UNIVERSAL CONGENITAL CYTOMEGALOVIRUS SCREENING:

EXPERIENCES OF NEWBORN SALIVA COLLECTION FROM

FIVE MINNESOTA HOSPITALS

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>> Dedicated to raising awareness.

>> Her name is Eva Lynn Townsend, and I'm her mom. Today I wanted share our story, our journey with CMV, and how we found out about the effects of CMV on our family and on our baby, and what you can do to prevent CMV. We recently shared a blog post with CMV Canada, and we're so thankful to get in touch with them and be able to work with them and share our story and raise awareness because that's what it's all about.

I got pregnant. I had a fairly healthy pregnancy. I was sick at one point in my first trimester. I went to the doctor,

and they said everything is fine. You just need to rest. Okay, perfect. About two months later we went for our ultrasound, and they had noticed an exogenic bowel. At that point they said it's common to find these, and a lot of times it's just ultrasound error, and they would just send me for a further test just to make sure. That wasn't the case because every time I went for a test, they would find something new. We got conflicting information quite a bit. One doctor would say she had congenital CMV, and the other would say she didn't. They sent me for a blood test, and they had confirmed they had a recent infection of CMV. They said, yep, they probably has it, but then they would say we're not really sure. That was a bit stressful.

Then from there I was followed very closely. Ultrasounds every week, I believe, I was sent, and then they sent us for a fetal MRI, and that's when they confirmed her ventricles were off. Following that were an ultrasound, and they noticed her head measurements were six weeks off.

They decided to induce me on September 2nd. My due date was originally September 22nd. They said she had an enlarged spleen, and she needed to come out right now. Upstairs went. It was crazy. We had an amazing birth. When Eva was born, they said she was healthy. We were a victim of ultrasound, that everything was fine. I was so confused because it went from, like, she's super sick inside you to, oh, we're completely wrong about everything.

So I felt really disconnected from her. I felt really uneasy -- that's kind of where our journey began. Lots of doctors appointments. Eva has been diagnosed with microcephali, cerebral palsy, bilateral hearing loss. She's nonverbal, but she

communicates in her own ways. She's got an amazing group of therapists that work with her daily. She's doing awesome. She's very happy, but, yeah, it sucks, and if I would have known about CMV, I would have been more careful around other children, just sharing utensils or more frequent hand washing.

That is our story, and I hope it gets to somebody that has never heard about CMV before, and you can read up on all of the amazing things that CMV Canada is doing to prevent CMV infection. Thank you.

>> Thank you, so much for sharing your story with us. As you can tell, there's a lot of passionate parents that we've heard from the last couple of days. We are going to move into our presentation. We will be hearing from Emily Graupmann and Whitney Wunderlich. In 2014 Emily graduated from university in St. Louis with her B.A. in biology, and after graduation she started in clinical research at the University of Minnesota, mainly coordinating pediatric infectious disease studies. Recently she's had the opportunity to explore other specialties and help with new projects. Whitney is a senior research associate at Allina Health in Minneapolis, Minnesota. She works in care delivery and her research focuses on mother-baby research. I will turn the time over to Emily and Whitney.

>> EMILY: Great. Thank you. Today we will be talking about the universal congenital cytomegalovirus that we have going on in Minnesota. We will talk at our newborn saliva collection at Five Minnesota Hospitals.

This is a brief look at our agenda for the day. We will be discussing our universal screening study that we have going

on here, going over our saliva collection process and some logistical considerations for saliva collection, and then Whitney will be going over some social considerations for saliva collection, common parent questions, and a few other aspects of saliva that we have come across over the past couple of years, and then, finally, Whitney will go over saliva processing and the accuracy that we have found and some procedural advantages and disadvantages of newborn saliva collection.

Since we are already introduced, that was great. My name is Emily, and Whitney will also be presenting today. We would also like to thank a lot of other individuals who have helped with this research. They are list odd this slide. A few are at the University of manipulate minimum, CDC, Allina Health and the Department of Health.

Just a brief intro to our Minnesota congenital CMV universal screening study. In 2016 we began with large universal screening. Currently in Minnesota the newborn screening program does not screen babies for CMV to the purpose of this study it to see if babies can be screened for congenital CMV universally and to also figure out the best way to screen for it.

Our interest is in distinguishing which method, blood or saliva, is best when screening for congenital CMV by adjusting the clinical sensitivity of PCR performed and saliva samples. We are performed the sensitivity of both the tests to each other and also standards.

In previous studies it's been found that dried blood spots clearly have a lower analytical sense at this time for CMV detection than saliva or urine tests. The chime study conducted at the University of Alabama Birmingham evaluated this

diagnostic for CMV and found a much lower dried blood spot sensitivity with 35 percent compared to saliva.

The structure of our study. This is our prospective study. We're collect data at 5 Minnesota hospitals, and our total goal is 30,000. At each study location our study team approaches families during their initial hospital stay to introduce the study, go over the consent form, and answer any questions that the family may have. If the family agrees to have their baby participate, we then collect the saliva sample from the newborn from the hospital room. We approach families on both the postpartum and NICU units. We thought this would be more representative of a universal screening program, which includes everyone.

The five Minnesota hospitals that we are visiting right now are in two different health systems. In the M health system, which is in collaboration with Fairview we have three collection sites along with their through NICUs, and we have two consenting study staff that go to these sites.

These sites began collection in 2016, so right at the beginning. The other hospital system participating in the study is Allina health. They have two hospital collection sites with two consenting study staff, and they began that data collection in 2017.

We are excited to be adding another study site for data collection this fall in St. Cloud, Minnesota.

Another important partnership we have for the study is the Minnesota Department of health. They contact providers for identified positive screens from the screening program, and they also send the dried blood spot samples of enrolled newborns for

testing. They help with quality assurance, program management, and tracking of enrollment and test results.

Finally, the CDC is an important partner in the study. They test the dried blood spots. They quality test saliva samples, and they'll also be doing the analysis for the study. Funding comes from both the CDC and the University of Minnesota.

So far as of March 2020, we have enrolled 15,697 newborns. Our enrollment rate is right around 70 percent, but it varies slightly by hospital with the highest enrollment rate being 81 percent. Of the babies we have screened so far we have had 86 positive cases. 70 of those being confirmed positive. There have been 14 false positives. 13 of those from saliva, and one from dried blood spot. Two families declined evaluation or a follow-up. Those two we don't have data for, which is pretty normal for newborn screening in general.

Our collection methods for the study. We are in charge of saliva and blood collection, so the study staff collect the saliva specimen at the bedside. All study staff are trained in our collection process and work in maternal and pediatric research departments. The dried blood spot specimens are collected for the newborn screening program by each hospital's lab staff and then sent to the Minnesota Department of Health. The study staff at the Department of Health are notified which families from the five hospitals consented to have this blood also tested for CMV. We let them know who to further test. They obtain punches from the dried blood spot card, and then these are sent to both University of Minnesota lab and the CDC lab.

This is a brief outline of our saliva collection process. It's step by step on there for you. Basically we wash

our hands, put on some gloves, and then we swab each side of the cheek for five seconds. Once we've done that, we snap off the end of the swab into a labeled microtainer. If the baby has -- in the past 30 minutes, we just check a box to indicate this, and then the microtainer is placed in the drying kit and left open for at least an hour. Once the saliva sample has dried, the tube's top is closed to prevent any further contamination, and then this process is written into the protocol and each new hire is trained to use this so there is consistency at each site and across the five sites that we are collecting data.

A couple of logistical considerations for saliva collection that we would like to discuss our setting, timing of collection, and supplies.

This area is the Twin Cities, and it's the largest metro in the state. So far we have found the demographics of our enrolled families are about 75 percent white, 10 percent black or African-American, and 80 percent Hispanic or Latino. It's good to see that our demographic of enrolled families is similar to the demographic makeup of Minnesota so far.

As I said before, we approach families in both the postpartum and NICU setting to get a good sample and get as many families as we can to be more indicative of a universal screen. The saliva samples we collect are kept at each of the five hospitals for the week until they are ready for packaging and transportation to the central lab. At two of the sites we are required to store the samples in a soil linen room since they are considered biohazards and for security they are all placed in a box that is in a secured locked room. The samples are stored with no patient identifiers on them. Just a study label.

The next logistical consideration is timing. During each week day the consenters run a census to see who may be eligible to be approached on the unit for the day. We approach families when they are in patient so we have between three, four, and 72 hours to talk to each family. The length of their stay depends on the delivery type and also the health of the baby. We try to approach each family, but unfortunately, some are missed by study staff, and some hospitals, the nursing leadership requires us to wait until the baby is at least 10 hours old before approaching the family to introduce the study, and this defeats the time frame quite a bit. Especially if they're leaving at that 24 hours. Timing of speaking with parents can be difficult because we are working around many other priorities such as sleep, pediatrician visits, newborn photography, lactation, and many more. Overall, parental consent is obtained to collect the saliva specimen and dried blood specimen within two weeks of birth. This time frame allows us a little more time to approach families with babies in the NICU who are there for a little bit longer. Another timing consideration is to have the best possible sample and reduce the likelihood of contamination by CMV in the breast milk. We try to wait to take the saliva sample at least 30 minutes after feeding. This is impossible, for example, if the family needs to discharge, we mark from the sample label, as you can see on the slide, with an X next to that fed 30 minutes. This is so that the lab knows about the timing of sample collection relative to feeding.

After collecting the saliva, we leave it open for at least an hour in the dry box. This is so that the DNA can be stabilized and unless it's dried, we close the top again, and

all samples are transported to the central lab within a week so that they can be tested. Finally, the supplies, each of our site gets their supplies from a central study lab. This insures consistency and availability across all sites. The supplies that we use include individually wrapped sterile swabs, microliter containers, study labels, humidity strips and desiccant packs, we've used a few different swab types, but everything else remains the same. In the beginning we used swabs that had wooden handles. We learned that the sample quality was compromised by the use of wood-handled swabs in a way that could reduce sensitivity, so in order to regulate and reduce any variability we switched to applicator that is have plastic handles. The lab reported this swab type has worked better.

>> WHITNEY: I'll be covering the second half of the presentation. I'm a senior research associate at the universal screening and Allina Health. I've been working on the study since we added Allina as a site in 2017, and I'm truly delighted to be hearing about the project. Just a couple of things. We heard most families have never heard from CMV before, and that rings true and talking to them. Those that have heard of it is because we believe that they have a child with congenital CMV or they work in health care. We have found that many patients are really engaged in active dialogue about congenital CMV and are generally serious about learning more. Parents have been receptive for having their child screened. We talked about the participation rate about 70% and 81% in one of the hospitals, though the families are pretty engaged. Families that choose not to participate generally do so quickly. Our speculation with that is that enrolling over 15,000 families is

that kind of seems that sometimes it's related to having so many things going on during the hospital stay and maybe increasing anxiety and stress if you are a new parent, being kind of -- opposed research or getting ready for the hospital discharge.

Families that have had other children screened or remember personally, and their willingness to have another child screened demonstrates our engagement of the project and then broader universal screening in general. We mentioned they're screening in the NICU. Rates are a little higher in postpartum, of course. Newborns are generally healthier. They do have a shorter stay than the NICU families, but many families to summarize the study as just a few swabs and just to walk through they don't feel like it's too cumbersome or anything like that. And approaching the families at the right time can increase participation of the families. In the NICU, we have three NICU settings that we do screening in. It does kind of get more difficult to reach the families even though they are there longer. Patients are generally pretty busy and are sometimes hesitant to take that extra time to do the study when they're visiting their baby in the NICU. There are more considerations for collecting the saliva sample on these babies, so we'll be communicating with the nursing staff, and to certainly see newborns in an ink baiter or have other equipment /HAFPD to them to help them with breathing. We consult with the nurses for the higher risk newborns before approaching a family.

Some other things to consider. Working with our non-English speaking families. All of or sites are now allowed to use a short form for consent, and this is a one-page document here for families who do not speak English, and that's available

in several languages. Originally a couple of the sites had translated documents, and so we were consenting in two languages, and every time there was a change or something like that, it obviously held up the process in working with these families. We're really excited that all the sites now have a short form, and that means we can continue to have our demographic population representative of what universal screening would look like.

In Minnesota two of the most common languages are for non-English speaking families are Somali and Spanish. It's often more difficult, and you do need an interpreter for translation, and then as an in-person witness for that consent process. In-house interpreters are generally for the entire hospital, so they can tend to have more of limited availability. The research might not be their best priority. We need to kind of ask for their help with a working patient when they're on the unit and being seen by the nurse or the physician.

Also approaching these families, another consideration is that the unit takes about twice as long to work with them, and there has been a little bit of a barrier to decide if we should do several families on the unit or our English-speaking families, and then run that risk of the other families being discharged. We really don't have a good answer to this. Every family being screened is really important to us.

Sometimes it's difficult to describe the medical parts of the study, but many families wonder if the screening is required, and if it's not a requirement already, they're more prone to pass on the screening. Then lastly, kind of in some cultures there's a different dynamic for decision-making, so

some families that require the mother and the father to make the decision or just the father and things like that and sometimes they're both not available. Something to think about. This slide contains a handful of questions that parents have asked during consenting and saliva collection. I just pulled out a few from our frequently asked questions blog, and you might be interested in, so some of the questions are around -- many families are curious about the virus in general and wonder why we've never heard about it before. They wonder if it's new. That's really a common question. They think about what's the importance of the screening. Some of you have talked to me about a research, and you are telling me it's voluntary. Is it important? They actually asked the nurses or pediatricians if they need to participate, and there's a lot of new information coming in for a new parent in general. This is just one extra thing for them to think about. Sometimes that can be overwhelming and so they want to defer to a medical professional.

Just to talk about the sample and the collection. With that question will it hurt my baby? We can reassure families that generally newborns won't even cry with the swab. It's much different than the poke for collecting the dry blood spots. It does play in our favorite that newborn babies are so sleepy in the first few days. We assure families that it's just a polyester swab. There's nothing on it. I often compare it to if I put a Q-Tip on the inside of my cheek, I might make a funny face, but not because it hurts.

Sometimes parents think about since the study is offering them to choose which collection method they would prefer, and often you will say the dried blood spots, since it's

already collected and some families say this they would -- they'll just have their screening done in the clinic. For that we have to know that this screening is not -- many children will not be screened for congenital CMV.

Some families kind of worry about selling DNA for babies and things like that, and file like we've gotten the question more as it's been increased popularity for companies of 23 And Me and people taking more ownership about data and other things, where their data is going.

Some questions about the tests. Parents are naturally interested in the outcome of the test of their child. We answer a lot of clarifying questions about testing and letting them know that they will indeed be contacted for any positive test. If tests do come back positive there will be confirmatory testing. Some families have asked if the child tests positive, will it be in the baby's medical record as a pre-existing condition or have any affect on their insurance. Families sometimes ask about the risk of a false positive. We do let them know that this is a risk that could occur, but, of course, that could occur with any kind of clinical test as well. Then, lastly, from the category of questions around sample storage and use. We are seeing many questions about if the information is stored in databases or will be sold. We kind of just circled back to our consent form and talk about the confidentiality, privacy, and storage procedures. I also like to remind them that research has a lot of protective factors of going through an IOD and working with human subjects. Then there's a consent form for families to allow us to use that sample for future research, and those families will answer, yes, that sample is identified.

Other considerations here.

>> Whitney, let me see if I can move you back up. It looks look you're going to need to join back in. I can -- I can advance your slides for you.

>> WHITNEY: I can just click here. I'm trying to join back up here. Do you want to just move the slides for me, and I can follow the notes here?

>> EMILY: I can do that.

>> WHITNEY: We're on the slide talking about nursing unit interactions. We find that the nursing staff are generally curious about this study and the study process, and they kind of want to know more about congenital CMV themselves and many times they ask if they can actually stay in their room and listen to what we're telling the patients who know more about it. We work closely with nursing leadership to see how the research staff would integrate on to the unit and attending nursing staff meetings and telling them more about what we're doing and communicating that to providers. There's a challenge of so many different nurses and so many different shifts and then also, like, turnover and things like that, and so, for example, in the NICU there's over 200 nurses. Our research team philosophy is just to educate continuously.

Over the course of the study we learned more about all kinds of nursing work flows and variances to collections encountered with our families as kind of working with lactation and doing handoff and the 24-hour newborn saliva collection screening care and discharge instructions. Communication overall has been really key for collecting saliva. For example, it's -- I feel like lactation nurses go into the room, and then, you

know, can't collect the sample, and so I actually -- is it okay if I go first or you go first or what's your schedule look like and kind of work together that way.

In the future we did have congenital CMV screening for saliva and the nurses were collecting it, I think it would be a really good thing for us to consider, and an advantage of nurses collecting saliva is that they are on the unit 24/7. Working mostly Monday through Friday daytime hours.

If you want me to the presenter view again.

Then just some other considerations, though. Through the collection of over these 15,000 samples, we've noticed that there are some elements of the infected samples such as community and other variables. I'm going to share with you some of our observations and what we've tried to do for optimal sample quality.

So we've had samples that kind of appeared to form, like, a black mold spot and things like that that we've had at the labs, and in order to address this, all of our sites decided to keep all the samples open for drying at least one hour, and then use the desiccant packets that you see on the screen. They are replacing humidity 30 percent or when the little indicator turns pink, and, you know, they're putting those containers as they're drying and we replaced them whenever that happens, and really the site, you know, where the storage location is happening and then sometimes -- for an example, we just kind of -- of the samples during the drying process. We just try to keep them apart on the rack bar as you can.

Some other considerations, so contamination samples or, you know, possible impurities, things that we've seen. Newborns

have other substances in their mouth prior to swab, so a few examples are the Sweet-ease, that's a sugar water that's used to calm a baby before a procedure, such as a circumcision. Sometimes oral medications that might impact the sample. We do notice that the sample doesn't look right, for example, has some color variation, different than a typical swab, we ask the family if we can swab that baby again, and then some of the things that could have a red tinge to them. The lab also thought maybe the pinching samples could be related to moisture or possibly bacteria and then, you know, thinking about the breast milk, formula, donor milk that could be on the sample. We did notice that some of our babies in the units were testing positive for saliva and then those were determined to be some of our most positive cases. We considered looking into this, and we knew that often those were the ones who were getting the donor milk saying that they'll be able to wait for the milk to come in, or maybe they're worried about the two babies losing weight and things like that. The researchers she looked at the -- to see if any of those had donor milk and were false positives, and those were the things there too that, sure enough, among the 13 of the false positives, nine, or 69 percent, consumed that donor milk compared to four of the 59 true positive or 7 percent. That was significant, and we actually had another app that we submitted on this topic that we will be presenting later this year on one of the CMV live tabs. More on that. We really like to explore the conclusion of the study, what role that plays in the results of the samples, but at this point we just don't know enough.

Then, you know, overall the consent of the lab and any

samples that appear abnormal and our procedures are just to test everything regardless of how it looks, so if we see a specimen that has mold or condensation, we still test it, but taking notes of that just in case.

About 82 out of the over 15,500 samples, to 005%. Something worth mentioning, and that was kind of interesting. Then here's a little -- here's a little picture of what one of the samples looked like.

A little bit about the saliva at the lab. Shipping comes each week. The saliva is delivered to the central lab. The courier brings the sample from the off site to the lab. And then they just have the ID number on them. We've had no issues with chipping at this point or receiving samples. It will be interesting to see when we have the new location that's outside the Twin Cities area. Just to see what that would look like and see what the larger universal screening looks line. The container that we use used to have a swab that would be a test tube and we switched to the microliter containers where actually the person who is collecting the swabs would put it into the tube, and this has helped the lab for efficiency because it kind of eliminated when they would do that for all the samples. As far as testing, all of the samples are tested in that same way for all the hospitals. We do this to allow enough time for us to have a positive sample, and we can do that confirmatory testing in the time frame. All the samples are tested using CCR, and testing positive came from the study. The time for running that test is about two and a half hours. 45 minutes of that is really hands-on, and it really brings it out in the instrument, and it gives time for the batch. The last thing is about an hour when

they receive the samples and sort everything, make sure it's okay. Then we do have about 10% of the samples get sent to the CDC for quality control test, and just want to point out that communication between the CDC lab and the universal lab and our consent Rick has been key to improving processes as we learn more.

How is saliva doing? You can see that saliva has been pretty accurate for detecting congenital CMV. The detection rate of 65 over 70 or 92.9 percent. Our results show that saliva, of course, has been a good job, but it's not perfect. The seven samples, five, or about 7 percent, were negative on saliva. The positive. Then where the positive -- where is positive for saliva, and it was not on the dried blood spots. Some experts say that babies -- some babies are not -- they have the virus in the saliva or urine, but they might not ever have CMD virus in their blood.

Then here we just have the summary kind of slide talking about just, you know, our experience of saliva collection and some things you need to think more about. We found families are generally open to that cheek swab. It's painless. It's quick. There's a high rate of detection in CMV using PCR for saliva. Something to think about is when we -- if it's a universal screening, thinking about the collection consideration, so rather than a few of those trained researchers collecting done by nursing staff or the lab, you know, we will see more of the variability of some of the things that we talked about. We need to consider the shipping logistics of a wider collection and think about false positives. Remember, we had 13 from saliva and one from dried blood spots. It's much keeper to use dried blood

spots than there are collecting universal screening. For us or to add collection and it's based on the cost of somebody's time alone.

Then kind of thinking about testing capability for any one screening program. Each state will have a different criteria for what can be added for those newborn screening programs. For example, in Minnesota just a few things. You don't have to consider any of the right conviction of the test. How much is it going to cost, and then moving forward on adding things.

Then go to it the next slide, please. Then we move to collection. Overall continuing communication is really key. It's been helpful with our families, and nurses and other health care staff in regular meetings with all of the lab test partners and things like that. Consistency has been key. Others who might consider data collection, there need to be detailed protocols for training across sites. Attention to detail. We really had a collaborative environment where we're diligent in the details and looking for proficiency in areas that we can improve on. Research is all about learning. If anybody sees something in this environment, they can feel free to speak up. We brought that to the consensus if you help in collecting and storing samples and then together come up with ways to try to problem solve.

Then, lastly, just focusing on the messaging of the importance of bringing for families will really help improve collection. Children who may be positive for congenital CMV to be identified and get treatment sooner. A few of the conferences I have attended with parents involved, I wish I would have known sooner. I feel like when the person who is collecting the slide

is really passionate about what they're doing and kind of bringing universal screening, making that a possibility for families can really sense that, and that's really helped the collection. That's kind of all we have here. We want to thank you for letting us share our experience screening in five Minnesota hospitals, and we will answer any questions that you guys may have.

>> Excellent. Thank you, Emily and Whitney. I have opened up the question box on the left-hand side of your screen. Please enter your questions in there. I actually have a question to kind of kick this off. I am wondering if, you know, just kind of how the COVID-19 has impacted your saliva collection and even processing your samples.

>> EMILY: We have been on hold for the past couple of months. The University of Minnesota health sites, we just actually got approval to get going again for the study last week. And so far I've been hearing that some parents are a little more hesitant than usual. They hear virus and kind of think a lot of things, but so far not quite sure what COVID will do for our testing everything. Hopefully we'll know in the next month or so.

>> Okay. Great. One of the questions, sorry if I missed it, but what was the accuracy of the dried blood spots?

>> WHITNEY: There's a paper that will be coming out soon about this, but we don't have that included since this is about saliva. I don't know the last calculation we have for that. There is a paper that is coming out, and we probably could provide a link for that, and in the study we're halfway through right now, so it's telling us something, but we don't know the

whole picture yet.

>> Great. Thank you. What is the per patient cost for saliva testing?

>> EMILY: I'm not totally sure on that. Right now everything is covered by the study, so one of actually the biggest questions that we get is will we have to pay for this? Like the parents asking if they have to pay for it or if it's billed through insurance. They are usually pretty relieved and happy to help when we tell them that the study is paying for any testing, though I'm not sure what the per patient cost will be for that.

>> Great. Thank you. The next question is, do you have any idea of what the cost of testing per baby including personnel and lab costs?

>> WHITNEY: Really not sure about that. I wish we had looked more into the costs, and I think that's going to vary state by state and what infrastructure exists for the state. You know, if you can do -- add it on to, you know -- like for dried blood spot, you can add it on to the panel of already tested -- or for things that are tested for. The blood is already collected, so -- and it's already shipped to the lab, and so that is the lower cost rather than having to set up a whole procedure. I think I have talked to patients before. Even if it was, you know, one cent for the swab, it's not just the cost of the swab. It's the swab and the staff time and then in Minnesota about 0,000 babies are born each year, and so that can all multiply very quickly. Especially when you this I about the partnerships that are involved in that type of thing.

>> Lots of questions coming in about costs.

Another one is do third parties pay for any of the testing? I'm thinking this is referencing, you know, insurance companies and so forth.

>> EMILY: I guess not at this time. The study will be paying for all the testing.

>> Excellent. Has the program been spurred by any legislation in Minnesota?

>> WHITNEY: I know in Minnesota they were trying to pass the Vivian Act for, I believe -- I hope I'm not mistaken -- but for obese to be able to educate their families about or maybe it is something that they educate their families about during pregnancy. That is not passed yet, but I know that we have a lot of families that are working on it, but I don't believe there's any legislation that has been passed at this time.

>> Excellent. One of the questions is what standard testing do all CMV positive infants receive? I'm assuming for the ones that test positive, what is -- what protocol do you have in place for the care and further testing for those infants?

>> EMILY: For the babies that come up positive through our screening, the first step is the Minnesota Department of Health will reach tout their pediatrician, and our principle investigator Dr. Mark Schleiss will reach out and go through next steps.

From what I understand it's a confirmatory urine sample just to kind of see what is going on and then audiology, opthalmology, and a head ultrasound.

>> It sounds like there's a protocol in place.

You said that Dr. Schleiss reaches out for the families, is that correct?

>> Yes, usually to tell them what's going to be happening next and to talk to the pediatrician.

>> Great. Thank you for that clarification. For universal testing, could the saliva sample be taken after birth and when the baby is stable to reduce false positives.

>> WHITNEY: In the context of research, right now families need to sign the consent form, and it's about a six-page consent form we have to go over with the families. Having becoming a new mom this last year and knowing what the first few hours after birth is like, it doesn't seem very feasible to approach a family at that time or that they would even listen and consent to the discussion, so it's more than just getting the swab. I think thinking of universal screening in general you won't have all those extra logistical considerations that you have to for research. Personally, like, on the -- if they didn't want research to impact their patient experience scores, and so had asked for us actually to wait ten hours -- until the baby is 10 hours old to approach the family so they can kind of get their bearings and get some sleep. You know, some moms have been up for 36 hours straight this time and things like that. I don't see that being super feasible, but I do think to request a sample before the feeding would be great, but they also put a baby sometimes to breast right away in the first hour of life.

>> Yeah. Interesting. I'm wondering if there's any possibility to do kind of a preconsent, so before the baby is even born. I don't know if you have explored that at all, but

that just kind of popped in my head as you were answering the previous question.

>> WHITNEY: That is something to consider. If they had a C-section or anything like that for a few hours, so I guess just having the clearance to go in that route, and if it's appropriate for research to be there. That is something to think about for sure, though.

>> Great. Have you had success with non-English speaking participants? It sounds like you have, but the attendee would just like a little more information.

>> EMILY: It's definitely been a mixed bag of success at a couple of our hospitals, we have the ability to use in-person translators, and other, like, phone translators, and I would say it kind of depends on the situation. We do our best to get in person if we can. That really helps with the communication with the family. We also have a couple of consenters who speak Spanish and Somali, and we have been able to translate our consent forms into those languages, which has helped a lot with availability and as well as kind of an in person touch to speaking with families that are not English-speaking.

>> Looks like we have time for just a few more questions. One of the questions is -- sorry. Somebody just moved the presenter over the question, so one of the questions is, do you know kind of what the follow-up is with some of the babies? Let's say they work with their pediatrician and maybe a disease specialist, et cetera. What do you know what some of that treatment protocol is and, for example, how many of the babies are being treated and maybe other interventions. Is there any

long-term follow-up?

>> WHITNEY: I feel like for -- I don't know if I interest speak to the question exactly how the person who asked it would like, but, you know, on one of the research staff to within the Allina Health working with the patient, so we don't know the whole picture for each patient and how they are treated at this point. It's the PI that follows everything after that, and it's kind of outside the context of research. The research is just a screening portion. That's really where a lot of my energy goes into, and so, you know, there will be, I think, papers related to some of these questions and kind of what we're seeing, and if anybody wants to reach out via email, we can certainly try to get some of the questions answered through curiosity, and I appreciate all these questions about the follow-up and things like that and something to keep if mind maybe for sharing for conferences and things like that.

>> I think some of the follow-up is testing and then what? It does make sense that the research has perimeters we will go ahead and end there. I'm going to stop the recording. Again, the recording of the webinar will be posted on infanthearing.org. Monday and Tuesday's webinars have already been posted on infanthearing.org and so if you are interested or you were not able to -- interested in relistening or not able to attend Monday or Tuesday, you'll be able to access those webinars, and today's presentation should be posted by the end of the week or first part of next week. We appreciate your attendance today, and sorry about the captioning getting off it a dandruff start. We will meet again tomorrow to hear about information from Angela Shoop and Albert Park about

collaboration that needs to go on in order for the treatment and -- to go well. Please meet with us tomorrow, again, at the same time. 10:00 mountain and 12:00 eastern. Until then, have an excellent Wednesday.

(Session concluded)