



NewSTEPS

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Critical Congenital Heart Disease Webinar
February 2016

Presenters: Dr. John Hokanson and Jennifer Macdonald

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

Thalia Wood: Okay. Again, welcome everyone who's made it out of the call right on time. Thank you so much. This is Thalia Wood at APHL and the NewSTEPS program, and this is the Critical Congenital Heart Disease webinar for February. Lisa, would you like to get us rolling and introduce who our presenters are today? Lisa, don't forget you start on introducing yourself.

Lisa Hom: All right. Thank you so much Thalia for the reminder. Welcome everyone to the February webinar. My name is Lisa Hom and I'm a nurse at Children's National Medical Center, and I'm one of the co-chairs of the Critical Congenital Heart Disease Screening Technical Assistance workgroup along with Amy Gaviglio, who is also joining us on the webinar. She is from Minnesota Department of Health. We're very excited about the February topic; Critical congenital heart disease screening data collection including hearing from two states about the development of best practices for surveillance and follow up, as well as exploring some of the more interesting aspects of what's come up in those two states.

Our first presentation is from Dr. John Hokanson. Dr. Hokanson gave us a brief bio and he's a clinical cardiologist at the American Family Children's Hospital in Madison, Wisconsin. He is on a faculty of the University of Wisconsin, School of Medicine and Public Health, as well as the chair of the Critical Congenital Heart Disease Subcommittee of the Wisconsin DHS. Sorry, John. What does that stand for?

John Hokanson: Sorry. Department of Health Services.

Lisa Hom: Great, thanks. Department of Health Service Umbrella Committee. As some interesting anecdotes for a month in 1992, he was voted the Best Pediatrician in Kalahari, granted he was the only pediatrician in Kalahari at that time. His

daughters refer to him as, “Dr. Killjoy,” and he considers himself a complete suburban stereotype, married with two children, a golden retriever and a minivan. Thank you so much, Dr. Hokanson. We’re really looking forward to your talk.

John Hokanson:

Well, thanks. I think that maybe have been too much information, but we’ll move on. Again, I am a clinician, so keep that in mind when you hear my opinions. That’s largely where they come from. I wanted to go through a little bit of a history of congenital heart disease screening, because I think some of it does come into play a little bit. I’m going go on to the next slide. Going back a decade or so by the early or mid-2000’s, there were already a handful of studies that suggested the pulse oximetry might be a way of picking up congenital heart disease in the honeymoon period that some children have.

We tried to get that or our hospital to do it. They weren’t quite ready for that. Like a lot of things, when you look into them, you find curious bits that turns up they were doing four extremity blood pressures on all babies an hour after they were born, which is an incredibly large amount of work, and probably entirely useless. At least we got them to switch around their blood pressure screening protocol. We’ll move forward again to the next slide. After a couple of years with that, we had a little more data, and we’ve actually began to do the single side oximetry that most of the studies up to that time had involved. We were actually able to show that blood pressure screening is huge amount of work and unfortunately, it doesn’t pick up Coarctation in the way you’d like.

Move forward to 2009, about that time, the American Academy of Pediatrics issued a statement on pulse oximetry screening, and basically said, “This is an interesting idea, but it’s not ready for us to endorse it yet.” That was about the same time as Anne Granelli’s study from Sweden came out, and unfortunately couldn’t be incorporated into that 2000 Guideline. Well, what she was able to show on a very large study was that both, you did a better job of diagnosing babies with congenital heart disease a few years pulse oximetry, and the really important issue from the study was they were able to show a survival benefit. Not only do you pick up more babies, but less babies die if you do that.

Granted, the Swedish system at that time was very different than in the American system particularly in the prenatal detection rate. Prenatal detection rate in the Swedish population there was very low. It’s not great in the US, but it’s substantially higher here than in Sweden. More studies came out shortly thereafter, and that led to the next slide, that by 2011, this was really gaining a lot of traction, and the US Secretary of Health and Human Services recommended that pulse oximetry be added to the Recommended Uniform Screening Panel. Pretty much all the major medical societies came on board and recommended the protocol that the Swedes had used to screen for babies.

The Health and Human Services, the HRSA put out a call for proposals for three-year projects, and partly, because they really have a no large scale studies

performed using the Swedish protocol in the United States. We really weren't quite sure how this was going to work out. We move on to the next slide. Six organizations got HRSA grants, Wisconsin was one of them. We launched our SHINE Project in attempt to help with implementation of pulse oximetry, but also to evaluate the results. We were thinking of using a large data project, where we would contribute to the general body of literature on the subject, and also bring our results back to policymakers and have them decide what would be the best way to do this.

It was also something that we were doing on a voluntary basis, because we did not have a state-wide mandate for screening or reporting. Our beginning part of our project was all as a volunteer basis, which will take things considerably more complicated. Let's move forward. This is the way we set up our project. It's not the same as every state. We decided to look for the 12 diagnoses that were outlined in that 2009 statement, not by the time of their intervention. If you look in the medical literature, there are two ways of determining if somebody has critical congenital heart disease.

One is to say that they have a certain list of diagnosis and that equals to critical congenital heart disease, or in the way the English and the Chinese have done it to say, "If you actually required an intervention under a certain period time, then you have critical congenital heart disease." Those two are not exactly the same. If you go on a diagnosis based approach, some of the children with these diagnoses will not require intervention immediately, but there are certainly some children with very significant health problems that will not be included. We also accepted the fact that we weren't really going to be able to accurately quantify how the screening would perform when picking up sepsis or lung disease or other diseases that might cause hypoxia that weren't critical congenital heart disease, because we knew we were dealing with a non-electronic database, and we didn't have the staffing to do it.

We had no intention of being a real-time safety net for babies. This was going to be a QA project entirely. Again, without a mandate to report, we had to rely on voluntary reporting. We don't have huge number of birth, 65 to 67,000 a year, but that's spread over 100 different birthing hospitals, and we've got at least 100 different home birth providers. We're dealing with a lot of people who are going to be dealing with a small number of babies and responding to screening failures quite rarely. That meant our educational purpose rather challenging. Move on to the next slide. This is what we decided to do. Now, our approach has been what's admittedly a low tech approach, because we don't have an electronic birth record like some states have.

We'll go on to the next slide. We collect a minimum data sets on our blood card, and that's manually entered by someone in the state lab of hygiene into what's called our, "WE-TRAC system." We only can collect a more expanded data set on patients of higher interest. Those will be children who have failed their screening, those who are known to have congenital heart disease, and then

during the time of the SHINE project, we also looked at babies born at home. We came across the babies with congenital heart disease both by the two children's hospitals; the Children's Hospital of Wisconsin and the American Family Children's Hospital's discharge summaries for any baby that have of those discharge diagnosis, and then also relied on our Department of Health Service Epidemiology Team to look at state discharge and death records to make sure we're catching all those babies with critical congenital heart disease.

We'll move on to the next. Like our hearing a blood screening, when a baby gets transferred from one hospital to the next, the screening responsibility transfers with the baby. Again, we try to get as many records as we could to catch as many babies as we could. We know that about 15% of our babies will go to Minnesota for more care, because of the rural nature of our state, and we still are struggling to track all of those. We'll move on to the next. This is our newborn blood card. Down on the lower aspect, there's one box that's for pulse oximetry. It includes the time and date of screening, whether the baby passed or failed.

We very quickly switched from positive and negative to pass and fail, and have a limit and a lot of confusion because of it. We also have the reasons why a baby might not be screened below, and that's helped us out a lot. Incidentally as we decided we were going to do that, as you can see right next door, we included similar boxes for why someone would have not been screened with hearing or with their blood. Our new approach is that every baby in the state gets a blood card and it's our vehicle for both our blood screening, our newborn hearing screening and our pulse oximetry screening.

Move on to the next. One of the questions that comes up is whether or not using that blood card as a vehicle could potentially slow down the delivery of the blood samples, and that's a true concern. We tried to leave it as the cardinal sin of newborn screening, being that she would interrupt the flow of that blood card, and we thought that testing would always prompt reporting, so we never wanted the hospital to delay the delivery of the blood card while they hang on to it so that they can report either oximetry or hearing screening. We looked at the sample of a few thousand blood cards from 2013, and we found that the majority, but certainly not all, had oximetry performed and reported within four hours of the blood card collection.

The blood card has to drive before they can ship it, but again, that shipping is a variable part of the equation. The biggest issue for each hospital is determining some workflow that allows us to keep the card near the baby, so that the pulse oximetry can report it. It doesn't really help us if the lab tech takes the card down to the lab, and lets it dry down in the lab, where the nurses can't get at it. The workflows have to be sorted out for each facility and they're different for each facility. We'll move on to the next. The strength of this low tech approach is that every baby has a blood card. If you have the blood card in hand, adding the minimum data set on pulse oximetry isn't very challenging.

It does convey to the providers that this is a unified approach in newborn screening. We came up with another low tech approach for those babies with a delayed pulse oximetry screening with simply they would photocopy the blood card and hang on to that until the baby could be screened. That turned out to be, again, a low tech, but fairly workable solution. Move on to next. The weaknesses, again, the workflows in each hospital are different and sometimes they change. The staff changes all the time. Collecting the minimum data set is fairly straightforward. Collecting the expanded data set is a very time consuming process.

We actually now have two dedicated coordinators that help us out with that, without which we would be sank. With regards to looking at other data, we have to rely on hospital coders to get the diagnosis right, which is more of a challenge than you'd hope. Getting state discharge and death records takes quite a long time. Unfortunately, we don't yet have a way for hospitals to directly enter information. They can still only use the blood card or a photocopy of it as their vehicle. We'll move on to the next. Just thinking about it in a different way, if you looked at a two by two table of the screening, if you're trying to determine true positive and false positive, for those that have failed their screening and do have congenital heart disease, that's the group of patients that we most understand.

We get an initial report of a fail off the blood card and we can then collect our expanded data set through multiple different children's hospital records and other sources. For those that have a false positive, we again get an idea that they exist from the blood card, but we really don't have a way to systematically assess other diagnoses. We don't have a database of other forms of congenital heart disease. We don't have a database of children with sepsis. We don't have a database of children with lung disease or pneumonia to keep track of what's that keeping up with.

For the false positives, we're relying on our surveillance of late presentation of congenital heart disease, and we know that that's imperfect. Our default is to assume the baby is fine if we never find out about anything. That's as best we can do, but it's not ideal. Let's move on to the next slide. In 2013, first of January, we started collected this data. We've used the processes that I described, and we later added in the reason why the baby was not screened. We had a reasonably good time collecting the expanded data set, because we had our team available.

We'll move on to the next slide. Well, right about that time, Lori Garg's groups from New Jersey reported their results from the first day to implement required pulse oximetry screening, and they looked at 70,000 babies. They looked at it in a very thoughtful way and didn't just look at babies that were tested by pulse oximetry screening, but also those babies that were only detected by pulse oximetry screening. They found 13 babies that really would have been missed cases of congenital heart disease were at not for oximetry, and they also found

a number of other babies with important diseases because of oximetry. This is really the first time that the Swedish protocol had been utilized in the United States and showed that, "Boy, this really was helping."

Everything was going really well, and it looks like all the lights were green and pulse oximetry is great, and the screening is great and everything's going well. We go on to the next slide. In the congenital heart disease community, things started to get a little uncomfortable. You never want to find things like this on CNN. There was a lot of media tension placed on one university hospital that had poor outcomes in babies with critical congenital heart disease. This was tough on the congenital heart disease community. People were very shaken by this, a lot of confidences were lost and the system at large, and the transparency of reporting. It turns out that a similar catastrophe happened back in the '90's back in the British National Healthcare system which led to a real change in the way the National Healthcare System operated.

Unfortunately, at that time, I was a pediatrician in the midland sending babies to Bristol for surgical repair. I'll go on to the next slide. At the same time as many of you know, a lot of scrutiny was placed on the newborn screening blood card process as well with issues regarding the timely use of it. Hospitals, not only sensitized about the care of critical congenital heart disease, more further sensitized about the issues of delays in newborn screening and the perception that they were not doing their duty to babies. Let's move on to the next. Next slide please. In Wisconsin, we thought we were going to set up this information, give it to policy makers and let them decide, but while we were still doing our project, administrative actions were taken that required pulse oximetry screening for all babies in the state.

On one hand, it's made our job reporting a lot easier; on the other hand, it became clear that people were a lot less interested of the end result of our analysis. A lot of what was driving this was the hospitals who wanted to make sure that they were seen as doing the right thing for babies. Let's go on to the next slide. Unfortunately, in 2015, there was another scare about poor outcomes in baby with congenital heart disease, and again an already anxious community is further sensitized about issues with critical congenital heart disease. People are very anxious about this, very anxious about screening congenital and hospitals are very sensitive to making sure that they're seen as doing the right thing.

Let's move on to the next slide. This wasn't triggered by these issues, but the SPS is now reporting outcomes on surgical data for congenital heart disease. It's publicly available. It ranks the different outcomes based on the complexity of the surgery, a stat one category is the more straightforward surgeries like ASD repair, a stat five category, we did something like a Norwood procedure for hypoplastic left heart syndrome. Each hospitals reported with their outcomes compared to the rest of the society for thoracic surgeon's outcome. Move on to the next. We'd started off thinking we want a big data, but now we've realized

that the people that really want to know about outcomes, and who's getting screening and what the screening shows are the hospitals, because hospitals and providers don't want to be seen as people that are not keeping up their end of the bargain.

Again, the whole community is a bit twitchy about what's been going on with congenital heart disease. We had set out to look at a big picture data and now we are having to shift to give hospitals individualized data. We'll go back to next slide, or go forward. Now, we've realized that, although we set things up in one way, our real goal is different, and always the real people who want our data aren't academics, politicians or public policy folks. They're the hospital administrators and QA officers. Move forward. If you ask a hospital, was able to say they screen and report the results of every single baby, but until you can tell them, "No baby Smith on June 3rd didn't get screen or failed their screening," it doesn't really help them.

Baby level data is what we really need and what the hospitals really want. Moving to the next slide. What we're helping to provide is a one-stop shop for all of the newborn screening and to create an electronic portal that'll allow hospitals to enter data even if the blood card has already left their possession. Again, the key to this now is providing that data to the hospitals themselves. I think we're pretty close. We'll move on to the next slide. That should be about it. Thank you.

Lisa Hom:

Thank you Dr. Hokanson. That was really fantastic. It was really great to see some of our CCHD issues put into the historical context as well as seeing how Wisconsin's advancement of those issues. I thought it was great too how you talked about the importance of nomenclature both for comparison purposes as well as for outcomes reporting. Thank you. We are hoping to have some time for questions at the end of this webinar, so folks could just hold off and think of their questions. We're going to go ahead and move to the next presentation, which we are very fortunate to have Jennifer Macdonald from Virginia.

Jennifer Macdonald is a public health nurse manager for the Virginia Department of Health newborn screening programs. In that position, she oversees program operations, so the newborn Dried Blood Spot screening, critical congenital heart disease screening, and early hearing and detection intervention or any in Birth Defect Surveillance Programs. Jennifer holds a BSN from Marymount University and a Master's in Public Health from the Virginia Commonwealth University. Thank you so much for joining us, Jennifer. We really appreciate it and are looking forward to your presentation.

Jennifer Macdonald:

Thank you Lisa. I really appreciate having the chance to speak to everyone on our surveillance program that's occurring in Virginia. Next slide please. You know John, that's a really nice description of the background of CCHD screening in Virginia and with the current challenges we all are facing, but I just wanted to have one slide into saying that in 2012, CCH received funding from HRSA as well

to address, implement patient challenges for CCHD screening and follow-up services. Next slide. I'm really just going to go straight to the nuts and bolts of our surveillance program and what has happened in Virginia.

Virginia follows basically the seven CCH heart effects that you see here. We are following them in a variety of ways. Next slide please. Our state is made up of roughly and probably up to about 57 now, but 55 nonmilitary birth hospitals. These are subject to the state regulations. We have a couple of Department of Defense, one major one in Norfolk [inaudible 00:24:15] Naval. Next slide please. CCHD screening in Virginia, planning and legislative mandates sign up continuously occurring. We have the benefit of that in our state. We submitted the grant in January 2012, but in April of 2012, there was an executive directed from our governor to start developing ... that actually mandated us to start developing plans for implementation of the CCHD program.

Soon after that, we received HRSA funding and then that started year one in May of 2012. Year one focused on basically having six demonstration project hospitals, testing algorithms, education and providing some clinical guidance on that. We also did a state wide survey asking all of our hospitals if they do CCHD screening and what are their processes and protocols, et cetera. Basically we've found out that all of our hospitals except probably one, I think, it was one that I remember noting, were already screening using pulse oximetry screening. We really shifted our focus in year two to go ahead and start really engaging the stakeholders in education in trying to collect some data.

Next slide. I'm skipping ahead a little bit, but I just wanted to give you the legislative mandate that has occurred that far. Like I said in 2012, there was the executive directed from the governor. In, I want to say, July of 2014, the Code of Virginia was changed, which means that the Virginia General Assembly passed verbiage to add to the code that says, "Yes. Virginia is going to mandate screening for CCHD, and the board is going to promulgate some regulations." Next slide. Then these emergency regulations that the board promulgated and we're still in process with this, the emergency regulations went into effect in January, 2015. We are anticipating that they will be in final mode come July of 2016.

Basically the regs at this point now say that, "The hospitals have to develop protocols for CCHD screening, evaluation around referral." We're really putting the emphasis on them, and CCHD screening is to be performed on every newborn and a newborn nursery. I didn't include the language, "And a newborn nursery," on the slide, but that has actively exclude NICU babies, home birth, prenatally confirmed CCHD, or those who had a recent echo. Then these screening results should be reported in the medical record, and then put into the electronic birth certificate, and we're going to talk about that, and that's going to be the props of our surveillance.

Next slide. Data reporting in Virginia, I'm just going to go over this very quickly, is that we have electronic EBC. It's called, "The Virginia Vital Events and screening tracking system," and the hospital registrars put all the information on that. There's the big paper that they fill out. There's lots of information. They put it in to the electronic birth certificate. Ironically, midwives do not have access to this EBC, because they still use paper, and that is actually a very important piece now and what we're addressing with CCHD reporting. That'll come into play a little later. The EBC feeds information into two surveillance on data collection portals.

One is for our EHDI program, our Early Hearing Detecting Intervention, and that's called visits. Then it also feed into our Birth Defect Registry, Virginia Care. Next slide. Virginia Care stands for the Virginia Congenital Anomalies Reporting and Education System. The mission of this is to really just the positive surveillance system is to collect data, to evaluate possible causes of birth defects, and improve the diagnosis and treatment of birth defects. This is also mandated in the code of Virginia as well. Next slide. Now, I'm going to go back a little bit, because before the code came into place, we started trying to collect data regarding the CCHD screening.

On January 1st, we started ... Not mandating, I'm sorry. It was a voluntary point at this time for hospitals to include the Dried Blood Spot Device ID and CCHD screening results in the electronic birth certificate. Next slide please. There's the arrows pointing to the NBS device ID number; some of us maybe unfamiliar with that. That actually got inputted into the EBC. Next slide. Then the CCHD data that we implemented in that timeframe. It was optional, like I said and it broke ... The information we were looking for was located under the congenital anomaly system. If you want to go to the next slide, I can show you that. This is the EBC and this is where they would put in the information.

At the time they checked that a pulse oximetry screening result was done and it was either positive or negative or not screened. Then if the baby did have CCHD, they could check that. It's very limited at that time. Next slide please. Before we went live, we started state wide training of all nursery managers and birth registrars that each birth hospital, the midwives and presenting birth centers were also invited to training. Although like I said, they still have the paper forms, so they cannot input it into the EBC directly, but can put it into the paper form. The paper form was updated with the new changes as well at that time.

The training's focused on the importance of the screening and how it can save babies' lives is really invested in this effort. Well, I'll talk a little bit later about hospital reporting on what day actually input it to us, because we're going to let them know how they're doing in 2014 and then in 2015. Hopefully, since it'll be mandated at that time, we'll have better rates. I'm going to get to them, I'm sorry. Next slide. We also talked about best practices, and this is what one of the hospitals sent us. We encourage this type of activity for the nurseries to actually log in, so it was easier for the registrar to put into the EBC.

Next slide please. The barriers and challenges at this time, obviously changes always the challenge. Since it was an optional field at that time, it was really important to gauge the birth registers and the fact that the screening can save babies' lives. One issue that came up was that a lot of registrars were used to submitting data within 24 hours of the birth. Of course, most of the time CCHD results were not available until after 24 hours. They found that their workflow changed too much by saving all the other data earlier like they normally would, and they would just wait to submit the certification once that log was still of help for them. Because each hospitals has a different way of charting the CCHD screening results, we couldn't train them on to where to find this data.

The nurses were also encouraged to work with their registrars to develop a process for this. Next slide. Like I said, we wanted to get a baseline data in 2014. We audited all medical records with the positive CCHD screening on the EBC, and one randomly selected medical record with the negative or missing screening result from each birth hospital per month on 2014. We took chart audits from the EBC with those failed screenings and any CCHD diagnoses that were inputted into the Virginia Care's Birth Defects Registry. Next slide. These were our results in 2014. We had a little over 84,000 live births in that year, and what we found is mostly likely, because it was voluntary that only 47% of live births had CCHD screening results documented on the EBC.

What we also found was, and this was a big thing that 92% of positive screenings on the EBC were documentation errors, and 98% of all CCHD diagnosis that were inputted into the Virginia Care Birth Defects Registry were missing CCHD screening results on the EBC. This baseline data was sent to all the hospitals with announcement of the emergency regulations from our Commissioner of Health in March of 2015. Next slide. I'm just going to say a few graphs that represents the data that I just talked about or spoke of. The documentation of CCHD results basically, it just showed that a lot of our hospitals were missing CCHD results in the EBC.

Next slide. This is what our positive screens. When we took the positive screens, what did we find out? We had 101 positive screens, 80 of them are documentations. We did find five CCHD diagnosis and 16 other which were a mixture of documentation and maybe some other diagnosis. Next slide. Our strengths in one of the patients, the strengths are we do have individual level data available. We can integrate our reporting into other infrastructure. Although I would say there are fewer cost. The cost can be a limitation also, and I'll talk about that in a moment. Our strength was that all of our hospitals said that they were performing CCHD screening, and then that legislative mandate made it a little easier for us to actually implement.

There's limitations of this study. Those chart audits were very time intensive. It took a long time to get that information. The EBC data was very limited. It's retrospective and not real time. We obviously found out that newborns who were prenatally diagnosed were not captured in that EBC data. Next slide. What

were the recommendations that came out of this 2014 study for us was that we really needed to clarify the Electronic Birth Certificate reporting to decrease documentation error, and as John said earlier we too clarify the language of positive and negative to include pass-fail. We want to link our EBC data with the Birth Defect Registry data to conduct more timely and accurate follow up.

We are doing minimal follow up at this time and I'll let you know about that in a minute. Obviously, we want to intensely continue education and training is what we're focusing on now as well. And 2015 data is currently being analyzed. I wish I did have it now, but I don't have it now. We plan on sending a new report to the hospitals and nursery managers in March to let them know of their 2015 data. Next slide. The recommendations, I'm just expanding this a little bit is that we clarify the positive and negative. We changed it to actually negative (pass) positive (fail) and not screened. That has already been done.

What we are currently working on right now and should be implemented by April 2016 is we're going to add the pulse oximetry values, so we can do a second tier test so to speak on making sure that they understand that those results were actually positive or negative. We wanted to add outcomes for failed screening. They're just cursory, but we wanted to add whether or not they were diagnosed with CCHD, whether it was a non-CCHD, whether it was in other hypoxia-related disorder where they ruled it out or even have a base where they could put other and then actually type that in. We're adding ICD-10 verbiage to clarify what is a CCHD diagnosis. Those will have the ICD-10 codes listed and with the verbiage next to it.

We also want to add multiple reasons why they were not screened, whether it was the parent refusal, was the infant in a NICU, was an echocardiogram done prior to screening, was there a prenatal diagnosis of PCH care. There of course will be other textbox for that. We're really looking forward to adding those and we do that in conjunction with our Office of Information Management and Office of Vital Statistics. It's a two-tier process where our Office of Information Management's going to change the EBC, but we also have to get the paper copy changed too. That is costing something. That is a little bit of the limitation as well.

Next slide please. Our current follow up is myself which I'm more of the administrator of the program that we currently have I have a quarter of the full time nurse. She also works Dried Blood Spot, but we're trying to do monthly follow up, and so we'll get a monthly report of failed screens and CCHD diagnoses in the Birth Registry. We will follow up to make sure that they actually have a diagnosis and especially the positive screens. We're trying to rule them in and rule them out. Then once we have the final diagnosis, we refer them to our Care Coordination Centers, which is the program within our Children and Youth and Special Healthcare Needs Program.

Next slide. Our education and training initiative is a big focus. In 2015, we visited over, I would say, half of our birthing hospitals to talk to them about the emergency regulations, screening techniques, see algorithms, et cetera. That's been very worthwhile project. We did that in conjunction with our Dried Blood Spot team, so we hit them twice with different information, and we are planning on continuing that in 2016. We might not make 25, but we have a workgroup that is really addressing, getting out into the state and then the birthing hospitals to educate them. On March 23rd, we're having a CCHD webinar for midwives, but it's geared to engage them specifically and give them the best practices.

We would love everybody to attend that. It's not just for Virginia midwives. We would love for everybody to participate in that if they'd like. We will, of course, do webinars on the new reporting updates, to the registrars and nursing managers in the Spring of 2016. Then one of our big initiatives during our HRSA grant was putting up this newbornscreeningeducation.org website. Next slide please. This offers containing medical and nursing education credits, and it's free basically to anyone now. At first it was free to Virginia residents, but we have expanded that so that anybody can take these education modules and earn credits.

Next slide please. The specific CCHD screening education module covers an overview of CCHD and screening including the rationale that's best practices for implementation and interpretation of results, their interactive scenarios such as answering parent's questions, where to place pulse ox sensors on a baby and interpreting case studies. You don't have to complete the module at once. You can sign in and out, and even review it even after you submit the post test. Like I said, anybody can take this. We also offer Dried Blood Spot education on that. Next slide please. We have a mock part two for physicians as well, and in this coming year, we will also have an Early Hearing Detection and Intervention Program module added.

That is it in a nutshell for Virginia on screening and surveillance. The next slide. I had some great crew this past year who are no longer in the program, Christine Cruz and Michelle, that a lot of our data collection and outcome analysis work, and for my current staff, Lily who is our follow up nurse and Beth, who is our epidemiologist who continues to help me with data collection now. Thank you.

Lisa Hom:

Jennifer, thank you. That was really fantastic. I definitely enjoyed your talk. We definitely saw a lot of similarities between the Wisconsin and the Virginia emergence of the program in terms of refining data collection and it reduced cycles, where you're really keeping your eye on global goals in terms of what you're trying to accomplish with your data. Thank you. That was fantastic. Fortunately, we do have a few minutes left for question from our presenters. I did have a couple that were submitted that I am going to go ahead and ask both presenters if they wish to comment.

The first question has to do with information for primary care providers for normal patients. If there are role in the Virginia and Wisconsin Department of Health for helping facilitate that, how do your programs handle, making sure that primary care providers, or are they included in the reporting piece specifically for normal results? Are there way for providers to confirm, or pediatricians?

Jennifer Macdonald: I have to be honest. In Virginia, we haven't engaged the primary care physicians as much as we should. They are always welcome to call us and we can see if the results are posted in the EBC, but other than that, we just have not engaged them as much as we should have.

John Hokanson: This is John. Part of that is because this should be concluded before the baby leaves the hospital. It's different from blood testing or hearing testing that might carry over into the primary care realm. If there's any lingering questions about this testing, the baby should not leave the hospital or leave the care of who's taking care of them. It's a little different. The need for primary care doctors to be involved in the loop is a little different.

Lisa Hom: Thank you. Sure and I know a lot of the responsibilities for giving the normal results of a CCHD screen is something from the owners of the hospital at discharge, making sure that information goes home with the families and is given to the primary care provider at their first clinic visit. A second question that we got in ... Thank you guys very much for your responses, was about, I know both of you guys touched on the denominator in your presentations in terms of making sure that we know that all babies were screened appropriately, especially those that we later find who had CCHD.

Virginia you talked about some interesting linking that were going on with you Electronic Birth Certificate data. One question that we got was how common is it for babies to be missed in terms of giving that feedback to hospitals, because half just are rough comment on ... Is it common that babies are missed? Are you seeing a lot of it in Virginia? It seemed like there were.

John Hokanson: This is John. I can ... A little bit have to do with your definition of CCHD. Our definition is a 12-diagnosis definition, which is a little different than some places do. If you look at our false negative, meaning babies that passed their screening and still had congenital heart disease, most of our babies that fall into that category have coarctation of the aorta. If you don't include coarctation on your list of CCHDs, then your false negative list gets a lot shorter. The definitions really do matter. About ¾ of the kids that passed and still had congenital heart disease in our hands had coarctation. It is the toughest one to find.

Lisa Hom: Thanks Dr. Hokanson. Jennifer, did you have any comments either on false negatives or on babies that simply weren't screened and documented?

Jennifer Macdonald: Well, I don't have any information on our false negatives, but I can say with the 2015 data that we're going to look at, we will be able to better assess whether or not some of those babies were missed and the reasons why, especially with our new EBC changes coming in. Maybe I can present on that next year.

Lisa Hom: Thanks Jennifer.

Thalia Wood: That would be great. I actually have several questions in the chat box Lisa-

Lisa Hom: Good, fantastic. Go ahead.

Thalia Wood: The first is, have you felt the ICD-10 codes to be reliable with specific diagnosis?

Jennifer Macdonald: We're just still figuring that out, because we just convert it to them in October, so I don't know that yet.

John Hokanson: This is John again. Andy [Pellet 00:48:11] did a study of discharge coding from several years ago in Wisconsin and found that in the past at least, it was not as good as you'd hope for. I see our hospital's discharge diagnosis list, and since I'm a clinical staff too, I have my ear to the ground a little bit about what babies are coming through. Unfortunately, even with ICD-10 coding, the list that we get is not as sensitive or as specific as you'd like. A lot of the kids that are flagged don't have anything that I'd call congenital heart disease, and I still like, "Oh, I know about that kid," but somehow they didn't end up on the list. It's the best we've got, but it's not perfect.

Thalia Wood: Great. Thank you. There was a question actually about the Virginia training materials, and Jen, I'd like to encourage you to send out a message, administer the link to those, and also with an announcement about your webinar for midwife. Could encourage people to attend? If you can do that, if you want me to send it out, you could ... This is Thalia. You could send me the information and I'll send it out.

Jennifer Macdonald: You were on my list. Yes.

Thalia Wood: Okay, good. To ask that questions out, well pretty ask about the slides. The slides of course will be available eventually when we get this transcribed. Okay. The next question is, is the SPS reporting data available to all, or do you have to be a member to view it?

John Hokanson: No. It's publicly available.

Thalia Wood: Okay, great. The question's also for you John. If a card comes in without any pulse ox data, what is the response of the Health Department staff? Do they wait some time for a photocopy or they contact the hospital?

John Hokanson: We don't have the capacity to respond to every baby that doesn't have a result. When we look at our data most recently, we were getting reporting on, if I remember correctly about 85% of blood cards had the results on them, and we think we can do better than that, but even if we got up to 95%, that's still thousands of babies with no result. We really just don't have the staff to follow up on thousands of babies a year with no results. Again, we try to stress that we are a real time safety net. We are a QA. We will report back to the hospital what their results are and then go over with them, "Well, this baby didn't have result," then I'll try to help them, see what might have happened, but we really just don't have any capacity to do real time surveillance like that.

Thalia Wood: Okay, thank you. The next question's for you, Jennifer. Are you willing to share what your hospital reports look like?

Jennifer Macdonald: Absolutely.

Thalia Wood: Okay. Again, you can send that to me and I will get it out to folks. The next question's, Michigan has seen false negatives with coarctations and hypoplastic left heart syndrome. We are trying to do education for primary care and emergency department staff that use up a similar type of screening algorithm is great to use in assessing any sick babies that may present after discharge from their birth hospitals. I guess that wasn't really a question, it was a comment. Did you have anything to add to that either of you?

John Hokanson: I couldn't hear. Did you say that they were encouraging people to use that algorithm beyond the newborn period?

Thalia Wood: A similar type of screening algorithm to use in assessing any sick baby that may present ...

John Hokanson: It would be a part of the normal clinical evaluation of a sick baby, so yeah, it seems very reasonable.

Thalia Wood: Okay. Next question is what happens to NICU babies in Wisconsin who may be ventilated or in oxygen at the time of the blood spot screening?

John Hokanson: What we tell hospitals is they shouldn't have their pulse oximetry screening done until they've been off oxygen for 24 hours, or on the oxygen they're going to go home on. Some babies will go home on supplemental oxygen. Their first blood card is photocopied, and then just kept at the bedside. When they finally get to the point where they screen the baby, they would put that information on the photocopy and then send the photocopy. Now, that being said, if like happens in probably 30% of the babies in a NICU, they get an echo anyway, they can fill out on the card, "Not screened due to normal echo."

We use the photocopy as the placeholder in a sense that they can report later, but also report again. If you've been in a NICU for two months and you've had

four echos, the chance that you have heart disease that we didn't pick up pretty small and it's reasonable to say, "You've completed your mission of screening for congenital heart disease by doing echocardiography rather than pulse oximetry." It allows the hospital to not screen that baby, because we really don't need that screening.

Thalia Wood: Great. Thank you so much. Well, that is the questions up from the chat box, Lisa.

Lisa Hom: Okay, great. Thank you, Thalia. Amy, did you have a view as well? Amy, are you still with us?

Amy Gaviglio: Sorry, but yeah, I'm here. I think John might have just answered this. It sounds like when you have this situation where a child has received an echo prior to the screen and so that's why you're not getting a screen. You have a checkbox that says, "Not screened, because of normal echo." I think we're trying to figure this out as well. How important it is for programs, you think, to try to collect all of those echo outcomes on infants who aren't screened, because they have that much, you mentioned, there's quite a few kids in a NICU. This seems like for us, it's been a ton of work and most of them are just showing PFOs or very small ASDs, VSDs. Do you think it's worth the time to try to collect that or to try to do what you're doing with just saying, "Not screened because a normal echo," and then only getting the CCHD confirmed echos, if that makes any sense.

John Hokanson: Yeah. I think it's going to be a huge effort, because-

Amy Gaviglio: It is.

John Hokanson: In some states and a lot of states, more than 10% of babies will end up in a NICU, but you're potentially dealing with a large number of babies of which many get an echo. Echo reports, as you figured out, have lots of extraneous data on them, which you really want to know is do they have critical congenital heart disease or not.

Amy Gaviglio: Right.

John Hokanson: Our approach has been that's all we care about. If some clinician, some bedside nurses willing to say that, "Echo is normal with respect to critical congenital heart disease," then I think we've done our duty of screening that baby for it, and then I don't think we need a copy of that echo report.

Amy Gaviglio: Okay. Are you finding largely that it is nursing staff who is the most comfortable with checking that normal echo box over a health unit coordinator or someone else in that-

John Hokanson: I don't think I have the experience to know that. I haven't been on that level. I suspect that it's usually the nurse filling that out, but I can't confirm that.

Amy Gaviglio: Okay. Yeah, I really like that 'not screened due to normal echo.' It would reduce a lot of work, I think.

Thalia Wood: Okay. This is Thalia again. Any of you on the phone call, is the final report from the multistate NICU project coming out soon?

Amy Gaviglio: This Amy. I believe so, but I also believe that there is no answer coming from it. Based when I was in New Jersey, listening into the discussion around what they found, and what they found is that no one can agree on what makes the most sense as far as the protocol goes, even though they looked at a number of different ways of doing it. It seems like there are several camps that came out of the project. There's the camp that says that, "Every baby should get screened, even if they have had an echo."

There was discussion about the potential for even an echo missing something depending on the timing. Then there's the camp who says, "Absolutely not. If you'd had an echo, you've done essentially the diagnostic test. There's no need to do the screen." There's some variations within that that's depending on whether they're on oxygen, how long they've been off of oxygen, et cetera. I believe it's in the process of being written up, but I don't know that it's going to have a recommendation to it.

Thalia Wood: That's all a good subject for our future call.

Amy Gaviglio: The ongoing NICU saga.

Thalia Wood: Exactly. One comment that I really like to share with especially with our presenters, because you both did such a great job. There's a comment that said, "Thank you. It's such a great session. Data is so important. It was great to hear what's working and what the challenges are." We're at the top of the hour now. You want to just wrap it up for us Amy?

Amy Gaviglio: Yeah. I would completely echo exactly what that person said. I think both of you talked through fantastic and I love hearing ... I think it's so helpful to hear about different approaches to the same problem, because I think we all have to look at what our capacity is, what our funding is, what our current processes are, what we have available to us in terms of birth certificates and birth registrars and birth defect registries. I think it's really helpful when you can present, and when you get to hear about, I guess, different ways to tackle the same problem. Thank you both, Dr. Hokanson and Jennifer. It was fantastic, and thank you all for joining on a Friday. We look forward to our next webinar which is going to be ... Thalia, help me out.

Thalia Wood: It will be in the second Friday in April. We didn't have it the second Friday this month, because of a concept which expired, so whatever the date is of the second Friday in April, I'm not sure what that is.

Amy Gaviglio: April 8, I believe.

Thalia Wood: All right, great. Thank you again everyone for joining us today and we look forward to hearing on the next call.

Lisa Hom: Thanks Thalia.

Amy Gaviglio: Thank you.