thank you for sharing your work. And I think hopefully you'll be able to share your screen and your slides over to us.

Melissa Bartick

Thank you for having me. Appreciate it. And I'm not sure my screen... and can you all see this? All right, so Lori Feldman-Winter will be presenting with me today and she's going to do the first several slides. So I'm going to hand this over to her.

Lori Felman-Winter

Thanks, Melissa, and thank you all for inviting us. It's really a privilege to be able to present today our work that also has to be provisionally accepted, we're working through revisions currently, so we'll be really excited to share this with the broad [] I am one of the members of a very large team.

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About a study, as you mentioned, really taking sort of a more macroscopic view of this issue, COVID-19 and infant feeding. And the group that we brought together was assembled primarily through the Academy of Breastfeeding Medicine, as an international organization, we really were able to work around the world to bring together the thoughtful experience, and also the outreach to be able to conduct this study. So I'm so really grateful for participation of all the people that you see on the side, as well as folks from my own institution. I'm a pediatrician, so a clinician at Medical School and University health care in Camden, New Jersey. And so we've also had the privilege of working with our own biostatistician and one of our medical students.

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So we have disclosures that are present on this flight. The study was unfunded and we have no industry ties. As you see before you thought there are no major conflicts of interest. So as a background, we wanted to conduct a study because this guidance was emerging from around the world and there were policies and guidelines regarding eating practices, particularly baby friendly practices, as it related to mothers that worked with COVID. We recognize that there were vastly different sets of guidance that from the WHO and in other countries such as in the US.

And with these policy recommendations, we were really interested in understanding if certain baby-friendly practices, primarily through practices that we'll talk about, were helpful or harmful to the transmission of SARS-COV-2 and subsequent hospitalization. So really the worst outcome that we looked at was hospitalization to the SARS-COV-2 to among infants.

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And so our study design was really unique in that we were asking mother so very similar to the way in which we audit for the baby from the hospital initiative, we ask mothers about their practices. We really wanted to know about the specific practices of the skin for one hour grooming within arm's reach and

direct breastfeeding. And I will say that having worked with health departments in our state and also with the CDC, many of these variables are not able to be extracted from charts. They're not present in any of the registries that are being conducted at the level of detail that we could actually query the mothers. So. So we have the unique perspective of really understanding the extent to which these maternity care practices were, in fact, in place. And so this was an anonymous survey it was short and it was translated into up to 10 languages

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And so we wanted to look in a retrospective fashion from the month completing surveys, what happened when the moms were infected and at least up through the first month of life. So for those moms that were infected during the perinatal period, so the babies had to be at least one month of age and we were interested in transmission during infancy [] 12 months of age. And we looked only at biological gendered mothers. And our survey opened in March... in May, sorry, And in 2020. And it ran through September. We closed our study because we started realizing that there were significant outcomes that we wanted to report. So as I mentioned, it was a survey that was translated into 10 languages and so we had a very far reach. We estimated...

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We estimated with the power of about 80 percent that we would need a total of three hundred and twenty four subjects to detect a seven percent difference in any of the three primary exposures of interest on the outcome of the ward hospitalization. And that was from what was at that time published in the literature. And there have been estimates anywhere from two to seven percent in the literature regarding that outcome to the infant resulting in illness. And so you can see we have a very large sample that we began with, and that really indicates to us that opened the survey.

Many were ineligible in that the most common reason for eligibility was that neither the mother nor baby had COVID, they did a survey for the infant in the age that I mentioned. And others didn't answer the research questions. They never completed the survey. In addition, we excluded non-genuine responses that were deemed genuine because the rapid sequence from the same country. So some were just testing the survey and others were deemed it was in this matter of language which country of origin. And, and so this got us to a sample of three hundred and fifty seven. And I'm going to turn it back to Melissa to present our results.

Melissa Bartick

OK, so we have respondents from 31 countries, 51 percent were from the United States. Twenty five percent from Europe. We going to in the interest of time, just talk to them and let you read some of those slides. We I do want to say we have a survey in Chinese and Hindi, and we did not get any respondents from India or China, even though we try very hard, especially for China. But we were told the Chinese mothers were just too fearful of filling it out because it was Western. So anyway, that is basically the distribution. So I just want to talk a little bit about the general characteristics of our respondents. About a third of our respondents were mothers of neonates and the rest were mothers of older infants. So just to go over the neonates, we had 81 mothers of neonates who tested positive, the mothers of infants who had the infection on the first three days of life, which is sort of comparable to the other studies that we see in seven point four percent of those mothers in the perinatal period, their infants tested positive. We had 11 hospitalized infants of the entire sample. Only six of those infants tested positive. Four of those infants were neonates, and two of them were on ventilators. And only one of those ventilator patients had a positive test. So we don't actually even know if those infants had COVID. We don't have access to medical records. Again, six of the hospitalized infants tested positive. We don't know if the other five actually had COVID or if they were hospitalized for COVID. So there's

some things we don't know. We had over 60 percent of our mothers of neonates had symptoms and over 90 percent of the older moms of older infants had symptoms. We had six infants who had COVID... older infants. Their mothers did not have COVID.

Comparing our data to other studies, this is just our data of the perinatal period, we have a seven point four percent positivity rate of our 81 COVID positive mothers. This compares to the very low rate in the AAP registry, but is just a little higher than some of the other ones that our study, the big Spanish multicentre study and the ATOS Italian study. We would expect, given that this is a self-selected study, that we would expect a somewhat higher rate of worse outcomes. So we had a somewhat higher rate of asymptomatic mothers than in a lot of studies and a higher infant positivity rate. We did have a twenty nine percent of moms of neonates separated due to COVID at birth. That was the way we asked the question, were you separated due to COVID? Seventy one percent directly breastfed their newborns. So this is sort of in line with some of the other studies that we saw. Over primary outcomes, that we looked at these three baby-friendly practices and we didn't see a statistically significant difference in this combined outcome of the infant, either testing positive or getting COVID symptoms, which were, for the most part, mild symptoms. However, our study was underpowered in terms of our sample size of neonates themselves. And now that we know the effect size, we know that we probably would have had to have quite a bit more neonates to see to... say for sure that this is safe or not. But in terms of the risk of hospitalization, there was also ... we did not see a significant increase risk. The study was underpowered to find an increased risk. But if anything you see from these relative risks that risk ratios... that if anything, these three practices seem to trend toward a protective effect. Our other outcome we were looking for is whether breastfeeding was protective against COVID in older infants. And we were unable to demonstrate that either. However, we did see some other significant findings, which was that disruption of these baby-friendly practices significantly decrease the odds that an infant would be exclusively breastfed in the first three months of life. So you see these went down to point thirty eight point one to one point one seven, and that these were highly statistically significant. So that taking the infant away or putting the infant in a separate room and not allowing direct breastfeeding significantly reduce the odds the infant would be exclusively breastfed in the first three months of life. And this was adjusting for most normal symptoms. We also found that among infants of all ages, the presence of maternal symptoms predicted whether the infant would become test positive or get COVID symptoms. It seems to be driven by the older infants. Although if you actually stratify by age, those odds ratios weren't statistically significant, probably due to sample size. So we think that the risk is probably lower in neonates because neonates are less likely to be colonized with viruses until they're a couple months old and breastfed, neonates are less likely to be colonized with viruses. A bit about the moms who said they were separated due to COVID, which was one of our questions. Almost 60 percent of them reported that they were severely distressed by this. When we asked them on like a five point scale, the average length of separation was six to seven days. And almost 30 percent of them said that when they tried to breastfeed, when they were reunited, they were unable to do so. So the separation turned out to be pretty harmful. So our limitations is that we were underpowered in the end to find safety with maternity practices among the neonatal sample. There was a recall and selection bias which skewed toward worse outcomes. But the fact that we only included people that had smartphones or Internet probably skewed the data toward better outcomes. We couldn't verify diagnosis with medical records and we couldn't verify genuine responses. We can't really generalize the study toward non breast infants because we had very few infants that were exclusively formula fed and our sample and like other studies, we didn't look at respiratory and hand hygiene. But in summary, we did find that disrupting baby-friendly practices causes significant harm. And it may be unnecessary, but more research is needed and you need a very large sample to show this. But separation of mothers and infants is harmful to both of them, and that symptomatic people seem to be more likely to transmit the virus. And we need more research with non-breastfed infants. So thank you very much. We appreciate your attention. And we're happy to take questions of time permits.

Mija Ververs

I have a question. This is my []. If I may. Did you see any geographical differences when you looked between these detail?

Melissa Bartick

We did not analyze us specifically for geographical differences, but there are certain things you're thinking of, maybe we should look into that. Now, you're muted.

Mija Ververs

Sorry, the guidelines recommendations change over time in some countries and certainly over the period of your inclusion period. So I was thinking maybe specific countries where separation was more preached. You saw a bigger impact on this separation and no breast feeding in other countries.

Melissa Bartick

Now, that's interesting. We did look at maternity practices and the new compared to the older infants because we asked all the mothers about it. You don't have a slide in this presentation about it. But we did see because the older infants were sort of a comparison group that the maternity practices changed over time, you know. And that was pretty interesting. But we don't know geographically. We might be able to look at that, though.

Nigel Rollins

If others have questions, please put your hands up just so that we can go through them in order to sort of be one or sort of particular. And you said that the disruption of services result in lower rates of exclusive breastfeeding. But what was the separation... was... how can you recall offhand how long was the period of separation? Was this full separation? And then the second question was what... not even explicit breastfeeding, but how many women actually, we started breastfeeding, if they were if the separation actually stopped breastfeeding, we didn't I didn't sort of gather from the slides whether people actually stopped breastfeeding as a result of separation or somehow they were still the baby was being brought in and what was being essentially stopped was the skin to skin contact. Can you just clarify?

Melissa Bartick

Sure. So we asked a couple of questions. So we asked if they if their baby stayed with them or if they roomed on and we asked them about skin to skin contact or versus their baby being taken from them. And we asked where is your separated from your baby due to COVID-19? And so so for nearly all of the women who said they were separated due to COVID-19, their baby stayed in a separate room. And then we also asked how many days were they separated?

And the mean number of days was six to seven. So-so we don't know if they ever got a chance to start breastfeeding. And then we also asked, were you able to breastfeed once you were reunited? And that

was the 30 percent that said no. There were a few women that also said that they had some time where their baby stayed with them. So it could be that they got reunited and then their baby stayed with them or their baby initially stayed with them, and then maybe a test result came back and their baby got taken from them. So it's kind of hard to know what happens. I don't know if that answers your question.

Nigel Rollins

Yeah. And then that's sort of what I was interested to know as well, was whether there was the numbers are not you can't afford probably to cut the numbers too many times, but whether the continued breastfeeding just yes or no, whether it was different by the newborn versus the older infant. So even the neonatal up to twenty days, was there a significant difference between the reinitiation of breastfeeding amongst younger infants that were separated compared to older infants that were separated.

Melissa Bartick

Oh, so the question about being separated was just applied to the infants separated at birth due to COVID it wasn't we didn't ask about older infants if they were separated due to COVID, but that's an interesting question.

Nigel Rollins

And we have a couple of the questions that Shelly and then Sarah and then Dan.

Shelley McGuire

Thank you, Melissa. Great presentation. And Laurie, that was great. So I'm really interested in a complex thing here that has to do with risk due to breast feeding to the baby and benefit. And getting the benefit of breastfeeding in this situation is really ... is really difficult. And you need that control group, right? You need the non-breast fed group or you need yeah, you need the non-breast fed group. And I'm just wondering if you said you had some babies who were maybe exclusively formula fed. I guess I'm wondering if you at all can use your data to look at benefits of breastfeeding or not only just breastfeeding, but provision of human milk.

Melissa Bartick

So we did ask everybody whether we were fed and so we had some infants, we had a small number who we compared direct breastfeeding of human milk versus our indirect... direct breastfeeding versus indirect breastfeeding of human milk. And we had ... and we looked at the risk of outcomes there and we could see whether they got sick or didn't get sick. But there were so few of those. So we looked at that. We distributed the survey mostly through like breastfeeding networks, because we're breastfeeding people. So it was really hard for us to recruit formula feeding mothers. We had so few of them, we were sort of victims of our own success, I guess.

Shelley McGuire

But we really tried to tell you we had the same experience. We specifically targeted non breastfeeding women as a control group, a national control group, and have a lot of trouble getting them. But really, that's the group we need. So thank you for trying.

Sarah Taylor

Hi Melissa, thank you all so much for doing this study and for doing it so quickly, I am sure that it was a lot of long hours there at the beginning, especially my questions a little different because you brought up the baby friendly practices and you both are experts in this area. We've been looking at our data at Yale to ensure that our mothers are still receiving the prenatal education they need about breastfeeding and therefore are initiating. And just this month, we saw a big dip in our mothers choosing to initiate and doing kind of an assessment of where that problem might be. Our concern is, is they're receiving less prenatal counseling and education because of the limitations with telehealth, with the visits being made shorter in order to facilitate patients not interacting in the clinic. Do you have any ideas? Have you seen this in other areas? It's just a quick one month data. It may not be sustained, but we just realize that the women who are delivering now have had nearly their entire pregnancy during this pandemic.

Melissa Bartick

I can speak from my heart of coordinating our state's baby-friendly collaborative results. We hear quite a lot from the hospitals in my state, Massachusetts that prenatal education has really suffered. So I've ... I've heard that. So that's really a shame that that's ... that's the experience.

Veronica Valdes

I will also say that there has been a study published looking at the fact that mothers who obtain prenatal care during this pandemic are at no greater risk of acquiring will be to their mothers who don't access prenatal care. So I think that message has to get out there, that just like we're doing in pediatrics that we have to share and promote the message that we have a safe environment to come in and be seen and get the same kind of care. And the same thing goes for in the delivery setting until rationale, good rationale to discharge early. You know, we want to be able to provide the same level of care with the same length of stay for mothers and newborns. I will also say that there may be even some undermining of the baby-friendly practices in the prenatal setting because of shifting policies. And some folks have... haven't shifted. We know that they are still using the policies that were iterated back in April and there hasn't been an adjustment and they may not know that, you know when interim guidance, for example, from the AP comes out on a regular basis and is really meant to be the for month until it gets reviewed every month. And so they're still using old policies and then discouraging things like rooming in and direct breastfeeding, where they haven't quite caught up with the new policies are.

Sarah Taylor

Thank you both.

Nigel Rollins

Thanks. Laurie for that. I think this raises a question that we've sort of asked before, you know, the documentation of experiences versus how do you change practices and sort of how do we ever take evidence? And this might be something for Alicia and Erin and others, Fatumata, we have been seeing global experiences being reported. How do these converted into changing behaviors and informing policy makers and those who are sort of organizing services? And it may be that we all become aware of these type of data and the consequences. It's a matter of how it goes from here. And Daniel, you had a question and then to Dan.

Daniel Robinson

Hi there, yeah, thanks, Daniel Robinson here at Northwestern in Chicago. I'm really struck by the differences in rates of positivity in the neonates across these reports and your experience, even at our busy center, we actually have not had a positive infant, although we had plenty of moms who are positive, asymptomatic, and symptomatic. And so I wondered if you had the ability in your cohort to look at positivity over time, is there something about everyone adapted from the earlier months just because of an inexperience, testing has likely changed from March to date, and so is there. Do you have the ability to look for any signals that there's something about time and experience or just change in practice, as we've all been talking about in the past few questions that might be a factor here to. And again, thank you for your work, very, very helpful.

Melissa Bartick

Thanks. You know, we did not think about that, but I think we probably could go back and look at any trends and if the tests were more likely to be positive earlier. So let me look into that and see. Thank you.

Veronica Valdes

Yeah, thank you. I agree and I think also just the availability and understanding of donning PPE has changed dramatically. As you know, anybody that's sort of in the clinical world, we have a lot of lessons that we've learned along the way within the hospital, how to reduce the spread and health care worker infection, everything else. So and the availability of PPE has definitely changed dramatically in different places, at least in the US. You know, again, we can look at that globally.

Dan Raiten

Thank you for sharing this this is this is a terrific and very informative. I have a question and then a comment asking for the larger group with a question to you is and I'm sorry if I missed it, you have the demographic breakdown. Do you have anything with regard to maternal pre-existing conditions prior to COVID? Now racial backgrounds, your body habits, anything of that sort that that may have influenced Mom's decision for the larger group? The presumption here is that guidance is that moms are being given out what's driving this and is there any way that we can capture preexisting notions about breastfeeding or what we all know about how moms make decisions about breastfeeding and in their competency, if you will, for lactation? Is there any way to capture that in this context and put it together with the impact of got to separate the two.

Melissa Bartick

We asked moms only their country, you know, since it's a global study, we could not ask anything about race because race means something different in every country. We did not ask things like age or BMI or anything like that. So we couldn't ask about that. And so we don't have that really. We only have what country they live in. So we don't have that because it had to ... the study had to comply with the general data protection regulation, which some of you may be familiar with. We could not collect IP addresses of any of the respondents so that we couldn't even get that on people.

Veronica Valdes

But we did collect data on the infants and we asked about pre-existing conditions, so we did look to see if we needed to control for any infants pre-existing conditions, such as prematurity, diseases, things like that.

Melissa Bartick

None of the infants had none of the hospitalized infants have any preexisting conditions. We know that they. Not all of them were [] or anything.

Dan Raiten

To the larger group, the question of how do we how do we tell what we have with the ideas that moms are being given versus, you know, their own reaction to that situation or attitudes and beliefs going into this? You know, I think that's an important distinction.

Nigel Rollins

We like to unpack that, I mean, let's certainly take comments and then anybody else from the wider group to also comment.

Veronica Valdes

Yeah, I mean, I think that we need more research to understand mom's health beliefs and the people that are important in their decision making before even entering the delivery environment, which then has additional impacts in terms of what the various policies and practices within a hospital setting might be. I think just the fact that there are such vastly different hospital practices is an obvious public health place to start. I think that we need to understand the best way to communicate across the board with the delivery hospital, ^personnel and folks making policies they stole from that delivery setting, and I do think also it's important in the prenatal setting to then really work with our providers to get at whatever might be undermining mom's health beliefs about the importance of breastfeeding, particularly a source of breastfeeding and ... and really having the experience of these very important maternity care practices that.

Nigel Rollins

Any other comments, I mean, I suppose. If you were to I mean, maybe I can also ask Shelly to comment, because I'm looking at these questions of differences in transmission risk, my sense is that the numbers are pretty small here and that we should be looking at what type of sample sizes are actually required to speak about this in a meaningful way. Shelly, you've been collecting data and recruiting for that, and I'm sure you have... I'm not sure if you have sort of those types of numbers at hand, but what would be the expected sample sizes ... might be a sort of precision of estimates. But in order to be able to compare between two different groups, I think we need to be careful of inferring anything from a study of three hundred and fifty.

Shelley McGuire

Yeah, I agree. I don't know the numbers. We'd have to run those. It's hard to even figure out, right. How do you run a power calculation in a situation with so little evidence? But again, I think we obviously need a lot more subjects and we need control groups. I mean, that's one thing that this field just does not have right now. We don't have a control group. It's very possible that the positivity rate in breast fed babies is much lower than in formula-fed babies. We don't know. Nobody asks these questions.

Melissa Bartick

We were just talking with our statistician about that because what we really care about is hospitalization rate. And there is just a new case study that showed in the population it was five point six infants per ten thousand live births. I mean, that's so tiny. So if you're going to pick up a difference, you know, you would need thousands. And, you know, I mean, we don't have that. I have to say, like when we started this study, we thought, oh, well, just posted on social media groups and we'll just get all these women to fill out our survey. And it turned out like there aren't that many women that had COVID that were having babies like we did. We just thought we'd have a thousand moms in no time at all. And we didn't, we... we had to actually like we had to fight for every mom to fill this survey out, like we had to find providers and get them to, like, contact the moms they knew of and stuff. I mean, it was hard to find these moms, you know, there in the news a lot. But there weren't that many of them.

Nigel Rollins

I mean, there have been systematic reviews on this, so the and I mean, there was one study certainly from New York, and they estimated 10 percent of women were at least SARS-COV-2 positive and not necessarily symptomatic, but up to 10 percent. And if you look at secondary transmission rates within households and anywhere between...the 20 percent mark, some studies have been higher, up to 30 percent secondary attack rates within households, you could model out based on those types of estimates, what would be the sample size to detect those types of rates.

But I think the general sense is that it is going to be thousands and thousands to determine any of these things and to look at anything as comparative in terms of health outcomes, which is really what's important is going to be probably almost probably tens of thousands to be able to determine these outcomes.

Melissa Bartick

And in some sense, that answers the question, doesn't it? Like if hospitalization is so rare that you would need thousands and thousands of infants to find a difference then maybe that's something right there, you know?

Veronica Valdes

And that we shouldn't be disrupting what we know, actually. Right. You know, because the magnitude of the degree of harm that we saw from the disruption, that's the thing is we know that now.

Shelley McGuire

We didn't know that six months ago and we were all trying to figure this out. So this is just this isn't just something we're doing now. So how do we how do we tackle this in the future? I think we're really fortunate that in this case, it looks like babies are protected. But the next time around, we won't know. We'll start from zero. We'll start from ground zero.

Nigel Rollins

So this is why this framework and the Cox process, I mean, if you don't have trans if the virus can't be transmitted, then you don't even need to think about the health consequences of a potential infection if the virus doesn't have that potential. I think that's where the merit of using the Koch's postulates in this way, because then you can just because people were reacting and saying on the basis of finding already fragments don't breastfeed. And that was an incredible jump and it was based on fear. But it comes back to the question of the communication of how to manage confidence and expectations, both in health workers and in and amongst very, very skilled, I mean, within your own community there, Shelly, a home within a community in the world like the US, where you have leading scientists, do you protect the confidence around an intervention like breast feeding? Because I think that would be a very interesting reflection. Maybe not for today, but it would be a very interesting reflection. How did that reaction occur so quickly?

Shelley McGuire

Yeah, it's a good question. And I think we're making really good headway here. So leave a bit of a legacy to handle this better the next time around.

Veronica Valdes

And, you know, I think that much of the recommendations around disrupting baby-friendly practices was not even related to the viral transmission for women. So it sort of goes beyond of it because I think it was about and fomites. So what can we do to prevent the possibility that through coughing and droplets and aerosols and fomites, can we do to separate the baby from these other means? And I guess it turns out that because that delivery hospital settings, so acutely aware of how to reduce that kind of spread, that really that setting is fairly safe.

It may be less safe is our data kind of points to in the home environment, as we're beginning to show now in terms of community spread within the home. And so I think, as Anjali points out, really what we would love to be able to do is look at breastfeeding as being protective of this infection at infancy. And

the control for to the [] may, in fact, be the most reluctant to participate in this study because, you know, just the kinds of structural barriers that may be related to the fact that formula feeding in the first place. Absent those that have a contraindication of breastfeeding, which is really rare. So. So I think it's challenging, we have to find ways to do that, to look at the potential protection offered through breastfeeding in addition to what these maternity care practices continue to support the scheme.

Dan Raiten

Can I ask Steve Abrams?

Nigel Rollins

I think he's dropped off their time.

Dan Raiten

Too bad, I was going to ask you if you are still and the pediatric community are wondering if there's any way to prospectively assess the impact of this in the prenatal period forward, you know, and get at some of the attitudes and beliefs and some of the other influences that may be impacting on choice. I think it's you know, I think this is an important study. But, you know, as you just noted, I think that there are ... there are other environmental, ecological factors that we consider here that we have today.

I think, Nigel, I think where we're up against it.

Nigel Rollins

Yeah.

Dan Raiten

So I just want to applaud the group were really glad that this continues to show up. We I think we were up to thirty eight hours, almost 40 people today, if you have any suggestions for presentations, we've got some suggestions from the last meeting. If you have any thoughts about the value of this group and what you how you vision this group of contributing moving forward, please let us know. You can send it through the Advancing Nutrition team and we'll compile that information as we go forward. So unless there are any other questions, I think where we're up against it. And I want to thank everybody for that belief that was terrific and I was terrific set about presentations, Nigel.

Nigel Rollins

Yet I can only endorse and agree with you there, done, and thanks for everybody just continuing to commit to the issues and sort of trying to improve the feeding and health outcomes of our children.

So there's no more sessions this year. And our next session will be in January, we will provide some more information a little bit closer to the time. But I hope you have a good season wherever you are. And that ... I think the hope that's now emerging a little bit with the cost of the vaccine, I think there

will be some questions that we'll need that are relevant to how the vaccine is received by people. And it does have an impact on feeding. And I think we can learn from that as well, as well as looking at what are the consequences of vaccine on feeding on the child. But thanks very much indeed and have a good weekend and stay strong and be safe.

Dan Rollins

Stay strong and be safe everybody



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