COVID-19 Infant Feeding Research Interest Group Meeting | March 5, 2021 RIG meeting

Webinar Transcript

Mija Ververs

So, I think it is a little bit over 10 at least here in the East coast in the US and good afternoon, morning, evening to all of you. We are very pleased to have you on this webinar. We have it every month and this time it's all about infant feeding from our research interest group where you are all a member sort of, informal member. We organized this while ago, I think it's now running 8 months or 6 months for these webinars. All the materials are recorded and available on the USAID website and I think Jennifer or Aaron, you can share perhaps the websites so if you are interested in previous recordings and how of course you can find it all there. So today, as I said it is a busy program and I will introduce myself first, my name is Mija Ververs, I work for John Hopkins in the School of Public Health and also for CDC in the US. We have around 6 speakers today and I am just ready to announce that next we have every on first Friday of the month our webinars, the next one will not be on the 2nd of April which would normally be scheduled but that is on a holiday so the 9th April will be the next one. So, I would like first to announce something from a request from Jennifer Youkavitch. She is interested to know if anyone of you on this webinar is hearing or doing themselves research about conducting, oh sorry, collecting data related to the effects of covid19 symptoms on lactating women. For instance, do you know of people researching effects on diet or other behaviors, etc. so please then connect with Jennifer Youkavitch and Jennifer you can put your email on the chat.

So, I am going to speak a few minutes about a new database which we have developed at the repository you might have heard of that and maybe like to ask for the first slide on that. Sorry I haven't introduced yet the speakers, but I think I will introduce each of them when it comes to that moment.

Ok next.

So, you might know already the two scientific repositories on covid, we have put on the Johns Hopkins website. One is everything from health and nutrition and one is a subset of that for breastfeeding and infant feeding. So, we have now organized a database to make it more usable for you.

Next Slide.

We know that the users come from over 150 countries and also the research papers from a lot of countries so we thought it might be good to make it accessible to many of you in the world.

Next Slide.

So, this database you can use for research purposes, I think that will be specially a good use of it. Clinical Care if you like, Public Health related to any Policy making. We have about over 5000 records on it.

Next Slide.

And I am just going to share with you, I would have done it live but internet is a bit sketchy here where I am at the moment. So, if you go to the website you normally use for the repository, the MCH repository, you see this on the website, and it shows you the number of publications we have in it and also the countries that are represented in that research coming from those countries. So, if you click on

that map if you are on the website please do it ideally not in Google Chrome because the database works better in other browsers.

Next Slide.

So, if you click on that map there you will see this. Now this is not meant to be read in detail but just how it shows. So, I will just tell you a few things how you can navigate through this to make it useful for you for your purpose.

So, next slide.

So, you can request, if you are in this database, you want to have all the new publications on MCH nutrition from this last week, you know that the repositories update every week. So, if you just click on This Week you will only have the 120 to 150 latest publications on the subject.

Next.

You can also do it by keyword, but I warn you it is not like a key word you can use like milk and infant or milk and something, you can only do one keyword. You can also as you see there in the right end choose your time period, maybe the last month, maybe the last 6 months or maybe the full repository that starts from 1st of February.

Ok Next.

So, you can also make a choice at only want to see systematic review for instance on Milk or any other subject or only reviews or commentaries etc. so you can click them. You can click also various options at the same time with the CTRL key.

Next.

So, you can also choose your country. If you only want to have research or publications from India, you can choose here or various like European nations or South America or any place of your interest of anything of publication in Japan.

Next.

And what I said you can also do various publications types or various countries.

Next.

And I come to the one but last so then if you have made a selection whatever topic of your interest, you can see here Download Total Repository and that's where it comes that Google Chrome is not so user friendly in this. When you do then download either the full repository if you like you can have 5000 plus publications in it and as you know the summary key points are all excerpts, we have written in the team of 40 students of Hopkins. It is not necessarily abstract because commentaries do not have abstracts as you know. So, these are all excerpts we have written, if you download them then you will see the next in my last slide and that's a very busy slide and it is not meant to be read but it is an excel file and even then, you can go further in filtering if you like. Filtering for all your [inaudible] articles if you like or JAMA articles or on authors you can date again from anything you like and even with keywords.

So that's from my side. Thank you, I am not sure whether there is any question now, we can do that for this purpose at the end. Lastly, I want to say something about the current repository, we are in a phase that we have done this now for over a year and we are looking for people to take this over. Ideally, I guess from the University but not necessarily or work together with it for a handover or collaborate it's been my job for over a year and I think it is time that other people pick it up so anyone interested in doing so or having a different repository with more thematic then I am welcome to discuss it with you so put your interest perhaps in the chat box.

Ok without any further ado I think we can now start to give the microphone to both Nigel Rolins and Fatmata Fatima Sesay, I think are you both there. Fatimata is from UNICEF and Nigel Rolins as you know is from WHO and they will speak a little bit about the Global response to Covid 19 vaccine. Nigel or Fatmata whoever is first, go ahead.

Nigel Rolins

Let me jump in and then I have just got 6 slides that might be of interest and would set the stage for Fatmata and I plan not to take too long so if you can just let me know if you see the slides. [Yes, we can see them]. So, this is an update on coverage from yesterday, some of the numbers are yesterday's and some from the day before but just only a few slides just to. Tell you what things are up, Wednesday it was 85 days since the first countries started vaccinating and 66 days since the EU countries received vaccines and 2 days since the use of COVAX doses. That would have been Monday. I will show this to you on the next slide as well. 265 million vaccine doses have been administered in those 85 days. However, 80% of those doses have been administered in 10 countries and there are at least 9 different vaccines, 3 different platforms that have been administered. Campaigns have been started in 115 economies, 65 High Income settings, 30 Upper Middle Income, 19 Lower Middle Income and 1 Lower Income that the beginning. Vaccines used by the highest number of Economies at the Pfizer – BioNtech, followed by the Oxford/AstraZeneca, Moderna, Gamaleya and Sinopharm. Show you distribution of these in a moment. Covax has delivered doses to 10 Countries to date, and 2 Lower Middle-Income countries have started those campaigns. So in total just over 9 million Covax doses that is the joint delivery mechanism have been delivered to date.

In terms of those 265 million doses, 52% of the country's highest coverage and this is taken from the Bloomberg Vaccine Tracker and this is from 20th of February, Israel is sitting at just over 50% population that have been given one dose. UAE, United Arab Emirates at 35, UK just below a third and Bahrain at 20%. And if you are in the US sitting at about 15% population have received at least one dose. Sure, many of you on the call have already received the dose and Morocco is sitting at 10%.

And as for the actual numbers of doses administered, the US is sitting at almost 77 million, I am sure it's over 77 million now with close to a million a day and China is sitting at about 40 million and the European Union even though is given a very low portion has actually given like 33 million and then the United Kingdom 21 million and you can look down the rest of the ratings, they are all the way down to where I live in France, not doing so well and then some other countries fare a little bit behind.

And if you see the rollout by country you will see that for countries that are classified as high income, that is 83 countries, 65 of them that is, 78%, have started vaccination and the countries are listed on the right and for Upper Middle Income there are 56 countries in that category and 30% of them that is 30 of them, or just over half have started and Lower Middle Income at 38% have started and only one Lower Income Economy, that's Guinea which is 1 of 29 countries in that designation have actually started giving any vaccines at all. In terms of what vaccines are used as I said 65 countries are using Pfizer – BioNtech, some of these are mixed so numbers don't add up so the same 100 % or the same overall number because some countries are given more than one and the Astra Zeneca is being dispensed in 53 countries, Moderna in 29, Gamaleya, that is the Russian vaccine. The Sinopharm and Sinovac are the 2 Chinese vaccines and then there is an Indian Vaccine and the J&J that's actually just starting in South Africa. And I think J&J are also piloting in Brazil. So those, I was asked to give a quick update on what the state of play is in terms of vaccine rollout and hopefully that gives an idea of where things are at. Some good signs and some things that are little bit disappointing in terms of actual distribution across the Lower Middle-Income settings. Over to you Miya, thanks!

Mija Ververs

Thanks Nigel, excellent. That is very informative. Fatmata, you have also slides or…

Fatmata Fatima Sesay

I have also one slide later; I just have 2 points to make that are to add from the UNICEF side not more for this side of a meeting. Thank you, Nigel, that was really enlightening and informative. So from the UNICEF side, just a point to note that we continue to lead and support the vaccine procurement and distribution through COVAX as noted by Nigel's presentation and we also continue to support the arrival of vaccines around the world and more recently in Cambodia and Soudan as well as Ivory Coast and Ghana, and we continue to support the rollout through community engagement and social mobilization networks to build acceptance for the vaccines and as updated in our last call we continue to follow with our regional teams on country rollout and the guidance on inclusion of breastfeeding women in the vaccine protocols across the countries and we have internally added a question on our quarterly covid questionnaire to understand the county level guidance and the data generated from this process that will continue to inform our country and regional advocacy on Covid 19 and breast feeding once we have full data in, we will be able to share it with you all. Then lastly, thanks to everyone we have also supported the development of FAQs this we have jointly developed by Infants Feeding Emergencies core group and USAID and this we will share through our regional office as well as the COVID 19 FAQs network and the COVAX network. We intend, we hope that FAQs will support and provide answers to healthcare workers and the public including the mothers who are breastfeeding on answering some of their questions that they have. And we do hope also that the FAQs benefit the broader UNICEF staff who have questions on the vaccine. So that is all from me and I have one slide which I would like to share which will capture this, thank you.

Mija Ververs

Thank you Fatmata, excellent. We have one and a half minute for clarifying questions for either Nigel of WHO or Fatmata from UNICEF before we go to the research. Any?

Dan Raiten

I have a question, since this is a research interest group that is in, from a research point of view at least if not from a humanitarian point of view. Are we collecting any data, is anybody in this network in a position to collect data with regards to risks that relates to vaccine response and the role of nutrition or anything of that sort, well particularly nutrition? Since we have a history of understanding with regards to nutrition and vaccine responsiveness so anybody has any information or is in a position to collect any information I think it will be an important piece moving forward. Thank you.

Nigel Rolins

Dan I can just tell you that through the COVID MNCH research network we are coordinating I think it is in 7 or 8 countries a collection of hospital-based data on severe COVID in children although that's not exactly the same it will be more like a case control data set but in the countries, we are collecting data on children who present with risk and in time and so that is an ongoing coordinated data exercise, which includes exposure of certain family to vaccines. But it is not the other way around, so the denominator is children who present rather than in children in general or their families.

Christina Chambers

And I am not sure if this is relevant to the question that you raised but women that we enroll in our [inaudible] repository in San Diego we do a frequency questionnaire with them so we have some dietary, typical diet in the moms and then of course information on if they are vaccinated while they are breast feeding at least what their antibody production is.

Mija Ververs

Okay, that's a very useful addition. Ok, we can discuss later more in the discussion part half an hour at the end. I would like now to give the floor to Steve Abrams from University of Texas in Austin, and he is Chair of Committee on Nutrition of the American Academy of Pediatrics. He will provide his information on policies from key pediatric and obstetrics communities and mostly but not exclusively for the US on breastfeeding and COVID confirmed mothers and vaccination during pregnancy and lactation. Steve, the floor is yours.

Steve Abrams

Let me bring the screen here, and then go the full screen. Okay so first of all, I have included in addition to national groups, some of the international groups, I realized some members of those groups are on this call so if I have anything wrong or if I have not found the most updated information, please correct me. I did all these lookups and copy overs just yesterday, and the day before so I think they are pretty up to date but sometimes one can have policies that are not obviously inclusive the goal is not be inclusive everywhere but to just give people an idea where the policies are currently at. So, the World Health Organization, which I think all of you are familiar with, WHO recommends that mothers are encouraged and supported in breastfeeding as its benefits greatly outweigh the risks and they support rooming-in and kangaroo care and the like. UNICEF also is supportive of breastfeeding with some comments about wearing a mask, washing your hands, etc. I think this is important again this is some of the global perspectives that are out there related to breastfeeding in COVID 19. The CDC has a very detailed website that I listed there that has literally a dozen different scenarios and I know that some CDC people that participate in this and are making comments on them. So, I didn't cover all of them but I did want to put this one in here about the scenario of a breastfeeding person who is suspected to have a confirmed COVID but the child does not have it and they talk about the periods of home isolation and guidelines for home isolation, washing your hands with soap and water, wearing a mask and the like. And again, the CDC website has detailed information on a least quite a few different scenarios related to Corona virus and breastfeeding.

The CDC also has some comments on the use of pasteurized donor milk which is the topic of the current interest group, current evidence suggests that breast milk is not likely a source of corona virus infection. They are also suggesting that pasteurization inactivates it. Therefore, pasteurized donor milk is very unlikely to be a source of Covid infection. Disruptions in human milk donations may be seen during the COVID – 19 pandemic. Available supplies should be prioritized as they generally are in the US anyway for donor milk.

Attention may be given to some organizational statements most notably this one from the American College of Obstetrics and Gynecology which reaffirmed in December 2020: Having corona virus should not stop you from giving your baby breast milk. While you are in the hospital or birth center or if you go home you should take the following steps listed somewhere in the CDC. If possible if someone else

is healthy and is taking care of your newborn; this is referring to ill mothers, significantly ill mothers. And talks about that. So, it is a fairly consistent policy.

In February of 2021, which is just last month, in relation to the vaccination issue, pregnant and lactating should be able to be vaccinated. The American College of Obstetrics and Obstetrics recommends that COVID vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on priority groups.

COVID 19 vaccination should be offered to lactating individuals similar to non-lactating individuals when they meet criteria for the vaccination. The society for Maternal Fetal Medicine and most American Obstetrics Maternal Fetal Medicine that is a subgroup of obstetricians who specialize in high-risk pregnancies, the society along with ACOG continue to firmly assert that pregnant individuals should be given the opportunity to make their own decision as to whether to receive the COVID 19 vaccine and that barriers should not be put in place to prevent access to them. They strongly recommend that pregnant and lactating people have access to COVID 19 vaccines.

The American Academy of Pediatrics Organization (AAP), my organization, strongly supports breastfeeding as the best choice for infant feeding even if the mother is infected with Corona virus and again talks about procedures if mom wishes to breastfeed directly.

The American Medical Association doesn't have that specific policy statement on their website but they imply their support which would probably in their Q&A section with Munoz Rivas who is the Pediatric Infectious Decease Expert Children's Hospital who comments again on behalf of the AMA that there is no problem with receiving corona virus vaccine in women breastfeeding their babies. Then she goes on to say that there is very low risk and then she says that pregnancy may be a different circumstance, but she makes no particular statement about vaccination during pregnancy.

Other countries, there are obviously many countries in the world, I just picked out a couple of countries, here, again, someone may certainly know more about national statements than I do and these may not be representative in Israel which is known to have extremely high vaccination rate, they are vaccinating pregnant women. I found this statement which is very recent literally from India saying that the Government there says that pregnant and lactating women should not be administered the shots. In this case they are referring I believe to the Pfizer & Moderna, the MRNA vaccines. Someone from India may have more comments about whether or not this really is enforced and if it's true for the other vaccines or not.

Canada guidelines are not that much different than any other country. But one of the things I thought was interesting about the Canadian recommendations is that they talk about the possibility of giving coronavirus vaccine to pregnant and breastfeeding and then they give a certain criteria about whom the informed consent should be given. What's interesting in this is they include adolescents 12 to 15 years of age for the Pfizer – BioNtech vaccine. This is interesting for the child that has completed was only for 16 and above EUA in the United States is 16 and above. This is the first time I saw someone saying in the study in younger teens being completed that the vaccines could be given in high-risk scenario which presumable might include breast feeding for adolescents 12 to 15 years of age. I thought that was kind of interesting when some of you may have more information about whether or not there are other countries that are standing in that age group in high-risk scenario. In Italy the recommendation is to go ahead and provide vaccination to breastfeeding. UK, they are concerned they have been very negative initially about breastfeeding and pregnancy and vaccination, they appear recently to have reversed that. I believe in terms of pregnancy they have somehow reversed that as well.

So, to summarize so we can have time for discussion, strong global support for breastfeeding, exist when covid positive although some suggestions that pumping may be preferred when feasible especially when mother has severe illness. Strong support for vaccination of breastfeeding women. More equipoise about vaccination of pregnant women but I think there is general support for option in most countries.

Adolescent pregnancy especially less than 16 years is not really addressed. I pulled up the CDC and J&J review that gave some data about 30,000 pregnant women were given that vaccine overall in the united states without a risk of miscarriages and a J&J comment is planning to begin a specific study in pregnancy soon.

So that's kind of a brief tour through some of what is out there I am sure some of you know more and this was not broad national coverage of the issues, but I believe that will give some idea of where things are at in terms of policy statements. We can take a few questions or later.

Mija Ververs

We hope to do it at the end, so we can consolidate some of the questions for the different speakers. Unless there is a very urgent question now is somebody from India here on the call to clarify what was said. If not, we continue to the next speaker. Rebecca Powell, she will present on SARS COV 2 spikes specifically milk antibody profile after MRNA vaccination and comparing it to what was found after infection. Rebecca, the floor is yours.

Rebecca Powell

I am just going to share my screen, one second. Here we go, okay. Hope you can see this, okay, so, I haven't spoken at this meeting before. I am a Human Milk Immunologist at the Icahn School of Medicine at Mount Sinai New York City. I have been running a large milk studies looking at the covid antibody profile in infected people and now we are starting to look at vaccinated people as well. So there has been many reports that this point including mine on infected people, what these antibodies generally look like. And today I am going to show you our preliminary report on the antibody profile after vaccination, so this is with the mRNA vaccines because that's all that's available, well that's about to change in the US. So, what I am going to show it, it is just really brief and informal but what we looked for this preliminary report again the participants received either the Pfizer or Moderna vaccine, which of course are mRNA based and I don't differentiate here between the two because I don't have enough samples to do that. These are all front line mostly doctors and other patient facing personal who enrolled in my study basically immediately when vaccine was available kind starting in mid-December in New York city. These are all local participants. In all of my studies, people pumped their milk at home so especially during the pandemic time of low contact, people pumped milk at home. They save it in a milk bag about one ounce or 30 ml per sample and they keep it at home nicely labeled and waiting for me to pick up or arrange a shipment and in what I'm going to show you here is the pair of samples, so these are pre-vaccine samples so everybody provided a sample pump just before they got vaccine, the first doze. They have been providing multiple samples but the other one I'm going to show you the analysis of now is about the all-important peak, a fourteen days post second doze time point and we have a lot of other time points in between that we will be looking at, but I'm not going to show you that here. So, in this analysis, the milk was accessed for IgA and IgG and total secretory Ab against the trimeric spike. So as some of you may know, human milk is about 90% IgA, roughly speaking and that's in the total IgA, most of that is in the secretory form which is a multimer of trimeric IgA wrapped up in what's called a Secretory Component, which is extremely protective and evolutionarily evolved that way to be more durable in the baby's mouth and gut and could be durable in other mucous environments as well. So, it's also found in other mucous environments. But here we are only interested in milk. The antibody I used to look at the total secretory antibody can recognize any secretory components that could be on IgN which I don't look at in this particular analysis, but IgN would be in much more minority or would be presented very soon after vaccination compared to IgG. So, we haven't looked at IgN for vaccination yet. So, the first thing I'm going to show you is data looking at IgA, which is the far

left, total secretory component and IgG. This is again looking at antibodies titers in the milk, just with milk, straight milk that has been diluted against the full trimeric spike. And so, you know what you can see in these 10 pairs of samples in the open circles with same color lines matched the closed circles, the closed circles are the fourteen-day post second doze samples. You can see that right away it is obvious that there is not very much secretory antibodies. This line is the positive cut-off, which I have based off of many pre pandemic controls where there is some cross-reactive background activity in the milk, but this is the positive control cut off so anything above here is meaningful and anything below here is not particularly meaningful or specific. You can see that the profile is quite IgG dominant which is unusual because in trimmed milk, milk is mostly IgA in the total. So, if you're getting very strong IgG reactivity then there really must be a lot coming from the periphery, the serum, and there could be some local production in the lymphatic streaming to the mammary gland that's not very much understood but there is definitely a dominance of IgG after vaccination. You can also see IgA so not all of these 10 participants seem to have IgA in their milk, and I will show you that in a more detail in a minute and you can see that comparatively the nature of these curves shows that either the amount of antibodies or the affinity of the antibody is clearly greater for IgG because even if you dilute the milk, you really still get these sinusoidal curves where else with IgA that not as evidence in most cases. And then secretory antibody is really quite low with only one real stand out for undiluted milk and a couple really hovering at the cut off. Another way to look at this data is looking at end point titer. So, we use a cut off of optical density. When we read the cut off one, which is arbitrary but fairly accepted. So it is essentially the dilution of milk, what dilution of milk will give you that optical density value. So, it is just another way of looking at the strength or the amount of antibody in there so again not just focusing on what is there, in these curves for undiluted milk but as you dilute out how strong is the titer and how high is the titer. So, its end point titer if you are not familiar is another way of looking at the quality of antibody response. So, it generally follows, right, so again you can start on the right here, you can see that generally speaking we have a couple stand outs, obviously there is lot human variations especially in milk. Probably many of know that, you can see that you know two little point high and then there is medium level and again the positive cut off is the dotted line. Sorry the positive cut off is this segmented line for example, which is actually disappeared here, but it is just below what I've listed here and then there is little dotted line with fine dots is what I used as a measure of what I call high titer, so its 5 times the end point of cut off values. So, it's just how, it's an easier way to think about, you know, are we getting a lot of pipe titer responses, you know, to compare because I have many data sets to compare against. So generally speaking, the IgG is fairly high titer because it all surpasses the five times end point titer cutoff.

Again, that's what we see, you know, in the titration curve as well, secretory antibody pretty low, you know, really this is the positive cutoff. You know, you really barely get any better passing that this one stands out backs 104 and then in IGA, again, you know, there's definitely IGA being made and for most of these people, but not all. And the strength of that response is variable. And you will literally have one that I would call high titer. So, what I want to do is then put this in the context of what we've measured after infection. So, this is a little bit small, but I think you can get the, the gist. And I'm going to directly compare it in a second. So, this is our data. Much of this, some of this is published already, where you can see the profile.

This is four to six weeks after infection. These are all confirmed PCR, confirmed COVID-19 cases. These people have recovered. They gave me their milk longitudinally. So, this is essentially the first sample, which is four to six weeks after infection. And you can see, you know, what we found, which again, we've reported already is that about 95% of people make an IGA response. And most essentially, nearly all of those people also make a secretory antibody response. And that as I'll show you this, this, the IGA and the secretory component response really correlates strongly, which we'll show you that data, you can see just straight off. These are endpoint titers. I did not mention that; the profile is visually quite different. And then you can see on the far right, the IgG again, this is the cutoff, sorry, the cutoffs down here, and this is the high titer cutoff.

So, IgG is there in about 75% of donors after infection. But it's not particularly robust compared to the IGA response. And that's, you know, maybe more expected because again, IGA, supposedly, you know, it is dominant right in milk. So, IgG you wouldn't expect to have such strong titers compared to IGA in a general sense. And then you can directly compare this to the data I just showed you and just get a visual so that I actually, you know, I made the scale, the scale looked kind of strange when I showed you the vaccination data, because I split it. But what I wanted to do was just show you that, you know, in the infection data, everything sort of the highest is 256 of endpoint titer. And then if you look down at the vaccination data, you can see that, you know, generally we have titers that don't come near that for most cases, for IGA and secretory component, especially very, very low. For IgG you know, the couple that are high are actually really high, like way higher than what we saw in infection. And that's just something I just wanted to point out. So, you can see, it goes way up a couple orders. I use a log based two scale. So those, you know, a log based to order is what I use for milk. So, you can see it goes up. So definitely you can just see that the profile is different, which, you know, we're talking about an intramuscular vaccination versus a, you know, mucosal infection. And so, this was what I expected to generally find but there's really very, pretty much no studies that do this kind of comparison. It's very rare and hardly any studies in the literature really look at secretory component reactivity. They look at IGA, Oh, there's IGA. Okay. Well, if there's an IGA, where's it coming from?

Is it coming from the serum is a dimeric secretory IGA, because that's the most protective and durable class And that's what we evolved to produce for babies to be the most effective. And that's why it is in the milk. [So, you have one minute left.] Okay. So, and then the last thing I already mentioned is that there's a strong correlation after Infection between IGA and secretory antibody. So then, you know, this strongly suggests that almost all the IGA we are measuring is secretory IGA, very strong, positive correlation. Whether you look at the ODE in undiluted milk, or at end point titer, and again, there's few data points. Because I can't use the negative values cause they're meaningless. Most of the secretory component measurements are negative, but there's no such correlation between IGA and secretory antibody for the vaccine samples. And that's it. So very different profiles is the message. That's all I got. Thank you.

Mija Ververs

Thank you, Rebecca. Excellent. Very clear and concise. I'll have the next speaker. Christina Chambers from University of California, San Diego. She will give us an update of where the UC San Diego human milk research biorepository is at the moment. With regard to the study and recruitment of women, collection of samples and analysis for infected mothers who have been vaccinated for COVID. Christina, it is up to you

Christina Chambers

Trying to get a share. Did, do you need to hand over the…, when I hit share screen, it's not coming up.

[you should be able to share at this point]

okay. When I hit share screen,

Nothing happens.

[Would you like to send me the slides so I can share them]

Actually, Lars, do you want to try sharing? I just sent them to him.

[Let me just pull it up really quick.]

I'm not sure why this is not working.

It is ..nope. Here we go.

Okay. Thanks. All right. So, I'm just going to give a very quick update on where we're at with the DC San Diego human milk research bio repository that we had in place before this all happened. Yeah.

[Nash, can you make it a little bit bigger? It's a bit small. At least for me it was screen.]

[I believe because my screen is in large format. Hold on a second. Let me do, keep on speaking. I can move to the next].

So, we, we recruit women into the human milk research biorepository all over us and Canada have some other people contributing from other countries. And we also I do a nationwide pregnancy cohort study that's been ongoing for about 20 years. So, we've been recruiting women who have COVID infection and also women who've been vaccinated. And a big component of that is women with auto-immune diseases because that's one of the things that we study as part of our pregnancy study. So, we're sort of enriched in our milk samples for that. So next slide.

Hmm.

Is it it's not moving forward? Hmm.

[Hold on A Second.]

So, I think the last, the last time we were on this call, we gave a brief overview of the design of the bio repository. And basically, women are asked to, when they enroll, they're asked to complete an interview that after informed consent, that gives us information about demographics, maternal child health, breastfeeding habits, all their exposures, and infant adverse reaction checklist. They do stress, anxiety and depression, questionnaires. They complete a food frequency questionnaire. And then we follow the children for growth and neuro behavior after that. These are all almost a hundred percent self-collection. So, we mailed them the kit and instructions and they return it via overnight FedEx. So next slide they provide access.

[You see this right now?]

Yep. This is better. Okay. So as of March, of last year, we opened for recruitment of lactating women who tested positive or symptomatic, not tested or had a high-risk exposure.

They complete the standard protocol. And then we also asked them about symptoms when they were tested and what the test result was, treatments and procedures and infant adverse events so if the child become infected and we collected a variable number of cereal milk samples from these moms collected if possible, prior to testing. And then after the test positive up to 180 days post test positive. So, we've had about 1,150 women asked to join the study through this month and 676 have consented and cereal milk samples received from 352. So, we previously published on the first 18 women in that sample who were test positive, and then it completed a second analysis of now 64 women serial samples who tested positive with basically the same result. And that's a paper that's under review, next slide.

But we now are proceeding to and very interested to see Rebecca's findings to examine milk for the presence, persistence of antibodies against SARS COVID 2 by onset and severity of symptoms, the test positive date. And also, is there any evidence of impact on milk composition, production and infant outcomes? Uh we have started a study to look at Remdesivir treatment in breastfeeding moms to determine what's the amount of time that it takes to clear the drug. And then we're also receiving some samples from Japan and Ukraine; next slide. And its terms of vaccination as of December with the first EUA Pfizer and Moderna vaccines. We opened for recruitment of lactating women who chose to be vaccinated, also doing the pregnancy part of this too. So, we have about 800 women enrolled in the pregnancy cohort who have been vaccinated.

The women, again, complete the standard HMB protocol. They also are asked additional questions about adverse events in the infant within one week after each dose. There's a scheduled seven to eight cereal milk samples collected from up to a maximum of a week before the first dose. And up to two to 12 weeks after the second dose for the two that are, were approved in December. So, we've had about 6,500 vaccinated women asked to join the study as of this week and of these 1,250 have been consented and cereal milk samples received so far from 200. These are all Pfizer and Moderna vaccinated women, of course. And we're now adding Johnson to the group. And again, looking at examining note for the presence and persistence of antibodies by vaccination brand and type and any evidence of impact on milk composition production or infant outcomes. And next slide is just a thank you for people who have supported this, because it, as we all know, it is really been a scramble to try to get funding, to be able to get this stuff done. So, thank you all in there.

Mija Ververs

Thank you, Christina. Thank you for Lars for slides. Excellent. Any results will be expected when?

Christina Chambers

Good question. I hope soon. Lars maybe can answer that

Mija Ververs

Lars?

Lars Bode

Hopefully very soon. Maybe even as soon as tonight.

Mija Ververs

Oh, wonderful. Okay. And you will let us know. I hope thanks. Now, the next speaker is Ryan Pace from the University of Idaho. Ryan is the last speaker for today. He presents or he will share results from the ongoing studies of COVID during lactation that seeks to address outstanding questions and related to risks and benefits of breastfeeding with regard to transmission duration of Milk-Bone neutralizing antibodies. And I'm sure much more, Ryan, go ahead.

Ryan Pace

Thank you! Okay. I just want to preface this by saying that. Okay. So, I'm a post-doctoral fellow in the McGuire laboratory at the University of Idaho. And I want to preface this by saying that I kind of set up this, today's talking to two sessions, the first session I'll be kind of sharing the finalized data and our recent paper that was just published in bio. It was previously shared on a SIF rig back in the fall. But I might just share it again to finalize the form of that data and results. And then the second part is the brand-new data. I'll be sharing for the first time, right in advance. Okay. So, I don't think I need to tell many people on today's call that breastfeeding in the context of COVID-19 in 2020 was filled with a lot of fear, uncertainty and doubt and to be honest, still somewhat persist till this day.

And I was exemplified by this headline in the New York times that was published last April, should you breastfeed if you have the coronavirus, should you? At the time we had some guidance that was being released by several public health and professional organizations that was advising that mothers with COVID-19 should temporarily isolate themselves from their babies. But more importantly, that this wasn't just occurring in the United States, it was also occurring across the globe. And perhaps even more significantly is that some public health organizations across the world were even advocating for the complete and total cessation of breastfeeding. So, it is pretty concerning. Again, this was a precaution that was implemented in order to stem a vertical transmission of SARS-COV-2 during breastfeeding. But at that time, we really didn't have any evidence for, or against vertical transmission via breastfeeding. So, our group got together with some other like-minded individuals to try and help mitigate some of these fears, of mothers, families, with respect to breastfeeding and COVID-19. We wanted to ask the following two questions. One can standardize protocols and methods that are validated for human milk research help to really clarify whether SARS COVID 2 was present in human milk, as well as looking at the potential benefits. Can human milk potentially provide protection against SARS COVID 2 impression and infants, for example, via maternal antibodies.

So, we formed the Pollen hypothesis in lactating women with a recent COVID-19 diagnosis. SARS COVID 2 is present in some milk samples, SARS COVID 2 is sometimes present on breast skin prior to, but not after cleaning progressed, SARS Covid 2, induces a specific IGA and IgG response in human milk and finally milk produced by most women with COVID-19 will function to neutralize SARS COVID 2 activity at least in vitro. So, this is the most multi-institutional study. We designed it as a prospective longitudinal study design. Woman needed to be 18 years of age and lactating. We recruited them within seven days of COVID-19 diagnosis, so early in their illness. And we collected repeated samples up to three times over the course of about a week. And we recruited 18 women who provided 37 milk samples and 30 times sets the breast skin swabs. And this is just the figure of the overall sample collection scheme of milk shown in the yellow circles in relationship to symptom onset that the triangles and COVID-19 testing with the squares.

Okay, so let's just get into the results. So we tested all 37 and those milk samples we collected for SARS Covid-19 using the CDC's RTPCR assay. None of the samples that we tested had contained any evidence of SARS COVID 2. We also tested the 35 sets of breast skin swamps, including the ones that are collected prior to breast washing, on the figure here now to notice in these gray circles, what we found there was that seven swabs had weak evidence of SARS COVID 2 and only a single swab tested positive. We then however, tested also the breast swabs that were collected after breast washing and all 35 of those tested negative for SARS COVID 2. So, this is kind of looking at the potential risk. So now we look at the potential benefits: concentrations against these SARS COVID 2 milk antibodies, family, IGA, and IgG.

So, we compared the concentration of these particular antibodies in our room with COVID-19 shown in the red circles with no samples that were collected from 10 women prior to the COVID-19 pandemic in early 2018. And those are shown in the blue circles. We looked at these antibodies specific to five different antigens, including three from SARS COVID 2 out of the three different SARS COVID 2 included the receptor binding domain and the spike glycoprotein as well as the S2 sub unit of the spike and the nuclear capsid protein. In addition, we looked at antigen specific antibodies to a spike protein from 2 human common cold corona viruses shown here is 229E and OC43. When look at the concentrations, what we saw was mainly there's an IGA response. This isn't again, too surprising, given the IgE is the predominant immune Gama globulin that in human milk. However, when we looked at the concentrations of IgG, we found that four out of the five antigens, we had statistically significant higher concentrations in the milk produced during COVID-19. You know, this was all three SARS COVID 2 antigens, as well as the spike protein from OC43. Now looking just with an IGA, we've had only a single

antigen specific IGA had a statistically significant difference in its concentration where it was substantially higher in our women with COVID-19.

More importantly we wanted to know whether or not these milk samples can actually neutralize SARS COVID 2 infection. So, we used the in vitro model and using live SARS COVID 2, and looked at the capability of these little samples to neutralize it. And so here you can see just the correlation plot of anti RBD, IGA on Y axis. And then microneutralization titers on the x-axis, as you go from left to right, you have increased efficacy of neutralization with everything. To the right of that dash line being neutralizing and everything to the left, not neutralizing. So about 60% of our milk samples we collected samples from our COVID-19 positive mothers, actually neutralize SARS COVID 2 infection in vitro, but more importantly, we also tested the pre pandemic samples and all 10 of those fail to neutralize SARS COVID 2. So this is the first data set that we just published that came out February 12th, however, it is a relatively small cohort, 18 women and 37 most milk samples. And really the questions remain, you know, how robust are these results to the RNA results on detecting SARS COVID 2. Will they hold in a larger cohort? As well as what does the milk borne anti-RBD IgA response look like over longer timescales; all of these women from the first day, we really only collected milk over the course of about a week. And we'd really like to know what that response looks like on this timescale. One to two weeks, three weeks, a month to two months and on and on. So that's exactly what we've done. We've now recruited another 47 participants from 24 States, highlighted here in blue. Obviously now we have this expanded cohort. We also grew our collaborative research network to include colleagues from eight participating institutions who else recruit participants, administer surveys, great team effort.

So, out of the 18 women from our first study, we actually re recruited 11 to provide additional samples out to two months, post diagnosis. We also collected most samples again three times within the week of diagnosis, and one month and 2 months. There were a small set of samples that were collected off schedule as well as up to a hundred days post-diagnosis. So, in the end, we've had a total of 316 milk samples from 64 women that we have available for analysis. So just on the right is the old graphical overview of those sample collections from our 64 participants in relationship to the original 18.

Okay. Again, results. So, we've now tested. We decided to test the first three milk samples, most proximal to start a COVID-19 diagnosis. This is 135 samples from 45 women newly enrolled again, once again, we find there's no evidence as far as COVID to an all 135 in those milk samples. So again, this was really reassuring as it shows that we had a vigorous [inaudible] and robustness in our first data set. We also tested all milk samples for anti RBD IGA, since this appears to be the specific antibody that is providing that protection against infectivity, you really found that 75% of those 316 milk samples contained anti RBD IGA that was above the limit of antigen specificity. And that about 90% of the women actually produced at least one milk sample that was anti RBD, IGA positive.

But again, we had this nice longitudinal data set. So, we really like to look at what are the temporal dynamics of this milk for anti RBD IGA response from two months following the onset of symptoms. And so here, I just have a, we have an accumulation curve showing the percentage of women producing milk, that test positive for anti RBD IGA on x-axis. This is the time from symptom onset. And just what I want to point out is that by day nine 50% of the women with these longitudinal samples were producing milk that contains anti RBD IGA, and this plateaued at about 92% at day 19. Look at this at the individual level, again, concentration with anti RBD IGA. This dash red line is our limit of antigen specificity, about 77% of our COVID-19 positive mothers were able to produce milk that raise the bug, that line of antigen specificity, and still as positive, and actually persisted up to two months or greater.

Smaller amount, we saw a transient response in about 15% of women that is, they were able to initially produce milk that contains anti RBD IGA, but then it falls below the line of antigen specificity and only 8% or in this case is only two women that provided samples over the entire two months produced milk that failed to contain anti RBD IGA. So just in summary, our data combined now really, really show that

SARS COVID 2 is extremely unlikely to be a in milk. And this is looking at milk from 64 women over now, 172 milk samples. In varying degrees of evidence or SARS COVID 2 RNA on breast skin. And we really actually think that this may help explain some of the discrepancy in the literature as relates to the presence of SARS - COV - 2 RNA in some milk samples i.e., contamination, via respiratory droplets on the breasts and or on the hands, overall all milk from COVID-19 positive women contain SARS - COV - 2 specific IGA or IgG, and that the concentration of anti RBD IGA correlates with the ability of that note to neutralize SARS COVID 2 productivity. And then from our newest study. And overall, we see that anti RBD IGA is present in milk from 90% of covid 19 positive women. And that this is really reassuring that at least 77% of the women from this dataset are able to produce milk with anti RBD IGA that persist out to two months.

So, taken together, we think these data suggest that on balance breastfeeding is protected with respect to infant susceptibility to SARS - CoV - 2 transmission. It also supports recommendations that COVID-19 positive women continue to breastfeed while taking precautions such as hand and respiratory hygiene in order to prevent transmission via respiratory droplets. And then just some future directions that we're thinking about [inaudible] out these samples up to two months, but it'd be really interesting to know how much longer do these milk antibodies specific to SARS - CoV - 2 persist. There's some evidence that antibodies persist for different pathogens for a little bit longer. That'd be really interesting to know. Also would be nice to know how does the quantity of the milk antibodies compared to the quality? For example, we see the IgG is in lower concentration but might actually have a higher affinity for neutralizing SARS - CoV - 2.

Other questions, as we're seeing from Rebecca Powell's data and free print that just recently came out, what is the impact of maternal vaccination on milk antibodies? And it seems to be a response, but it's slightly different than the natural infection. Also, what's the impact on milk composition in general, and then finally kind of last but not least, you know, we are now just under a year since many of us first started our research projects. We started off from scratch. How can we be prepared, better prepared for the next pandemic? We all know it's coming. It's just a matter of when. So, I've got four papers here that really outlined kind of a roadmap on what we can do the next time we have to face this similar challenge.

So, and again, this is really last but not least acknowledgement slide. Everyone on this site has touched some aspect of this project. This was a multi-institutional multi collaborator effort and funding and support, none of this work would have been possible without us receiving emergency funding from the Bill and Melinda Gates foundation, as well as the National Science Foundation, with support from Medela and Milk Stork. I'm going to put a plug in… other than this the International Society for Research in Human Milk and Lactation was also instrumental in putting us in touch with our colleagues across the world, really in order to get this research done. So, if you're not a member or you're interested in joining, I would suggest check out [inaudible] and that's all I have.

Mija Ververs

Thank you, Ryan, before we go to other questions and answers, I want to thank all the speakers for their very clear and concise presentation and their enthusiasm and commitment to speak today. It's always an honor to have you speaking. I think Christina Chambers has dropped off. Lars will take over if there are questions for her. Dan you're going ….Dan from NIH is going to facilitate the Q & A session, correct Dan?

Dan Reiten

I can go ahead or Jennifer, I'm happy to help in any way. Jennifer and Erin can read the chat box so I think there is some questions in there can go there. I want to act on Mija's thanks to the presenters. That was fascinating presentations are learning a lot, got a lot to learn. So, I'll turn it over to anybody that wants to run it. Jennifer, Erin?

Erin Broekhuysen

Sure. So, there's a question in the chat box and a few other people, I think, have the same question for all of the milk antibody studies. Are any of you, anybody on the call looking at serum antibodies in mothers and babies?

Rebecca Powell

Yeah. We're going to complete in this. We have matched samples, especially early after infection. So that's ongoing.

Ryan Pace

Similarly, we have actually collected blood from some of these participants, from a lot of them so we will be looking at vaccine questions.

Anti Seppo

Yeah. Likewise, here in Rochester, we have the same setup collecting capillary samples from mothers, not from infants.

Erin Broekhuysen

And in the chat, I think her questions were sort of answered as I saw it going through the chat. So, if anyone else has any questions they'd like to raise, please do so.

Jennifer Youkavitch

I'd like to mention one from Alexandra in the chat, she was asking which stage of lactation the samples came from. And I think this came up during your presentation Rebecca Powell. I believe Christina Chambers responded for her study, but Rebecca Powell, do you have an answer to that?

Rebecca Powell

So, for both of those data sets, it's very mixed. I have, you know, all the stages right now and as our numbers, I mean, I have about 800 people enrolled in the infection study, for example and about 300 people getting each of the mRNA vaccines enrolled in the vaccine study. And we're opening up to J&J so you know, it's a wide range. So, when I get the numbers, I'll be assessing by lactation stage essentially to see if there's any difference.

Ryan Pace

Yeah. So, we have apparently wide range of stage of lactation ranging from, our median is around six months postpartum but a range anywhere from a couple of weeks after delivery to 32 weeks.

Shelley McGuire

I have a question for Rebecca if that's okay. Rebecca in any of the moms that you presented there, did any of them have COVID-19, I'm wondering if responses are different?

Rebecca Powell

Right, so in the vaccine group. Yeah. So, I do, I of course asked that question. The people that I was analyzing straight off, none of them reported any positive COVID tests or symptoms like any suspected infection. I have 10 pairs here, but I started with a few more for this dataset because three of them quite clearly had positive antibody in the pre vaccine sample and had no clue. But again, these are all doctors and other patient facing professionals in New York City. And, you know, I think many people had it and didn't realize so that, you know, we, we told them, you know, what we found and, and we can clearly see it. And their pre vaccine samples had the profile of an infected previous and previously infected person. So, we excluded them for this analysis, but we will be looking at those groups of people separately, people who had COVID and then get vaccinated.

Shelley McGuire

Can you say anything about their responses? Did they seem to be even more robust or is it just too few data to.

Rebecca Powell

It was very few. I could generally say, you know, the vaccine boosted the response, certainly the IgG you know, I wouldn't say it did anything to like the secretory antibody total, but, you know, it was just a few, so I don't want to make any real statements here.

Shelley McGuire

Understood. Thanks. Great study. So impressed.

Dan Reiten

Can I go back to my original question? Is there any reason to suspect that there may be a variation in response to the vaccine? You know, most of the testing, the pre-testing the vaccines were done in the North we haven't done much in the South and low resource settings. Is there any reason to think that we might have a different response different than other vaccines that we've seen, like BGG or others where there's, you know, pretty high failure rates related to various, you know ecological components? Anybody wants to respond to that? Was that unclear or is that what we like to call pregnant positive?

Rebecca Powell

I would say that nothing can be assumed. I mean, you know, I think it's going to come down to a lot of concurrent infections with other, you know, parasitic infections, other endemic infections, you know, these groups of people all over the world where their immunology is going to be very different. So, I don't think we can just assume that let's say you just efficacy, not even based on viral circulating strains, but just, you know, if you could rule, if you could just exclude that issue, which is not a small issue. I can't, I can't say we can assume efficacy will be identical. I mean, just there's a huge variation and response in terms of antibody titers in even just, you know, any one particular population, you can see that from the published, you know, phase one, two data from, you know, these mRNA vaccines or any other vaccines, and you can see in the milk that there's a huge variation of response in the milk for reasons unknown. And we don't know if this is correlated with their serum response or not. So, I, there's always a massive amount of variation, right?

Nigel Rolins

Hey, Nigel here, could I jump in with two questions? The antibody response is part of the mother's immune responses. So, I'd be interested to know what you're seeing in the vaccination. How does that compare to the…, you know, what happens in breast milk? For example, whenever the mother gets a different type of vaccination, nothing to do with COVID, but if she gets a booster for something else like hepatitis I mean, are the orders of magnitude of antibody in the same sort of areas what you were seeing, but then, I mean, the, the question I think that maybe people are interested in is what's the, what is the implication for the child? Because breast milk is only one of many body fluids where you may be picking up on an immune response, which is essentially just the mother's response to the infection or the to the vaccination from a child's perspective, are these levels of antibody likely to confer any benefit in terms of the protection? I think Ryan was getting at, that maybe I mixed up the presentation, but to separate what is simply a measure of the immune response. And then secondly, what that actually means for the infant, if they're breastfeeding, I know the studies weren't set up to do that, but from what you know of other antibody responses, whether it's possible to speculate.

Ryan Pace

I think that's an excellent question. I see Anti popping out so maybe he has an answer.

Anti Seppo

Oh, I don't have an answer, but I'm willing to speculate. That's what you asked for. Right. I don't think ingested antibody, IGA ingested by the infant would have protective effect systemically. So, there was no known mechanism for humans to absorb ingested IGA antibody in the gut. There are for some animals, but not for humans. However, there's a big difference. Of course, if the mother was infected prenatally and then, you know, had the antibodies postnatally because the transplacental IgG would have ended up in the infant prenatally. That's a, that's a key differentiator here. And then of course there's the, the sort of the dark view of things where the ingested IGA would actually dampen any vaccine responses over any immune responses. There's always that theoretical possibility.

Nigel Rolins

Thanks Anti. I mean, the reason I'm asking is that I think these discussions become conflated and people can infare that these antibody responses, as much as they are a mirror of what the mother's antibody, people will also be wanting for clarity on what this means for the child as well. And so, I think it's helpful to articulate the implications for the child separately from, from what, you know, what demonstrates in the mother.

Dan Reiten

What we're hearing is that the vaccine to an uninfected or previous or uninfected mom was acting as immune response. [inaudible]

Rebecca Powell

Well, I mean, yeah, I mean, we differentiate here what we're talking about. I mean, milk antibody and its protective capacity, you know, in the whatever theoretical sense we're talking about, because of course we're not directly measuring that in the babies right now, that is what's called passive immunity. Okay. So that's a temporary protection of the infant via the milk that bays their oral nasal cavity, goes into their digestive tracks. It does not pass into the systemic blood circulation as was said before, right? This is not an active immune response generated by the infant. That would then be protective for months or years. This is a reoccurring temporary response as the baby feeds each time. So, we can't speak to what is the protective dose. That is not what we're looking at here that is very difficult to study. What we can say is these antibodies are specific for the virus. We know that they're neutralizing. If a baby is exclusively breastfeeding, you know, 10 times a day, and continuously bathing their oral nasal cavity in response in the context of a virus that is, you know, you get infected through droplets that are in the oral nasal cavity and affects both the respiratory and GI mucosa. Then, you know, I do not believe it's any kind of leap to say that the likelihood of some protective effect is there. I always like to mention, you know, we evolved to produce, especially a secretory antibody response that we know is highly protective against a lot of gastrointestinal pathogens. And it's a life-or-death protection in countries where that is going to be a life-or-death situation, breastmilk is protective. We know that, right? So, you can look to that past history of study. You can look to the evolution of the what's called the internal mammary response. So, what the mother ingests in her environment and breaths in, those are the antibodies that are produced in her mucosal, immune systems, specifically, mostly in the gut immune system. Those are the plasma cells that secrete antibody that traveled to the mammary gland to produce a response that is responsive to the environment the baby is in. That is protective in a life-or-death type of way in many, in many situations. So, I always like to look at that and I know we can't measure, the dose that's important. And then, yeah, you know, in the context of vaccine versus infection, there's a difference. There's a difference. It's a different type of stimulation. And we don't know if this vaccine antibodies will be necessarily, you know, potent enough, durable enough, compared to infection, but there, I think likely to be better than nothing. And that's maybe the best you can do, but you know, what I do, my field of study is how can we make maternal vaccines for the improvement of a milk antibody response? Right. So that's why I study this because I'm trying to also highlight that maybe our current vaccines don't that very well and we can change that.

Dan

That was great. Very clarifying. Thank you.

Erin Broekhuysen

Okay, great. We have a few other questions in the chat. One came in from Lori. Is anyone looking for, or is there a value in looking for anti, excuse me, anti-idiotypic antibodies post-infection or vaccination? Does anyone have a response?

Anti Seppo

Not specifically. I would assume it's hard to say whether we are looking at anti idiotypic anti bodies or specific antibodies to the virus.

Rebecca Powell

Yeah. I mean, there's, there might be value, but yeah. I mean, it's not something I'm doing right now. There's many things we could do.

Erin Broekhuysen

Okay. Thanks. We have another question from Linda. I wanted to ask whether all mothers were directly breastfeeding, or some were expressing milk and giving expressed milk to their infants.

Rebecca Powell

It's a mix for my studies, especially in the vaccine study, because it's a little bit of a different population because they were all you know, working moms, doctors, nurses, some of them do exclusively pop compared to my infection group, but the numbers are big enough that that likely won't be enough of a difference that I can't really compare. But yeah, there's both.

Dan Reiten

Yeah. In our study it's close to about half of exclusively bread feeding versus providing expressed milk.

Erin Broekhuysen

All right. There's a question for Steve. Go ahead. Did someone have some, someone else have something to say?

Steve Abrams

With regard to the issue of why people took different ways of looking at what to do about the breastfeeding infant baby, I would comment in addition, we tend to be very cautious about babies. I think in the initial phase of the epidemic there, there was a lot of uncertainty about whether or not babies would just have a disastrous response to being infected that wasn't justified based on what happened. And there was there for this kind of tendency, you know, to take some actions against breastfeeding in the life. I also think that in the United States, in some countries in Western countries there's kind of a default and appropriately that, Oh my gosh, if there's anything from breastfeeding that could risk a baby,

let's stop breastfeeding because we have all the formula we need in America and in Western countries. And so, I think that the global perspective on the support of the breastfeeding isn't as uniform within the medical community in the United States, that's just the reality. So, I think those things kind of combined to lead to some of those initial responses that would be my perspective.

Erin Broekhuysen

Thank you, Steve. Mija had a question for you. We all had access to the same scientific data with COVID and breast milk, yet guidance buried so much. What is your take on why this has happened?

Steve Abrams

Well, that was actually what I was answering. I'm sorry. Maybe I wasn't clear that, that the guidance varies, the reason the guidance vary was and the way I, I think that we, we tend to not want to put babies at risk for anything. And, and, and whereas as a global group, we might see that the risk of not breastfeeding was very high relative in the United States. That's not the perception in general for better, for worse, that's not the perception. So, I think the risk benefit kind of look until people were much more convinced that there was safety for babies. There was a tendency to say, well, we can just default to formula.

Erin Broekhuysen

Great. Thanks. I think that those were all the questions that were in the chat. Does anyone have anything else you'd like to ask?

Shelley McGuire

I did have one other question, I guess this is for Lars, because Christina Chambers mentioned that you guys are going to be looking at milk composition, and I'm kind of wondering what, what you're going to be looking at. We are, we're too. We're also interested in looking at the effect of vaccination on milk composition. So, I'm just kind of curious what you guys are going to look at.

Lars Bode

It's just the standards micronutrients oligosaccharides of course, a couple of specific bioactive spec diets. So, it's the, the garden variety of what is available for us and what is somewhat validated in terms of technology and analysis. Milk volume, I think is something to be aware of because there are certain reports and we see that as well, that after first and second does each milk volume seems to drop and women have really concerned about that. I think I'm not sure if anyone else sees that in their study as well. But we've seen this quite often now.

Shelley McGuire

Have you had any reports of milk changing color? We've heard this anecdotally after vaccination.

Lars Bode

Yeah. We've seen that too. And I saw there was a question in the, in the chat we've had that a couple of times as well. And you know, that really then raises the question when it comes to milk composition. Is there anything in the vaccine that bleeds over into the milk? And we're always talking about this. The mRNA that comes through very unlikely is the actual adeno virus going through very unlikely, but the components that are part of the packaging system might come through, although the concentrations and dilutions are probably so low, but I don't think there's much data on it. So, I think that's something also to take a look at.

Shelley McGuire

Yeah, I agree. I think, I think this is a really important issue and so glad you guys are going to be looking at it. We're hoping to use some multi Omix approaches, but we'll see if that happens, but that's what we're hoping to do.

Lars Bode

Yeah. Well, some of the unfortunately, some of the composition is proprietary and when it comes to the molecule composition, so we're trying to get some information on what we're actually looking for there. And it's a bit difficult to see what kind of peg they using, what kind of other nanoparticle composition they're using. So that's what we're struggling with a little bit.

Shelley McGuire

Yeah, but I mean, I think this is, this raises this larger question of how do we study these sorts of things when we don't know what to look for. And you know, as we look to future pandemics and sort of providing guidance as to how we address these issues with both infection and vaccination with breastfeeding and lactation, I mean, there is a great need for the research community to have that information.

Lars Bode

Well, you, you saw in the in the Lancet letter that we published with Raphael and Ricardo, where we specifically asked for the vaccination developers and manufacturers to team up with scientists early on in the development to really, you know, lay out all the information and this can be proprietary and it under, under CDA if necessary, but at least team up and see, is this stuff bleeding through or not? And what are the implications of it? I think moving forward, that's a call that we could emphasize a little bit more moving forward.

Shelley McGuire

Yeah, I totally agree. Thank you. Thank you.

Dan Reiten

It sounds like, Lars; the first step is what you're doing, is looking at what we know about components in human milk. I would, I would imagine the fat composition would be the first person to look at, in terms of color changes. And then once you've ruled out, what's going on in terms of the composition, then you can figure out, is it something from the actual tip, like the volume of the vaccine wouldn't be enough to change the color.

Lars Bode

Right? So, the color changes independent of what we know in terms of volume or oligosaccharides or whatever it is. So, this could be something that's bleeding over potentially. And some people were saying that could be the peg, that's coming in. I doubt that because the concentration is probably not high enough. I don't know, actually. But yeah, it could be many other things as well.

Rebecca Powell

Yeah. I mean, it you know, just inflammation in general. I mean, there's reports of inflammation, the mammary glands, mastitis after vaccination, which just, you know, scrum, the draining lymph nodes is not an unreasonable, unexpected response. It's not like a COVID-19 specific vaccine response. And so, the color changes are probably an inflammatory difference. I'd imagine.

Mija Ververs

I would like to, I am sorry to intervene here, but to conclude today's webinar, we've come to our 90 minutes moment. And I think a lot of people have still other things to do. I'm sorry to cut you off, but we will have another webinar in I think the 9th of April, again, at the same time, again, for 90 minutes, we will send you invitations for that. I wanted to thank the speakers. I want to also thank all the audience that was so committed to stay till the end and most for the steering committee and the working groups for the COVID and infant feeding group. Thank you for organizing this and take care everybody and stay safe.

Dan Reiten

Can I just please encourage everybody? Yeah. Where we're moving ahead. We'd really like to hear from you. So, if you have any thoughts about the [inaudible] of the rate we are doing our business here, the way we're communicating with you, and if you have any ideas for future meetings, we want to keep sustain this activity as long as you guys in the community feel like it is a value. So please give us your feedback. It'd be very helpful. Thank you.

Mija Ververs

Thank you. Thank you, Dan, for that addition. Wonderful. Have a good day. Bye-bye.

Erin Broekhuysen

Everybody have a good day everyone

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