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EHDI – Florence

The Utah Cytomegalovirus (CMV) Mandate: A Five-Year Review

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March 5, 2019

4:15 – 4:45 pm

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>> Do we just start at 4:15 or do you tell me? Do I wait for your signal? It's 4:20? Oh... okay... they're doing ten minutes between sessions this time? Instead of five, right? It made a big difference this year ‑‑ they really listened to our comments. It's too hard to get to the next place in five minutes.

All right... I got the thumbs‑up, so we're going to go ahead and start. First of all, I want to thank you so much for being here. I'm the last half of the last session on the last day, so... I really didn't think I'd have anyone in here besides my colleagues, so... anyways, you get a treat for coming. These are our CMV ‑‑ we have lots of CMV swag we've done in Utah. They're nice vanilla mint SPF15 lip balm that say "protect your baby to prevent CMV." I'm going to pass this around... help yourself.

>> Thank you.

>> Well... thank you for being here. Okay... so... my talk is a review of the Utah Cytomegalovirus Mandate. Our legislation took place June of 2013. I'm Stephanie Browning McVicar.

In our state, our program is 3:1. It's the EHDI programs, it's EHDI, it's our cytomegalovirus public health and also our children's hearing aid program. They're the three audiology state laws in Utah that reside with us. I want to give a big shoutout to Jill Beckar, she's our CMV data and follow‑up coordinator. She's retiring in a few weeks. She didn't want to come.

So... anyways... she was a huge help in terms of helping to put this presentation in the data together.

So... for the Department of Health, we have to put our mission and vision of our Health Department on all our slides. I'll let you take a peek at those. Strategic priorities for Utah are to be the healthiest people in the nation to optimize Medicaid and be a great organization to work. If anyone asks you if I read those, please say yes.

They do check up on us. So... there's a few learning objectives I want to cover in this short amount of time we have here today. I just want to talk about some of the issues that we had to face, having nonuniversal CMV screening mandate, which no one has at this point anyways, a universal screening mandate. I want to show you some of the preliminary outcomes, show you some of the challenges we met, some of the successes and give you tips on strategies that we took to make our program better.

So... for those of you who are not familiar with the Utah CMV law ‑‑ and I apologize ‑‑ I'm not doing anything about CMV and the virus and prevention strategies and there were lots of really great sessions that were here that you could look up. That went over those types of details ‑‑ we have a two‑prong state law ‑‑ a public education component that puts our program in charge of educating women that will be pregnant on the risks of CMV and also medical providers. There's lots of different groups listed that we have to provide this information to.

Here's some of the fun stuff we've done over the years... we've had lots of transit campaigns or we have CMV ads on buses and trains and inside the buses and trains and Spanish and English and billboards and we try to hit our demographic of childbearing women and so... we target a lot of our universities and we have CMV ads in their football programs for Utah state and university of Utah and of course, BYU. We have them in our musical theater bills and we have them, also, on the big screen ‑‑ we have public service announcements that we play in our ‑‑ in our Cinemark and our mega plex theaters that run throughout the year to try to capture our demographic and Shannon knows, usually in the summer, we sponsor the Salt Lake Bees. We don't have a national baseball team, we have an AAA team. We go and it's usually 105 out and we're on the concourse, handing out hand sanitizers and serving women who walk about CMV. It's a really inexpensive way to have fun during the summer. A lot of families with children come to the ballpark.

And here's just a few more of those. So... that's the education part... for the testing part ‑‑ if the newborn baby doesn't pass the newborn hearing screening tests and I'll define that for you in a minute, their medical practitioner must test them before 21 days of age. We know that's because that's the window to detect a congenital infection versus an acquired infection.

And... that we also were in charge of creating information to disseminate to families and also to their medical providers, so they knew what to do in terms of getting the testing done.

So... in the rule, we clarify the code or the mandate and we ‑‑ we clarify that the baby must not pass their in‑patient screening at the hospital level and also their out‑patient rescreen when they come back.

So... if they don't pass that second out‑patient rescreen ‑‑ that's when they need to be tested for CMV, or... if the baby has their newborn hearing screening for the first time and doesn't pass... if they're already over 14 days of age... even though they only didn't pass one screening ‑‑ they're to go ahead and have that CMV testing done, because they already lost two weeks of life, in terms of getting the testing done.

So... we're a two‑stage state ‑‑ like a lot of the states that are here with us at the conference. The babies are screened at the hospital, maybe around 10 to 12 hours of age and then, they'll be rescreened. If they don't pass, they'll be rescreened again right before discharge, even though they might have two or three screenings in the hospital, that's still considered one screen. It's the in‑patient stage and the babies come back about ten to fourteen days for their rescreen. We realize making the recommendation to come back in ten to fourteen days, if the families missed their appointment ‑‑ the clock was really ticking and pressing on getting the CMV testing done in time if they didn't pass that one. Now we recommend that the babies really ‑‑ the hospitals try to get that back in about seven to ten days of age. All of our hospitals provide rescreening at no charge to the families.

This is just a pictograph of how our Utah Newborn Hearing Screening system works, when the family comes back, brings the baby, if they pass the out‑patient screen ‑‑ they're referred to their medical home to have a monitoring of their speech and language development, continuing monitoring of their hearing. As we all know ‑‑ the screening is not 100%. (?) If they don't pass, two things happen ‑‑ they go to a Pediatric audiologist for their auditory brainstem or diagnostic hearing test and also going to the lab to get their CMV drawn.

Now... drawn, I mean urine, or... saliva. So... blood is not a recommended assay and so... our testing that we use, our PCR testing, it's sort of the gold standard at the moment. We caution our families to make sure if you're getting a saliva swab, that they wait two hours after nursing before they take the swab.

In the beginning, there's not a lot of data on that. There was one study and we recommended to wait one hour ‑‑ the one study that was out there said they knew it was present in breast milk for 30 minutes. We went an hour, thinking we were conservative. We had false‑positives. Positive on saliva, negative on urine. We made the recommendation for two hours or more. Since that time, that seemed to take care of that issue.

Also, in our rule, we had a special populations and newborn clause. It's up to the discretion of the medical care provider, of our special population babies. Micropreemies are babies that are born very sick. If they can't have their newborn hearing screening before 21 days of age, it's up to the discretion of the medical provider if, whether or not they're going to test them for CMV.

We also had a reporting requirement that when a test was done, the medical provider who ordered it needed to get us the test results within ten days. Naively, I thought, it's a law, we're going to get every single test resolved ‑‑ we discovered that that was not the case and... we were always chasing down these test results.

So... we've done a few things in the years hence and... that has certainly helped us getting more and more lab results.

One of the benefits that we found with our CMV testing rule is that it improved our EHDI system. We hypothesized that more babies would meet that three‑month diagnostic milestone and so... I know it's kind of hard to see the graph, but if you're looking at left to right... two years before the mandate, we were completing about 60% of diagnostics before the three‑month milestone and... we looked at 18 months after the mandate, four years after and five years after the mandate and we saw steady improvement in that milestone attainment.

It's a lot of work, but so worth it, not just for the families that you're providing the services and the babies are getting what they need, but it was an amazing benefit to our EHDI program as well. We all know, the earlier, the better, right?

We look at a lot of our data and say "we got this many babies that were tested within the three‑month milestone, but what was the average age?" Are most at three months or two months? Before our mandate, our average age of diagnostic was at 40 days. Five years after the mandate... in that fifth year ‑‑ the average age of diagnosis was about 29 months. Today's 29 months. You stink, Utah, sorry. (?)   
[laughter]  
 >> 29 days. If they decide to go to the 1:2:3 which they've been threatening for awhile ‑‑ maybe we'll be in good shape because our babies are getting screened, rescreened, getting their CMV testing and getting their diagnostic ABRs all before one month of age. We're excited about that.

Another benefit was really scrutinizing what was happening at the hospital level with the in‑patient screen and out‑patient screen. We discovered some of them were not following state protocol ‑‑ what they were doing ‑‑ the baby would come back for the out‑patient screen ‑‑ if they didn't pass that ‑‑ they were having them come back again to, to rescreen them before they were referring to ABR and CMV testing.

So... sometimes they were doing it because of the population they serve. They have a lot of transportation issues and things like that. We have tribal communities in Utah that might not have insurance and... for whatever reason... they're doing what they think is best... but what we told them ‑‑ if you have to do an extra out‑patient rescreen ‑‑ please... if they don't pass that first out‑patient screen ‑‑ get them testing for CMV and so... we found that not only did they stop the rescreen process, but the babies that were getting a second rescreen were getting their CMV test so... that was really important. In the first year ‑‑ 15% of babies that were getting the multiple rescreens at out‑patient received CMV testing. In last year, we were 87% of those kiddos getting testing done as they needed.

One really super cool thing ‑‑ the neonatologists were one of the groups that came to me in the beginning and said "we're not happy with this legislation, we don't want the state telling us what we need to do" and... I just kept saying... you know... I'm just Stephanie, I'm just the messenger. I worked with them to do our special populations rule and... what we saw was because CMV became sort of top of mind awareness, we started seeing more and more NICU babies that were getting tested for CMV. We got some results. This baby's one day old, this baby's three days old, what's going on? If you see overtime ‑‑ the fifth year is at the far right. We're finding about 90% of our NICU babies across the state were being tested for CMV, which is really incredible.

In the summer of 2016, they put together a protocol that stated if any of the NICU babies had any of the ten symptoms that are listed... that automatically irregardless of whether or not they had their newborn hearing screening, they'd be testing for CMV. We're trying to collect that data, sometimes it's harder to get the babies that were tested in the NICU. Their CMV testing, what we found so far, the inner uterine growth restriction seems to be a pretty high‑risk factor on NICU babies for having Congenital CMV. More to come on that as we collect more data over the years.

So... we want to also ‑‑ we look at how many babies hit the mark of 21 days because... we know that if they're ‑‑ if we test them after 21 days and they're positive ‑‑ it's possible it was an acquired infection.

So... we did pretty good with the testing in the first couple years... of our mandate and then... in 2017, Jill, our data CMV and follow‑up coordinator ‑‑ she started providing assistance to try to get these families in to make the 21‑day window on the testing. And... sometimes when she would reach out to the families, she called them and it'd be a few days before they called back. Sometimes by the time those babies, if she helped them along, got tested, it was over 21 days. If we took out those babies that she had to help out with ‑‑ the rest of them did really quite well. 93, 94% of babies, just standard, were getting tested before the 21 days of age.

We also wanted to see the babies that missed the mark... were they missing it by a long amount of time or were they close? We found about half of the late CMV testing occurred within one week of 21 days and about 77% occurred within four days of 21, close, but no cigar. We knew if we could just take away a few days... we could make it.

One of the challenges is the out of hospital births being screened for CMV. That's why we wrote in the rule about the babies that get their screening after 14 days and if they don't pass, they need to be tested. Sometimes those babies get screened late because they're not right in a hospital that has access to hearing equipment right there.

In our first year ‑‑ only 3% of out of hospital birth babies ‑‑ and we have about 1500 a year in Utah, receive CMV screening, but we've seen a steady increase in our fifth year. We were up to 55% and people are like... that still stinks, but... it the better than it was and it took us 20 years to get 90% of those babies screened for hearing.

So... we're still working hard on it and hopefully, it's not going to take us 20 years to get CMV testing done on those babies, just in case you guys are curious ‑‑ I'm a data geek ‑‑ I like to track everything and saliva testing is done ‑‑ like, the blue line and urine is white. You can see it's about ‑‑ it's almost 50/50 on babies who are tested by saliva or urine. Babies are tested by saliva and receive a confirmatory urine. That's a different way of looking at it.

It was harder on the refer after 14 days, that's because of the out of hospital birth, but what we've seen is there's been a study increase in compliance over the years in all the groups. If we look at the percent of eligible testing per year of the babies that were supposed to get the testing ‑‑ the first year, we had 36% in the first six months ‑‑ there was a big learning curve with the providers. They had to order it and... in the last six months... of our fifth year... we were at 96% and... we're actually now at 98% in the last six months of 2018. And... I know I'm running out of time ‑‑ but I wanted to show you, if you look at different steps along the way that helped us get on the right path... we ‑‑ when we started the mandate ‑‑ we didn't have a reporting module. Everything was done by paper, it was done by different notebooks that had to be locked up. Our high track developers, our EHDI information system, they created a module. Hospitals could do direct reporting of lab results if they received them and our data coordinator started in 2015 when our direct service clinics closed at our Health Department and she became our data coordinator and... right in the center of your graph, in 2015, she started doing CMV report cards. She started creating them for the hospitals so they could see how they were doing and how they were comparing to their peers across the state. Apples to apples... so hospitals of similar size.

And then... we finally were able to get a CMV standing order in 2016, so our Medical Director put together an order. As soon as the baby didn't pass that second screening or met criteria, they were able to give them the order and they were able to go directly to the lab and that was just huge... and it ‑‑ we had to jump through so many obstacles to make that happen, but now that we have it ‑‑ it's been a really great thing.

When Jill started calling the families to get their testing done ‑‑ it helped, but... she found that if she could, a query was developed ‑‑ she runs every week ‑‑ when she sees a baby who is due for testing, she can call their primary care provider before their two‑week check‑up and tell them, this baby is coming in ‑‑ please make sure they get their CMV testing and that pushed us up above 90% to get us where we're at right now ‑‑ this is just a sample of what our order looks like.

It has information on CMV and why the baby needs the test. It has the order right there for the diagnostic AVR. Because it's signed by our EHDI Medical Director ‑‑ we automatically get those results from the lab. Here's an example of some of the report cards ‑‑ they've gone through many different versions, she tried to let people know how well they were doing. And what she found when the babies were tested, why that was ‑‑ sometimes it was that the physician got the order, but decided not to do it or the family broke their appointments or things like that, so they knew what happened after they left the hospital.

And... started giving them a graph of how their testing has been over time and we're trying to give them kudos if they're doing a really good job and then gently telling them if they miss some babies, what we found out, why that was ‑‑ maybe it was the message where the parents didn't quite understand what was happening ‑‑ that's a lot better now with our standing order.

And... do I have five or ten minutes? Five... okay... so... a couple other items with our data. We were able to tap into some other electronic medical record systems and able to get a one‑year grant to help audiological diagnostic testing and CMV lab results sent to the Utah EHDI program through a special linkage. This is kind of complicated, if anyone's interested in that ‑‑ talk to me after or pop me an e‑mail. That's complicated ‑‑

We also can break it down ‑‑ we have a large inter mountain Health Care system. Maybe 70% of the babies are in that system. We notice that in 2016, they were still only getting about 2/3 of the babies tested and Shannon, she's our audiology and compliance coordinator ‑‑ she worked with the corporate compliance person ‑‑ officer ‑‑ that sound a little scary, but she was able to get standard protocols at all of her hospitals to make sure these babies got tested and now they're doing amazing at 96%.

So... in five years, real quick, we've tested 1100 babies and... 29 of our hearing targeted infants. This is not NICU infants or special populations. These are just the babies who were tested solely because they didn't pass the newborn hearing screening. We identified about 2.6% of the babies. We had an additional nine who were inconclusive and if we included those ‑‑ they were 3.5% inconclusive. They were tested after 21 days and there were no other abnormalities.

Our hit rate's about three per hundred of the babies we test, show up positive for Congenital CMV and... the hearing loss, we did find... I don't know if you were in the room with the Boston group that was here. 86% of the babies had a unilateral hearing loss. We were able to find looking through medical records, calling parents and doctors and that ‑‑ follow‑up testing on 23 of the 29 babies and the bilateral rate, significantly increased and... the two progressed from normal hearing to bilateral. Three progressed from unilateral to bilateral. 48% had progression in severity or laterality. Is this when the progression happened. 40% within the first 12 months of life. 30% between 12 and 18 months, 20% between 18 and 24 and 10% between 3 and 4 years of age.

Let me just quickly go back ‑‑ I know this is draft data. I'm hoping we will publish and be working on that, but... a lot of the babies were mild to moderate at the start or severe to profound.

Because of our mandate, Congenital CMV is a qualified diagnosis for early intervention and a baby who has tested for CMV, under one year of age, had Congenital CMV added to our disease reporting rule. We automatically get the lab tests on that. There's overall awareness that's increased in the medical community as I showed you. We improved our three‑month milestone. A lot of the babies are getting earlier intervention. We decreased some of the out of best practice protocols with some of the hospitals. We have a Congenital CMV clinic now at our Children's Hospital. If a baby has Congenital CMV, they get infectious disease, otolaryngology and ophthalmology all in one stop shop.

The standing order is the way to go if you have a similar program and sometimes the only abnormality for these infants was not passing the newborn hearing screening which prompted other testing done, which guided their treatment. And having a dedicated data coordinator for CMV alone is essential. She works 32 hours a week. That's her ‑‑ she's my super girl. She's leaving me.

Sixth year, we want to survey the parents who didn't participate in the testing to see why they did not ‑‑ why they refused the screening. We want to look for possible sources of many ‑‑ the testing isn't done at the state lab. The cost... was ‑‑ is 200 to $300 and it is now one of the ENTs negotiated it with the big system to get it down to about $100. That's huge, but can be cost prohibitive and what we found too ‑‑ the babies who had normal hearing at their first diagnostic ‑‑ those are the ones we haven't seen follow‑up testing on ‑‑ so, we want to reach out to them and get them back in and see if they're starting to show any type of hearing loss.

And we want to create an EI protocol for CMV children. That's it! I know this was really fast. Don't contact Jill, because she's leaving me, but... this is my e‑mail and my phone number. We have websites and we have Facebook pages, so... I know this was quick, but if you have questions and you don't want to stick around, that's fine. Call me, e‑mail me ‑‑ I'll try to answer any questions that you have. That time goes so fast. Holy cow.

[Presentation concluded at 5:44 p.m. ET].

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