



NewSTEPS

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Critical Congenital Heart Disease Webinar
June 2016

Presenters: Dr. Ilona Narayen, Dr. Devyani Chowdhury, Jennifer Holshoe, Dr. John Hokanson and Gretchen Spicer

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

Thalia: Okay, and now I'm going to go ahead and mute the phones and see how that works until we get in to the discussion portion. Bear with me one more minute.

Speaker 2: The conference has been muted.

Thalia: Okay, and now for the initial speakers just do star 7 on your phone to unmute yourself and we'll go ahead and get going. Welcome again to the June conference and Amy, are you on the phone?

Amy: I am here. Can you hear me?

Thalia: Yes, thank you.

Amy: Perfect. All right. Thank you all very much for joining us on this warm Friday. Before getting started and before getting in to the presentations, I want to quickly outline the new format that these CCHD Technical Assistance Webinars will be taking moving forward. After discussion with our CCHD Technical Assistance Work Group members, we really came to the realization that the conventional webinar format that we have been using was likely not providing the guidance that was really needed at this point to programs, given where many of us are in terms of implementation. We really discussed that the issues that we are dealing with now with CCHD implementation really seem to require more discussion rather than straight presentations. As a result of that, these webinars are going to change a little bit and I'm personally am really excited about the new format. Hopefully the new webinars will accommodate more discussion and provide and outlet for discussion around CCHD on a regular basis.

The format now will include a more brief presentation at the beginning to introduce the topic of the day or set the tone for the remainder of the time, which will be then, heavily discussion based. This discussion will be facilitated through a combination of poll questions that we have ready, as well as questions from participants as they are

brought up. That's just a brief overview of what to look forward to today and moving forward in the future.

Today, we focus on a topic that I think continues to come up, not only in the realm of CCHD screening, but certainly throughout newborn screening as a whole, and that is implementation and management of screening within the out-of-hospital birth population. We are very lucky today to have a guest speaker from the Netherlands who, thank you very much for joining us. I know it is evening over there, so thank you for taking an evening to be with us. We have Ilona [Narayan 00:02:49], is a researcher in the Neonatal Department at Leiden University Medical Center in Leiden, Netherlands. After graduating from her medical degree, she started with a four year PhD project to assess the feasibility and cost effectiveness of CCHD screening in the Dutch Healthcare System with home birth deliveries. Whenever you are ready Ilona, it's all you.

Thalia: Ilona, are you able to unmute your phone?

Amy: You can hit star 7 to unmute.

Thalia: I may have to unmute everybody. If I unmute everybody, please be cognizant that this is being recorded and keep the background to a minimum or mute your own phone. I'm going to go ahead and unmute the phones so we can hear.

Speaker 2: The conference has been unmuted.

Thalia: Okay, now Ilona go ahead and try to say something for us.

Ilona: Good morning, it is for you, I guess? For me, it's evening indeed. I hope everybody can hear me.

Thalia: Yes, we can hear you fine. Thank you so much.

Ilona: Perfect. Well, thank you for the introduction and for the interest in the experience of screening after home birth in the Netherlands. I would say that I have not conflict of interest and, I don't know if you can go to the searchlight for me, and the next one. The Netherlands is a tiny country in Western Europe. It's mostly famous abroad for having windmills, tulips, and varying bizarre outfits with the wooden shoes. Some of you might also know that we are also famous for having a high rate of home birth in this reach.

On the next slide, you can see a picture of our country and this shows that in the colors, the time in minutes to the closest hospital with 24/7 obstetric care in our country. What you can see in the figure below, you'll see that most inhabitants live less than 10 minutes from the closest hospital with 24/7 obstetric care and this is why

home birth deliveries are feasible with the quick access to obstetric and neonatal care if needed.

In the next slide, you can see a table with home birth rates per country. You can see that the Netherlands has a really high home birth delivery rate of 20%, which is high, especially for a developed country. Then, for our Dutch prenatal care system, see it in the next slide please. We have around 180,000 births per year, of which 70% are clinical, that means that they are supervised by a clinical midwife or a gynecologist in the hospital. When a clinical birth is uncomplicated, the mother and the child leave the hospital around 5 hours after birth and a community midwife performs the followup visits starting at day two or three of life. Even after an uncomplicated clinical delivery, there is very early discharge from the hospital.

The other 30% of births that are supervised by a community midwife can be either at home or in a hospital where you can rent a room or in a birthing facility such as a birthing hotel, but then there is no gynecologist or pediatrician involved in the delivery and also not in the followup. If you look at the next slide, you can see [inaudible 00:06:41] our community deliveries. In the Netherlands, we have 101 hospitals with obstetric care, but we have 1,850 community midwives working in our country. They supervise only the low risk pregnancies and they stay for approximately three hours after birth and the first followup visit is done at day two or three of life. The day of birth counts for day one of life. The midwives don't have the pulse oximeter in their standard equipment, they do have a stethoscope and oxygen, but furthermore they have all they need in one small bag.

For the CCHD screening, and then next slide, thank you, we all know that it is accurate, cost effective and acceptable. The AAP recommends the screen 24-48 hours after birth because then there are fewer false positives. However, there are also settings [inaudible 00:07:37] that is not feasible, for instance after early discharge or after home birth, and both are the case as standard practice in the Netherlands. For that reason, there is a struggle. If you would screen earlier, there might be a higher false positive rate, maybe also earlier detection of significant pathology. Amongst the policymakers in the Netherlands, there were a lot of concerns over when and how to screen, and especially who would perform the screening and what the cost would be for the screening. If you would ... the Midwives performing the screening, it would mean that all the midwives need a pulse oximeter and that would make it more expensive.

Before the government wanted to implement the screening in our country, they wanted us to perform a feasibility study and that was the Pulse Oximetry Leiden Screening Study. Just below the red arrow you can see Leiden, which is a small city, with 14 midwifery practices and three hospitals. To assess the feasibility of CCHD screening with an adjusted protocol, adjusted to the working schedule of the community midwives, we included on the term infants that were not being monitored and who did not get an echocardiogram. In these infants, pre and postductal oxygen saturations were measured with a handheld pulse oximeter. We [inaudible 00:09:06] performed measurements at two time points with the first one being at least one

hour after birth, because the first hour would be for neonatal transition and skin to skin contact. The second measurement at day two or three, so during the first followup visit from the community midwife or in the hospital when the infant or the mother were admitted for a longer period.

Ilona: The primary [inaudible 00:09:39] was the percentage of infants screened with this protocol as a fraction of all infants with parental consent. Secondary, we also assess the other pathology besides the lungs [inaudible 00:09:53] screening and the perception of mothers in the community midwives [inaudible 00:09:58] for them. In the next picture, you can see a screening algorithm we used. You can see that we had the same cut off values as used in the AAC protocols but we have only a repeat measurement once, if you have an abnormal value. All infants receive a measurement at least one hour after birth and day two or three. If you look right at the bottom, you can see that at day two or three of life, we did not receive a measurement when there was an abnormal screening. The reason for this is that the midwife had only 20 minutes for their whole followup visit.

Ilona: We decided to first screening algorithm, you can see the same cut off values, you can see that we measure at least one hour after birth and at day two or three of life. That we only have one repeat measurement in the first hours after birth in case of an abnormal screening. At day two or three of life, we did not repeat a measurement in case of abnormal readings because the midwives had only 20 minutes for their entire visit and they just said that there was not time for an extra measurement. In the next slide you can see what happens in case of a positive screening. All infants were referred to the Pediatric Department of our University Medical Center where there was physical examination including the pre and postductal oxygen saturation measurement and an echocardiogram was performed in case of persistent abnormal saturation values.

All negative screenings were followed up at least one month. In the next slide you can see that we screened over 3,000 infants and this was 99% of all infants with parental consent. Out of ... In our screening population, during our period, there was only one infant with a critical congenital heart defect which was not detected during the fetal ultrasound. This was an aorta interruption that the infant was not included in our study unfortunately. There were 3,059 screenings. 32 of them were positive, 17 of them in the first hours after birth, which you can see at the left, and 15 at day two or three. In these first hour positive screenings, 14 out of 17 had pathology such as noncritical CHD, persistent pulmonary hypertension, or infection or other pathology. At day two or three of life, we had pathology in only 2 out of 15 infants, so the detection rate of pathology was much lower.

Then we also assessed the satisfactions of the mother. This was done with a questionnaire sent by the community midwives to the mothers that they supervised. As you can see here, most mothers were very positive about the screening and the

lowest question, would you recommend the screening to other, was answered with yes in 96% of the cases, so that positive. We also assessed the satisfactions of the midwives, also with the questionnaire. We asked them what the time was to screen and they said that the average time per screening, so the pre and postductal measurement, was less than five minutes. They did not think it was medicalization and all of them wanted to implement the screening. Furthermore, they also think that the pulse oximeter provides useful information in other situations such as [inaudible 00:14:38] or when there is doubt to refer an infant or not.

This was just the feasibility study so we can now say that screening after home birth is feasible but we still don't know if it's cost effective. Our government wants to know that as well so in order to assess the cost effectiveness, we are now performing a larger implementation trial in the region, as you can see in the picture, with 72 midwifery practices and 14 hospitals. Those are more than 350 midwives. We aim to screen at least 20,000 infants. We now also implemented a repeat measurement at day 2 or three of life because we think we might have less false positives at that day. We started in July of 2015 and we think we can end it in December. We have now screened 14,000 infants. We detected CCHD in the first hours after birth, but we also detected the CCHD at day two with normal reading at one hour after birth.

One case of the positive screening was one already in the first month of our trial. This was a neonate one hour old. Born in a hospital that also participates in the study, with a preductal and postductal oxygen saturation of 60 and 70% and no other symptoms, no [inaudible 00:16:12] abnormalities. The echocardiogram showed a transposition of the great arteries. Since this was also a cardiac care hospital, a rush [inaudible 00:16:23] procedure to open the [inaudible 00:16:25] could be performed already two hours after birth with a successful switch procedure at 13 days of life. This was also why most of our midwives and nurses are very convinced of the screening because this infant was only one hour old but it did have such a low oxygen saturation.

Our next steps would be first to finalize out implementation study. These results will go to the Health Counsel and after that the government will make a decision to implement the screening or not. However, we now, at the experience that midwives and the hospitals are very positive about the screening and that most of them are already performing the screening as a standard practice and will continue to perform the screening. I think we will not wait for our government decision. That would be the future prospectus. I want to thank you all for your interest and for your attention. I can answer some questions now or if you have a question later, please send them to my email. I'm very sorry that I cannot attend the whole webinar. Thank you.

Thalia: Thank you so much, that was fascinating. We do have one question in the chat box for you before you have to go. What is mean by medicalization to reach 100% of midwives who answered no?

Ilona: In the Netherlands, there is amongst the community midwives, they want to have the birth as natural as possible. They do cord clamping or sometimes they wait for even

30 minutes and they don't want to use any medical devices. They just see what happens. The nature that performs the delivery and the followup. At first we had a lot of discussion with the midwives that they would see it with their own eyes if the baby was cyanotic and they did not need a device to detect it for them. At the beginning, there was a lot of skepticism, but now, they also say that it's not. That's a Dutch word, we say medicalization, but now they all say it's not medicalization, it's just confirming what you see with your eyes and it's having the color and the number. That is the most [inaudible 00:18:48] from the midwives, is about we don't need a device, we can see it with our own eyes. That was very interesting that they in the end say that it was not the case.

Thalia: Okay, thank you. We have another question in the chat box. Are community midwives nurses, life certified nurse midwives in the US or direct entry, as we would call it?

Ilona: Sorry? Can you repeat that question?

Thalia: Are most of your midwives certified nurse midwives, like we have in the United States, or are they direct entry midwives?

Ilona: We don't have the same system as you have. I think it would be more like a nurse midwife. In the Netherlands there is a training for the community midwife and if you want to become a clinical midwife, to be a midwife in the hospital, they have to do extra months for study. It's like a basic midwifery training, they can only perform the low risk births.

Thalia: Great. Thank you so much. If anybody else has a question, please do star 7 now to unmute yourself and ask before Ilona has to go.

Amy: Ilona, this is Amy, can you hear me?

Ilona: Yes I can hear you.

Amy: All right. Thank you again so much for your presentation. I have found it very interesting in the US, in our algorithms that we promote, we are very firm on the, or we seem to be fairly firm on the trying to do the screen after 24 hours of age to allow the duct to close and reduce the false positive rate. I think if I was looking at your slides correctly, it looks like your false positive rate, when you do your pulse oximetry at one hour or age was very similar to your false positive rate when you do it at two to three days. Were you surprised by that? Can you maybe explain why that might be the case because I think that's something very interesting for us, even in the US, for our out of hospital births who have a similarly tight schedule and have a hard time integrating that.

Ilona: Indeed we were also surprised by this because we also thought that the false positive rate would be higher in the first hours after birth, but we also performed a study before we did this study, and that was also with community midwives, we gave them a pulse oximeter and advised as well to measure after birth or around 20 minutes

after birth and you could see that already after 10 minutes, most of the infants had oxygen saturations of around 98%, so in that case we thought well, most of the healthy newborns will have normal values at least one hour after birth.

Maybe our screening time was 1.8 hours after birth already, so it was really quite early. What we did ... What we were also surprised about it that our pathology in those first hours was also higher than we expected. We thought that most of the infants with false positive screenings in the first hours after birth would have no pathology at all, it was just a real false positive reading, but they did have pathology. That would suggest that it is abnormal to have readings below 95% one hour after birth. We were also surprised by that because we expected higher false positive rates as well. I hope this answers your question.

Amy: Yes, absolutely. Thank you.

Thalia: Do we have any other questions? Well, if not, thank you so much again for presenting for us today. We're going to go ahead, I know you need to leave, and let you go.

Ilona: Okay.

Thalia: There is one more question.

Ilona: Oh, yes.

Thalia: Presumably, overall, CS rate lower than the United States?

Ilona: That is indeed true. We have less CS, C-section. We have them only when there is a medical reason to do them. Normally, women deliver vaginally. The rate of C-sections is very low, especially in the [inaudible 00:23:25].

Thalia: Thank you, again, so much for this.

Ilona: Thank you.

Thalia: This is a great presentation, yes. Amy, I think we'll go ahead and if you just want to tell what the next part will be like here then?

Amy: Yes. Can you hear me?

Thalia: Yes.

Amy: Okay. Perfect. For the next part we have the three midwives on the call ranging, I think we have two or three, we'll see when we get to the last one, representing Wisconsin, Pennsylvania, and Michigan. We just asked them to briefly do one slide on what their practice looks like in terms of both quantity of births and how they have implemented CCHD within their practice. We'll let them talk about their practice and then we'll open it up with some poll questions or if you have any questions that you

would like the midwives to answer, please chat them or ask them as well. It looks like we are starting with Gretchen. Gretchen if you can hit start 7 to unmute yourself.

Are you there?

Thalia, do you know if Gretchen was going to be on?

Thalia: She was on. I'm just looking at the participant list now and it looks like maybe she got off. Why don't we go ahead and see if she comes back on. We'll just move on to the next midwife. There we go.

Amy: All right, I know I heard [inaudible 00:25:17] on.

Devyani: And I'm not a ... Sorry, I'm not a midwife, I'm a Pediatric Cardiologist. I work with the midwives. We can share our experience in Pennsylvania. In Pennsylvania, I just want to give you a little bit of a background about a project that when Pennsylvania state passed the regulation about universal screening for CCHD we were able to put a program in place in the hospital, but we felt that we were not able to accommodate to our out of hospital births. You have to remember that Pennsylvania has a huge plain community, which is the Amish and the Mennonite community, which are uninsured population, they do not want to take insurance. This is a self [inaudible 00:26:06] community which brings in a different level of challenge because cost becomes a huge part of this.

I just want to share some things with you that, for a delivery with a midwife, a family pays anywhere from \$1,800 to \$2,500, which includes anti-natal and postnatal care. If we were offering pulse ox screening to these patients and the pulse ox was positive, they would have to go to a children's hospital where an echocardiogram costs anywhere between \$5,000 to \$9,000. That was a huge deterrent to pulse ox screening in Central Pennsylvania with the midwives because they felt pretty strongly that they would lose their clientele because they were offering a test that would then send the patients to a hospital and then the test may be normal, but the family is stuck with a huge charge and a huge bill, which is much more than the cost of delivery. That was one piece we had to deal with.

The second thing was that our midwives also leave the family at three hours of life. At three hours after birth, the midwife leaves the patient, even if they're at a birthing center, they go home. I got a call from a midwife who lost a baby who, at 9 hours of life, she left the baby, she thought the baby looked good. The baby died and ended up having a hypoplastic and she said, we wouldn't have diagnosed this anyway because we don't do the screening for 24-48 hours. Then we talked a lot about this project and the other challenge is the state doesn't provide pulse oximeters to the midwives so they were buying these \$40 Walmart pulse ox's which were not really helpful and reliable to do this.

We connect with Ilona in Netherlands where they do have a large number of out of hospital births. We also looked at some Polish studies and realized that a lot of

Europe was doing early screening. We actually ruled out our program as a newborn wellness screening in Pennsylvania and we have an algorithm that has two different features in the AP algorithm, first we do an early screen at one to three hours. There is a second screen at 24-48 hours, and the third part, which is not on the slide, is that there is a mandated six week followup. We do make sure that our patients come back for followup because one of the challenges we find with the AP screening, even in the state of Pennsylvania, there's no way to capture a false negative rate. This would at least help us capture that and this is critical for us.

Plus, the other piece is we have a very high risk population, unlike Ilona's population, which goes through a very rigorous screen before they decide who's low risk and who's the patient who can deliver at home. We don't have that luxury. We have a very high risk population that is prone to genetic disorders, that does not receive any ultrasound-type of anti-natal care. They get anti-natal care from a midwife. The other piece of the midwives can be an entry level midwife, 8th grade educated, or can be a certified nurse midwife. There is no regulation in Pennsylvania that somebody who is just 8th grade educated cannot deliver a baby. We had a vast different type of people we had to deal with. We had to deal with cost issues and the cost of pulse oximeters.

We ended up writing a grant and getting funded through couple of organizations. We bought our pulse oximeters and we also set up training workshops. We regularly hold training workshops to train the midwives and only they pass our training are they given the pulse ox and the condition of giving them pulse ox is that they would give the data back to us including the six week followup. It's an IRB approved study so we do consent the patients. The project only started in September of 2015. As I mentioned earlier, our demographics, most of our patients are plain patients, which is 89%. 12% were other patients in the area.

Interestingly, Pennsylvania is the state in US that has the largest number of home births. I was personally surprised about that. I thought Alaska would be that state, but it's not. We have close to 4,000 out of hospital deliveries right now. Our algorithm was early screening, late screening, and a six week followup. We really, as I said, called it a newborn wellness screen because we may be diagnosing more than congenital heart disease and we kind of presented it to the community that we are just not interested in heart disease, no baby should be blue whether it's heart disease, sepsis, pneumonia, whatever else is going on. It's really to look for cyanosis in a baby. We follow the typical AP protocol. We follow the algorithm, but for early screening, if the baby needs a repeat screening, we only do two repeats because the midwife does not stay that long with the baby. At best, they would do two repeats.

We so far, have data on about 400 patients. Because of the six week followup, there is a little bit of a lag in collecting the data. We have diagnosed two babies with heart defects, one baby had heterotaxy syndrome asplenia. If this baby wasn't diagnosed, this baby could have presented in septic shock or could have been very sick. This was on an early screen. Then we diagnosed a baby with a common atrium and AV canal. This was also an early screen. We haven't detected any sepsis or other pathology. I do have anecdotally one more patient who is not in this database who had a positive

screen at three hours of life and had persistent pulmonary hypertension of the newborn. We, personally, with early screening, have not detected an early false positive, but I would say that the AP algorithm of retesting the 3% difference had a learning curve with the midwives. Sometimes, we call it an inappropriate pass in our algorithm because the midwife should have repeated the pulse ox, but did not repeat it. Then I think, as we get more positive patients, the midwives come more and more on board.

Right now, our limitation is the pulse ox's. I just heard from Department of health, I had given them a presentation, that they would be giving us some funds to buy pulse oximeters for the midwives. We have also created a lot of educational material. We have laminated cards, we give them out with the pulse ox and that is something that is available to them. The other thing, as I had mentioned earlier, the cost of echocardiogram. We are able to offer them a echocardiogram for \$150 now. We do that as a special case for them and I have my own practice, I'm able to offer a lot of that help. As a cardiologist, I'm available to all the midwives.

That is in summary, our program. I do think that early screening has really helped us. One message I would say is that, which I think anybody who is trying to implement a screening program should remember, that you cannot just take a program just because it is approved by the state or recommend by AP and just try to plug in to your community. You may have to customize it for the needs of your community to make it work. That's what we've done. We've only ... We still have some more patients to collect that data on, it's an ongoing study, but early screening is a good thing for this, right now.

Thalia: Great, thank you so much. Amy, just to let you know, we do have Jennifer on the phone so we'll look at her slide next.

Amy: Okay. All right, Jennifer, if you can just hit start 7 to unmute your phone.

Jennifer: This is Jennifer.

Amy: We can hear you perfect. Go ahead.

Jennifer: Okay. Great. My name is Jennifer Holshoe. I'm a Certified Professional Midwife in Grand Rapids, Michigan. I just finished my training with a pretty busy busy home birth practice that worked in a more rural population, but now I'm starting my own practice in the Grand Rapids area, which is a much more urban population. I personally, now am not working with as much of the Amish and plain community, but I still am filling in some and working with the practice I trained with and they do have a rate of about 25% Amish and plain population. That's a little bit different as far as care goes and risk factors. For the most part, my practice is very low risk. A lot of screening for low risk and now that I'm in a more urban setting, definitely more anti-natal care in addition to what I provide as a midwife. A lot of them are also receiving an ultrasound and blood work through a medical care provider in addition to working with me. Then a lot of screening out if risk factors develop during the pregnancy.

I received a pulse oximeter, on loan, through the state of Michigan, through the grant program, which was really helpful to me because that was another big startup cost as I started my own practice. I was really grateful for that ability to start right out with the screenings without having to factor that cost in. Throughout my training, I did a lot of screenings for the practice that I trained with. I attended approximately 50 home births per year. That's what I expect again this year in my own practice and with them. We do the screening, we always do a 24 hour, or as close to 24 hour, postpartum visit as we can. We stay about two to three hours after the birth and leave when everything is very stable. Then at the 24 hour visit, we're doing the newborn metabolic screening and the pulse oximetry screening.

We try, when we get there for that 24 hour visit, to do the pulse ox screening first, or one of the first things that we do so that if it's not a negative screen, that we can repeat that within an hour. That 24 hour visit, for me, is usually about an hour long, that's usually about how long I'm there. Then that way, I can repeat it right before I leave and we can make a decision regarding what kind of followup needs to happen after that failed screening. I'm reporting the results for the screenings through the state single sign on, reporting that electronically where the other newborn screening information is filed.

I would say, personally, myself, I've screened probably 35 or 40 families at a 24 hour visit. Only one family that I have worked with personally has had a failed screen and they were referred to the Children's Hospital in Grand Rapids and that turned out to be just a transient respiratory thing and the baby was discharged, I believe, about 24 hours later, doing fine. I think after this, so far, what we've heard in this webinar, I am really rethinking an earlier screen, possibly one hour, before I leave for the birth, using the pulse oximeter that I have in my birth bag and adding that in to my protocol because it seems like that would be helpful. I am very grateful to have the pulse oximeter that I have in general. I do think it's useful for a lot of other issues, especially if I did have to do any kind of resuscitative efforts. I'm really grateful to have the pulse oximeter to help me guide pulse resuscitative care for my families.

Thalia: Great, thank you so much Jennifer.

Jennifer: Yeah.

Amy: Perfect. Well, thank you both. Thalia, do you see if Gretchen is on yet or no?

Thalia: No, it doesn't look like she came back on.

Amy: Okay. Perfect. Let's then, if anyone has any questions for Jennifer or Devyani before moving on to poll questions, let's open it up for that. I have a couple but I'll wait to see if anyone else does.

Perfect. Okay. I'll go. I'll start the ball rolling. For Devyani, I have a couple questions for you. Your six week followup visit, I think that's a great idea, especially in terms of

looking at false negatives, can you explain a little bit more of what that visit involves? Is it purely a clinical exam or are you repeating a pulse ox at that time?

Devyani: The six week visit is something routinely done by midwives in the area. It's like a standard of care. That's when the midwives are, sort of, discharging the patient and then support the mom and the child. The advantage of the six week visit is multiple. Number one, we know that if we missed a congenital heart disease with our screening and the baby needed urgent intervention, within the first few days of life, so it helps us with that. Number two, we know if the baby died or lived. Somehow the baby died, something happened, we at least have that data.

The third thing is in terms of whether we do pulse ox or not, we have encouraged the midwives but we don't force them to follow this protocol because at six weeks, this protocol of doing right arm, left leg is really not important other than ruling out cyanotic heart disease. If they hear a heart murmur or something and they want us to do that, they can. It's up to them. They have the pulse ox, but mainly to get data on that baby that was screened as to what happened in six weeks. Did they show up in a medical facility? All those things are lost to followup. We don't know what happens at that point. The patient can travel to different health systems and we don't know that. We close the loop if every baby's alive and what happened to them in the first six weeks.

Amy: Perfect. Then, I really liked what you call the screen, in terms of the wellness screen instead of a CCHD screen. Has that helped in terms of better understanding the purpose of this screen and what you may or may not pick up? Any additional thoughts you have on calling it a wellness screen instead of a CCHD screen.

Devyani: I think it helps a lot because I always struggled with this concept of a false positive. Then all these babies had problems that needed to go to the hospital. In order to simplify this, simplify it for the midwife, and for the family, we want to make sure that your baby is not blue and the baby should not be blue, whether it's the heart, it's the lung, it's brain, it's the blood. Your baby should not be blue. That message is much clearer to give than a message that says, "Oh, we're trying to rule out critical congenital heart disease, blah, blah, blah, blah, blah." It becomes very hard. Just want to keep it very basic. No baby should be blue. That's it. Why should a baby be blue?

Amy: That's fabulous.

Devyani: That's the message we give. That has resonated very well with the community. We haven't had a single family refuse it and because we paid for the pulse ox's through the grant money, we make sure the midwives don't charge the families for this test and the families want to know if the kids is blue or not. Brings it down to their level.

Amy: That's fantastic. Thank you. It sounds like Dr. Hokanson is on the line and will be able to share Wisconsin's experience as well as they have been quite a bit with the home births and particularly in addition to the slide, Dr. Hokanson if you could also talk a

little bit about your thoughts on this idea of earlier screening, I think that would be really helpful. Again, star 7 to unmute.

John: Hi, this is John.

Amy: All right, perfect.

John: Okay. We started maybe a little earlier and didn't have the thought of doing the early screening, we just went with the straight AAP recommendation. We're probably up to about 2400 babies screened now. We're running at about a 1% failure rate, which is kind of like the Netherlands, it sounds like. We definitely found that our plain clothes families were screening a lot later than our English families. It's a little trickier to get back for that 24 hour visit if that falls at a time that's inconvenient for the family or inappropriate culturally. We do find that screening is coming a bit later than we'd hoped for. We're very interested in whether or not an early screening program might be feasible because that might really help us out.

Amy: Perfect. Thank you. Does anyone have any further followup questions before we open up some poll questions and hopefully garner some more discussion? I think you just have to hit star 7 to unmute yourself if you want to ask a question over the phone or you're welcome to chat with Thalia and she can read them.

John: While that's happening, I had one other question I'd be curious for the midwives or other people to comment on. The original data that suggested the early high false positive rate at less than 24 hours was from hospital born babies and some of it from the US where there is a really high C-section rate. I wonder if that doesn't have something to do with some of the babies being a little sleepier in those first few hours and that those babies born naturally might tend to a little more likely to do well with an early screening, which is obviously home birth all over the place.

Devyani: I think it's just a question of transition of circulation, right? I mean, so you're saying that C-section would delay a transition of circulation from intrauterine to extrauterine life. I don't know. I think some of it is ... We didn't find ... We don't have C-sections obviously in out of hospital births, I don't know if that has something to do with it, but I think that we should re-look at that and see if that is a true false positive or that was a little bit of a hypothetical thought process. I mean, I did not really find very strong data when we put in early screening in our population.

Jennifer: I'd be happy to speak to that as an out of hospital midwife. It's only anecdotal experience, but my experience working with babies started as providing hospital labor support for families. I witnessed a lot of babies in those first few hours after birth, both vaginally born in the hospital and born by C-section and then now, as a practicing midwife, seeing the subtle differences in transition after a home birth, where the interaction is really more family centered, a lot more quiet, a lot less stressful and obviously, always vaginal at home. I feel like I see babies that are much, much more alert. Their initial breastfeeding experience is much less interrupted, they usually latch and nurse a lot sooner and I think that the hormonal balance for the

family is entirely different than in the hospital setting. I realize that's something that has probably not been studied intensely but I see major differences and I see babies and I see babies that are by far, much more alert and aware and interactive in, especially the first hour, but hour to two after birth than I even did in my hospital experiences.

Devyani: I would tend to agree with you about the stress level. I do think it's ... When I talk to my midwives, they tell me that they do the delayed placental clamping. Then you talk to them and how they are doing it, it definitely seems far more natural. I don't know if that has anything to do with that, the delayed cord clamping or I really don't know that. It's a good thing to consider and see that maybe we'll have a higher false positive with early screening in hospital births. That's a good question to answer. And separate the babies based on C-section and vaginal delivery and see if that is a confounding factor over there.

Jennifer: I think one thing that happens at home births, like you mentioned, that almost never happens in the hospital is the delayed cord clamping, not just for a few minutes but it's generally standard practice as long as the bleeding normal, that we aren't clamping and cutting the cord, often, until after the placenta has delivered. And certainly never before the cord is really finished pulsing and we can visibly see that it is drained of blood. I think that that's probably a very, very big difference between hospital births and home births.

Devyani: Yeah. Very different. I mean, the cord pulsation is a big part and I don't know if the water births have any different impact. Believe me, being a physician, I used to think this is crazy. Deliver a baby in water? You've got to be out of your mind to do that, you know? Now I see a lot of patients and they seem to really do well. And the midwives are very confident that the way to manage these patients.

Amy: Perfect. This is fascinating. I have to admit, I have not thought at all about the type of delivery having a potential impact on the pulse ox, I just think it further adds to the complexity of this screen and in monitoring and finding the most effective algorithm. I really appreciate all this discussion. I think it's really though provoking. Does anyone have any questions or thoughts?

Thalia: There is one more question in the chat box. It's for Devyani. Have you found in Pennsylvania any false negatives, how many, and why do you think you found them?

Devyani: We have only the 400 hundred patients that we have, we haven't had any false negative, but I can just speak anecdotally, I cover our hospital births too. Recently had a baby with a co-arctation who passed the screen, had a heart murmur, and that's why I ended up seeing the baby and the baby had a very tight [inaudible 00:49:55]. Two or three babies like that who have passed the screen so I'm not totally convinced that even with the 3% difference the screening is really the best for a co-arctation, because you really have to be ductile dependent to be able to get that. Co-arcs typically are not so ductile dependent. They would present at 5,6,7 days of life. I don't know if our screening is really good for that. I think our screening is really good for

cyanotic heart disease, but for co-arctation, I really think we see have ... Every practice will tell you that and unfortunately there is no good way to capture that data. Even the two babies that I had recently, I don't even know where to report it that they were false negatives.

John: This is John again. I can say the same thing. In our out of hospital population, our false negatives have been co-arcs, and in our state wide data, the co-arcs are the ongoing thorn in our side for false negative.

Devyani: We are actually just to say we are starting a project for machine learning for co-arcs specifically, to see if we can put this electronic stethoscope and get some machine learning experience on these babies to pick up co-arctations because I don't think pulse ox is doing it. I think to pitch pulse ox to the community, that you're going to pick up co-arctations is a very wrong message. I hear a lot of people presenting it that way. You really have to present it that you're going to pick up a blue baby. You're not going to pick up a lot of left heart issues. People get this false sense that, oh they passed the pulse ox screen, if I don't feel the femoral pulse, I'm okay. I hear that a lot from my pediatric community that, "Oh the baby passed the screen, couldn't have a co-arc." Just have to be careful about that, I think.

Thalia: [crosstalk 00:51:51]

Jennifer: Just to add, [crosstalk 00:51:53]. Go ahead.

Thalia: I was just going ... There's lots happening in the chat box, so when you're done, I'll go through what's been going on in the chat box.

Amy: Oh, why don't you just go to the chat box. I was just going to say we've seen the same in Minnesota in terms of false negatives and co-arcs, so I agree that that is something that is probably less likely to be picked up than to be, more likely to not be picked up than picked up.

Thalia: Before I go to what's in the chat box, I see that Gretchen, you're back online, did you want to say anything at all about the slide that I have up that's yours? Push star 7 if you want to say something. Okay, well, I'll give her a chance again. The question, I've heard this a few times where the pulse ox is only done twice in out of hospital births, do we feel this is okay rather than three screens, and the thoughts on this approach?

Devyani: I can tell you two or three really doesn't make that much of a difference if you're physically done it. I'm sure, John, you can comment on it, that if you have that 3% difference, you usually can sort it out at one point whether you are accurate or not. You leave the pulse ox on for a while. I rarely come across an issue that two times they failed and the their time they passed. If they're going to fail, usually, if you're good at doing what you're doing and you can assess the baby, I think the three times is a little bit of an overkill, personally. I don't know any data that people have failed the two times and then the baby is positive the third time only.

Thalia: One of the comments in the chat box is actually just a comment. Then [inaudible 00:53:29] we've seen false negatives for hospital births for co-arctation and hypoplastic left heart syndrome. Then there was another question, Are the midwives' out of hospital birth screen results reported to the public health department or someplace else?

Devyani: The midwives, I can speak for Pennsylvania, the midwives have, when they do the PKU card, they're supposed to put the pulse ox on that. If they don't have the pulse ox written on it, they get reprimanded by the state and they have to respond to that so some of the midwives are upset about that because state doesn't give them the equipment and they can't afford the equipment, so now the state has modified that, they ask the question, 'Do you have a pulse ox?' If they don't have a pulse, then they are not reprimanded for that.

Amy: I would say in Minnesota we ask our midwives to also report to us just as we do the hospital births and it sounded like that was true for Michigan as well, is that correct?

Jennifer: I'm reporting electronically. I send in, when I do the metabolic screening I just mail that in. There's no place on there for me to report anything about the pulse oximetry readings, but later on, usually within a few days of doing the screening, at 24 hours, then I go on to the state's single sign on and report that information there. It is linked to the newborn screening number of that patient.

Gretchen: This is Gretchen Spicer. I think you can maybe hear me now.

Thalia: We can. Thank you very much.

Gretchen: Okay, I tried to respond a few minutes ago and I guess I hadn't done all the steps I needed to. In Wisconsin, it's on our blood card, we report both pulse ox and hearing screening results so that works just great for all of us.

Keri: Hi, this is Keri in Michigan. Just to add to what Jennifer said, we give our midwives access, like she said, to our online reporting system, but we also provide them with a paper form that they can submit with their blood spots and then it's routed to our department to be entered in to the online database so if some of our midwives, maybe aren't as comfortable using the internet or don't have access to it, then we do provide that means for them to report as well. Then like I said, they can just submit it with the blood spot card so that they don't have to do any additional mailing or anything of that sort.

Amy: Thalia, did you have any other questions or comments in the chat box?

Thalia: No, that is it and gosh, we're almost done. Did you want to do a couple of questions real quick?

Amy: I don't know, we only have three minutes. I'm wondering if we hold off on those.

Thalia: Yeah, this has been a great discussion.

Amy: Yeah. I think this has been fantastic. There is so many new things for us to think about. I really like the comment, Devyani, that you said in terms of really needing to think about modifying the protocol to meet the needs of the community. I think this really gave us some great food for thought on how we can do that in each of our states and as a screening community. Thank you again to everyone for staying on, I know Fridays came sometimes be tough. I really really appreciate the very robust discussion and all of the food for thought for us to take home and think about over the weekend.

Thalia: Absolutely. The last few comments in the chat box were really good, thank you. I learned a lot, thank you. This has been an awesome call.

Amy: Perfect. Just a reminder, that these are archived and recorded as Thalia mentioned at the beginning, so if you have anyone else that you think would benefit from listening to this, please share the link with them. I hope that more people want to listen to this because again, I think it was fantastic. I think with that, we will give you all a couple minutes back in your day and thank you very much.

Thalia: Just a reminder, the next webinar will be Friday, September 23.

Amy: Thanks Dahlia.

Thalia: Yeah, thank you everyone.

Amy: Bye, thank you.