NewSTEPs
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Critical Congenital Heart Disease Technical Assistance Webinar

October 2014

Presentations on Recent CCHD Publications

- Lisa Hom
- Dr. John Hokanson
- Dr. Gerard Martin
- Dr. Marci Sontag

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

Recording: The conference has been muted.

Marci: I'm so sorry. I just realized that as muting me as the presenter, I had muted myself. I apologize for that.

I am very excited as part of our NewSTEPs CCHD efforts to announce that we have two co-chairs who will be leading our technical assistance efforts related to CCHD technical assistance newborn screening. Those two co-chairs are Lisa Hom from Children's National and Amy Gaviglio from the State of Minnesota. They will be guiding our efforts through the upcoming years and leading our technical assistance work group.

There's a work group of about 15 individuals who come together to help us think about these webinars as well as other activities for new [stuffs 00:02:13] related to CCHD Newborn Screening and technical assistance.

As part of Lisa and Amy's efforts in this area, they will be helping to lead these monthly webinars. I'm very excited to introduce Lisa Hom. Lisa, are you on?

Star, seven to unmute.

Are you guys hearing me?

Speaker 3: We can hear you, Marci.

Marci: Thank you. I don't see Lisa on the list, so [inaudible 00:03:05], if you wouldn't mind shooting an e-mail to Lisa to make sure we're not having some technical difficulties on her end?

Speaker 3: Of course.

Marci: Thank you. I will go ahead and get started with some of the slides to just announce some activities that are going on at in the coming month. Hopefully, many of you are registered for the Newborn Screening and Genetic Testing Symposium that's happening this month, the 27th and 30th, in Anaheim, California. This is a fabulous meeting that has a lot of activities specifically related to NewSTEPs.

We don't have the exact data on this. I think this is Tuesday, but I'll have to ... We'll double-check that. From 4-5:30, we have Point of Care for Critical Congenital Heart Disease, a session entirely dedicated to CCHD. You can see the topics are listed here. I encourage you to visit those. Then, we also have a special session, The Current Status of Critical Congenital Heart Disease on Newborn Screening, which is going to be on Tuesday evening from 6:30 to 8:00.

There's going to be a panel that's going to be moderated by Amy Gaviglio and Richard Olney. They will lead us to what's the current status, and also give us a chance to really meet as a small group of those interested in working in CCHD implementation.

There's also an international perspective session on Thursday, October 30th, bright and early in the morning in which Dr. Martin will be talking about Critical Congenital Heart Disease Newborn Screening. I think Lisa is on. Lisa, are you ...? Star, 7 to unmute.

John: Now, can you hear us?

Marci: Oh, we can hear you. Excellent.

John: Star, 7. What a great thing.

Lisa: Sorry about the technical difficulties. Thanks so much for the introduction, Marci. My name is Lisa Hom. I'm at Children's National in Washington, D.C. I just wanted to give a brief overview of the presenters that we have this afternoon. I think we're going to start with a nursing paper. Unfortunately, neither one of the authors was able to make the

call but they're very happy to have us share their work. I will be doing the nursing paper.

Dr. Hokanson, from the University of Wisconsin, will be sharing two of his 2014 recent publications. Marci will be sharing with us an overview of U.S. publications from 2014. Dr. Martin will be speaking about some of the work that he's done internationally, as well as some of the recent research studies and publications done coming out all over the world.

It will be a great call. We'll go ahead and get started with the first publication. This is a research paper that came out of Duke. It was conducted at a 46-bed labor and delivery unit in North Carolina. That's about 3,000 births a year. What this team of nurses, led by Donna Ryan and Elizabeth Bradshaw, were able to show was by implementing an online educational program; they were able to demonstrate significant improvement both in knowledge, as reflected in test scores, and in correct documentation. Their results are right there and very impressive.

Another key finding, I actually spoke with Donna yesterday, was somewhat intuitive, but significant improvement was key to education prior to implementation. I know sometimes those things don't always go in the correct order. This paper just demonstrated how important getting those online modules and testing out to nurses before implementing can be.

Another key that they wanted to highlight to this group was the importance of quality improvement monitoring. That's to ensure adherence, and compliance and sustainability. They monitored a three-month post-intervention and demonstrated that they still had great adherence to documentation and improvement in knowledge and test scores, so people will retain what they have learned.

Next, I will turn it over to Dr. Hokanson. Dr. Hokanson is a pediatric cardiologist at the University of Wisconsin-Madison. He is the director of their echocardiography lab. He is also the principal investigator of the Wisconsin SHINE project. Dr. Hokanson, are you on the line with us?

John: I hope so. Am I audible?

Lisa: Perfect, coming through great.

John: Okay, great. We had two papers that we wanted to mention real quickly. If somebody could go to the next slide, the first one is about our early experience with using a Pulse Oximetry program in the out-of-hospital

population for planned home birth. We've since then, since publication, probably got about another a thousand babies enrolled and have similar data. What we found is, certainly, the Amish and Mennonite communities were big portions of this population.

One of the reasons we focused on them is our earlier work had shown that their rate of missed congenital heart disease was substantially higher than the hospital-born population. One of those factors, I think, has to be the fact that the Amish, particularly, very seldom get prenatal ultrasound. We found in our population that, really, only 13% of the moms in the Amish community had a prenatal ultrasound. Among the non-Amish population, prenatal ultrasounds were essentially universal.

We had the initial data on the 440 children. The vast majority is PASSED. We did have three FAILED, and five times the algorithm was misinterpreted. We can go on to the next slide. We found that, particularly in the Amish community, we tended to get a little bit later screening. It was generally a little harder to coordinate efforts to get back and to see the baby after the delivery, but the vast majority of the screenings were still done within a window that we've hoped would be helpful within those first four days.

Next slide, this is a really busy slide that shows that although most of the babies on the bottom row passed and repeat screenings weren't required very often, unfortunately, sometimes when the repeat screening was necessary, it wasn't performed. We did have five situations where the algorithm wasn't followed. In one time, the baby was thought to have failed when indeed they passed, and one the other way around, and then a few times it should have been continued, and wasn't.

We did have three children that failed in that initial cohort. One of them had an AV Canal with a common atrium, because that baby went on to have a two-ventricle repair, they don't count it as critical congenital heart disease, and we had two babies with sepsis. We did have one baby that had a coarctation with a VSD that passed their screening.

I'm going to the next slide. These are just some of the absolute saturation values. Again, we had in that initial cohort no babies that were completely normal that passed. Since that time, we have had at least one false-positive. We had another baby that spent three days in the hospitals getting their saturations to come up because of persistent fetal circulation. Then we've also picked up one girl with a tricuspid atresia. So far, our false-positive rate has been acceptable and it's been pretty well received among the community.

I'll go to the next slide. One thing that's come up is what hardware we're using. We did have the luxury of being able to issue the same device to all of the midwives, Amish birth attendants and public health nurses. That was the Masimo Rad5V. We've been using a reusable probe and a disposable probe wraps. The midwives in general prefer the thicker blue foam wraps. Those come at a cost to 60 cents apiece, but it turns out you can use Koban, or a generic equivalent, which is obviously substantially much cheaper.

We looked into whether or not we've had to do formal calibrations for the handheld devices. The Masimo corporation does not recommend that. I talked to our clinical engineers. For our clinic and hospital-based handheld units, the clinical engineers don't recommend doing it either. I hope that means that we're going to be okay without doing it in the field because they presently aren't.

Then if we go on to the next study, when you start looking at the literature, it's clear that coarctation of the aortas continues to be an issue. It's a very common congenital heart disease but it's very difficult to detect. The studies that look at the number of deaths from this congenital heart disease, usually hypoplastic left heart syndrome and coarctation are the two big players. In those studies, usually there's a few more hypoplastic left heart syndrome deaths than coarctation deaths, but coarctation comes in a close second.

Before the two-site protocol was approved and recommended by the Secretary of Health and Human Services, our home hospital was doing two-site blood pressures at 24 hours. This had been done basically for longer than anyone could remember. We couldn't really even identify the origin of that practice. When we looked back, we had 10,000 babies who had both pulse oximetry screening as a single site measurement and blood pressure screening at 24 hours at the age or before discharge.

The next slide, this is a little different protocol than we currently recommended. This was the two strikes, not three strikes like we get now. The cutoff for blood pressures was 15 millimeters [inaudible 00:13:51]. To fail the blood pressure screening, they had to have a 15 millimeter arm-leg gradient in two locations. To have failed the Pulse Oximetry screening, it would be very much like the current computer protocol except cutoff after the second strike rather than offering a third.

I'm going to the next. About 1.5% of babies failed, or I should just say required a second screening most commonly for blood pressures. A total of 13 failed the screening process, again, predominantly for blood

pressure measurements. If we look at only a single site Pulse Oximetry, we really had an extraordinarily low failure rate.

I'll move on to the next. These are some of the blood pressure and saturation numbers. The protocol did not require an echocardiogram for failed blood pressure screening, so they weren't always done. Only one child has a potential for unknown situation. Of the four that did not have an echocardiogram done, three of them had documented normal physical examinations at one year, which at least is a close approximation to excluding critical congenital heart disease.

I'll go on forward. The one baby that failed both screens really failed pretty spectacularly. They had the first saturation of 88% and 30 plus no meter gradients across their arm and leg, but had a normal echocardiogram. I'll go into the next. It turns out that the babies that had failed had again significant arm-leg gradient, that we never identified any aortic arch obstruction either immediately or in follow-up.

I'm going into the next. From a clinician's point of view, coarctation remains particularly troublesome. It's one of the most common of the CCHD lesions. It's very difficult to detect prenatally. It's the weak part of our Pulse Oximetry screening with the Granelli and Ewer papers showing less than 50% detection with Pulse Oximetry. I think our study shows that blood pressure screening done at 24 hours is just done too early, and it's not reliable enough to look at for a map screening system.

I think the phenomenon that we really on for Pulse Oximetry screening is completed through cardiac mixing or ductal-dependent blood flow. We anticipate the ductus is open at that time of screening. Blood pressure screenings rely more on ductal closure. That usually doesn't happen until the babies go home from the hospital. Unfortunately, our data does not support using blood pressure screening as a way of closing the gap that remains with coarctation.

Thank you. I think, we'll move on.

Lisa: Thank you so much, Dr. Hokanson. You will have an opportunity at the end of the presentations for discussion and questions and for the answers. Next, we'll hear from Dr. Marci Sontag, who as many of you know is the Associate Director of NewSTEPs, as well as an Associate Professor Epidemiology in the Colorado School of Public Health. She will be giving us an overview of U.S. recent publications and research as well as a paper that her team published earlier this year.

Thanks, Marci.

Marci: Thank you so much, Lisa. First, I'd like to present today as it just came out earlier this week, I think, some ... the group in Boston about the prenatal and newborn screening for CCHD findings from a nursery. Specifically, I think, what this can inform us about is a flip side to what Dr. Hokanson just said about detection rates at various hospitals and how a tertiary care centers that might be most babies are detected through prenatal screening as opposed to the Amish population that Dr. Hokanson just talked about.

The [inaudible 00:18:08] of this was to compare the motive diagnosis in two groups of infants to CCHD. Those were infants born at Brigham and Women's Hospital. I have that backwards. Anyway, BHW ... BWH, Brigham and Women's Hospital [inaudible 00:18:32] to that, and that infants that were born in other hospital have been transferred to that tertiary care center. There were five who are at risk for CCHD either by prenatal ultrasound or by newborn Pulse Oximetry Screening.

[Inaudible 00:18:50] on their paper, and you can see the infants born at BWH in the first column, infants born in other hospital in the second column. I'd like to really bring your attention to the number of prenatal screens or prenatal detections at BWH, and really one that was not prenatally detected at BWH. It was post natal detection versus those who were born at other hospitals and transferred in.

100% of the infants' with CCHD were identified prenatally with the seven core defects that we're looking at as recommended by the Secretary's Advisory Committee, where only a third of those were detected prenatally by the outside hospitals that were transferred in. You'll notice here that there was one case of interrupted aortic arch and a VSD that was identified post-natally. That infant actually also was not identified on newborn screening. It was identified through symptoms.

They had a [inaudible 00:20:04] rate of their first screen of 0.5%. Thirty-four of the 35 passed in second screen. These are of infants who were born at BWH and were entered into the normal screening program. These were infants who were not the high-risk infants that were already identified prenatally. This was in their well-baby nursery. One infant did fail all three and following echo results that could identify that infant with pulmonary hypertension, so a supplementary finding to the typical CCHD newborn screening, but not one of the seven targets.

They did notice that of those 35 infants that failed the first screen, that failing that first screen was associated with infants being large with just gestational age, having a birth weight of greater than four kilograms and also with sex. They have one false negative as I mentioned earlier. Not as [inaudible 00:21:00] prenatal ultrasound also missed on newborn screening, and the baby will have a murmur and cyanosis 10 to 12 hours after the screen unfortunately was diagnosed before discharge and have surgery.

The summary of this or the take-home point of this is that fetal detection of CCHD is excellent in these tertiary care centers. They have a very comprehensive program at BWH for prenatal ultrasound and echos that are interpreted by radiologists, and those are moved forward to echos as necessary for those infants. This really gets at the importance of thinking about the hospitals that are being served by the screening programs. If the detection rate is lower, it might be due to really high detection rates of prenatal screening.

I'm actually going to skip this paper, and come back to it in just a minute, and talk about this paper here first. This is a paper from the state of Nevada, in which it's very similar to what they're finding in the Boston area where any suspected fetal heart disease that is detected through ultrasound in the region are referred to Maternal and Fetal Medicine offices. Fetal cardiologists are on-call throughout the region to help interpret that and to perform echos as needed.

All fetal echos were under with real times ... on site supervision of a fetal cardiologist. Due to this change that this region in Nevada has made between 2003 and 2006 to the most current data of 2012 to 2014, they have increased their prenatal identification from 36% to 71%. Their goal really is to have 100% prenatal identification, which is for all of the defects, that might not be possible to get exactly to 100% but I think it's a very great goal to be trying to identify these infants earlier, and then using newborn screening as the safety net as needed.

Now, I'm going to go back to a study that came out of our group here in Colorado earlier this year talking about the feasibility of CCHD and newborn screening at moderate altitude. I'm going to present the results of this paper. At the Newborn Screening Symposium later in the month, I will also present some of our recent findings from a couple of other studies that we have done talking about where we are right now with CCHD newborn screening as well.

This was a study implementing the sea level protocol, as described in the Kemper article, at moderate altitude. We're considering moderate altitude here is about a mile high here at the University of Colorado Hospital wards, 5500 feet or 1694 meters above sea level. Our initial expectations when we implemented this protocol is that we would probably have 3% to 4% of all infants that we screened would be failing at this altitude based on some preliminary data we had.

We were actually surprised with the proportion of infants failing. Actually, it was about 1%, 1.1% in the first thousand infants that we screened at the hospital under our research protocol. We also learned as been previously discussed that there was a learning curve in our nursery. In the first 500 infants, eight of those 500 failed or about 1.6%. In the last 500 infants, we only have three out of the 500, and three infants fail or a failure rate of 0.6%.

This is still significantly higher. This is total fail, and not just fail in that first screen but total fail would go on to need additional workout whether that be an echo or whatever the clinicians have decided. This is specifically higher than what's been published in literature, which is typically 0.2% or even less than 0.1% at sea level.

When we saw this improvement over time, we realized that it was time the nurses had learned how to really accurately take these Pulse Oximetry measurements, and let the Pulse Oximeter value really or the results settle in before they call the baby a failure or the screening a failure. We also saw that fewer infants had incomplete screen. We were just getting better with that quality improvement. The longer we did it, the better we were doing and getting the complete screens.

We concluded there's a proportion failing at altitude is greater than sea level, but we have decided this is a total of a failure rates, and it's in hospitals that are less than 7,000 feet. Additional sites [inaudible 00:26:29] some other hospitals in the Colorado area, and we said, “Under 7,000 feet, we're seeing failure rates between a half and 1% much higher than at sea level. Right now, we're thinking that's tolerable, and we're moving forward with a mandate for CCHD Newborn Screening in our state.”

However, when we do that same type of study in hospitals greater than 8,000 feet, through personal communication with Dr. Jeff Brown at Vail Valley, they had seen failure rates greater than 30% using the sea level altitude or sea level algorithm. They then have also tried putting the

children under an oxygen hood to see if that helps, and there still have a failure rate of over 10%.

It's really not realistic to implement the sea level algorithm at greater than 8,000 feet. There's a gap between 7,000 and 8,000. We haven't done enough studies yet. We don't have enough data to know what to do in that gap. Right now, we're looking at under 7,000 feet; we're still pretty comfortable. Greater than 8,00 feet, we're not comfortable. Between the two, we're still evaluating the data.

Then the last paper that I'm going to present that has been recently published is from Matt Oster's group from Atlanta. This is looking at quality improvement in screening for CCHD Newborn Screening, and really and the tool for assessing whether this is a true failure or not a failure of the screening algorithm. They did a randomized crossover trial of a paper tool versus the computer tool for CCHD screening, where the paper tool, you have to look at the numbers and say, "Yes, this baby has failed given the [Kemper 00:28:19] protocol. The computerized tool which would give you that answer and say, "Oh yes, this baby ... This failed, but this doesn't fail. This screen fails. This doesn't fail."

You can see here from this figure that only 55% of the scale screens were accurately assessed with paper versus 95% with computer. Look at that far right side of the figure; you see that they're much more accurate with the computer algorithm helping to assess, "Yes, this is truly a fail." That's a big number of true fails that were incorrectly passed on as being passes and could have been babies that were missed by the screen.

I'd like to also draw your attention to the hyperlink at the bottom, that pulseoxtool.org. You can go on there. You can also download an app, and you can put in the numbers related to a specific CCHD newborn screening results and a buffet based on the current temper protocol. Is this a fail or a pass or a re-screen? What's the next step?

This is a great way for [inaudible 00:29:35] to really assure we are following up the infants that maybe we followed up appropriately. I think that is the end of my slide. I'll hand it back to you, Lisa.

Lisa: Marci, thank you so much for that overview, really helpful. Our next speaker will be Dr. Gerard Martin. Dr. Martin is the Senior Vice-President at the Center for Heart, Lung, and Kidney Disease at Children's National Health System. He is a pediatric cardiologist, and has been involved in extensive research and advocacy both for critical congenital heart disease

and specifically from a Pulse Oximetry Screening both nationally and internationally.

He'll be giving us some highlights about work internationally, and presenting some of the kidney papers that have come out in 2014.

Marci: I am going to actually ... I'm sharing my desktop, and hopefully you can all see that, so we can see the animation that are in your slides.

Lisa: Okay, thanks Marci.

Marci: Yes.

Gerard: All right, let's see. Lisa wanted me to be feisty. Anyway, this one, it just almost over animated us, but the whole idea here is from the very beginning. Really over 12 years ago when this whole Pulse Oximetry story began with Dr. Hok and the folks at Hopkins to the group at Long Island Jewish with Dr. Koppel to beginning studies by Anne Granelli in Sweden. What started in the U.S. with the what if with Pulse Oximetry really turned into a lot of our really formative papers that came out of the Nordic countries and the Euros' group in the UK the value of Pulse Oximetry.

Unfortunately, that's just zipped through all those old papers. Of course with Ann Granelli from her first paper which identified the possibility of Pulse Oximetry to her population-based study, where they did nearly 40,000 children which showed us the improved sensitivity and specificity when we paired physical exam with Pulse Oximetry, which led us in the United States to re-look at this and make our sweeping recommendations with HHS to try to do this across the country.

Of course, it was Anne that pointed out the importance of these secondary characteristics. Just a quick 30 seconds starting in the U.S. really getting going in Europe, and really the big study being Anne's study here which led us to the U.S. protocol.

Now, the question is, "What is Anne up to now?" If we go up into 2014, this is Anne's latest publication, which was Acta Pediatrica in which she basically did a survey of the Nordic countries, and said, "What are you all doing?" Now of course if we look at Europe, what we would see that really the Norway, Sweden, Poland, and Ireland are really at this point the countries that have those national recommendations to screen. It's not that they are fully screening, but they have national recommendations to screen.

Switzerland is also on board. There's been a recommendation, but it's not yet a national recommendation. It's really that coming from the experts in Switzerland saying, "We should do that." Most of the Nordic countries are using recommending a protocol as we use in the United States. The way that this was done in Sweden, Norway, and Finland is really a bottom up approach where they said, "We can do this, and we'll move it across our country."

As a result to that, those three countries are really near 100% implemented. Denmark and Iceland have been a little bit slower to implement. Iceland to my knowledge is not really too involved in screening at this point. They do like to point out that they have the lowest infant mortality in Europe, and that perhaps from their standpoint, they don't need to screen. Denmark has claimed high prenatal detection rates, but my understanding from talking with Anne is that they are now looking at implementation in Denmark.

Again, even though they are claiming high prenatal detection rates, I think as John presented earlier in his talk, we can't forget the importance of the secondary conditions. We'll show some data that Andy has put together. These secondary conditions may turn out to be five to 10 times more important than the CCHD conditions. I've lost my … Here we go. Moving on to Asia and of course China, and the great thing about China is once they start doing anything, you can be sure that they're going to do it big. They're going to get numbers quickly.

Following a group that went to China, and Andy Ewer and others went to China and returning and did some speaking on this a couple of years ago. There is already been some screening that was going on in Beijing and Shanghai, but basically, they started to put together their numbers. Lo and behold, what they found in the China study is that, one; you can really get going there. They did 51, sorry, 122,000 babies in these 13 provinces.

They had a much lower false positive rate with Pulse Oximetry screening than clinical exam alone, and that's something that several of us have talked about that the finding of a murmur has a lot more false positives than a low Pulse Ox screening. Their study is really twice as big as the next biggest study, which is the Polish study that we'll talk about. Basically of their false positives, about 47% of them or 180 of the babies did have some type of clinical disorder that required further intervention or monitoring.

You can see here this whole idea that Pulse Oximetry plus clinical assessments had a nice sensitivity rate around 93% similar to what Anne Granelli's data had shown. Andy Ewer wrote a commentary to this article which appeared in [inaudible 00:37:38]. The group was doing earlier a screening in China, and he pointed out this whole idea of the optimal timing of screening may deserve further consideration. He pointed out that if you go to the [guard 00:38:01] New Jersey paper and look at their false positive rates and their fewer cases of heart disease identified, some of that may relate to waiting to 24 hours and that there are a significant number of babies that weren't detected prenatally, but becomes symptomatic in between six hours of age and 24 hours of age that then don't get screened.

Andy I think is making the argument that perhaps we need to adjust the time at which we do our screening, so we can balance our lower false positive rates against the likelihood of timely diagnosis. In other words, even though they're still in the hospital, some of these babies are starting to get sick at 20 hours of age. If we test them, if we do the screening a little bit earlier, maybe we'll keep them sooner.

He also pointed out that less than 1/3 of the positive infants needed an echo if there was an assessment first of the secondary targets. That's also an important point for us to consider. Andy has looked at his region on near Birmingham, and looking at what is happening there. Just over three years, they screened almost 26,000 babies. Most of them were screened after 12 hours, but the main age was seven hours.

They had 208 babies of the 25,000 that did have a positive screen. They basically turns out to be around .8% of all their live birth. They did have congenital heart defects detected, and 79 of them were the critical lesions as identified by the AHA, AAP, although three of them were considered serious and another five were considered significant. That was going to need follow up or either surgery or catheter based intervention. They did have two babies that were missed by all screening efforts.

Andy once again, as had done by Anne Granelli, pointed out the importance of the other significant diagnosis. They had 55 cases of pneumonia, 30 cases of sepsis, 12 cases of PPHM, four meconium aspiration, 41 infants with TTM, and three babies with pneumothorax. That all were identified through their PulseOx, which is I think quite impressive and important for us to continue to make everyone aware of.

If we look at this across the board, transitional circulation, mild TTM was a significant contributor. It was 221% of their positives. He likes to say that since they had been doing the Pulse Oximetry, they've had no infants with cardiovascular collapse in the post natal ward. They've identified significant clinical conditions, 165 out of 200 [inaudible 00:41:45] are almost 80% of the positives.

One of the things that he points out, because they do these secondary conditions screening first, they do not perform echocardiograms on all babies; they are only doing echos on approximately 29% of the babies. If you find inflammatory markers, you find an abnormal chest x-ray; you don't have to go to the echo additionally. Then of course other 61 babies that did have echos, 48% of them or 29 did have positive findings.

Again moving around, we want to get all the continents. This is the Australian paper. They were a significant pilot of looking at their implementation there. Basically, the bottom line on this one is going to be once again the secondary targets as well as the lack of a significant burden on their echos because of screening.

They looked at 18,000 infants. The false positive rate was quite low. The sensitivity for CCHD was around 80%. They only did nine echos as a result of the screening. Basically, they found four babies with CCHD, but more importantly, they found six babies with secondary targets.

This is a study from Italy two years ago, actually a little over a year ago. We met ... We'll talk about this. We met in Torino, Italy, and we encouraged pilot studies to be done in Italy and Spain. This was one of the studies that was done in Italy. In this pilot study, they did nearly 6,000 asymptomatic babies. They only did post ductal measurements. The screening was done 48 to 72 hours after their physical exam. They had no true positives. They had one false negative. That was in a coarctation that was missed by Pulse Oximetry and clinical assessment.

Moving on, let's see. Where are we going now? We're going to go to India. This is a study again where these investigators were looking at a little bit more of a rural population. We're going to see that the ... A little bit of a difference is that there was a high rate of continuity in this community. They also looked at the characteristics of the family and noted the number of patients that had a family history of congenital heart disease.

In this group, looking at the post ductal only, they basically found that approximately one out of every 600 asymptomatic newborns identified

through CCHD. Again, sensitivity rate around 66% just on PulseOx alone, specificity quite good at 99%, but really impressive rate of CCHD in this community. I think perhaps that reflects a little bit higher rate of the [consanguinity 00:45:40].

This is Lisa's attempted humor. We have a question for everyone here about what do Wisconsin and Netherlands have in ... How are Wisconsin and Netherlands similar? The common answer would be of course cheese are a packer fans or the cheese [has 00:46:12] in Wisconsin, and also in Netherlands, I don't think they call them cheese though, but also both of this we just do have the issue around home births that they're dealing with. Basically, Wisconsin I guess has somewhere close to 2% of their birth being home births, whereas actually now in the Netherlands, almost a third of their deliveries are home births.

They have been looking at a screening project in the Netherlands on how to do the screening in the home birth. Dr. Narayan is a pediatrician who has been working with nurse midwives. They have worked out this protocol for their ... [Inaudible 00:47:15] just presented that at the Torino meeting last month. This is where the measurements are done at approximately a little bit after an hour after birth.

The nurse midwife does hang around for that first hour after birth, and then performs the first screen like the U.S. protocol that the hand or foot is less than 90, it's considered a positive screen. Then if it is between 90 and 94 or greater than 3%, they do a repeat measurement.

They are finding that they are having difficulty at time keeping the nurse midwife around for that repeat test, but they have been able to do that. A little bit about their results, they are following up with that. They do have some preliminary data. Whoops, oh wait, don't have preliminary data; I'm sorry. I remember for the meeting where I was, they've had some false positives because of the early screening. They have not had many true positives at this point in time.

This is a little bit older, but will at least give you an update that on the experience in Abu Dhabi, we had presented this early. Dr. Asbury in the first year, 86% of their births were screened. They had 20 infants with CCHD identified. They are now over 80% screens with over 34 cases detected. This is now what has happened in the Emirate of Abu Dhabi. They are taking the Abu Dhabi experience, and moving it to the other six emirates, so they will be screening across the UAE soon.

This is the group that met a little over a year ago in Torino. We met again this year. In the first year, we got agreements from France, Germany, Italy, Netherlands, Spain, and Sweden to do pilot studies. Since the group first met, I think that wasn't the things that we are very pleased with, except the UK national screening committee did recommend further study on CCHD screening. It's going to be done again as a pilot in the UK. They came close to doing it as a country recommendation, and hopefully with further pushes will continue.

This group is looking to put together a meeting next year in Spain in November with the World Association of Perinatal Medicine, in which we are going to be hopefully getting the World Heart Federation and the European Union Rare Disorder Committee present at that with each of the pediatric societies from each country to try to have a stake holder meeting to get a EU recommendation.

Right now, this is our most recent world map as far as where we think things stand. This can be gotten off the website. We really think great progress is made when we looked at the number of countries that have pilots versus the countries that now either have a national recommendation or 80% of the birth's being screened. There's been tremendous progress.

Thank you.

Lisa: Thank you so much Dr. Martin for that overview. Now, we have a few minutes for questions for some of our presenters as well as an open forum for some discussions. Before we do that, Marci, did you want us to ... our webinar participants where this publication's page is on the NewSTEPs site?

Marci: Absolutely, we're actually updating all of these publications that we just talked about today, and adding them to our NewSTEPs site. Would you like more information about these specific publications, you can go there. Go to www.newsteps.org. You can find the information about these publications as well as ways to connect to the [inaudible 00:52:16] and other information specifically related to CCHD Newborn Screening and Technical Assistance.

Lisa: Great! Thank you, Marci. In addition, we have also touched base with many of these authors, and they are very open to discussion with folks in the United States were screening. The authors on the call as well as some of the authors' whose work we presented today are definitely interested in having discussions with us and with anyone who have questions.

Are there any questions, Marci, that are coming in on the webinar prompt?

Marci: I don’t see any questions that are being typed in. you can feel free to type questions or press star, 7 to unmute yourself if you have specific questions.

Gerard: John, this is Gerard. Can you speak to the review of your studies and about what you think we need to be saying to the groups that are ... where there is a hospital, where an academic hospital with a large number of referrals in, where they are better screened for them to be aware of the secondary conditions which are going to be as important if not more important than CCHD?

John: I think we'll be able to add to that. I don't know if I'm still on audio with some of our upcoming, because again we are finding in our statewide data about a quarter of the kids that fail l are fine, about a quarter of the kids that fail have heart disease, but about half of the children that fail have something not CCHD but something important that you're glad you found out about.

Gerard: I must admit I had a chilling, and I told the story a couple of times. That chilling conversation with a cardiologist that should go nameless who said to me, "All through the lead up of the secretary [inaudible 00:54:33] recommending saying, "This is the stupidest thing I've ever heard. I don’t want this done." When I saw her this March, she came up to me and she said, "Gerard, I need to talk to you. I am now a great aunt."

I congratulated her. She said, "My niece failed her PulseOx." I went, "Oh no, what was wrong?" I said, “Where was the surgery.” She goes, “No, sepsis. The PulseOx saved my great niece's life.” This was one of the most adamant cardiologist for don't do this. I think this story, we need to keep this message going for this is more than CCHD. I think Annamarie Saarinen has been a great advocate on this spreading that word that it's not just heart disease, even though a lot of us have gotten into this for heart disease.

Lisa: Well, thank you very much. I think that this will conclude our October webinar. I just want to make a quick announcement about what's to come. I think Marci mentioned earlier that we're actually switching to bi-monthly webinar. Our next webinar will be in December. I also did want to announce that there is another session at the end of October at the In-person APHL meeting in California.

There is going to be a session on health information technology, section five, where Kristy Tomasco from Michigan Department of Community Health will be presenting on Newborn Screening for CCHD, therefore six months of data recording in Michigan using multiple electronic options. Annamarie Saarinen from the Newborn Foundation will be doing an CCHD screening interpretation and data sharing between providers and public health to improve outcomes.

One of the focuses of the webinar, we've gotten some feedbacks from our technical advisory folks and from everyone that called in from Public Health that one of the focuses will be on health information exchange and technology in terms of how to get data from hospitals to public health and population based tools.

With that, Marci, did you have any other announcements?

Marci: I don't. Thanks everybody for participating.

Lisa: Thank you.