PENNSYLVANIA DEPARTMENT OF HEALTH
Bureau of Family Health
Division of Newborn Screening and Genetics
Joint Advisory Committee Meeting

Date: June 12, 2012

Meeting Locations: PA Department of Transportation, Bureau of Construction Material, Materials Testing Laboratory, 81 Lab Lane Harrisburg, PA 17110-2543

Ms. Melia Belonus introduced herself as the Director, Bureau of Family Health. She thanked all the members from both of the committees for starting the first combined effort in working smart.

Board Members from the Technical Advisory Board and the Advisory Committee in Attendance:

Advisory Committee Member Attendees:
James Zeigler, AuD., FAAA, Committee Chair
Elca Swigart, PhD, Reading Hospital, Committee Vice-Chair
Judith Sexton, Director Clarke School
Steven L. Shapiro, MD, York Hospital (Absent)
David Chi, MD, Children's Hospital of Pittsburgh
Ms. Hadley Haas, Parent Representative

Board Members in Attendance:
Gerard (Jerry) Vockley, M.D., Ph.D., Chairman, Children's Hospital of Pittsburgh
Robert Cicco, M.D., Co-Chairman, Western Pennsylvania Hospital
Cheston Berlin, M.D., Penn State M. S. Hershey Medical Center
Ying Chang, M.D., Penn State M. S. Hershey Medical Center
Kaitlyn Kormanik, Children's Hospital of Pittsburgh
Rita Rhoads Martinez Reed, Quarryville Birthing Center
Ed Smith, Magee-Women's Hospital
Andrew Unger, M.D

Department of Health Attendees:
William Cramer, Director, Division of Newborn Screening and Genetics
Caryn J. Carr, Office of the Secretary of Health, Policy Specialist
Douglas Snyder, Assistant Legal Counsel
Arthur A. Florio, Program Administrator, Newborn Hearing Screening Program
Suzanne Bellotti, Program Administrator, Newborn Screening Program
Carolyn Ellison, Program Manager, Newborn Screening
Barb Kendro, Bureau of Labs
Ron Tringali, Bureau of Epidemiology

Public Attendees:
Stacy Antoniadis, PaTTAN King of Prussia
Juli Baumgarner, PaTTAN Deaf-Blind Initiative
Sharon Behun, Director PA Office for the Deaf & Hard of Hearing
Emily Berry, Program Coordinator, OZ Systems

Dr. Robert Cicco, PA Chapter of the American Academy of Pediatrics
Anne Gaspich, PA Guide By Your Side
Kathryn Geary, PA Hands and Voices
Cindy Griffith, Pennsylvania Training and Technical Assistance Network
Bob Wise, PerkinElmer Genetics
PJ Bordani, PerkinElmer Genetics
Bill Slimak, PerkinElmer Genetics
Kate Hagarty, Clarke School
Lynn Hepp, PA Chapter of the American Academy of Pediatrics
Susan Kershman, PaTTAN King of Prussia
Carol Knightly, Children's Hospital of Philadelphia
Jenna Novak, Clark School for Hearing and Speech
Dr. Louis Sieminski, Past Board Member and Audiologist, Hearing Center of Northeast PA
Terra Tolley,
Paul Vetter, PerkinElmer Genetics
Lindsey Smith, March of Dimes
Teresa DeSantis
Delores Smith, March of Dimes
Jen Ebersole, American Heart Association
Jeana Novak

Ms. Belonus opened the meeting by thanking Board Members and the public for attending. She spoke about the Governor's mandate for responsible spending and the switch to holding Board meetings in locations where the Department of Health (Department) is not charged a fee. She explained that the Department has struggled over the past year to balance the need to maintain expert engagement while reducing costs where possible. Historically, there was little concern about federal spending; however, the reality of today is we're watching events in Washington closely and anticipating what may prove to be significant cuts in the Maternal Child Health Block. To date, changes with the activities of this Board serves as our poster child for how can we get the biggest bang for our buck, keep our experts together and maximize what we're able to do with the funding we're allowed to use. The Technical Advisory Board and the Hearing Advisory Committee do a lot of similar and related work. Because of the way science is changing, and with the addition of congenital heart disease to the menu of screens for all newborns of Pennsylvania, we need to tap into the expertise from both sides and understand the point of service delivery system, business processes within medicine, and science and technology from the newborn screening center. So today's our kick-off and we're hopeful it's going to go as smoothly as all the planning has. We appreciate everyone's flexibility with us and look forward to a really robust day of sharing information and expertise.

Will is going to walk you through the structure of the day. I will be leaving for another meeting but will return this afternoon. If anyone has any questions or concerns, I will address them now. Again, because PennDOT did some pretty thoughtful planning we have the ability to divide the room, so were' going to be doing that later on this morning because we know it's important for each group to do their own business.

Mr. Cramer noted staff was still getting used to this site and the technology available which surpasses anything previously available. He continued by outlining the process that led to the decision to merge the two advisory groups. But before jumping into that, Suzanne Bellotti requested he announce to everybody that attendees needed to specify their name before speaking so the transcriptionist can capture the information. The Division of Newborn Screening and Genetics has two advisory groups that staff work with closely: Newborn Screening and Follow-up Technical Advisory Board and the Newborn Hearing Screening Technical Advisory Committee. These two groups each met separately as least three times a year and addressed very specific issues to their independent programs. It's really no surprise that one of the main reasons we're taking a look at merging the groups has to do with the economic situation in the state and across the nation.

One of the things we, as a state agency, were tasked with doing was taking a look at and evaluating the necessity, productivity and cost-effectiveness of different processes and procedures we have in the state. When first presented with evaluating Boards and Committees, it was apparent our Advisory groups were necessary. And due to the Newborn Child Testing Act and the IHEARR Act, program is required to have and utilize Advisory groups. It goes without saying that the work the boards do is vital to program operation. Program needs expert guidance and our groups have proven to be very productive.

We also have to measure cost-effectiveness by looking at what we're doing and how we're operating. We can do better on that front. For years, we have been meeting at the Dickinson Center where we paid for the room space. While Dickinson is a convenient and comfortable locale, the Department paid to use the space. So, one of the first things we committed to doing which actually came down as a directive, was to not pay for meeting space. Upon further research, we found the State has space with ample technology and this site is becoming more popular, as more and more agencies figure out it exists and tap into the resources.

While it may have been challenging to find the meeting location today, future meetings should go much more smoothly since we now know how to find the Transportation Laboratory. We plan to hold the October meeting at the PaTTan Offices. After we use the PaTTan Office location, I would like feedback from the two board and committee members as to which site they prefer. Attempts will be made to use the preferred site for future meetings.

Another option would be tele-meeting. And I talked with several of you about setting up meetings by Web and tried to determine if that would really be an option for us. It sounded good and would cut down on Board member travel; however, we still need to provide accommodations such as interpreter services, transcription services, etc. and that's the reason we need to do it at one site. If we had multiple groups across the state meeting and telecommuting or tele-meeting, we would need to make sure that we had interpreter service sat each of those sites and those costs add up pretty quickly. Therefore, we determined that having a meeting here in Harrisburg three times a year is most cost effective. We never really know if and when we're going to need an interpreter onsite. If somebody does request that, we need to make that accommodation. We also have our transcription services and

one of the things that we get by having a transcriptionist is they double as cued speech. And of course, we make sure we get everything documented verbatim the way it happens during the meeting.

And the final thing we took a look at was our catering services. And I know that you've heard discussion on both ways about whether or not we're going to provide lunch. When it comes right down to it, it's going to be cheaper to provide catering services onsite, so that we can continue with our work, move through the day, get everybody out at a decent hour so we can get back on the road and get the member that come by train back down to the train station in time manner.

The only thing that's not on the agenda, but I will mention, is for those individuals who travel by train. Rather than having everybody take a cab, we are able to provide a state van to transport members to and from the train station. We just need to make sure that you let us know that you need that accommodation and we'll provide it. The van will shuttle back and forth.

So what we get by making these changes is the elimination of costs for the meeting room, reduce planning and coordination time, minimize catering expenses, and reduce time demands on everyone . The not-so-obvious reasons for merging the groups: In the past couple of years, there have been changes in the landscape of newborn screening, with more and more attention being given to the care. Traditionally, newborn screening, again, was focused on the blood spot; hearing screening was our initial point-of-care test that was introduced with very significant state legislation, the IHEARR Act, which created our Newborn Hearing Screen Center.

We had discussions that add congenital heart disease, which would be the second point-of-care screening and we know it's not going to follow the normal metabolic path. It's going to be more in line with the way the hearing program is run. So even though the economy may have hurried along this change, it's actually something that we've been thinking about for a while. Knowing that adding CHD will require the medical expertise of the Metabolic Advisory Committee as well as the experience the hearing committee has had in implementing the point-of-care program, it only makes sense to create the arena and we can benefit from both sides. And that's what we're trying to do here.

When we're talking about merging the two committees, I'm talking about taking the first period of the meetings to address joint concerns. Anything administrative that comes up affecting the newborn screening, the division and how it plays out will be able to address in the beginning, including congenital heart disease. Once we've addressed joint concerns, we want to provide the means to split into two groups and let you address specific things for your programs.

So it will impact the time that you have to work together. In future meetings, we're probably going to get in, get to the point, address joint issues, then let you split off and deal with your own kind of things.

One concern overheard in recent weeks is that joining the groups was going to water down the purpose of your work. This was and I really want to emphasize that the goal here is to get the expertise of those medical experts in your specialties, as well as your experience implementing the program via blood spot or point-of-care.

In some past meetings, we actually have been a little more lenient and allowed people to contribute if they needed to. Going forward we want to make sure the board has the opportunity to address Board business and if somebody from the public wants to comment, they'll be afforded that opportunity once the Board actually requests somebody to contribute at any point in the meeting. That will give us a little more structure and help us control meeting time.

Somebody also questioned the joint chairman regarding who will be in charge of this first part of the meeting. We view that as being more of a staff function, either myself or one of the program managers will kick off he meetings. The chairman of the two separate advisory groups, metabolic and hearing or point-of-care, will continue to run their meetings when we split out into our separate groups.

The last piece that needs addressed is travel. We sent out a detailed summary to all the board/committee members explaining the travel reimbursement policy. It was actually redone and went into effect on January 1st of this year. Basically it requires any state travel, employee or non-employee, functioning on any business, needs to make sure that we're traveling via the cheapest route possible. Many of you don't request reimbursement for your travel, but you basically have the right to be reimbursed for your travel. If you are looking to be reimbursed for travel, you need to make sure that you're getting in touch with our travel arranger in the division, who will figure out the cheapest travel options.

The next part I need to address is the restructuring going on within the division itself. Historically, we've had the Newborn Screening and Follow-up Program. And their main concentration has been on genetic and metabolic screening. They currently are dealing with 28 conditions. Originally, they had six mandated screens, up until Act 36, which gave them 22 more for follow-up. So they're currently dealing with and following 28 conditions. The hearing screening section does follow-up and early intervention for hearing screens. We also have the genetic section, which primarily supports hospital and community-based organization infrastructure for comprehensive specialty healthcare needs of children. We are looking at making the focus of the Newborn Screening and Follow-up Program conditions screened using the bloodspot filter paper. The hearing screening section will handle all point-of-care conditions. The genetic section will focus on case coordination and helping to bridge for gaps in transition between the newborn and the metabolic. Additional changes will be forthcoming to equalize staff workloads.

On May 11, 2012, the program submitted a tentative plan for implementing CHD. Again, I stress tentative, because we need the Board's input on what we put together. But we are actually looking to implement CHD and that approval was received on May 17th. I'm actually going to be addressing a part of this later, in the separate meetings, but the Metabolic Technical Advisory Board recommended the addition of two conditions. Basically, when they put the recommendation in, one was congenital heart defect and one was severe combined immunodeficiency disease .

When we take a look at implementing these two screenings, we have to take a look at our laboratory information and the systems, as well. Basically, we have a new system in place for hearing screening.

Hearing staff received the Oz System and is currently utilizing it in production. Our metabolic side continues to need a new system.

With the redesigns discussed previously, staff has been working to examine how systems will need to work together going forward and integrate requirements for all three program areas. Therefore, we are still looking at a period of time before we have a replacement for our old Prequel system. That plays into how implement new conditions. We must have a way to deal with incoming data. Right now I don't know that Prequel is going to be able to handle another condition. So SCID implementation is dependent upon successful implementation of a new laboratory data management system.

CHD, on the other hand, is not so dependent on a new system. Because it's not a blood-spot test, it's not going to have to filter through that laboratory system. We can focus more on aggregate information and hospital reporting. So one of our tentative plans for CHD is to target January 1, 2013. What we're looking at, initially, is aggregate reporting from our hospitals. Something to the effect of the number of pulse ox screens performed each month, the number of echocardiograms performed each month, the number of pediatric cardiologist referrals each month, confirmed cases each month. Draft forms were passed out for review and feedback.

Along with that we're looking for treating physicians to report patient level information on all confirmed cases. A draft form was passed out and we need the feedback on whether you think we're hitting the target or we need to get something different. These reports, once they're submitted, will end up coming in to the division, and I'm going to be working with our program administrators and our business analyst within the division to actually take these hardcopy reports as they come in, transcribe them into whatever database (Access, Excel) we need to have to track, work and analyze the data.

I don't anticipate that being too much for the division to handle until we get a new system that can actually absorb the data. So the good news is we have the green light for adding CHD, I have a tentative implementation date of January 1, 2013.

We also did a preliminary inquiry of our 104 birthing hospitals. Of the 104 hospitals surveyed, 50 responded. Of those respondents, 24 reported that they are currently performing pulse ox or will be by the end of July. Eighteen (18) reported they do echocardiograms onsite, eleven (11) have pediatric cardiologists and ten (10) have the ability to offer consultations at the hospital. So we know there is some work hospitals will need to be doing to ramp up.

We also had an initial meeting with the Hospital Association of Pennsylvania (HAP). And that was in early May. We both agreed that we need much more discussion on the subject, but what the initial impressions were is that from taking a look at that inquiry data from the hospitals, it basically looked like NICUs were performing screening relatively routinely; other pediatric wards were not so consistent.

There is no easy accessible reported mechanism. Mary Marshall shared that basically the nurses in the hospitals are reporting the pulseox information and the screening information in the patient records. But whether or not that's electronic and able to be pulled out easily, we don't know. And it was suggested we pull a representative sample of those hospitals that we received responses from together

to discuss how we should proceed. Ms. Marshall confirmed Mr. Cramer's comments were correct. The goal now is to make the January 1, 2013 deadline. Mr. Cramer passed out the CHD reporting forms. If anybody on the board has comments, the DOH staff is open to those comments. He also offered more time for the advisory board to review the forms.

Mr. Slimak questioned if these plans include quality assurance, standardization, training requirements, and certification or qualifications of operators. Will that be part of the program? Mr. Cramer's response was that we need to address quality assurance at some level. What is tentatively planned is that the division will be securing a contract quality assurance nurse. But we're looking to hire somebody specifically to serve more of our quality assurance needs, be able to assist the metabolic and point-of-care program nurses with training, outreach, and technical assistance in hospitals. We are still in the preliminary phase of ascertaining this position.

Dr. Cheston Berlin commented that Hershey Medical Center screened 976 babies and zero were picked up as having CHD. That isn't a correct number, as it should have been ten. So where are those babies? Is this an operator error or is it the time that the test is done? There's just so many variables involved, that I think we have to do some rather sensitive program that training experts use. Mr. Cramer noted that in the studies done on pulse ox screenings, the positive, not the false positives, but the actual positive per the number of screens was only a couple per thousand. Dr. Berlin noted the overall rate is ten percent, so there should have been at least several cases. Disease and other diagnoses were made. Dr. Berlin is concerned about the technology of this process.

Dr. Cicco, an endocrinologist in Pittsburgh, stated his concern with the process as it's set up now. He expressed there would be a wide variation of terms of what the results are from various hospitals. So there's clearly a need to make sure that this is being done properly to minimize both the number of false positives, especially so that we're not doing echos, but also minimize false negatives. The concern Dr. Cicco has is who will perform follow-up tests on positive screen and if you have a cardiologist in your hospital and they come and perform the echo. But that won't be the occurrence in all hospitals. A lot of the babies will either get consultations in another hospital, maybe the paper (form) will be transferred to another hospital, and that's where the echo is done, and ultimately where the diagnosis is made. And with this process, you're putting the responsibility on the delivering hospital of tracking the baby to figure out what the outcome of the positive screen was. Dr. Cicco doesn't feel this process is going to work because what happens is that the baby is transferred and sadly sometimes falls into a black hole. And the hospital where he was born doesn't know what happened to him. So to expect a hospital to come back and say, we're going to track and call and dig up the information on those kids, it doesn't really work that way. What it means is somebody's got to track them and figure out what is the outcome of those positive screens. And then the question becomes, is this doable…on a state level? Now, we're back to identifying how many expected positive screens we're going to get, because if it's 7,000 positive screens, that's going to be a lot. Even the period to follow up should be way shorter that it is here, so that the ability to or the need to track for long periods of time like we've had to do with hearing is going to be less.

But he feels the number of positives that we're going to get is going to be a relatively small and manageable number. So the basic question we need to ask, who's going to track and follow the positives? Is it going ----? Do we ask the hospitals do as best they can, but also have the state track them? Or are we going to lay it on the hospitals to try and get that-----? Because I could be giving you bad information, if you just lay it on the hospital, so - - - .

Ms. Rita Rhoades a nurse midwife, noted "on the back where you put "individual", it says midwife, but on the front you just have hospital birthing facility. And even though I'm from a birthing center, there are many midwives delivering only at home. Ms. Rhoades continued by saying there are doctor's still doing home births. So, the form needs to say hospital, birthing facility, birth practitioner and not just a midwife, because in certain areas there are doctors doing home births. The other thing that's important is when the hearing screening committee a lot was being charged and midwives couldn't afford the hearing screening machine. But the state was able to provide the midwives with the screens. And, sometimes, midwives share because they're close to each other. But at least they were available. And the hearing screening among midwives is a fairly high acceptance rate, because the machines are available. Ms. Rhoades says they've seen the prices of pulse ox machines and as part of a birthing center as being part of the standards developed 913, so we would be doing it anyway. But we're still wondering how we're going to afford it for the home births, because it's fine to have one at the birth center. But when you have six midwives on staff and they're all out at home births, then you also have to buy one for every nurse midwife who's going out.

And if each machine is $5200 plus the disposable things for each baby, which you would be charging the midwife. But she proposed that maybe the state look at somehow, maybe pulse ox is available for the out of hospital midwifery community. She feels that's one way, especially, with the lay midwives and wants the state to be aware.

Mr. Cramer noted that money is tight, but the state will certainly consider it and see what can be done. He also suggested that a subcommittee from both the advisory board and advisory committee be developed so these issues could be resolved. We can revisit this.

He questioned if there was any other business?

Mr. Unger noted that either committee had the cardiology expertise, so maybe we could bring someone it to assist.

Mr. Cramer agreed that that's one of the things Ms. Ellison brought up, that is, adding a cardiologist to the committee.

Mr. Jerry Vockley noted that as we've scanned the number of diseases it's not going to be possible to have a specialist for every disease on the RUSP. So we need to get out of that mindset. We can bring on ad hoc expertise as needed. If you're talking about implementation, we could get for CHD, we could get an ad hoc committee that would cross over the two committees, plus bringing on the necessary expertise. I mean, you just have to be careful, because otherwise, we, the chair designed by a committee that no one can ----. I just wanted to help for two seconds and actually say thank you for

letting us know that this is being implemented, because this is the first official notice that I received on the original recommendation from the committee. And it's nice to get that feedback. It would be nice to get maybe something in writing when a decision has been made like this. It would be nice to send it around in advance saying a decision's been made, rather than coming in and evaluating and implementing it. Just a point of courtesy in the future for your hard working volunteers. Ease up on morale even though you can actually accomplish something. And the third point, if you're still talking about costs and we've been ----we put forth a proposal about how to generate revenue to take care of costs related to newborn screening----and I think that we can continue to urge the program, the department, the Secretary to seriously consider that. We can't do this for nothing. Your staff can't do this for nothing. We need to fund these efforts. And I don't know if that recommendation got back to the hearing committee. But the recommendation was that we go to a filter paper fee that would bring in the money to the program for to pay for all of the extra fees that we have. At this time, there was an OFF RECORD DISCUSSION.

Dr. Sieminski noted he was involved in the development of hearing screening in this state. And the sponsor of the bill, Senator Charles Lemmond died this past week. And every time he came into my office, he said "How's the program doing?" And we developed that program based upon his legislation. That took a lot of hard work and volunteers to sit on boards and work with the department. And I watched as that program grew. And we knew it grew because of the statistics, the data. Every year we picked up more kids with hearing loss. When we picked up more kids with hearing loss, not only did we change lives, we saved money. They estimated $100,000.00 per kid. And I'm sitting here talking about cost savings of meeting this. And I'm saying to myself the directions are going the wrong way. We need to pick up more kids to save a hell of a lot more money and change kids lives. It bothers me also that we have a joint meeting, I don't like being joined. I had a purpose on that board. That board met and developed that program the best way we can, I know you have a job to do. What bothers me is that this decision was made without any input from volunteers who serve on these boards. It was unilaterally decided by the Department as of saving money. I commend that. I'm a taxpayer. I'm not sure if it's legal. We'll see. I'm not sure if it's legal. That legislation signed into law giving us specific guidelines for doing it. We were to meet and do the peoples work for hearing impaired children. I commend all the other volunteers on all the other boards. Go and do your work, do what's right for the kids and the families. But I'm not sure I agree with the way this is going. And the way we will know is I'm going to be watching. Next year, I want to see the statistics and if your statistics start falling down, you're going in the wrong direction. I'll make $1 bet. I hope I'm wrong. I hope I'm wrong. I hope I come in the meeting and say, way to go, we're picking up more kids. I don't think we will. Why? We cut funding. Like the gentleman said, we need money. Programs need money. They took $264,000 out of our budget that changed kids' lives with ----picked up 400 kids last year with hearing impairment. It's just wrong.

Mr. Cramer thanked Mr. Siemiknski for his comment.

Mr. Andrew Unger said there's actually a little bit of a difference between screening for congenital heart disease and screening for hearing. Because model hearing impairment can be very significant. But there are many congenital heart lesions that really are insignificant. They're there. They make a noise.

You’re not going to be symptomatic – they’re not going to be symptomatic from it. The most that’s ever going to happen to you is maybe antibiotics when you go to the dentist. So I think, then, it’s understandable that you have this great concern about resource contractually, because it really does make a difference if the kid has 30 bp hearing loss. It really doesn’t make a difference if the kid has a tiny muscular TSD. So, the trouble is that we have apples and oranges being put into the same place.

Mr. Cramer asked for any other feedback from the board or the public. He concluded this portion of the meeting. The joint group is to break at 11:00. We can break and reconfigure the room and each group can get started with their separate work.

If anyone is willing to serve on a subcommittee, Point-of-Care, CHD, please let me know. We’ll be putting something together. The meeting concluded at 10:32 A.M.