Congenital CMV: Advocacy and Legislation, in partnership with Midwestern University and Phoenix Children's Hospital

Presenter: Stephanie Browning McVicar, AuD, CCC-A

- [Moderator] It's my pleasure to welcome Dr. Stephanie Browning McVicar. She is the director of the EDHI program as well as the Children's Hearing Aid Program and the CMV Public Health Initiative in the State of Utah. If you'd like to learn more about Dr. Brownie McVicar, you can read her full bio on the course registration page, and at this time, I'll hand the mic over to you.

- Hello, everyone. I am so honored to be here with you today. I thank Midwestern University, Phoenix Children's, and AudiologyOnline for having me here with you. These are my disclosures, and then these are today's learning outcomes.

- I was angry. I was angry that I had never heard of it.

- I studied child development, I studied psychology, and I had never heard of it. And I was kind of frustrated first of all, that my son was affected by something that could have been prevented.

- My immediate reaction was, how do I not know about this? How have I never heard about CMV?

- That was one of the public service announcements that we created in Utah, and they involved very strong advocates for CMV awareness, and they are actually mothers of children who are affected by congenital CMV. And what we see here is that parents play a huge role in advocating for increased awareness and even for legislation. If you go back 10 years in time, in July of 2013, Utah became the first state in the U.S. to have a public education and testing law for cytomegalovirus.

- The benefits, or just...

- We have started a nonprofit called the Utah CMV Council. Utah passed a law requiring the Department of Health to inform women about this virus, they feel that strongly about it, so the Utah CMV Council is helping to spread awareness.

- I like it, and I've learned a lot today. We need these at Channel 2. Hello? Robert, 2News, in Sandy, at the 2 Your Health Expo.

- And this, the Utah CMV Council, was an advocacy organization created by Utah CMV moms. And they became our advocates and our partners in the enacting of the legislation and the implementation of it. And that's not unheard of, there have been several large national organizations that were formed by parents of children affected by congenital CMV. Janelle Greenlee from California started Stop CMV in 2003, and Farah Armstrong from Texas started Maddie's Mission, named after her daughter affected by congenital CMV in 2014, our Utah CMV Council founders. And these parents, after the Utah legislation was passed and after we were about a year into it and the Utah CMV Council was up and running and thriving, these advocates got together and said, "Why don't we pool our resources and let's all work together and become one organization?"

Which formed the National CMV Foundation in 2015, of which Kristen Hutchinson Spytek, again, a mom of a child affected by congenital CMV, is the president. If you fast forward a year and a half, almost a year and a half after the Utah legislation, there were other states that were following suit, and there were a few more states that had legislation enacted or proposed, and the gray states had legislation and discussion. So in just a matter of a couple years, there was quite a bit of impetus for new legislation about CMV in the United States. Two years fast forward again, and you'll see more color on our map here, and there were more legislations being proposed, enacted, being talked about.

In 2020, again, you see more colors as the awareness efforts and educational pushes for legislation continue to grow in the United States. And then if you fast forward to this year, 10 years after the Utah legislation, you'll see a lot of color on this map. And the turquoise states all have an education and screening law. Minnesota was the very first one to have a universal CMV screening, so all newborns are being tested for congenital CMV. The states that are orange might have a different type of legislation, so Ohio, their legislation designated June as Congenital CMV Awareness Month in their state. New Jersey passed a universal CMV screening law, but it's predicated on becoming law after, or when, or if, congenital CMV is added to the national RUSP, R-U-S-P, or Recommended Universal Screening Panel, which is a recommendation for universal newborn screening conditions in the United States.

And although application is put in, it was not accepted, and that is something the National CMV Foundation is still working on diligently. I also have on this map, that some states just have screening legislation in the yellow. Some have just testing legislation, in the light or the periwinkle blue. And some states have gone a few times up for legislation, and so Maine, in 2017, their legislation established a committee to investigate universal CMV screening in their state. Fast forward five years and they ended up passing an education and hearing-targeted screening. So some states have universal CMV screening, the one actively doing that right now is Minnesota, and then there are several states have what we call hearing-targeted CMV screening.

Because of the close connection with congenital CMV infection and childhood hearing loss, they're predicated on the law on the failing newborn hearing screening. So if a baby fails newborn hearing screening, they're to be tested for CMV. And in 2023, this year, Connecticut, although they currently have a screening law, they are trying to amend their hearing targeted screening to universal. And I just heard this morning, that I think they may have passed the universal screening legislation yesterday. And it's actually been a big week for CMV legislation because on Monday, Representative, let's

see, Richard Blumenthal from Connecticut, he's a Federal U.S. Senator, announced federal legislation screening for all babies in America, and $30 million for research and education, so that's just incredible.

So I'm anxious to see what happens with that legislation. Getting back to The Power of Parents, some of the state laws are actually named after the child who was affected by congenital CMV. And if you're interested in learning more about CMV-related legislation, this is a great reference that maps CMV related laws across the United States. So let's talk about Utah. So back in 2013, we had a law that was passed, as I said, but it started with this little lady named Daisy Doutre. And Daisy was born and had a rather diagnostic odyssey of unfortunate events, where there were some steps missed along the way. So eventually, when she was 18 months of age, she was diagnosed with hearing loss, and it rapidly progressed to a bilateral profound hearing loss.

And Daisy's grandmother just happened to be Representative Rhonda Rudd Menlove, and she's a state... She was for many, many years, a State House of Representative that was a very, very strong advocate for families and children. And Representative Menlove said, "Oh my gosh." And her mom, Sarah Doutre, one of the founders of the Utah CMV Council, said, "How do we not know about this? I've never heard of it, I would've done anything I could, if there was anything I could do to try and lessen the risk of a congenital CMV infection, I would've done it." And so, Representative Menlove sponsored legislation and she said, "Okay, we need to have a law that lets women know about CMV, and we need to have a law testing these babies early on for CMV, just in case there's some treatment that can be helpful to them."

And there's plenty of other non-medical treatments that are helpful, which we'll talk about later. But she was able to get that legislation passed, and here is when the law was signed. This is our previous governor, Governor Herbert, and he signed it into law

and there were a lot of families present and celebrating this great victory. So this is what our Bill was, it was House Bill 81. It was two parts, it was a public education and testing initiative. So it directed the Department of Health to create a public education campaign and to inform pregnant women or women who may be pregnant all about CMV. It did have a fiscal note attached. We had a little bit of funding to get up and running between the citing of the Bill in mid-March of 2013 to the beginning of the law in July 1st, 2013, about three and a half months.

And then we did have an ongoing appropriation of $30,800. In 2014, in the fall, in conjunction with our wonderful partners at Utah State University, the National Center for Hearing Assessment and Management, otherwise known as NCHAM, we put together a National CMV Public Health and Policy Conference. And because of that conference, Representative Menlove was able to procure an additional $40,000 to help with those expenses. And it turns out, we were able to keep that level of funding until our funding was cut in the legislative session of early 2020. And so, it experienced... We were part of the COVID pandemic cut, so we are no longer funded, we're still educating as much as we can, I just don't have the money to do our large-scale public awareness campaigns.

So the Letter of the Law, it was assigned to the department and we were involved right away, the Early Hearing Detection Intervention Program, right, when the representative was talking about writing the legislation. And so, we were assigned the program, the ones responsible for making sure that this law was followed. And as I mentioned, we had to do a public education campaign, and there were also some specific groups that we had to provide this information to over and above women and pregnant... Pregnant women or women of childbearing years. And some of them are childcare providers or women that work with young children, as young children often are shedding the virus, 'cause it's a ubiquitous virus that's very common and it's all over the place, that they

have a little bit of a higher risk because they're around young children, so we need to educate them as well.

Here's some of the materials that we had up and running by July 1st, 2013, our "What Women Need To Know" brochure, this is the outside, this is the inside. When we were planning how we were gonna run this program, I wanted the Department of Health to be the one-stop shop, I wanted all of the information to come from us, and so I assembled a great team of experts around me to help in putting these materials together that were thoroughly vetted. We wanted them to be evidence-based, state of the art, we update them as things change. And so far, I think it's worked really quite well with our partners. This was our Congenital CMV and Hearing Loss brochure.

When a baby had to be tested for CMV, we wanted the family to receive a brochure because cytomegalovirus sounds rather scary, and we wanted to tell them why they were having that test and because they failed their newborn hearing screening, why they would need to go for a CMV test. And then, we also talked about educating childcare providers, so we did have a specific brochure for childcare providers as well. We had a... This is one of the flyers, we did lots and lots and lots of health fairs. We still do them, they're starting to pick back up again, now that the pandemic hopefully has settled down a bit. And all of our materials are also done in Spanish as well.

And we do have some specific for our American Indian families, that we worked with our tribal councils on creating. And then I just wanted to tell you that we merged with the Department of Health, the Department of Human Services, so we're now the Utah Department of Health and Human Services. So we just merged and we're still in the process of transferring all our materials, updating them into the new look and feel of the new department. And this is the beginning of what our new "What Women Need To Know About CMV" will look like. In addition, because our CMV testing was tied to

newborn hearing screening, we needed to alter our prenatal brochures that are handed out to pregnant women.

And so, this is our prenatal brochure that we had in place 10 years ago, that talked about, we added CMV, we added families knowing about how timely the testing was. And then this is our new one that's been created for our new Department of Health and Human Services. So even if you don't have legislation, if that's something you wanna do in your state or with your hospital system or your clinic, you can always add to a newborn hearing screening brochure, or any brochures about hearing testing or hearing screening, information about cytomegalovirus. So by the time July 1st rolled around, we did have a dedicated website, all of our educational materials were available. You can check it out if you feel like you wanna look at these in a little bit more detail.

But again, I wanted us to be the one-stop shop, be the place where people look to for information, and so we had many documents that were created in collaboration with my CMV expert working team. We had a document on CMV core facts, we had a specific care document for pediatric providers and OBs. I had a lab testing document so that people knew which labs did the testing, what codes, what were all the requirements for the specimens. And then we have a materials order form where people can order any of our materials, and they're all free. In addition, we created a series of public service announcements.

- You don't even know you have it. You may have some very light symptoms, but generally, no symptoms at all. However, if you're pregnant and you catch cytomegalovirus or CMV, and you transmit it to your unborn baby, it is one of the greatest causes of birth defects. It causes more disabilities than things we all hear about, than Down Syndrome, than spina bifida, than a lot of those other things. We struggled a lot with Daisy's hearing loss because she was not diagnosed very early. We

didn't know she had CMV and we didn't know the potential for a progressive hearing loss.

- The thing you need to be concerned about, it is transmitted through body fluids, and so you don't wanna get a body fluid on your hand and then touch your eyes, your nose, your mouth. And they think the most common way a woman gets infected when she's pregnant is through urine or saliva of a young child.

- It seems like an inconvenience to say, "No, wait, let me get you your own spoon," or, "I'll get my own spoon," or, "Let's get you your own drink," for nine months, if it could possibly reduce the risk of your child having disabilities or losing your baby, it's worth it.

- This was created as a leadership project for our LEND trainees, so LEND stands for Leadership Education in Neurodevelopmental Disabilities. It's a multidisciplinary learning collaborative for graduate students. It promotes family centered and multidisciplinary, interdisciplinary care for children. And every year, that cohort of trainees has to do a leadership project. And so my trainees of course, always did a CMV project and this was one of 'em, and I'm only bringing this up because if you want to do a public awareness campaign or anything involving CMV, go and talk to... See if you have a LEND program in your region. Talk to universities and colleges. Oftentimes, students are looking to do a student project, and even marketing students are a good place to look at and they might be able to do some things for you at little to no cost.

Here are some of our large scale campaigns that we've been able to do. Again, I haven't been able to do it since we lost our funding in 2020, but this billboard on the top-right is still standing. So that's been up for years and they've kept it up there for free, so it's pretty amazing. But we did, you know, bus campaigns on the outside and the inside, and billboards in English and Spanish, and then the top-left is a flyer that we

had in the programs for the University of Utah Football Games. We sponsored CMV Awareness Night at the ballpark with our Salt Lake Bees, which is our AAA team. Every time we did it, we had a family with a child affected by congenital CMV throw out the first pitch, and of course, all the firefighters loved our families out there.

We interviewed, walked along the concourse and interviewed women if they knew about CMV, and tallied that data, and we have... Throughout the whole season, we'd have billboards that stayed in the outfield. On our sponsor night, we got a lot of press, and so when they did the Simba Cam where they hold the babies up, you know, everyone's watching the screen then, 'cause, you know, babies are so cute and that, right after that, we'd play that public service announcement that you just saw. And in addition, we would have signs all along, that lit up all along the inside of the concourse, especially around where they had the snack shacks and refreshment areas. And we had... This was the ad that we had in the programs, and then this was just one of the sunsets at one of the games that we went to.

In addition, we would try to sponsor when they had family nights, so we would have a lot of women of childbearing age. And this was again, one of the ads that we did in the programs, and this is what we had in the concourse for that time. We also did several, several campaigns with movie theaters, with Cinemark and Megaplex, and the same thing, we would have these around the theater. And in addition, while you're waiting for the movie to start, we would have our public service announcements play. And we did that for many, many years. In addition, any sort of college, university, community college, if they had arenas, we made sure that we had signs up in the concourse and information in their programs, and these are just some more examples of that.

And in addition, like down at the bottom here, this little gal, this was for the University of Utah Women's Gymnastics Program. I would try to do something that would get attention inside. And then, as like I said, we did do our campaigns in both English and

Spanish. And then there was the train going across the street from our building, and I threw my sneakers on and ran across the street, and there you can see our CMV data coordinator, Jill, taking a picture of me, I wanted a picture in front of the train. But let's talk about the testing requirement now, so that was the pep bulk education piece. For the testing, it directed the medical practitioners in care of the infant to test the infants, and it was predicated on failing the newborn hearing screening.

So the Letter of the Law stated that the newborn had to be tested, if they failed the newborn hearing screening, that they should be tested before 21 days of age. And what is critical about 21 days of age, meeting that timeline, is if the test is done before the baby is three weeks of age and it's positive, we know the baby has a congenital infection. If a baby acquires CMV either through the birth canal or postnatally from the mom's breast milk, that's an acquired infection and it takes three weeks for that to show up in the baby's body fluids. And so, I can't stress enough how important meeting that 21 day window is in getting the CMV testing done on these infants.

Part of the legislation along with our educational efforts, again, I just showed you that the medical practitioner was the one in charge of ordering the test and talking to the families, and it was up to the department to educate the providers on what they needed to do. That's what the previous slide said. And one of the things that we did is we tried to educate as many physician groups as possible, and when our law was getting passed and getting implemented, we'd put an article in the Utah chapter of the American Academy of Pediatrics, on what pediatricians need to know about the public health initiative. We did articles in our Family Practice Association, we did huge email blasts to different provider groups.

Also when they were getting notified, the primary care provider, that they needed to order a test, we created a fact sheet to go along with the order. So again, reminding them why they need to order this, how they need to order it, it has all the information

and our phone number and website in case they need help. And then we also created posters that they could hang in their office, to remind them on what they needed to do when they received a fax form saying you need to order this test. And this is something that came about as the mandate went along and we realized even though the specimens are urine or saliva, not blood, sometimes from the beginning, blood was being drawn on the infants, and for no reason.

So we tried to make posters to say, "Hey, please don't do it on blood." We would have the screeners, when the CMV testing, when the child became eligible, when they failed, gave this information to the family. So if the family goes to the lab and they start to get out a needle to draw blood, they'll be like, "Wait a minute, look at this. It's not supposed to be blood." And it's because for CMV testing for adults, when you're looking at an acquired infection, they're drawing blood, it's a blood test. But for the presence of CMV in a baby, when we're looking for a congenital infection, it's on urine or saliva, those are the two gold standards for the specimens.

And saliva is great 'cause it's quick and easy. You take a swab of the mouth, the baby's mouth, the only caveat on that though, is there can be contamination from breast milk if there's the virus in the breast milk, and so we do recommend that you wait two hours after feeding before a swab is taken. And because of their risk for false positives, if a baby is positive on saliva, they need a confirmatory test on urine. And then we also provide updates as time went along, on how things are going. Remember to do this. And then also, this is one from 2018, whenever you're doing an article or an interview and you're talking about hearing testing and hearing screening, we always talk about CMV in there as well.

So when you have a law, you write a rule to kind of define the further details of the law. So for example, in our CMV rule, we clarified, what does it mean to fail a hearing screening? So we're a two-stage state, which I'll show you a schematic of in just a

second, but the newborn must fail both hearing screens. So the one done in hospital, if they fail, they come back as an outpatient. So if they failed at first and the second, they need to be tested, or if they fail their first hearing screening and they're already two weeks of age, they need to be tested for CMV. So this is what it looks like.

Like I said, the inpatient stage, baby screened about 10 to 12 hours after birth. If they don't pass, they'll be screened again right before discharge. If they still don't pass, they'll come back as an outpatient, between 7 and 10 days ideally, and be re-screened. If they don't pass that re-screening, they're referred to a pediatric audiologist that has expertise in testing infants, to have their auditory brainstem response test, and then they're also referred to the lab at the same time. Also in the rule, we have a clause on special populations of newborns. One of the most important things I found out as I was doing my traveling roadshow and talking to physician groups and providers, is, one, I would tell them, "Please don't shoot the messenger," because there were some providers that were upset that the state was telling them how to practice medicine, and I totally get that.

And so I would say, "I'm here to help you. I'm here to partner with you." And I talked to the greatest group of neonatologists in the state, and they were pretty upset. Like, when I walked in the room, they're like, "Oh, the state is here." And I'm like, "Well, I'm actually Stephanie." But they were wonderful to work with and what they were concerned about is a lot of their babies are very, very sick, and many of them are not gonna have a newborn hearing screening before 21 days of age. So they're like, "What are we gonna do?" So I said, "Well, let's... Maybe we could write something in the rule." And so we do have this clause, where if there's a medically fragile child who cannot have a newborn hearing screening before 21 days of age, it's up to their provider of care to decide whether or not to be tested with CMV.

And I'm gonna show you by the end of the slides today, an incredible transformation that had taken place with our neonatologists and our NICUs. We also put in our rule, that we needed to get the results of the test within 10 days. It was quite a complex process and we would start with one process and then go for several months and say, "Gosh, you know, some people didn't understand this, we better tweak it." And so there's several reiterations, but don't ever let perfection stop you from diving in and doing the best you can right off, and then just continue to improve it as you go along. So for example, the way the law was written, the providers, the primary care providers, were the ones that had to order the test.

And so we had to figure out how the hearing screeners at the hospital were gonna let the providers know, and to make a long story short, we went through several reiterations of the fax forms, trying to get them notified that the baby needed the testing and then trying to get them to write back the results of the testing and send it back to us. And it was quite, quite a process. And again, we kept creating and changing things as we went along, to try and make things better. One of the game changers was amending some rules that helped us to be sure that we were getting all of the lab tests, because even though I was like, "Oh, it's the law, we'll get 'em all," well, I found out that that was really pretty naive on my part.

So one of the things that we did was we updated the communicable disease reporting rule. We did some rule updates to both our early hearing detection intervention of newborn screening rule, our CMV rule, and we also, right from the beginning, I knew I wanted to create a registry and track longitudinal outcomes and long-term data on these babies, so we amended some rules, and this was what we wrote in the communicable disease rule. So any lab doing electronic lab reporting, which is all the labs that are doing CMV testing here in the state, have to send the results, no matter what they are, to us, when they're testing for CMV in any infant less than or equal to 12 months of age, so that was huge.

And then also, as we went along in time, we updated our CMV rule to say that the newborn should have CMV testing done if they failed just the one screening and they still hadn't come back for their repeat outpatient before 14 days of age. And then we also put in there, that gave us authority about creating our positive CMV registry, and we even updated this as our newborn hearing screening rule, again, that gave us the authority to collect this information. This was huge for us. It took us a few years, but having a standing state order for the CMV testing has been just amazing in terms of smoothing the process out for everyone. So when a baby is going to have the CMV testing, there's a state order that is given to them, it educates the family at the top on the CMV test requirements, it reminds them this has gotta be done before the baby's 21 days old, it reminds them it's only on urine and saliva, don't breastfeed your baby before two hours.

And because the order is written by the EDHI Medical Director, the results automatically come to us directly from the lab. And I cannot stress enough how amazing this has been for our program. In addition, many insurances need an order for ABR testing, so we added that to this order as well, because when the baby needs CMV testing, they often need their ABR testing, so we added that as well. This is a timeline of events that have really helped us improve the number of babies that are receiving their CMV testing. Having a dedicated CMV data coordinator in 2015 was huge. She's since retired and I have another one and he's amazing. But having someone who is fully dedicated on CMV testing has been huge, because they can intervene and do follow ups.

So we have a query that's billed, so if we know there's a baby that's eligible and we haven't seen the test results yet, we will intervene and reach out and help facilitate the lab testing if it hasn't been done yet, and that's been huge. So we track our data, we look at it, and why are we not at 100%? So sometimes we discovered the baby fails

the inpatient screen, the outpatient screen, and then instead of the test being ordered, they're having them come back for one more outpatient screen, which is not best practice. So we've discovered sometimes that happens. We also are trying, we tried, one or two years in, to start holding the hospitals accountable for compliance with this law.

And so this was an early version of a report card, so to speak, a performance report. This is our current one that we list how they're doing with their babies that are eligible for CMV testing. Every year, we have a State EDHI Conference and we do recognize centers of excellence and we do include CMV testing numbers as a criteria for the awards. And we also have a dedicated award every year, for the CMV Center of Excellence. The other reason why we're not at 100% for testing is for our out of hospital births. They definitely have improved in CMV testing over time, but 50% is definitely not where we wanna be at, and that's something that we've been working really, really hard on improving.

So this graph shows that the number of... We have 89% of babies born in hospital and 11% outta hospital, which is fairly big, we have a pretty high out of a hospital birth rate here in Utah. But if you look at the CMV tests that were not performed because the family refused, one-third of refusals, over one-third of refusals, came from families who were born out of hospital. So we've done a lot of dedicated training with our midwives and have information we've made for them, specifically for out of hospital births. We've done webinars on teaching them how to do saliva collection themselves on the babies, we've presented at their midwife conferences and put articles in their newsletter.

We've added midwife champions to our newborn hearing screening advisory committees, so that's something we're still really, really working hard on. Now, I alluded to this several slides ago, about the neonatologist concern about the CMV testing, so fast forward three years in time after the law started, and a guideline was

put forth by the largest neonatology group in the state that said, "We think we're probably missing kids that have congenital CMV, particularly in our population of neonates. So we really need to think about doing some high-risk testing. If any of our babies have any of these risk factors, we need to test them and we need to test them right away because of the time sensitivity."

So that was really, really neat, that on their own they decided, "Oh, I think we might be missing some CMV," so it definitely created more top-of-mind awareness. And how we found out is we started getting CMV test results and the babies were day one of age, first day of life, day two of life, and we're like, "What's going on?" And so it was because of this new high-risk testing that was recommended. Fast forward a few more years, and in 2019, I'm part of a CMV research working group, I've been part of it for, I don't know, 16 years or so, and with our partners and our CMV specialists in the state, we put forth a actual protocol for high-risk CMV testing, which... The largest healthcare corporation which has the majority of our birthing hospitals are following a high-risk CMV testing protocol, and that was instituted in the fall of 2019.

And these are the 11 criteria for early risk, increased risk testing. So when you look at our numbers, if you look at all of the cases we've identified with positive CMV, you can see a huge spike in 2020, as 2019 is when we first started the high-risk testing protocol in that healthcare corporation, and that was at the end of 2019. So high-risk identified cases, first we saw an increase when they started doing that recommended guideline, and then we saw a lot more after they started doing the high-risk testing. And what's interesting, and we're not alone, many other states and other countries saw a decrease in cases, congenital CMV cases, during the pandemic, and that's just 'cause people were staying at home, and children weren't in daycare, and people were just more isolated.

This is my favorite graph. So, let me explain it to you. When you look at over time, this is 2013 to 2021, 'cause we have full data for that, the number of CMV tests that were conducted are in the blue lines here. And again, you'll see a huge increase. Our birth rate is going down a little bit every year, so that's why you see this little bit of a decrease from 2020 to '21. But the percent positive cases which are reflected by these percentages on the far-right, so 8.8% of the children that we tested in 2013, tested positive. Fast forward to 2021, and although there was an exponential increase in tests that were conducted, you can see our percent positivity continues to go down, where it was at 0.4%.

And so that's really exciting and I think it shows that hopefully, all the education and awareness efforts have been having an effect. This is our high-risk test, we analyze all of our data, we're looking at of those 11 risks that are on our high-risk testing protocol, how many of them are prompting an actual test to be done? How many of them are testing positive? And this is just some information. The majority of kiddos that are being tested because of the high-risk protocol do have interuterine growth retardation or small for gestational age. And if you wanna know more about this, we just published an analysis of our high-risk testing program, and it just came out a couple of months ago.

So in terms of CMV test specimen, again, remember, we're not doing blood, urine or saliva. When we first started, it was about half and half, half urine, half saliva. This represents the first tests that were done. Over time, you can see an astronomical increase in urine versus saliva. And that's because saliva, if it's positive, it has to be repeated with urine, and so most of the time, people are just going ahead and getting a urine sample, and that's the gold standard, it has excellent sensitivity and specificity. When we look at demographic analyses, pretty much our cases have aligned with the population of the county that they're in. We also found that in terms of gender, there were pretty much equal amount of positive children that are male versus female.

And also, the maternal ethnicity lines up of congenital CMV cases with our population in Utah. Same thing with race. We track the baby's hearing very, very diligently. This is partial data that's been analyzed. This doesn't line up to 100% because we're looking at ears, and sometimes there's an asymmetry in the child's hearing in their ears, actually a lot of times. But for example, the hearing at the first ABR, 52% of the babies had hearing loss. At the most recent diagnostic result, almost 90% had hearing loss. And again, we know about the propensity for congenital CMV losses to progress. We also saw the biggest difference in mild to moderate hearing losses becoming severe to profound. Hearing loss progresses, and we track at what point that happens, and you can see we broke down by different points of time.

54% of the children did show progression within the first 12 months of life, and then the next biggest group was 25% progressed between 30 to 80 months, and our average time was 18.5 months for progression. We have a very strict to have a baseline ABR, whether or not they fail their newborn hearing screen or not. And then every three months until the age of three years, they need to be tested, and then every six months until the age of six years, and then annually thereafter, and then sooner at any time, if concerns arise of course. This, I wanted to show you that hearing loss fluctuates. I wish there was a phenotype, a typical phenotype for congenital CMV hearing loss, but it's kind of all over the board.

And now here are some specific cases where we saw improvement after a few months, and then the next time we saw that then they decreased again, and sometimes they improved again or decreased, and so it definitely fluctuates. And so, that's why we really need a super strict monitoring schedule, because if the kids are fit with amplification, I mean, you need to be sure that their amplifying how their hearing is currently in what they need. Early hearing detection intervention, the national EHDI milestones are every baby should be screened before one month of age, they need to

be diagnosed before three months of age, and early intervention enrolled before six months of age. And these are very important, that's all research-based, evidence-based, and we know that research shows that the baby has to meet the one and the three and the six to have their best chance of success.

And so, in Utah, we always say we're the half-three-six, 'cause we need to have our babies screened and re-screened before a half month or two weeks of age, to allow for CMV testing before three weeks, and then the three and the six. So I hypothesize, when we got this law, I wondered if having the scrutiny on timeliness and getting the baby screened and re-screened in enough time to have CMV testing, if it would have an effect and improvement on our three month milestone, and it surely did. So in the two years before the mandate, we were... 28.9% of babies received, met that three month milestone. In the first two years after the mandate, 56% of the babies had reached their three month milestone.

And in the most recent two year span, almost 78% were getting diagnosed before three months. And so, we really saw a huge increase and a huge benefit just overall in EDHI, and it improved all children, so whether or not the children even had CMV testing or not, just after 2013, there was a huge increase in this milestone attainment. And we did publish a paper that talks about the benefits that we saw in improving our diagnostic milestone, and if you wanna check it out, it's in Pediatrics 2017. So what do we do with our positive kiddos? They're tested with saliva, they're confirmed with urine, like I said, they're referred to our multidisciplinary congenital CMV clinic. And in that clinic, it's a one-stop shop, it's up at our primary children's hospital.

They get to see pediatric ENT, infectious disease, neuro, ophthalmology, audiology. That's where all of their blood work and scans and their head ultrasounds are done. The team then decides, is this a child that could benefit from antiviral therapy? But it's a really awesome clinic. So we started off with interest in our stet CMV research

working group that I talked to you about. So the specialist would talk and discuss cases and then eventually, it came to be, why don't we just form a clinic itself? And so we do have our CMV clinic, which is great, and even if a baby is born in a far-reaching part of our state, like in the southwest or southeast corner, they can actually come up to Salt Lake City to our primary children's hospital and be actually put in as an inpatient, get to see all the specialists, get all their testing done as a one-stop shop, so it's been a wonderful thing.

And these specialists will guide, they'll reach out when we have a positive case, they will reach out to the primary care provider to help them know what's the next steps for that family. The child's also automatically referred to early intervention. It is a qualifying diagnosis for EI, and that became... After we had our law passed, we were able to get it added to our qualifying diagnosis for early intervention. And even if they don't have any known concerns or delays or hearing loss, they're still eligible and have their growth and development monitored over time through EI, and then they're entered into our registry and then tracked for longitudinal outcomes. So some highlights of our Utah hearing-tested CMV testing.

As I said, it's now a qualifying diagnosis for EI. Overall increased awareness, top-of-mind awareness of CMV, and the risks of CMV during pregnancy has exponentially grown in this decade. As I mentioned, there's huge improvement in our three month EDHI diagnostic milestone attainment. We have a multidisciplinary clinic now, and there was times when the only reason why the child was tested was because they failed their newborn hearing screening. But once they got in to see their specialist, and get tested, and have scans, and have blood work done, they discovered that this child has a lot of signs of congenital CMV, like paraventricular calcifications in their brain, and they discovered that this was a child that, gosh, they really could benefit from early antiviral therapy and they never would have been tested if it wasn't for our hearing-targeted testing.

So for states, and/or hospital systems, or hospitals that only wanna do universal screening or nothing, the hearing-targeted testing has really done a lot and it's opened the door for, like I said, the high-risk testing that has occurred, and increasing that top-of-mind awareness has really grown, which is very exciting to see. As I mentioned, being able to add the reporting of CMV tests to us via the communicable disease reporting rule, has been huge, you know, just getting the test receipt, and that standing order, I can't underscore enough how great that has been for everyone involved, especially for the families too, 'cause we know when they get to the lab, the correct test is gonna be done.

Having CMV champions is essential. So people in your corner who are gonna go and talk to other hospital systems that may not be doing the high-risk testing protocol, and talk about how important it is, because these babies are being missed, and I'm doing that example specifically because we have those that are trying to reach out and do presentations and lunch and learns to those other birthing hospitals and neonatologists who may not yet be on board with high-risk testing. Having a dedicated person tracking these tests and doing follow-up with the families and providers is huge. If you can get electronic lab reporting, it's best, and that standing order facilitates it, and same thing with the communicable disease rule, because those results automatically get sent to us at the department.

And education never stops, providers, you know, there's new providers all the time, and so it's an ongoing, it's ongoing. Every training that we do, we talk about... Any newborn hearing screening training, any children's hearing aid program training that we do, we're always talking about CMV. And there's a lot of times that you can get CMV into a conversation and talk about the importance of early testing, and even more importantly, awareness of it and how women can do some behavioral strategies to lessen their risk. I'd like to personally invite all of you to come to Salt Lake City in honor

of our decade of our legislation. We are hosting again, the National CMV Public Health and Policy Conference here in Salt Lake City.

It is over Columbus Day, so maybe that might help some individuals where they might have that day off of work, so that's less time they have to take, but we would love to have you here. And this is our website, and also the website address of the amazing National CMV Foundation. And I am here to take any questions. Oh, that is the link for the conference, cmv.usu.edu, and registration is open.

- [Moderator] Thank you so much, Dr. Browning McVicar. We're gonna go ahead and open the floor for questions. We don't have anything in the queue as of yet, but feel free to drop any comments or questions that you have for Dr. McVicar, and we'll get to them.

- I think there was a question that was just put in here and the question was, "What was the biggest challenge?" Okay, I think one was overcoming the resistance of some in the medical community, about the legislation, because they did feel that the state was overstepping their bounds in legislating the CMV testing. So that was a barrier that had to be overcome, and that was overcome through use of partnership, and working together, and trying to do everything possible to be their partners in this, and give them the tools that they needed to be successful. Another challenge, sorry, there's more than one, was being able to get the lab results back. And so, that was a struggle and we did a lot of quality improvement projects in the process, when we knew we just weren't getting the test results.

And so, we overcame that with the various steps that I said about amending some rules and having that standing order to give direct reporting to us, and that was really, really big. And then, this is a question from Kimberly, "I wasn't sure what the light blue color on the map meant. What is the state of screening for CMV in California?" They

have proposed legislation, it has not yet passed though, but that's something they're actively working on. And I know that there are some, I know LA County is trying to conduct cytomegalovirus surveillance, so there's a lot of movement and effort in that. It's just that there is not... The legislation that they put forth has not passed yet.

And, well, I shouldn't say it's passed, it actually did pass, but then the governor vetoed it, they said because of cost. And so, that's... There's still a lot of interest and discussion regarding that. Have we had difficulty getting babies tested on time in more rural communities? Well, I'm gonna have to say no, believe it or not, and that's because our rural and frontier hospitals are small, they don't have as many births, and the newborn hearing screening coordinators and team there are very well connected with their community and the rest of their hospital, and so we didn't find a lapse in testing in those hospitals. Actually, just the opposite. We found, you know, if there was a hospital and they had 20 children that needed the testing that year, that they were getting 20 children, because they have the time and the ability to take that baby right down to the lab or have the lab come to them and get the CMV testing done, and they're very responsive and then letting us know, giving us, like closing the loop, sharing the results with us.

And I think it's because they have the time with the smaller birth load. The hard part in the beginning, was the really high birthing hospitals that might have had like 4,000 births a year, when that was a lot harder for them to keep track of. But that was in the beginning and now they're all really, really excellent. Could we have done this without funding? I'm gonna say yes on the testing for sure, because the funding did not go towards the testing at all. We just assumed any of the time and costs of personnel on this. The funding did go towards our large scale public awareness efforts. But you can still do education and awareness, and you can do lunch and learns, again, you have to have a division, or a bureau, or an office, that is willing to support you in that, in educating about CMV.

But if you can pair it along with something you're doing anyways, like let's say you're going out to a hospital and talking to them about the importance of newborn hearing screening and the state protocols, that's a perfect time to educate them about CMV and to think about, if the baby fails their newborn hearing screening, they should be tested for CMV. And why is it important? Because it's gotta be done before 21 days. So if you can pair it along with something you're already doing, I think you can totally do it. And if you wanna do larger campaigns or even just having materials or educational materials, again, try and work with students and university and colleges if you can, and they might be able to help, and that could be a low cost solution.

At what age is antiviral administered? So if the specialist determined that the child has the clinical signs that evidence shows could benefit from antiviral therapy, it needs to be started within the first 30 days, is what research is showing now, so it needs to be started early. It's not without risks, so it's heavily monitored. There's a lot of blood draws that occur throughout the treatment. Studies have shown six months of treatment right now, is the preferred length of antiviral therapy. The next question was, "What..." Oh, do we use the blood spot to help determine congenital CMV? So it is not our standard screening specimen, we use, and our state public health laboratory doesn't have validated assay for congenital CMV testing, I wish they would, but that might be something they might do.

They keep telling me they're waiting for it to get on the RUSP, the Recommended Universal Screening Panel. But we do have an MOA with them, where if there's a child that has late onset hearing loss and they're doing etiology studies, so for example, a three-year-old has late onset hearing loss, we do have the ability to have the dry blood spot pulled and then we will have a CMV PCR test done on the dry blood spot. And if it's positive, it's great and then we know it's a congenital infection. If it's negative, we still don't know. It depends on the assays, I know Minnesota's, their congenital CMV

testing on dry blood spots has a really high sensitivity, and I know it varies based on lab and techniques and that, but it's a great thing to do, particularly in those late onsets as part of our etiology studies.

And then, what are our next steps? Our next steps I think are, now that we have a really robust registry that we've created in REDCap, we're at the level now where I think we could do some really, really in-depth longitudinal analysis on these kids, particularly because we've been, you know, testing them now for 10 years. I'm also always trying to improve the process and we're working now, on closing the loop on providers, and particularly pregnancy care providers such as OBs or maternal fetal medicine, to make sure that they know that a baby has been born that has congenital CMV. And again, it's that top-of-mind awareness, and the incidence is 1 in 200, which is a lot.

However, if not, if there isn't universal screening, we don't really even know what the incidence is. It's supposed to be 1 in 200, but if the babies aren't being tested and they're completely without signs and they pass their newborn hearing screening, we may not ever know. So it's important when there is a known positive, that that feedback loop is closed and it's reported back to their pregnancy care providers, so they do realize that, yeah, it's real and it is affecting some of your patients and their children. And how are parents? Well, we... Our parents are still wonderful. Like I said, the power of parents, not only with advocates, but we have our parents along the way, and vetting our materials.

We have two parent consultants that work for the EDHI program and they're right there with us, providing the parent perspective. We are adding additional parents. We try... We have what we call an EDHI Volunteer Parent Network that our parent consultants have created, and we do have parents of children that have their hearing loss from CMV that are a part of it. So again, bringing them to the table, listening to them, how the process could have been better, and helping to advocate. And a lot of them will

volunteer to help us when we're doing an educational event too, it's really pretty amazing. So the next question was from Lori, "By doing the congenital CMV screening, how much has hearing loss and other orders... How much has hearing loss and other disorders decreased in positive cases?"

I'm not... I don't quite understand that question. So, Lisa, I mean, Lori, are you saying that with treatment? Oh, okay. Thank you. Okay. We do have a researcher here, Dr. Albert Park. He's amazing. He's a preeminent researcher on congenital cytomegalovirus and he is a pediatric ENT, and he's been doing studies of antivirals in children that are... It's a research study offering treatment for antivirals, a randomized control trial for treatment for children that only have hearing loss, and looking at their outcomes. And he published a study maybe two years ago, that... What they found was the antiviral treatment with children that only had hearing loss, it appeared to halt the progression of hearing loss, like keep it at bay during that critical time for language acquisition.

So, you know, in the early toddlerhood, it was able to keep the hearing loss from progressing. But what he did find then, is eventually, the hearing loss did progress. So is that not successful or is that successful? Because during that critical window of communication and language acquisition, as we all know, that's so important, if it was able to maintain usable hearing, I call that part of it a success, but it's interesting that the results of antivirals may not be permanent, and there's still much more that needs to be studied in regards to that. But that was a great, great question.

- [Moderator] Thank you, Dr. McVicar, I think that's the end of the questions, and we're gonna go ahead and wrap. We just wanna thank you so much for being part of this series. For those of you who missed the first couple, they are available on AudiologyOnline. And please stay tuned, this is only the third of seven courses, so thank you so much, Dr. McVicar.

- Thank you so much.