

Dr. Marion Koso-Thomas
Dr. Elizabeth McClure

Behind the Mask

March 18, 2021

GB: Good morning. Today is March 18, 2021, and I have the pleasure of speaking to Dr. Marion Koso-Thomas. Dr. Koso-Thomas is a program scientist for Global Network for Women's and Children's Health Research. She is part of the Pregnancy and Perinatology Branch of the Eunice Kennedy Shriver National Institute of Child Health and Human Development. We also have the pleasure of speaking to Dr. Elizabeth McClure. Dr. McClure is a prenatal epidemiologist for the Center of Clinical Research Network Coordination at RTI and is also an adjunct professor at the University of North Carolina at Chapel Hill. Thank you both for being with me and talking today.

So briefly can you introduce what the NIH-funded Global Network for Women and Children's' Health Research is?

MKT: The global network is a cooperative agreement funded by NICHD to conduct research, particularly clinical trials in maternal and child health in low resource settings across the globe to address issues around maternal and infant mortality and morbidity. We focus on trying to find strategies to reduce the burden of infant mortality and maternal mortality around the world.

EMc: I think the global network has been around almost 20 years and we've done a lot of important studies as Marion said to help mothers and their babies across countries in Africa, Asia and Latin America.

GB: When did the Global Network for Women and Children's' Health Research begin to provide studies, and what was it like to transition so quickly to another topic of study?

EMc: Sure, I can start it. At the time of COVID, about a year ago now, we were in the middle of doing a number of different studies at our sites, again in India, and in different countries in Africa. All those countries, as happened in the U.S., shut down because of the COVID pandemic. We ended up having to suspend a lot of our research activities because most of the health workers who go out and visit mothers and babies at home stopped during the pandemic.

Pretty quickly the investigators in the network recognized the importance of COVID on pregnancy and so we started working with Dr. Koso-Thomas and others at NIH on trying to plan how we could come up with a study that would help us better understand the impact, especially in these low resource settings. I don't think it was so immediate--I would just say it was a few months where it was pretty challenging

because we didn't fully understand what was happening and its potential impact. But quickly people realized that it really was an important health issue for women and children.

GB: Yeah. Definitely. Will you please be more precise as to the start up.

MKT: With regard to the question of when we started. As Dr. McClure mentioned, things move very quickly around the world and, after we suspended trials, the question then arose: What could we do to understand what COVID was doing in our communities and our locations? We had approval for a protocol that had been created roughly around October of 2020 when we were able to put together very quickly a plan to study the impact of COVID in our settings, to get IRB approval for those studies and then start training to get the studies launched. October 2020 is when I would say we were able to take action and get the trials going.

GB: Will you please describe the premise of the COVID studies that are going on currently within the network and discuss how they're being conducted?

MKT: Unlike other places around the world, our settings, as we mentioned earlier, are very low resource. They're low-income countries so one of the things that other places have been able to do is testing and variant identification--all those kinds of wonderful things. However, in our areas, testing was not something that we thought happened quite often. What we've done with our study is accepted the premise that we don't have the fancy technology to test for the antigen. So we decided to do is look at the antibodies which, when you're exposed to COVID, your body produces some molecules that you can use to identify the presence of infection. What we're doing in our study is not capturing active infection, we're just seeing how many women in our population were exposed to COVID, that may have had it whether or not they had symptoms of it. We're collecting their knowledge, attitude, and practice around what they thought COVID is.

EMc: That's right because we really don't know how many pregnant women were being exposed to COVID, and then if being exposed is associated with worse outcomes. Also as Dr. Koso-Thomas just mentioned that knowledge, attitudes, and practices are really important because, especially in low resource areas, we're finding a lot of women were avoiding going to prenatal care or avoiding delivering in a hospital because of concerns of catching COVID. So we're looking at that very carefully to see if there are perhaps other indirect impacts of COVID in these settings.

GB: I guess I was wondering how you are going about doing those things like assessing the antibodies? The data you were saying is that a lot of women aren't going [to the doctor] which may have adverse effects. How are you acquiring that kind of information?

EMc: That's a great question. Because we've been working in partnership with the communities for almost 20 years, we have an existing structure we call a registry. We enroll all women early in pregnancy with our health care workers and our research staff and track them until the babies are born and six weeks postpartum. We were able to actually use that system we already had in place to start asking the women other questions about COVID and, with consent, collecting samples to test for COVID.

GB: Samples being tested in their site or in their home countries and then the data is sent back to the U.S.?

EMc: Exactly. At each of our sites, part of the goals of the global network are to help enhance research capacity or build capacity in the country, so each site is testing in a country with support from us and training from us, and then they have the data to look at locally and help their Ministries of Health. Also we can look at it together with NIH to understand it globally.

GB: How easy was it to enroll the goal of 2 000 women per for this study? Have you all met that goal and what was it like to try to achieve that?

EMc: As Dr. Koso-Thomas said, we started in October and part of our goal also is to look at trends over time. So we have about a one-year enrollment period. We're really at all the sites on track in terms of meeting those goals.

GB: That's great.

EMc: Partly because our teams have been working in the community so long, we have very high consent rate to participate.

GB: That's wonderful. So I know it's probably very early seeing that you just started in October, but what have your observations been thus far across the eight sites? What have been the similarities and what have been the differences?

MKT: Our network is very unique in that we have sites in, as Dr. McClure mentioned, southeast Asia, Africa, and Guatemala, so we've always had diversity in our sites. The similarities are that they're all in the low resource countries. The differences are myriad, cultural differences from Zambia to Pakistan and so on and so forth, and so when it came to looking at COVID every country, as you can see even here in the U.S., places in the north and the south have different approaches; they have different rates of infection. Some places had none, in fact they hadn't seen any COVID for months and months and

months well into the pandemic because in DRC, the Democratic Republic of Congo, the site is very rural, and they weren't even seeing cases. So we've had a variation in what we've seen from site to site. Some sites are big, and they have very big clinical centers and hospitals, and they were able to ramp up the trial very quickly and some are much smaller. Some have home births, some have hospital births, and so it's been a very interesting difference in sites. The similarity again is these are all low resource settings that we've worked with for many years, but it'll be interesting to see what the actual results show when we get the data in.

GB: Have you noticed anything in particular in terms of mothers' health, the babies' health, and once the child is born, in their condition?

MKT: We're trying not to attribute any outcomes yet to COVID because it's a little early to say what we're seeing, but one pattern that is consistent, as Dr. McClure mentioned, is access to care. Women are very cautious about going to health facilities. Because we track attendance at prenatal clinics, we have definitely seen that there is a shift of women who are not wanting to go to the hospital to either deliver or have their babies born there because of COVID; that's the earliest sign we've seen, but I'm sure we'll see more trends as we analyze the data next year or at the end of this year.

GB: So have you seen any palpable degree of passive immunity between mother and child yet? I know that's a really big topic right now.

McC: Just as Dr. Koso-Thomas said, for our study it's a little bit early to speak to that, but you're right, it's an important question that we'll definitely be looking at. The one really nice thing about our study is that we have samples stored so as more advanced testing becomes available, we can look at that for the mothers and the babies.

GM: That's great. Are you looking at the variant as well?

EMc: At most of our sites we don't have the technology right now to look at that variant, but it's something again as more testing becomes available and easier to use, we may be able to look at it later. We've gotten reports, like for example in our Kenya site, that there is the South African variant present in the country so I suspect we may see some of that.

GB: How do you correlate all the data from all these research locations and how do you clean the data and make it digestible for scholastic consumption? In what forms do you disseminate it in terms of dashboards models and other visualizations? It doesn't have to be for COVID because I know you're very early on, but just in general with the network?

MKT: That's an excellent question. Dr. McClure is an expert at that.

EMc: Part of what I do is work at what's called a data coordinating center. We collect the data across all the sites and perform some analyses centrally but also support the sites to do it locally. So we have some looks at site-specific data as well as some more we can compare and contrast, like some of your questions earlier, and then we do have dashboards to help the sites locally. Because this is an observational study, they can share it with their Ministry of Health and each of them take responsibility for local dissemination. And then with Dr. Koso-Thomas and NIH we also try to make it available for a wider audience.

MKT: So, Gabrielle, you can understand the volume of work they do. The GN actually has at least 600,000 mother-baby pairs information coming in each year to the data center for analysis, everything from the live birth to still births the time that they were born to the baby birth weight. Everything is coming to them and they analyze it every year.

GB: Yes, so huge amount of work, and, yes, that's why I was asking. So how often is the data especially for the COVID studies being submitted and reviewed? I know in other studies they're kind of doing things a little bit differently given that they want to get some things out there.

EMc: Right. So the sites actually submit in real time, so we do have data on an ongoing basis. I think because we're doing the antibody testing the test results aren't quite available yet, but as soon the testing is done, they become available. But there's a little gap in that.

GB: Have you all built any new tools or enhanced any existing tools based on the COVID situation?

MKT: That's a great question. The tools that we're using are data collection tools, so they're new in the sense that we now collect information on exposure. We will now have testing which would be the antibody test, but most of what we use are forms that they're familiar with, data forms that they've used before. But we don't have a new tool per se just more information we're collecting that's a little different from what we've collected in the past. The knowledge, attitude, and practices is definitely something that we haven't always asked and so that is a sort of a new tool, but the methodology is what we've used for the past 10-15 years because we have the registry.

EMc: It's because the one thing we added recently was the questions around vaccine. Even though most of the sites were working, the vaccines are not yet widely available, but we hope they'll be coming available.

GB: Also are you interested in what types of the vaccine?

EMc: Absolutely. Each of our sites has a very different range of vaccines that are available across the different countries.

GB: That's interesting. What have been some challenges you all have experienced to date with setting up your COVID study and have there been any surprises?

EMc: I think definitely one of the challenges initially was getting the supplies for collecting samples, just because of global shortages. There's also challenges around shipping, test kits and that kind of thing because also there are fewer flights. It's harder to get supplies to our country, so that's definitely been a challenge.

MKT: I think one of the pleasant surprises was the speed at which we got approval to do the study. Typically in our sites, approvals from, and I use the word IRB, (I apologize as you did say to make it simplified), institutional review boards, they're the ones who decide if a study is ethical, especially they have approval to do a clinical study. In our studies it usually takes a year, if not a year and a half, to get approvals to do the work, and this time around it was done within weeks. That was a pleasant surprise because I think everyone around the world understood the importance of the data from COVID and so they were very, very quick in getting the approvals that the sites needed to do the work in the field.

GB: That's wonderful. So you're still in an initial phase of your study. What are some of the next steps that you will be looking at for the future, especially as there are some aspects that might be too early to assess right now with how COVID affects?

EMc: Yeah, I think you're right. Some things we'll know more about once we get some data, but in terms of next steps as Dr. Koso-Thomas said, I think we understand COVID will be around for a while, so some of the questions that we are asking now we'll continue to keep in our existing registries going forward, so that we'll have a longer-term outlook on the challenges and issues around COVID. We have considered, and again, it may be too early to think about this, we'll need to do some longer-term follow-ups of the babies that are born. Again, it's a little early to make that decision. Because we have really good relationships with the communities and the women we work with, we could reach out if we needed to or thought it was important to do longer term follow-ups.

GB: Have there been any change in your process because of COVID that you would like to see adopted once the pandemic is over? How will you all go about conducting studies or questions you ask? Is every study very different?

EMc: Well, each study is different, but what we have done more of is obviously Zoom webinars and training. Our site coordinators have really been engaged that way and have enjoyed that and I think we'll continue that even after the pandemic. We normally meet together in a smaller group with the investigators twice a year and that's been in Zoom format which has worked pretty well, but I think we would like to at least have maybe not as many meetings as we had, but still have some in in-person meetings.

GB: Can you both say more about your personal roles in this initiative and how your personal educational and professional backgrounds prepared you for handling a health crisis like pandemic?

EMc: Before I worked at RTI I worked at NIH where Dr. Koso-Thomas is. So I felt the NIH background helped me prepare for this. I do feel really strongly about public health and global public health. I think because we have had that 20-year relationship with our research partners in the countries, that really helped us be prepared to quickly respond. Also, we had the trust of the communities already, so we weren't a new research group coming in at a time when people were struggling. I think the thing I have missed the most is having some more in-person time with our colleagues, but it's been a really good year in that way.

MKT: I mean from a professional perspective, as Dr. McClure said, I am a pediatrician, and my background is in public health. So I have an appreciation. I can see what a pandemic means and, interestingly enough, I was detailed with CDC during the Ebola pandemic and so I was on ground in Sierra Leone and Guinea, and I was there to see firsthand. It was a very severe epidemic, but these are times when everyone is very anxious, and you have to appreciate that personal perspective of how much stigma there is around people who get sick. And people have differences in opinion about how transmissible it is. These things play in the back of your mind when you're dealing with this and so from a professional and personal perspective it took us all for a loop, but we sort of got ourselves together and started thinking how we could deal with what we were faced with.

EMc: Of course, for me as an epidemiologist--I think this is probably the first time in my life that the general public knows what an epidemiologist is--it's in the news finally.

GB: Has that been the biggest opportunity you feel, like for both of you that people have more of an awareness of public health?

EMc: Absolutely. I think being able to explain to people and helping people understand. I think before the pandemic a lot of people didn't even know what NIH was and now, I think with NIH's leadership there's a lot more awareness of the importance.

GB: I just want to transition from you quickly from scientists to people living through the pandemic. Personally for you both there would have been some challenges and opportunities that are presented by COVID.

EMc: As you can see, I'm working at home and actually today our director sent this out marking officially one year that our offices have been closed and I've been literally working here at home for the last year.

MKT: There are some nice things about it but also some challenges. I'm very much a simple person; I'm not a people person. I don't do chats by the water cooler at all, but I'm finding I miss it. Even so, I never was part of the team at work that would chat for hours. I usually go to my desk and I do my work and I leave, but it's taken a bit of a toll to be home and feel isolated. We usually have our meetings twice a year, in June and January. We do not have that, so it's been a bit of a challenge. I enjoy the fact that I am obviously not paying for gas and I can wear pjs underneath on my bottom. It's been so great. It's been sobering .

EMc: For somebody working in global health: I used to travel one or two trips per month and I've not been on a plane in over a year now. It's really a strange feeling and I do miss that a lot. I miss seeing some of our colleagues and friends.

GB: We're going to end on a sort of a fun question. What will be the most difficult habit formed during COVID that you think will be hardest to break when the pandemic is over? I can say for me it's having to wake up in time to commute.

[Laughter]

EMc: Absolutely and I'm a runner. I like running in the morning and so it's been so nice to be able to run and still get on an 8 o'clock call, sometimes still in my running clothes. That will be a hard habit to break to have to commute back into that.

MKT: I love cooking and I've been experimenting with all kinds of different recipes and stuff and so being able to go into the kitchen whenever I feel like it, whip up a three-course meal. I'll miss that.

GB: Well, thank you both. I wish you the best with your research and I hope to be hearing more about it as it develops, and I hope that you and your families continue to stay safe.

EMc: Thank you so much.

MKT: Thank you, Gabrielle.