



NewSTEPS

A Program of the Association of Public Health Laboratories™

Critical Congenital Heart Disease Technical Assistance Webinar

June 16, 2017

Neonatal Intensive Care Unit (NICU) Part 2: New Jersey NICU report

Kim Van Naarden Braun, PhD

Epidemiologist

Division of Congenital and Developmental Disorders,
National Center on Birth Defects and Developmental Disabilities,
Centers for Disease Control and Prevention

Division of Family Health Services,
New Jersey Department of Health

Regina Grazel, MSN, RN, BC, APN-C

Program Director

New Jersey Department of Health CCHD Screening
Program and Infant Zika Surveillance
New Jersey Chapter, American Academy of Pediatrics

Please direct all comments/questions pertaining to this presentation to Erin Darby at erin.darby@aphl.org or 240-485-3844.

Amy Gaviglio: All right, Erin can you hear me?

Erin Darby: Yep, go ahead.

Amy: Perfect, this is Amy Gaviglio calling, I am co-chair of the CCHD technical assistance work group and just want to thank everyone very much for joining us on this Friday afternoon for our CCHD TA call. We have really been looking forward to this presentation for quite some time and are really excited to be able to share this information with you today. As many of you know, New Jersey became the first state to mandate CCHD screening in the U.S. and did so quite successfully despite only being given about 90 days to do so. Since then, they have led the way in numerous CCHD efforts including the one we will hear about today, which is examining the implementation of the screen in neo-natal intensive care units. I believe today we have both Jean Grael and Kim Van Naarden Braun here to share with us their work, and I will introduce them both and then I'll pass it over to you two to start the presentation. Jean Grael is a certified perinatal clinical nurse specialist, with more than 30 years of neonatal nursing experience. She holds several clinical designations including ANCP board certified high risk perinatal nurse, NANN neonatal developmental care specialist and certified breast feeding counselor.

Jean is currently serving on the national association of neonatal nurses, the board of directors as the immediate past president. She's employed by the New Jersey chapter of the American academy of pediatrics and is the program director for the New Jersey department of health, critical congenital heart disease screening program and Zika infant surveillance. Then we have Kim and Doctor Van Naarden Braun is an epidemiologist formerly with the National Center on Birth Defects and Developmental Disabilities at the Center for Disease Control and Prevention and the New Jersey Department of Health. Various substantive areas of expertise including the epidemiology of neurodevelopmental disabilities, newborn screening and maternal and child health. Dr. Van Naarden Braun holds a PHD in epidemiology and is the senior outcomes analyst in population health for Hackensack Meridian health. Jean and Kim I will pass it on to you at this time.

Jean Grael: Thanks Amy, thank you so much for inviting us to present here today for NewSTEPS, can you hear us okay? Is this volume fine?

Amy: Yep I can hear you.

Jean: Okay terrific. Thank you again and I have Kim Van Naarden Braun here with me and she's going to start in giving a little bit of the background for our evaluation of CCHD screening in the NICU.

Kim V. Braun: Excellent, good afternoon everyone. Jean and I are going to talk about our experiences with evaluating critical congenital heart defect screening in the NICU both in New Jersey, but primarily focusing on a multisite perspective evaluation that we conducted with a series of colleagues over the course of the past year and a half. I would like to acknowledge our co principal investigators, of which there are 19. Our initial conversations were focused on New Jersey as that's where we're located but we

actually had quite a number of other very esteemed colleagues across the country that were interested in becoming involved in our project, and so we acknowledge and thank them. As you know the prevalence of critical congenital heart defects in the United States is approximately two per thousand or 7200 infants each year.

In the absence of timely detection and intervention of a CCHD, an infant may experience significant disability or death. Since 2011, screening for early detection of CCHD using pulse oximetry has become near universal in the United States as a public health program, mandated in most states. In many states, this legislation requires screening of all infants regardless of their clinical setting or status. In unique complexities for infants on supplemental oxygen and those born extremely premature are present and the lack of specifications for NICU screening and concerns of higher false positive rates, have led some states to exclude NICU infants from CCHD screening with the assumption that routine monitoring is sufficient to detect unsuspected CCHDs, yet generalizing a lower risk of undetected CCHD to all NICU infants may be problematic.

This slide presents the handful of previous works that have been done on the NICU population with respect to CCHD screening, using pulse oximetry and a number of these are either single center studies or were case studies on infants that were screened in the neonatal intensive care unit. A recent study by Gong et al in Texas was a multicenter study and the screening were done, two screens were done, the first did 24 to 48 hours and the second, pre-discharge. They didn't exclude any infants and no CCHDs were identified due to screening. They found an overall false positive rate of 2.3%, which I'll underscore because in our analyses, we evaluated false positive rates also, so a false positive rate of 2.3% and one infant with CCHD was missed but not screened, and so their recommendation was that screening should be done excluding infants with a prenatal CCHD diagnosis or echo cardiogram before the screen. These are two characteristics that were of interest to us and were a big part of our conversation. We'll share with you how we tackled these two topics in particular.

Jean:

As Amy mentioned New Jersey was the first state to mandate and implement CCHD screening and so our legislation is very brief, it's stated here on the slide. "The Commissioner of Health and Senior Services shall require each birthing facility licensed by the Department of Health and Senior Services, to perform a pulse oximetry screening, a minimum of 24 hours after birth on every new born in its care."

This applies to all infants regardless of hospital setting, and so to help guide screening for the NICU population, our CCHD screening working group commissioned by the Department of Health really helps to guide implementation here and so as Amy mentioned we had to implement very quickly and so in a very rapid fashion without much evidence as Kim has presented, needed to come up with some sound recommendations. So, briefly in the NICU, screening should be performed at 24 to 48 hours of age or as soon as medically appropriate after 24 hours of age. Screening must be performed prior to transfer out of the hospital at greater than or equal to 24 hours of age. In all cases, screening should be performed prior to discharge to home. This is our recommendation, it does leave some interpretation to exactly how to implement that to the hospitals.

With several years of screening experience under our belts, we continued to meet with our CCHD screening working group, developed a subcommittee for NICU and discussed where are we in terms of NICU implementation of CCHD screening and we had a continual evaluation for the need to add administrative roles. We really wanted to have this group of experts weigh in on the need to add administrative roles, or look at further refining the recommendations. The primary questions raised with this group are do all NICU infants need to be screened, could there be exclusion criteria, particularly for infants that receive echocardiography prior to the time of screening, for infants with a pre diagnosis of congenital heart defects, or those babies that are extreme premature? Then what is the most appropriate time for screening, what about the role of supplemental oxygen, should we be screening when babies are receiving oxygen and how does the receipt of supplemental oxygen play into the screening?

This group wanted a little bit more information, so there wasn't a lot to provide background to actually implement administrative roles and so through the help of the New Jersey NICU collaborative, we administered a survey talking about screening practices, and what we found was pretty consistent with what Dr. Park had presented at the last webinar on NICU part one, that in fact the screening practices are very variable. So, this is just a snapshot of the New Jersey screening survey that three respondents or 15% indicated they would screen at 24 to 48 hours after birth, regardless of the infant's medical status and yet 35% were screening just prior to discharge home. 50% were screening at variable intervals, they were screening a minimum of 24 hours of age but then beyond that it could be any time, so some were screening babies that were medically stable without oxygen at 24 to 48 hours, but then if they were unstable or on oxygen, were screening as soon as possible without a real specified time frame, but as soon as possible.

Then others were screening well any time after they were stable or weaned off of oxygen. As you can see, quite variable and this was consistent with our environmental scan at the time with the national landscape. There were two areas where we were seeing quite a bit of variability and one was in terms of the timing of the screen, when to do it, so some were doing it universally across all gestational ages and clinical statuses at 24 to 48 hours and others were doing it more universally as a pre discharge check. So, variability in terms of supplemental oxygen and gestational age as well. The other big question and variability in practice had to do with excluding babies so looking at the NICU as a place where universal screening could be performed or excluding certain infants with pre identified characteristics such as a prenatal diagnosis or an echocardiogram before screening.

Other instances for exclusion were for length of stay, so in some instances, babies with shorter or longer length of stay were not required to have screening performed and then others was the issue of a physician override, so in certain instances, some states or some individual birthing centers were allowing physicians to write an order that a baby would not need screening, if certain conditions we met. This is what we were faced with at the time in 2013, we reconvened the group and with the evidence at hand with the limited research at the time, the recommendations from the group were to continue the current protocol, not to make any drastic changes and that further study was warranted and so with the recommendation to continue further study, that's exactly what we did

and I'm going to turn it back over to Kim who will talk about our evaluation of CCHD screening in the NICU.

Kim: So as Jean demonstrated and illustrated, faced with minimal evidence, empiric evidence and mandated screening to guide our implementation, our objectives were to evaluate the feasibility and burden associated with early timing options for screening and the issue of exclusion of infants with a prenatal diagnosis of CCHD, echocardiography conducted before the screening or those born prematurely from universal screening. We conducted a prospective evaluation of CCHD screening and implementation in the NICU. Stage one was targeted for 24 to 48 hours after admission and we had a modification to this component at stage one, which was only for infants on oxygen at stage one.

The modification was such that re-screening was only required if there was a greater than 3% pre and post ductal differential in the saturations. Saturations of less than 95% that were consistent with clinical profile were deemed conditional passes by our algorithm and saturations that were less than 95% and inconsistent with clinical profiles were regarded as fails. Stage two was conducted only for the infants that were on oxygen at stage one and it was conducted optimally within 24 to 48 hours of weaning from oxygen. The safety net we had a pre discharge screen done only if stages one and two were not completed, so it really, truly was a safety net as opposed to being a pointed stage of our screen, screening algorithm.

I'll go through quickly here, the schematic of the flow chart of our algorithm that I just described, stage one being all infants at 24 to 48 hours including those on supplemental oxygen. This represents our modification that infants on supplemental oxygen were to be screened also, but according to the modifications, so if the first set of screening measurement was less than 95% and consistent with clinical profile, and the difference is three or less, there's no need to re-screen. If the first set of screening measurements is a difference of 4% or greater, a re-screen is necessary. If the difference is 3% or less a pass, if the difference was 4% or greater after three attempts, then the infant failed. For these infants they were screened at stage two because they were on oxygen at stage one, optimally this was performed 24 to 48 hours after weaning. This dotted box represents our pre discharge screens.

Our prospective evaluation using this modified algorithm was performed and we also conducted an implementation survey in the NICU, which we'll talk about, so the study was comprised of 21 units across five states, California, Illinois, New Jersey, New York and Minnesota, so our co principal investigators represent each of these five sites. The study population included a total of 4556 infants, that were born over an eight month period from February through September of 2015. Infants were included if they were in the NICU for more than 23 hours and participating NICUs used data that New Jersey recommended or AAP algorithm for determining past re-screen and fails and for analysis purposes, we universally applied the New Jersey thresholds because all failed screens per the AAP algorithm would also fail the New Jersey algorithm and also of note is that the participating NICUs in our evaluation, were all within high resource settings of pre and perinatal care.

I'll walk you through our study population as I mentioned, our total number of infants in the evaluation was 4556, we excluded 436 infants that either had an incomplete screen or they were deemed having a late stage screen as their only screen, since we were really trying to evaluate early screening as one of our primary objectives. Nevertheless, we looked at this exclusion group and it was quite informative to understand the nuances of why infants were being screened late, how many and then also issues around quality assurance, quality control, interpretation of the algorithm that resulted in an incomplete screen. This resulted in 4120 infants with at least one set of complete screening results within one or more of the defined stages, 3423 were screened at stage one, 24 to 48 hours, 579 were on oxygen, 2844 were not on oxygen and 833 were screened at stage two, with 232 screened only pre discharge, again an interesting number.

As I mentioned, the New Jersey recommended algorithm thresholds were used during the analysis to determine past re-screen and fail rates, and we feel it was surely appropriate since all failed according to the AAP algorithm would also fail the New Jersey recommended algorithm. As I mentioned earlier on, we also calculated false positive rates for CCHD specifically and that's calculated as the number of infants without a CCHD who failed on the first set of screening results, divided by the number of infants without a CCHD that were screened. Of note, when we calculated false positive rates, we deemed conditional passes as passes, but analytically and as we have in our paper that's going to come out shortly, we've calculated it including the conditional passes as fails as well. Of the 4120 infants with complete, appropriately timed screens, 56% were normal birth weight, 72% were not receiving supplemental oxygen at 24 to 48 hours and 92% of infants did not have prenatal CHD diagnosis or echo prior to the screen.

Collectively the majority of our NICU infants or 68% had neither pre identifying factor and were not on oxygen, thus comprising a sub group of infants who may benefit from early screening at 24 to 48 hours. Of the 3423 screened at stage one, 0.9% failed, or 32 infants and 99.1% passed, that's inclusive of the 138 conditional passes. Of stage two screens, 0.6% failed or five infants, resulting in 99.4% passing and the stage one fail rate was low for infants not on oxygen, 0.7%, and of infants with only a pre discharge screen, all passed. Looking closer at the infants on supplemental oxygen, we found that despite the modifications, fail rates were significantly higher among infants on oxygen, 2.1% than among infants on room air, 0.7%. The fail rate for infants on oxygen increased to approximately 26% for infants when conditional passes are considered fails, an important point to underscore.

As they anticipated, stage one fail rates were highest among infants not on oxygen, born extremely low birth weight, less than 1000 grams or extremely premature at less than 28 weeks, at 7.4%, 9.5% respectively and notably higher through these groups when conditional passes were considered fails. Looking more closely at infants that failed stage one, of the 32 infants, 66% did not have a prenatal CHD diagnosis or echo prior to the time of the screen. 63% were not on oxygen, of the 21 of 66% that didn't have a pre identifying factor, only seven had an echo in response to their failed screens. We did find one infant with a previously unrecognized CHD that was detected by screening and this was a baby that was born term, normal birth weight, not on oxygen, admitted to the

NICU for hypoglycemia and had pre and post ductal saturations of 93 and 94, and this was an infant with a ventricular septal defect. Of the five infants that failed stage two, 40% or two infants did not have a pre identifying factor and so as with stage one, screening at stage two did not identify an unsuspected CCHD.

To talk a little bit about the infants with a CCHD in our evaluation, we had 24 infants with one of the 12 CCHD targets, only 17 had complete stage one and stage two screens and therefore were included in the screening outcomes analysis. Of the 17, only two did not have a pre identifying factor, important to tie this back into the fact that our NICUs were representing high resource settings. These two infants had aortic arch anomalies and although they passed the screen, they both presented with signs prior to the screen. Five infants failed the screen and an additional three were conditional passes, so without modification for clinical management on oxygen, eight infants would have failed the screen or 47%. We assessed the burden of screening in our evaluation using three measures, which included evaluation of false positive rates, measuring the burden of unnecessary echocardiography and then we attempted to measure this as a part of our implementation survey.

So, this side illustrates our false positive rates, the overall false positive rates of screening in the NICU was 0.8%, false positive rates were highest among infants screened on oxygen, 2.1% and those born extremely premature, which was our highest false positive rate at 3.8%, compared with stage one screening on oxygen, the 2.1%, false positive rates were significantly lower for stage one not on oxygen, 0.5% and stage two, 0.6%. You can see comparing the overall column to those infants without a pre identifying factor that the false positive rates were actually quite comfortable. Moving on to our second measure of burdens, the frequency of echocardiography performed unnecessarily, we found that approximately 13 infants in the NICU had an echo cardiogram during their hospitalization, yet only seven, or 0.2% were performed solely in response to a failed screen, so that's how we defined burden as it wouldn't have been done, had the infant not failed the screen, yet of these seven of this very small number, one did identify an unsuspected congenital heart defect, the VSD.

Our third informative measure of burden was the implementation survey that we conducted, this was implemented among the nursing staff and there was representation from each of our participating NICUs. Nursing staff reported low burden during the evaluation and this was measured on a Likert scale of zero, no burden, to ten, extremely burdensome, and this was mean of 3.5. 80% reported that a NICU specific CCHD screening protocol, helped facilitate differentiation between screening and routine monitoring with pulse oximetry. The nurses also reported, and 81% of them reported that utilization of the evaluation protocol increased awareness of an unsuspected CHD in the NICU and we'd like to also point out that as a part of this survey, we gained information that having variation in the NICU increased the likelihood of missed screens and so that fed into the responses to the protocol facilitating the differentiation but also the increased awareness, the fact that this was a universal protocol applied similarly to all of the infants with no exclusion criteria, and that there was some reduction in burden, due to the modifications.

As all of our infants with CCHD were identified prior to screening, a limitation of our evaluation is that we did not have sufficient power to conclude that screening with pulse oximetry in the NICU was not of benefit and we were acknowledging that going into this effort that not having an estimate of how many infants would be detected in the NICU due to screening, calculating a power estimate was actually quite challenging, and so we knew that that prevalence would be very low and yet we were aiming to assess the situation and gain some empiric evidence to guide implementation, yet major strengths of our evaluation were that we had the ability to prospectively implement a multi stage protocol and assess different aspects of implementation, we were able to collect individual level information on pre identifying factors that enabled us to further refine the population potentially benefiting from screening, so we didn't exclude any infant from the beginning. Information on echocardiograms performed in response to the failed screens, was really crucial for quantifying resource burden.

Our findings demonstrated that the NICU population is quite heterogeneous with a large percentage of normal birth weight infants not receiving supplemental oxygen and therefore similar to the well-baby populations for which CCHD screening was initially intended. In the absence of systematic screening, approximately two thirds of our population, so those without a pre identifying factor and not receiving supplemental oxygen, were at risk for late detection of unsuspected CCHD and had the potential to benefit from early systematic screening at 24 to 48 hours. Exclusion criteria based on pre identifying factors and gestational age is not straight forward and impacted a very small proportion of our NICU population resulting in negligible added burden.

Additionally, exclusion of this small sub group, as I mentioned, introduced potentially problematic practice variation resulting in potentially missed screens, so the small proportion of infants born extremely immature, extremely low birth weight, higher incomplete screen rates and false positive rates, compared to other gestational ages and birth weights, emphasized the challenges in this population and the need for further exploration as to potential modifications of timing or of the algorithm thresholds. Our false positive rate results, the frequency of unnecessary echocardiography and the implementation survey together, all indicate that the burden of systematic early screening is very low. In total, we feel that our findings suggest that CCHD screening may have a meaningful role in the NICU without the significant added burden as previously perceived. I'm going to turn it back over to Jean to talk about our recommendations for implementation and reporting in New Jersey.

Jean: With our summary from the evaluation, that universal screening in the NICU is feasible with minimal burden, how did we use these results from the evaluation and apply it to recommendations for implementation and reporting in New Jersey. We recreated a one pager and conducted webinars to share the information with our NICUs, and so the question on who to screen, so this was one of our early questions, based on our evaluation findings and subsequent input from our experts, this didn't change, so we are continuing universal screenings that we don't have exclusions of babies with a prenatal diagnosis, the echo performed prior to the screen, or those being transferred out.

With the evaluation findings that it is feasible to do universal screening and the burden is minimal, it was so far well received by our birthing facilities. When they are shown the

data that the prenatal diagnosis and the echo before screening impacts a very, very small population, and with the risks of variability and potentially a missed screen when we start excluding populations, again this was very well received. Another issue that came up in terms of using an echo cardiogram prior to screening as a path for not having a screen performed, our experts were concerned about the timing of the screen, who was performing the screen, the timing of the echo and who was performing the echo, such that in our experience we have had echos performed that didn't pick up a CCHD and subsequent echos did pick up a CCHD on the same baby, so they were reluctant to utilize an early echo as a rule out. So, then when to screen, this was the other big question.

Based on the evaluation findings, the recommendations are to screen as early as possible, so for those babies and we found that the majority are not on oxygen, medically appropriate, larger babies, to go ahead and screen them like the well-baby population at 24 to 48 hours and that for those babies who are on oxygen or receiving other respiratory support, to screen them as soon as possible within 24 to 48 hours after weaning from respiratory support. Until we have provided our birthing facilities with education and resources on both the department of health website and the New Jersey AAP website, have provided a comprehensive New Jersey reference guide for CCHD, have included the newer NICU guidance in the updated document and we've also included the NICU guidance in a free online course for nurses and instructions for accessing the course can be found on both the Department of Health and the NJ AAP website. That's free for anyone to utilize.

So where are we going with this next? Our future directions, well our manuscript is in press, it has been accepted by Journal of Perinatology, we're hoping for the publication soon, and then of course this is really just the beginning that there are multiple opportunities for additional analysis and further research and evaluation is needed to optimize screenings for early identifications on CCHD in the NICU. We do have some interest with our PIs in further examining the role of the differential in identifying CCHD, so that is a new project that we'll be embarking on. So, Kim mentioned the individual PIs, we'd like to now acknowledge all the participating NICUs in the evaluation, also the work in partnership with the New Jersey NICU Collaborative, New Jersey AAP, New Jersey Department of Health and Rutgers University Office of Continuing Professional education who really helped support us in the study instrument. So I think we are, we're on time to turn it back over to Amy and open it up for questions.

Amy: Perfect, can you guys hear me?

Kim: Yeah we can.

Jean: Yep.

Amy: Okay thank you guys so much, this was fantastic and I know I had the opportunity to travel out there and hear some of the discussion and it was very, very interesting and the work you guys have done on this is just really helpful to all of us. I will open it up for questions and Erin I don't know do they need to hit star seven?

Erin: Yeah if anyone wants to ask a question, press star seven, or alternatively go ahead and type your question into the chat box in the bottom left and I will read them out to the group.

Amy: Okay I will start with a question, I was thinking of some questions as I was listening. So certainly I think one of the things in addition to doing the screen that we struggled with is the reporting of the screen and I'm wondering if you encountered any additional barriers to the reporting of results within the NICU outside or different from some of the issues we see with reporting in the well-baby nursery, or did that seem to go pretty well as well?

Jean: So one of the things that came up was for babies on oxygen, so I want to just point out that the algorithm that we presented was for the study and we're not recommending that this algorithm would be implemented in the NICU, so we used that algorithm to evaluate particular timing options so it was a little bit more burdensome for the NICUs who were performing the evaluation because they needed to do the screenings at these particular times and then communicate those results. So that was identified as an area that would need some work. With the recommendation that most babies get screened at 24 to 48 hours, that was well received, it's how to track and we talked about different ways, maybe in electronic medical records, some were even doing a paper tickler reminder, that the baby would need to be screened when they weaned off of oxygen or respiratory support. So this would be some additional communication that would need to occur and it was a shift from doing it at discharge, in terms of a discharge checklist, to screen earlier. Did you have other comments Kim?

Kim: Yeah, no I think you hit it that during the evaluation that we did receive feedback, that collecting information at multiple time points was a challenge and that's why Jean mentioned that the algorithm was specifically to address the issue of unnecessary burden for infants who are on oxygen and that was being managed clinically and appropriately as such, so to reduce the number of repeat screens there. But this issue of tracking did come up and was noted and was another piece of information that underscored challenges for infants on oxygen because we all know how important the reporting is as well.

Amy: Okay thank you, anyone else have any questions or Erin do you have any in the chat box?

Erin: I don't have any in the chat box yet, but just as a reminder, if you do want to ask a question, press star seven on your phone to unmute or go ahead and type your question into the chat box.

Charleta Guillory: Hello?

Amy: Yes, hello.

Charleta: Yes this is Charleta Guillory from, well it's Texas Children's Hospital in Houston, Texas ...

Amy: Hi.

Charleta: Medicine. Actually I'm a member of the TxPOP (Texas Pulse Oximetry Project) team, which has worked with the department of state health services here and we have been struggling with the exact same thing in terms of how to screen our babies in the NICU here. As part of the TxPOP program we've actually had 15 hospitals that are already in place, it was led by Dr. Alice Gong from the University of Texas, San Antonio and we were challenged in trying to find out the best timing for doing our babies. We ended up doing them at 24 to 48 hours of life, we also found that it was also in the very smallest babies where we had the highest false positive rates, but yet before a baby left the unit, at the time of the second screen, which was at the time of a hearing screen, we did a second screen, which was basically almost like your safety net screen.

We actually published that, I think it's in the Journal of Perinatology, she did earlier this year and I just wanted to say that I think we had about 2000 babies or 1900 or so, and we're definitely interested in working with your team, please don't leave Texas out, we're working here and it would certainly be better not to work in a silo but to be able to share and work with other states, so thank you so much for the great work.

Kim: Thank you so much for the comment, it is always good to have Texas on your side too because you guys can give us so many babies.

Jean: Absolutely thank you.

Charleta: We have the system in place with TxPOP already so we have 15 hospitals already, ready to go so thank you so much.

Kim: It's good to hear that your recommendations are similar in trying to move that needle to earlier screening for NICU babies and then providing a safety net to make sure that all are screened.

Jean: Right and I think we were trying to emphasize, maybe more specifically that the screening after weaning happen as early as possible and that it not wait 'til pre discharge, since particularly amongst the very little babies, that timing might be variable or quite long.

Kim: We were trying to get that little buzz phrase of "screen after wean."

Amy: I was just thinking I love that so much, I just typed it out. I would second the fact that it's interesting to hear that you guys are both choosing that 24 to 48 hour time period instead of discharge so very interesting. All right so does anyone else have any questions, or comments? Otherwise I have lots of them, I can keep talking. Okay well I will ask another question of you guys, I know you mentioned this in terms of future directions and that there are quite a few other things that you are going to be able to look at. I'm particularly curious if you have done much in terms of correlating pulse ox values for the coarcs since we know that is one defect that we seem to be very likely to

miss, have you been able to look at that and have you seen anything interesting in terms of sat values around that coarctations?

Jean: Go ahead, go.

Kim: Well so we as a part of our paper one of the appendices actually lists all of our CCHDs and their saturations, so you can look for those specifics when they come out. Interestingly we did have a few coarctations and one was an interrupted aortic arch and that passed the screen and there was one that was a 96 in 100 on one screen and then they didn't go further because they didn't recognize the differential and so that was considered an incomplete screen, but it's interesting that that was a baby that was not prenatally identified, didn't have an echo but then became symptomatic later. Interestingly in many of the instances, had our population been representative of NICUs that were not in such high resource settings, where echos might not be as frequent and infants might not be prenatally identified as frequently, we would have had a population that could have potentially been detected and this speaks to needing sample size that is maybe more representative of the resources across the country but also just significantly larger.

Jean: Yeah and Amy, our experience with the evaluation was similar to what we're seeing nationally and that we are challenged with consistent pick up of coarcs and aortic arch anomalies, so we need to look somewhere else beyond the current status of pulse ox screening for reliable detection of these defects and so, I guess anecdotally we didn't focus on the false negatives, we didn't have any reports of any babies being missed in our evaluation, however the screening did not pick up all of the CCHDs in the aortic arch and the babies present, luckily the babies have presented while in the NICU, but that is a continuing challenge, and a couple of the PIs are continuing some study into the differential and the contribution, specifically in terms of aortic arch anomalies.

Kim: Okay and Amy just speaking to that a little bit more is that is what drove our modification was that we left that differential in, requiring a repeat screen if that differential was present, particularly to address the aortic arch (48:23) anomalies early and to see if we would miss anyone early. So, we did try to get in an aspect of that and because we have all of the saturations, we do present the saturations for all of our CCHDs, but as Jean mentioned, it's a really important question.

Jean: And shifting away from the evaluation to New Jersey's specific experience, we have not had any babies detected solely due to the differential, that the babies had one or other extremity as we know New Jersey's just one extremity less than 95 will trigger a fail and so all of the coarcs that we picked up had one extremity less than 95.

Amy: Okay, very interesting, yeah I think this will be a great opportunity especially if they're going to be screening or you're recommending still screening infants with prenatal diagnosis or echoes, to get some of the correlation we might not see if you're excluding those populations, so you guys will ... Go ahead sorry.

Kim: Well we advocated in New Jersey for collecting all of the data, even on those that are prenatally identified, precisely to get at what I think you're suggesting is just having the data, the saturations on all infants with coarcs, regardless of whether they're pre identified or not is informative, because then you tweak on the algorithm, so thanks for the question it's a really important one.

Jean: And it did help with just similar processes, the feedback we got from many nurses was it's better to do it on all than starting to look at different exclusion populations, so that it becomes a norm, it becomes routine that all babies need to get a screen and that really the percentage of these pre identified kids was really quite small in our evaluation.

Amy: Yeah I think that that is such an important point that you guys brought up and one that I think even I forget about sometimes is the importance of consistency and uniformity in newborn screening, not just even were up in programs but certainly for our stakeholders in the hospital, I'm really glad that you guys look at the relative burden of doing ad hoc screening based on different criteria versus just more truly universal so I think that's a really important point and I'm glad you brought that up again. Anyone else have any questions or comments before we wrap up? It's a quiet group today, it must be nice outside. All right well, I think we will wrap up then and I want to thank you both again so much, the work that you did was and continues to be fantastic and you're going to continue clearly with some of the future directions you're taking things in to contribute to our understanding of the screen so thank you so much for leading the way and being our guinea pig at times. We really appreciate it and I wish everyone a happy Friday and a happy Father's Day weekend.

Jean: Great thank you, thanks for the opportunity.

Kim: Yeah.

Amy: Thank you guys. All right.

Jean: Bye.

Kim: Bye.