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Critical Congenital Heart Disease Webinar
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Presenter: Dr. Monica McClain

Please direct all comments/questions pertaining to this webinar to Thalia Wood at Thalia.wood@aphl.org or 240-485-2701.

Thalia Wood: Good afternoon and morning everyone. We'll get started here in just a second as we just put up the slides that announces what we're talking about today. I'd like to invite Amy Gaviglio to get this webinar started. Amy? Amy, unmute yourself. Star-seven.

Amy Gaviglio: Okay, sorry. Did that work?

Thalia Wood: Yes, thank you.

Amy Gaviglio: Thanks, Thalia. Thank you to everyone for joining us today for our Quarterly CCHD-TA Call. Today, we'll be talking about how screening programs can interact with State Birth Defect Registries to better understand the effectiveness and outcomes of Health Oximetry Newborn Screening, which is certainly a unique aspect to this particular screen and that there are other state programs that are also looking into how many cases are diagnosed with CCHD each year.

We're very lucky today to have with us Dr. Monica McClain who has done work in this area. Dr. McClain is research associate professor at the institute on disabilities, as the University of New Hampshire. She received her PhD in epidemiology from Tulane University and has a strong background in applied research, medical screening, and public health. The focus of her career as a epidemiologist has been on the evaluation and implementation of evidence-based practice in medicine and more specifically, genetic testing and medical screening. She was the PI for the HRSA funded CCHD Newborn Screening Demonstration Project that involved five New England states.

With that, I will let Dr. McClain start. You'll have to hit star-seven to unmute yourself. We cannot hear you yet.

Thalia Wood: I'm going to see if I can unmute her myself, here. Wait. Monica, are you there?

Amy Gaviglio: While Thalia is working on that, I will also remind everyone that we are hoping to make these TA calls more discussion-based, making sure that you're really getting what you need out of these calls, as well. Certainly, as you're listening to Dr. McClain's talk, please think of questions that you may be grappling with, in terms of working with Birth Defects Registries or even just basic questions that you have so that we can have a nice discussion afterwards. I do have some poll questions that we can go through as well, that can get the ball rolling if we don't hear from anyone else. We want this to be as helpful for you, so please speak up.

Gerard: Hi. This is Gerard. Can you hear me?

Amy Gaviglio: Yes.

Gerard: Are you sharing slides? I'm on your ReadyTalk Conferencing site and they're ...

Thalia Wood: Yes.

Gerard: ... it's just light gray. Are there slides up?

Amy Gaviglio: There are slides. I can see them. You might have to go out and come back in, maybe.

Thalia Wood: This is Thalia. Monica, I did unmute your phone. Can you say something so we can see if we can hear you now?

Monica McClain: Sorry. I was trying to join by phone and that's why there was a moment of echoing. I am now using my computer audio. Is this okay?

Thalia Wood: That's fine. Go ahead and just tell me when you want me to change slides for you.

Monica McClain: Okay. Sure, go ahead and change ... Next slide.

The project that I'm going to be describing what funded by HRSA, actually under two separate grants. One was for the CCHD Demonstration Project and the other, this was an activity of the New England Genetics Collaborative, as well. For those of you who aren't familiar with the genetics collaboratives, I'm showing a map that shows how HRSA has divided the US into seven regional collaboratives. We have a coordinating center. That's where the blue circle is, in Washington D.C. Actually, it's in Maryland so the NEGC comprises the six New England states.

We collaborated with the New England Birth Defects Consortium, which is a collaboration of all six New England states birth defects programs. The NEGC,

the New England Genetics Collaborative provided funding support to this project for the work on the activities I'm going to be describing. Next slide. Thank you.

We have three objectives for this study. One was to evaluate the documentation of Pulse Oximetry ... Sorry, A Pulse Oximetry screening for newborns with CCHD. The proportion of cases that were detected prenatally, clinically, or by the screening and then the outcomes of CCHD cases through the first year of life. Next slide, please. Five of the six New England states participated. They're listed there. The first Effects registries pulled information for all infants born in 2012 and 2013. We were focused on the primary targets of CCHD screening so it's the seven conditions that are listed there on your screen. Next slide, please. Here are the results. The name of the birth defect program is listed in the left-hand column. Then the next column is the type of registry that the state uses for their birth defects program. They were just under 160,000 live births in that two-year period. The number of infants with CCHD was 159 for a live birth prevalence of 10.2 per 10,000 live births across New England. Next slide, please.

Here's the breakdown by the seven primary CCHD screening targets. There were as you can see, 179 total CCHD's detected among 159 infants, meaning that some of those infants had multiple types of CCHD. Next slide, please. For these cases, they're broken down by state, here. You can see on the second row, about less than half had documentation in their hospital record that Pulse Oximetry screening was performed. The rate varied substantially so Connecticut had a very low-rate and you might recall from the previous slides that that was because they have a passive surveillance system. The high was New Hampshire that had it noted in 91% of the records. There was wide variation in the documentation. Of those records that noted that Pulse Oximetry screening was performed, about 75% actually had the Pulse Ox values that were written into the hospital record. Vermont, 100%. There were only five cases but all five had values. You can see the range there that varies from about 40% up to the 100%. Next slide, please.

We excluded Connecticut because of the low rates of documentation and looked at the remaining four states. There were 93 cases of CCHD that were noted. Of those, half were diagnosed prenatally. The other half were equally diagnosed by Pulse Oximetry screening or symptom-based screening. There were a few cases that we weren't able to ascertain how the case was diagnosed. Next slide, please. Then we further looked at the outcomes in their first years of life. There were 18 deaths. Fewer than half of those occurred within the first week of life. We looked at surgeries. We were able to ascertain the age for surgery, about 80% of that 159 infants. Almost half, they had their first surgery in the first week of life. The rest were between one week and up to one year of age. Just under a quarter had two surgeries in their first year of life. 5% had three surgeries during their first year of life. Next slide.

The conclusions from this study was that there is a low-rate of Pulse Oximetry screening documentation in the medical records. We found that the birth prevalence of CCHD was 10 per 10,000. Prenatal diagnosis occurred in a little over a-third of the cases, and that Active Birth Defects Surveillance Systems provided more complete data than the passive system. Next slide. For Birth Defects Registries to be useful and helping to evaluate the process of CCHD screening, we recommend that there be training for the professionals who conduct the screening on the importance of documenting results in medical records, providing funding and training for the state Birth Defects Registries to systematically collect and report on CCHD screening and outcomes, and increase collaboration with state newborn screening and birth defects programs to ensure followup of all CCHD cases and over-site of the sights that are providing screening.

I believe that was my last slide. I think the last one is just for questions. I did go through that a little bit quickly. I was just asked to give a brief summary, but I'm happy to answer questions or provide more details.

Amy Gaviglio: Thank you.

Thalia Wood: Thank you, Monica. I do have a question in the chat box for you. If there was a prenatal diagnosis, how many were sent out-of-state for delivery?

Monica McClain: We did not collect that information. I'm not able to answer that question.

Thalia Wood: Anybody have a question. You can type one in the chat box for us, or you can just do star-seven and unmute your phone to ask a question.

Monica McClain: Also, if there're others on the line who work with programs and might have an answer for their state, that might be helpful as well.

Amy Gaviglio: Monica, can you hear me?

Monica McClain: Yes.

Amy Gaviglio: This is Amy. I have a question and I know has always it seems, been a concern with the Birth Defects Registry. There appears to be a delay in when they're notified of a case. Can you speak to a little bit about did you see a lot of variation? Were they usually getting report of case within three months, a year? Did that differ between states that had active and passive registries?

Monica McClain: It definitely varies among states. I don't know that it's related to whether the surveillance system is active or passive. I think it varies, at least in some states, by legislation. We looked at periods of 2012 to 2013, which when we did the study was at least two years out. We were able to have complete ascertainment, but I know it's coming in New Hampshire for instance, for my state. They collect data once a year and go in and abstract all the information.

They're in New Hampshire, is definitely a lag time. It could be up to a year before people can collect, abstract that information.

Thalia Wood: Is there anyone else? Oh, hang on. Oh my goodness, there're questions coming up like crazy in the chat box. Hang on a second, here. "Thank you for presenting the results of your evaluation. We in Texas, are currently evaluating a legislative policy mandating the reporting of Pulse Ox data, via newborn screening. We are finding that we are now, are receiving a small number of CCHD's via newborn screening compared to our active surveillance. What recommendations could you give to a state that has an active surveillance?"

Monica McClain: I'm sorry. It's great that the Pulse Oximetry values will be met, will be required to be reported. We found that there were a lot incorrect interpretations so a lot of time, people might say that an infant passed or failed screening when in fact based on their Pulse Ox's, it should have been interpreted differently. I think that in order to help evaluate the screening performances, it's really great that you would have that, being able to document the values. That would be a start. I guess it would depend on the goals of your program, as far as what else you might want to collect but just the fact that Pulse Oximetry was performed in New England, was not routinely collected. Obviously, you would want that information, as well.

I think there was that other question about all up of that infant, whether they were actually, if they were transferred out-of-state, that might be more difficult. I know that there are a lot of restrictions about sharing data across state lines, but it would be interesting to be able to follow from the time the diagnosis was made, whether prenatally or postnatally. Then when the diagnosis, to when they were actually participated, or their data were entered into the registry.

Thalia Wood: Thank you. Actually, there was that little to bit to that last question but looks like you answered it for what this person was requesting. Thank you. Another question or another comment, rather is, "Incidences of CCHD and rates of prenatal diagnosis seem low. Makes one think there may be babies with a prenatal diagnosis that aren't included."

Monica McClain: I think that what we found in New England is for instances, babies who were born in Rhode Island, which is almost all babies are born either at or very close a tertiary center, almost there were no cases detected by screening because almost all of them were ascertained prenatally. However, in northern New England, Vermont, New Hampshire, and Maine, many of those woman don't have access to the events of all ultrasounds etc, and so we see higher rates being detected prenatally in northern New England. I think the combinations of our populations in New England average out to where many or most are detected prenatally to only about a-third are pre-detected prenatally, depending on where you live and where you receive your face.

Gerard: Hi. This is Gerard. Can you hear me?

Monica McClain: Yes.

Gerard: This is fantastic work that you've done. Again, Gerard Martin in Washington. I agree about the comment about the prevalence, but we have to remember that this is only the primary conditions that were listed in the very first AHA paper. We really do think that the expanded list, the 12 conditions if not, 13 that now the CDC group talks about, maybe a more appropriate list of conditions. I know that these are the ones that we started with. I think if we included the 12 or 13 conditions. If we can figure out how to count critical AS, we would see that prevalence number go out. My other comment is despite that, I think your results are very encouraging. They're very similar to those that were published by the group in Germany, [Reedy 00:18:39] where they had very high prenatal times. They had just over 50% of their cases found prenatally. If you looked at the remainder of the conditions, they were half-found by clinically and half-found by Pulse Oximetry, which is essentially what you've shown, as well.

Again, this is very strong evidence that this is a valuable addition. I couldn't agree with you more on the needs for the active reporting because only with active reporting are we going to learn about the proper administration of the test, and to being able to do quality improvement work. In other words, to make sure people are applying the rules correctly or ultimately as Andy, as your's says in Europe. He says, "Only if we report them all, will we be able to strengthen our screening guidelines." In other words, are we using the right algorithm? Right now, we're using an algorithm that was meant to minimize the false-positive rate, not maximize on the testing all babies. It was really a "Let's not have a lot of false-positives".

I think a move like Texas has done is very important. I just want to thank you for putting this work together. I think it's awesome.

Monica McClain: Thank you, and if I can add to one of your comments. I think what I wish we would have also been able to do in this analysis, in addition to including all of the CCHD diagnosis is to be able to say which disorders were associated with being detected prenatally versus which ones were detected, either by screening or symptomatically. You know, just some very preliminary things that we saw for this project that wasn't part of this birth defect surveillance but in our demonstration project is we were finding that some of those secondary targets were being detected by screening and the types of lesions that were detected by screening seem to be pretty consistent. The TAPVR's, the TAPVR's, it was more common to detect those by screening. I think by having that information as well, would help to determine algorithms and what might be appropriate or not.

Gerard: One question also, were you able to look at that in your region? I guess what I'm getting at is, I know California has started to do this. They had the really important data early on that showed the number of babies that were dying each year in the state of California. That really hadn't changed much over, gosh ... I

think it was like two decades. They've looked at the first two years since screening started. They're not finding change, but they don't know how many of the hospitals, when the hospitals turned Pulse Oximetry Symmetry testing on. I think it's still too early to know what impact. Do you have from your data, any idea of the babies with CCHD were diagnosed post-discharge versus pre-discharge?

Monica McClain: Yes, we have those data. I'm not able to tell you which of those babies actually died.

Gerard: Okay. That's really ultimately, going to be the most important thing, isn't it? That we show there is a survival benefit for a less harm for the babies that have a timely diagnosis before any neurologic and organ damage is done that may prolong their hospital stays and cost more for the system?

Monica McClain: That is interesting. Now that I think back on it, we may actually have that. I will have to go back to the data set to make sure. I think we were only provided information in the aggregate so that's why initially, I didn't think we could go back to see in which of those cases those deaths occurred, but maybe. Thank you for that comment because now it will help me to go back and see if we have that information.

Gerard: If there're other things, I would be more than happy to talk. I'd love to see your data more because I think I could come up with five or ten other questions.

Monica McClain: Great.

Gerard: I never have [inaudible 00:24:27] ask questions.

Monica McClain: Are there any other states that you're aware, or anybody on the call, where the other two are being linked? Has anybody else used the Birth Defects Registries for this?

Amy Gaviglio: Yeah. Can you hear me, Monica?

Monica McClain: Yes.

Amy Gaviglio: This is Amy again, in Minnesota. Yeah, we are linking it. We actually are getting our raw Pulse Ox's values, as well. We actually, just kind of changed the way we started working with our Birth Defects Registries is because I guess, in an effort to try to utilize their ability to abstract and try to increase the timeliness that they're being notified of results, we actually, in addition to the hospital sending them the ICD-10 codes with diagnosis, we actually are now serving- by "We" I mean the newborn screening program, is serving as kind of a case reporter as well, for the Birth Defects Registry. We report to them when we have a failed case, and they will actually go in and do the abstraction. It's a lot faster than they're used to which is nice for them, but it also gets us the followup

information more quickly. That's a new approach that we have literally, just started with our Birth Defects Registry, outside of that case-matching to see where the false-negatives are and other outcomes.

Thalia Wood: Thank you, Amy. We actually have a couple, another question on a comment in the chat box, and then we actually, were going to ask those questions, Monica, to the whole listening audience about their linkage with birth defects in a few minutes. One the question is, "Did you note gender differences in surgery repair for CCHD's as you followed the infant for the first year of life?"

Monica McClain: Again, it's been a while since we did these analyses. I don't recall ever having the gender information but if we did have it, we didn't use it so that could be why I'm not remembering. We did not look at that and I would have to go back and see if we received that information.

Thalia Wood: Thank you. The next one is actually a comment. I think because of what Dr. Martin talked about in Texas. It says, "We are linking them now in Texas. The full 12 or 13 CCHD diagnosis but the data is preliminary. We have a two-year lag period, but finding that most of our CCHD's are being found in via active surveillance versus new born screening post-op." That was just a comment. Then we have another comment here, "In Alaska, we literally had this conversation yesterday with our Birth Defects Registry. We don't get raw data from facilities, just total numbers i.e. we screen versus how many babies referred. We are now hoping to do linkages between the Birth Defects Registry and new born screening. Our Birth Defects Registry usually just gets ICD-10 codes so we are working together to confirm cases."

Do we have any more questions or comments for Monica? Dr. McClain? Otherwise, we do have some survey questions that Amy's going to lead us through.

Marci: Hey Thalia. This is Marci. I have a couple of comments. My first comment is about the Birth Defects Registry and in Colorado, we just started screening and beginning of this year and are collecting the Pulse Ox's data through the electronic birth certificate, but we are collecting, we're matching with the Birth Defects Registry and haven't gotten to the extent of what Amy described, but had pretty good luck in being able to match those in pretty decent time. My second question is, you mentioned when you were presenting, or actually my only question is when you were presenting, that you were able to identify some misinterpretations where somebody said the baby failed, or they didn't, or visa-versa. You think the Birth Defects Registry, are you able to then go back to the institutions and help to education? Are you using that for quality improvement or is it because of a delayed agenda being a little bit lost?

Monica McClain: I think that and interesting question, and I think that states that have an active system could do something like that if they didn't have a long lag time. I guess, even if there was a lag time they could still go back and use that for quality

improvement. When I said that we were finding misinterpretations, that was not in the birth defects part of this study. This was in the actual demonstration project, so when states were sending it, that's when we saw the incorrect interpretation. I think that to the extent that those hospitals or providers that are reporting on the values, it could be used for that purpose. At least for the positives, I think it would be really difficult to see if there were false-negatives that would probably be overwhelming but at least for the cases that are identified and the Birth Defects Registry to see, and they were detected by screening to see what their values were.

Marci: Got it. Thank you. That's very helpful. That's in my mind, this is one of the biggest benefits public health can provide to CCHD screening, is that monitoring of the interpretation of the test. Are the nurses, the facilities, interpreting this correctly and look reporting, especially those positives, appropriately? Potentially, could be something that could be missed in birth defects but as I think as you point out, some ways around it especially with the active surveillance. Thank you. This is a very interesting presentation.

Amy Gaviglio: Marcie, I think it's a really good point. Now, I'm thinking more about the linkages. I think where we also really can help is going back and looking at those cases that are not picked up by screening, or prenatally, those so called, "Complete false-negative cases" and looking at what were the Pulse Ox's values and really thinking, or at least being able to use that data to rethink or refine the algorithm in order to pick up those cases if that's what we ultimately want the goal to be.

Marci: I'm in complete agreement.

Amy Gaviglio: I could see you're nodding.

Thalia Wood: You want to go ahead with the poll questions then, Amy?

Amy Gaviglio: Sure. Unless you have any other comments in the chat box or if anyone else has any other questions, or thoughts, or experience with their Birth Defects Registry that they want to share? Again, it is star-seven to unmute yourself.

Gwen: Hi. This is Gwen Faust from Michigan. Can you hear me?

Amy Gaviglio: Yeah, we can hear you.

Gwen: Just to mention what's happening here, we are linking our newborn screening card number so that with the Pulse Ox's symmetry screening and then can also, check it against the Birth Defects Registry. We also have hopes of being able to connect with the centers that do pediatric cardiac surgery in the state, in order to determine false-negatives, but we haven't been able to actually make that happen yet, due to IRB and other considerations. In our own institution, we have been able to followup on some infants that have been admitted with

critical congenital heart and look back to see what their Pulse Ox's symmetry was. We have found obviously, some false negatives and also as someone else mentioned too, we are finding situations where the screening algorithm isn't completely adhered too, so that makes for some differences, as well.

Monica McClain: Thank you. That's really interesting. You guys are always so great in Michigan. I think of linking your systems as much as you can. I guess, similar to what Marci asked, we have also seen quite a few times where the algorithm is not being followed, even though our system is supposed to tell them what the result is, they seen to override it, at times. Have you in your institution, come up with ways to make that better? Do you have any thoughts on how maybe we, even as a greater program, can make that easier on the end-user?

Gwen: We get a preliminary report twice a week and have key people to look at it to try to detect those things and correct them than before we actually submit to the state. Then if the state finds differences, they let us know. Then we followup moving backwards. It's not perfect, but we've certainly seen ... we started reporting the screening in spring of 2014 and definitely, the adherence to the algorithm and the correct reporting has certainly improved in the time since that started.

Monica McClain: Just another followup question. Sorry. When you say you followup on those cases, do you actually bring that child back in to do another screen or make a recommendation to the primary care provider?

Gwen: Actually, we're trying to catch it before they even go home. Most of the ones that are questionable tend to be the babies that are in the neonatal intensive care unit, and are there a bit longer. Otherwise, if they have been discharged, then we will get it and see if there appears to be a reason to followup outside of the hospital.

Monica McClain: Thank you.

Thalia Wood: This is Thalia. We do have three more comments in the chat box here. They are actually comments, not questions. The first one just says, "You've given us lots of good ideas. Thank." The next one says, "Hi. It's Jean Grazel in New Jersey. All failed Pulse Ox screens are reported to the Birth Defects Registry. This allows us to identify the unique contribution of screening to the early detection of CCHD and other conditions. All Pulse Ox screening results are now reported to the electronic birth record. This gives us the ability to review the electronic birth record screening data and match it to CCHD findings in the Birth Defects Registry. We also use this mechanism for QI interpretation of screening results and state-wide screening coverage."

Then there's another comment that says, "It was constantly found that the false-negative rates are very different for the different regions. Coarctation continues to be our Achilles Heel."

Monica McClain: I don't think that they are alone in that. I think that's pretty common. Certainly, thank you for your comment, Jean in New Jersey. You guys have also done a fantastic job. Thank you for sharing that with us. I'm glad that that comment will be captured with the recording because I need to go back and listen to what you're doing again, for my own sake.

Speaker 7: Yes, I can just add to the comment of coarctation. We have seen also false-negatives for hypoplastic left heart syndrome.

Monica McClain: Wow.

Speaker 7: I know. It's scary.

Monica McClain: Was it because the difference was? Do you remember what the stat failures were?

Speaker 7: He stats were decent, interestingly enough. Yes.

Gerard: There are a number of babies with hypoplastic left heart syndrome that are having stats in the 96, 97 range.

Speaker 7: Exactly. Is anybody doing the profusion index and seeing anything different with that?

Amy Gaviglio: This is Amy from Minnesota. We are collecting it if the Oximeter collects it or has it. It's hit and miss because not all Oximeters have it. At this point, we're collecting it. I'd have to go in to be honest, and look and see how often we get it but we haven't done anything with it, yet. I'm not sure if other states are doing it or looking at it, either. We just happen to get it because we're pulling directly from the device. I know that's been mentioned before is a possible further refinement. That's a good question.

Gerard: It might be tough with hypoplastic. It's been good with Co-arctation and with [Viboras 00:39:15]. The problem with the hypoplastic with the high stats is that they probably do have their [duct 00:39:23]. Their ductus is wide open. They probably have normal PI's. Amy, your points thought about PI and I've heard other neonatologist state this, that they are still uncomfortable understanding what a normal PI value is. I know [Ann-Cronelly 00:39:43] gave us a really nice head start on this by giving us a ballpark of what her numbers of patients have with left heard obstructive conditions as far as [inaudible 00:39:59] us to less than .8 or less than .7 but we don't know how tight the population is around numbers in that range. In other words, it will be a real hard to come up with sensitivity and specificity. It always has looked like a promising tool. It's just there's still a lot to be learned yet, on using it.

Thalia Wood: Thank you for that, Dr. Martin. Amy, would you like to go ahead with the poll? I don't have any more questions or comments in the chat box.

Amy Gaviglio: Yeah. Let's move on. This is a pretty basic yes/no question and really, I think we were just hoping to get, to Dr. McClain's question, a lay of the land in terms of how many programs are actually have that active connection. If you could just hit one or the other and then press the next button. You could see it move in real-time. All right. It looks like 70/30-ish. I'm curious- No, we're still taking. I'm curious for those who answered no, if you would be willing to speak a little bit to why that might be the case? If there are barriers that you have, in terms of maybe data-sharing or trying to link two different programs, I'd be curious to know from anyone who answered no.

Linda: Amy. This is Linda [Kincaid 00:42:05] from New Hampshire.

Amy Gaviglio: Hi, Linda.

Linda: Hi. We don't connect with our Birth Defects Registry because our Birth Defects Registry is currently non-existent. They lost funding in this funding cycle so we have no Birth Defects Registry, at all. We're working on getting state funds for this, but at the moment, we don't have one.

Amy Gaviglio: Got you. Anyone else who answered no have additional barriers outside of having one to connect you with.

Julie: Amy, can you hear me?

Amy Gaviglio: I can.

Julie: Hi. This is Julie from Nebraska.

Amy Gaviglio: Hi, Julie.

Julie: The reason we don't link with our Birth Defects Registry is because the legislations that enabled our CCHD screening did not authorize us to collect data at all, and no funding to do so, either. We do have Birth Defects Registry and they do select what they can. As far as the screening, we do not.

Amy Gaviglio: Julie, your role is largely just to educate that it be done as more standard of care?

Julie: Exactly. We developed regulations for the hospitals and physicians.

Thalia Wood: Amy, there are couple of comments in the chat box. They keep coming in. It says, "In Ohio, one of our most daunting barriers is the electronic data collection and delays of getting the data into it." Then Delaware said, "Our birthrate is so low, we haven't had no positives yet." Wisconsin collects post-ops in the newborn hearing screening application, not in the Birth Defects Registry.

Amy Gaviglio: Okay. Interesting. Connecting those two points of care. I can see that. Interesting. All right, you have any other comments or should we move onto the next questions?

Thalia Wood: Yeah, there's no more comments. We'll go ahead and move on to the next one.

Amy Gaviglio: This one is really moving all over the place. This is interesting. I don't know. Marci, do you want to speak at all to this, in terms of the case definition work-group and what you know, in terms of birth defects case definitions? Sorry to put you on the spot.

Marci: ... what you're looking at.

Amy Gaviglio: You broke up. I'm sorry.

Marci: I'm sorry. Can you hear me? I'm on my phone and I have [inaudible 00:45:19] ?

Amy Gaviglio: Yeah, we can hear you a little bit now.

Marci: I can't see what you're looking at. What would you like me to comment on?

Amy Gaviglio: Oh, okay. Sorry.

Marci: I'm sorry.

Amy Gaviglio: I should have said something. The question is, if programs have worked with the Birth Defects Registry program to ensure that the same case definitions are being used for CCHD, and it's about a 60/40-is breakdown of 60% saying, "Yes," about 40% saying, "No." I just was wondering if you wanted to talk a little bit about the case definition work-group and maybe, how that may help ensure that [inaudible 00:46:03] ?

Marci: Yeah.

Amy Gaviglio: Thank you.

Marci: Absolutely. We're working on case definitions with a case definition work-group. Many maybe, most of the people in the work-group are on the call today. This is to use case definitions really for the purpose of newborn screening. We are building from the case definitions that have been built by the Birth Defects Registry. What we want to know is, what is the basic information that a newborn screening program would need to know to say, "Yes, this is a case of 'X', 'Y', and 'Z'?" How does it differ from what the birth defects program has and if groups are linking, how do we just build from those links rather than creating from a new system?

We are meeting again next week. We've had I think, just one meeting so far, but have been really trying to dig into what those definitions currently look like from birth defects in order to then make a seamless system, or as seamless as possible between birth defects and newborn screening to ensure that we are collecting similar data where possible, between the two systems.

Amy Gaviglio: Thank you. I guess, for those of you who have said, "No," which actually includes myself, I guess we will stay tuned for that. That will be very helpful. Do you have any comments in the chat box, Thalia?

Thalia Wood: Actually only one for Monica. It was Dr. Hokanson said, "Please thank Monica for a great presentation." He had to sign off.

Amy Gaviglio: Okay. Thanks, Dr. Hokanson. All right, let's do the next question.

I believe Thalia, you set this up but you can multi-select or no?

Thalia Wood: No. They need to choose the one that is the most important to them and I apologize I had to abbreviate the responses because I'm limited on characters. Amy, I don't know if you wanted to read what the complete responses were supposed to be?

Amy Gaviglio: I don't remember them.

Thalia Wood: That's okay. They actually didn't pretty much self [inaudible 00:48:17].

Amy Gaviglio: These are pretty self [inaudible 00:48:17].

Thalia Wood: Yeah. Just answer the one that's most important to you or is the top priority.

Amy Gaviglio: This looks like the confirming case matching. I think this is probably just making sure your Birth Defects Registries have the same cases as you have. That is how I am interpreting that. That's in the lead at 42%. Comparing Pulse Ox data with cases of 28% and then identifying false-negatives at 25%. It's about 3% saying, "There's no separate interaction." I'm guess that may be for those of you who don't have programs or are not collecting data. I think we've spoken a lot to all three of these already certainly, in terms of Dr. McClain's work and comparing Pulse Ox's data with cases identifying false-negatives. I don't know if anyone has anything else to add on this one. Anything, Thalia?

Thalia Wood: No. There's no comments in the chat box.

Amy Gaviglio: Let's move onto our final one. I think this was something that we wanted to end with. Of course, we always want to be looking at how we can better serve everyone, in terms of what they need to maybe better collaborate or figure out

how to collaborate if they haven't already, with the Birth Defects Registry. This is again, most important, correct, or your top choice for what resource would be helpful to best engage with your Birth Defects Registry.

All right. Looks like we have two that are going back and forth in the lead. In-person meeting to work with Birth Defects Registries, I am always a big fan of in-person meetings, as well. I'm sure new [sets 00:51:04] is not always a fan from a cost perspective, but we can certainly talk about that. I know that at the beginning of CCHD, there was an in-person meeting. I think that can be very valuable, both in terms of learning what you're specific state does in terms of their surveillance but also for them to learn how you are collecting data or if you are collecting data.

The other one is "Guidance docs and program rules". I'd be curious for people who chose that, if they could speak a little bit more to what they interpreted that to mean, just so as we look to putting things together, we actually get you what you had hoped for. For anyone who chose the guidance docs or documents, could you speak a little bit about what you think would be most helpful, in terms of that?

Julie: Hi. This is Julie.

Amy Gaviglio: Hey, Julie.

Julie: I didn't really answer that one. I said, "Other" but it kind of links to that. I was thinking that a guidance document with the kinds of questions that our data would be able to answer, would be helpful, as our data systems get developed. I think that idea was sparked because of what Dr. Martin had suggested, that he probably could come up with five or ten additional questions just looking at the data that they had from the presentation today. I think that's a great place to start is, what are the questions we need to know within what roles? Is it over-site? Is it followup? Is it quality assurance? Is it research? Is it quality improvement? If you could categorize what the questions would be and what the purpose of collecting that data would be, that might help us develop good data systems.

Amy Gaviglio: I feel like you were literally, just in my head, Julie. I seriously have the exact same question of, are we followup? Are we surveillance? Exactly, what are we trying to answer? I am bias, of course. I think that's a fabulous idea. I think that is something we should definitely work on because I think a lot of us have those exact same questions. Even those who have developed our data systems are kind of still asking those questions and what our role is. Thank you so much for saying that.

Thalia Wood: Absolutely. I think that a lot of people feel that way, as we've had those internal discussions. Another comment in the chat box is also on guidance docs if we only put guidance docs in the program role. Houston said, "Guidance documentations on what information people are using as diagnostic criteria based on the ICD-10 code. How to confirm patients? Our Birth Defects Registry wants flow-sheets, as such as so that everything can be replicated."

Amy Gaviglio: That's a great question.

Thalia Wood: Maybe, an in-person meeting with guidance docs as your topic would be appropriate for states.

Amy Gaviglio: Yeah.

Marci: This is Marci. Just thinking, I had the same thought when Dr. Martin presented or asked the question and said he had 10 additional questions. I was like, "Oh my gosh. What are they?" I would love to hear from Dr. Martin. Then there's probably, every [inaudible 00:54:50] would say, "Look at that data. I would have added sometimes just when we get together, we start sparking additional questions, different ideas come up." What can we really do with this because sometimes we do struggle a little bit with what our role is, what can we best do, and what can we best do with the data we have? We all can't have a complete data system so if you just have birth defects data, what could you do? If you just have screening data and you're not linking to birth defect, what can you do? What are the best questions to improve your program?

Then that leads to those guidance talks of, "Okay, what do we need to be asking and of whom, and when?" We love in-person meetings too, Amy. It's just a matter.

Amy Gaviglio: I know.

Marci: It's finding the funding and the time to do it, but I think there's something to be said about getting a group of really smart people together and having a conversation. You can't get things done in any better way, I don't think.

Amy Gaviglio: I agree. I was just joking with you.

Marci: I know.

Thalia Wood: There was one other comment in the chat box that's, "Somebody marks the guidance documents mainly because simply due to program turnover." I think that's always an issue with folks too, with fast turnover. We're almost at the top of the hour. Amy, do you want to wrap us up?

Marci: Yeah, I think so as long as you have nothing else in the comment box. Thank you first of all, to Dr. McClain. I think even though you gave a brief overview, it

obviously sparked a lot of interesting questions so thank you so much for taking the time [inaudible 00:56:27] because I know it's a little last minute for you, but thank you. Thank you very much. Then thank you for everyone who took the time today to be on the call. Definitely, we will be looking at the results of these questions and thinking about best steps moving forward, in terms of helping everyone with this specific topic of working with the Birth Defects Registries.

I think with that, Thalia, you have anything else to add?

Thalia Wood: Yeah. I have a couple more comments, came in real quick. "This is the first, CCHD webinar I've been able to sit in on. Thanks. Great presentation to start great discussion. Thank you." The second comment, it says, "Regarding guidance on program roles is on-point. Identification of funding sources to gather and analyze the data is [inaudible 00:57:21]." Well, I think we can all agree with that.

Marci: Yeah, we certainly could add that to the discussion because certainly, this can't be done without funding and resources. Thank you from whomever added that. That's a great point. All right.

Thalia Wood: Thank you again, everybody. This has been a great call. I think we have had some great discussion. That's what we were hoping for. That's what the format of these continuing, on-going forming webinars is all about.

Marci: Perfect. Thank you everyone, and have a great rest of the day and weekend.

Thalia Wood: Thank you.