SECRETARY'S ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN

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Friday, January 28, 2011

AFTERNOON SESSION

PUBLIC COMMENTS

CHAIRPERSON HOWELL: We have three people signed up to comment. If the people are not in the room, we will miss their wisdom.

The first person on my list is Kelly Leight.

(No response.)

Jim Bialick.

DR. TERRY: Jim Bialick is not back.

CHAIRPERSON HOWELL: And Annamarie Saarinen.

(No response.)

As we've been talking about today, we have really a very tight schedule that we're going to adhere to. I'm told that there's already a little bit of flurrying that's going on and, although it may not be much, those sorts of things tend to slow things down, and our colleagues who are trying to get elsewhere will be a real problem.

I am going to be commenting actually for Tracy Trotter. Tracy has worked very, very hard on the congenital cyanotic severe -- congenital heart disease, and just before the meeting that was held here he had a family emergency and was not able to come. So I'm going to report on that meeting.

REPORT FROM THE CCCHD MEETING

CHAIRPERSON HOWELL: As you all will remember, in September the committee reviewed the final draft of the evidence for critical congenital cyanotic heart disease and voted to add this disorder to the panel, with the understanding that the following activities would take place.

The first was the National Institutes of Health shall fund research activities to determine the relationship among the screening technologies, the diagnostic processes, the care provided, and the health outcomes of affected newborn with critical congenital cyanotic heart disease as a result of prospective newborn screening.

The second was the CDC would fund surveillance activities to monitor the critical congenital cyanotic heart disease link to infant mortality and health outcomes.

HRSA would guide the development of screening standards and infrastructure needed for the implementation of a public health approach to the point of service screening for critical congenital cyanotic heart disease; and that HRSA should fund the development of, in collaboration with the public health and health care professional organizations and families, appropriate education and training materials for families and public health and health care professionals relevant to screening and treatment.

The other document at the seat of members of this committee is a confidential copy. It's a pre-publication from the U.K.'s health and technology assessment report on newborn screening for critical congenital cyanotic heart disease, a remarkable document with

extensive data.

So we convened on January 13 and 14 a committee formed by the congenital cyanotic heart disease workgroup, and I'd like to share briefly with you some of the results of that meeting. The meeting was held here in Washington at the Hart House, which is the offices of the American College of Cardiology that are based here. It was a remarkably, I thought, effective meeting. I stood in for Tracy and the co-chair of the meeting was Bill Mahle, who is a pediatric cardiologist who's been very interested in newborn screening for congenital cyanotic heart disease for a very long time.

Let me just briefly go through some of the outcomes of that meeting. It had -- there were about 35 people present at the meeting, but an enormous representation of participating organizations, and I'll let you spend just a little bit looking at this, because we had the NIH, as you can see. We had obviously this committee. We had birth defects programs, the Academy of Pediatric Cardiology, medical genetics, the American Heart Association, the Association of Public Health Laboratories, as you can see, Baylor, Cincinnati Children's, the Mayo Clinic, New York State Department of Health. We had the folks from Sweden, who have been active in this area. We had the representation from the Birmingham Group that had prepared the document that you have before you, University of Maryland, and Utah.

I think it's fair to say that there was an enormous representation of neonatologists and cardiologists who have been active in this area and a great deal of information was there, and a great deal of enthusiasm.

The invited speaker was Andy Ewer, who is the senior author of the document you have before you that's the U.K. health technology assessment document. There was a lot of data that came from Europe, presented by Ann Granelli. Alex Kemper and other people spoke, as you can see there.

(Slide.)

As far as the general comments about the meeting, there was wide support to begin screening, and there was a great deal of unpublished evidence, including the document which you have before you, that the number of additional echocardiograms will be very small if the appropriate cutoff levels for oximetry are applied. Messaging is critical. Not every kind of heart disease will be picked up, obviously. But also, as you're very much aware, non-cardiac conditions will be identified. For instance, if a baby has a severe pulmonary problem that results in lowered oxygen saturation, that baby would be picked up.

The group addressed the key issues needed to begin implementation in a safe, effective, and coordinated manner. The pulse oximeter, again there was a great deal of information among that very auspicious group of cardiologists and neonatologists that were there, and very, very important things that they had learned already in these big studies, that the oximetry technology, it was very important that it not be sensitive to motion. Obviously, everybody who deals with babies is aware of the fact you need something that's not going to be affected by motion.

There was a discussion about reusable probes that can

decrease the cost of screening a great deal. The right hand and foot appear to be the most appropriate place, and I might point out that measurements in both places is recommended. The timing, there's a good bit of data there. Also, the current data suggests that under 95 percent or 3 percent difference between the probes at the two locations would be a cutoff value for requiring further study.

There was a discussion, however, that there needs to be more data about the impact of high altitudes, because the studies that are available, extensive studies from Europe, have not taken place at elevated altitudes. (Slide.)

The short-term follow-up and diagnosis, obviously this would take place in the center frequently. The echocardiogram, a discussion of in-house transfer via telemedicine. I think that most of the people around this room are aware of the fact that one of the few well-organized, or certainly moderately well-organized systems in American medicine, is the handling of sick babies. There virtually is -- virtually every small place has a system whereby if the baby has a problem this is what we do, and those systems involve established transports and referral lines and so forth. This is going to be, obviously, invaluable.

However, it was felt that there needs to be development of protocols within the nurseries before the screening begins, so that there's a consistent pattern and this is exactly the way it should be done.

(Slide.)

The training and the education, with protocols to opt in

and opt out of screening for the parents. Training of the screeners, training needs. Again, this is interesting because virtually every unit, even the small ones, today are doing pulse oximetry. But one would have to establish the exact location and so forth for this particular program.

Public education. Some material has already been developed and presented and the Children's National Medical Center that has screening programs in the metropolitan Washington area has a well-established toolkit all ready to go, that is already in use. And there is a need for a clearinghouse of information.

(Slide.)

The cost, the setup costs are there, the oximeters and the probes. The diagnostic, the maintenance of equipment, primary screening time, diagnostic cost, insurance coverage, etcetera; and obviously the interesting thing is there currently is no code for oximetry screening that would be a prevention screening, as opposed to the screening indicated because of some clinical indication.

(Slide.)

There was considerable discussion about how the results would be handled. It was hoped that they'd be embedded into electronic records and that existing codes would be used. Health information exchanges should be promoted. Public health programs can play a really important role in assurance and quality assurance, and birth defect registries could track the impact of the screening.

(Slide.)

At the end of this discussion, it was decided that a group

would develop a white paper that would describe implementation plans of how one would implement this program and some specific suggestions about how to do that. That would be presented to this committee, develop a consensus screening algorithm, and by that I mean the placement of the probes and the current best information about the cutoff levels for the oxygen; a central clearinghouse of information would be required, and then rollout into nurseries once implementation and surveillance plans are in place.

(Slide.)

So that's a very brief overview of this meeting. Other people in this room were at the meeting and might well wish to comment. But I think, in summary, there was a wide representation of a group present, considerable enthusiasm about doing this, and the awareness of what needed to be done to move it out, a feeling that there should be some substantial efforts in pilot programs and so forth before you roll it out to all the nurses.

I must confess I was thinking very much as I was at the meeting it would be very much like the SCID issue.

The other thing is general agreement that many of the systems are in place in this country to help with handling of the data that come out of these programs.

I don't know if anyone else at the meeting -- Michele, would you like to comment, or anybody else, about key issues that I've not hit on?

DR. LLOYD-PURYEAR: No, I think it's probably more appropriate for Coleen, one of the members, committee members.

CHAIRPERSON HOWELL: Coleen, would you like to comment, please?

DR. BOYLE: Thank you very much. I thought your summary slides were excellent, Rod. I guess the only thing I would ask, on the next steps slide, whether you see this -- or whether the white paper was going to include all of what was underneath that? Maybe if you can go to that last slide.

CHAIRPERSON HOWELL: Can we pull that back up?

(Slide.)

DR. BOYLE: Well, anyway, I can describe it.

CHAIRPERSON HOWELL: There we are.

DR. BOYLE: Do you see the white paper including the consensus screening algorithm, perhaps laying out the idea of the clearinghouse? I don't know. I was just wondering how all of these things are going to happen.

CHAIRPERSON HOWELL: Certainly. They were discussed as issues that should be at least raised in the paper. So to answer your question, I think the answer to that's yes.

DR. BOYLE: They all would be?

CHAIRPERSON HOWELL: Yes.

DR. BOYLE: Particularly the last one, in terms of actual implementation.

CHAIRPERSON HOWELL: That's critical. That's the key thing, and we would anticipate that this group -- one of the things that's very interesting, some of the folks that were there at the meeting have had direct personal experience in transporting this

technology to other hospitals, particularly the Children's people that were local. They have actually, they've developed it in house, they've done it here, but then they've developed the system and taken it out to a smaller hospital, and they have experience in actually doing it there and seeing what happens and how to handle the data.

But I think that this could be very informative. This is a very well-organized group. It was really fun to be there, because they have it together. There's networks there and so forth.

Now, the other thing that we discussed somewhat, the National Institutes of Health has a number of national registries of various and sundry cardiac things, for want of a better word. And figuring out how they might relate to this will be important. That's a big issue.

DR. CHEN: Dr. Howell.

CHAIRPERSON HOWELL: Yes?

DR. CHEN: It's Freddy Chen.

CHAIRPERSON HOWELL: Yes, Freddy.

DR. CHEN: With a question. It looked like -- was this actually convened by the American College of Cardiology? The other question is, it sounds like this was an effort that was maybe already under way even before the committee took its action; is that correct? Or did this come out afterwards?

CHAIRPERSON HOWELL: Two comments. Number one, it was convened as a working group of this committee. It was kindly hosted at the American College of Cardiology, but it was a working group of this committee.

Now, some of the folks there have been thinking about and involved in and doing certain pilot studies in newborn screening for hypoxia for a long time. So the point is that this was not a new idea to them, but they were enthusiastic that the committee had taken it up and was making an effort to move it along.

Kellie.

DR. KELM: Dr. Mahle --

CHAIRPERSON HOWELL: Yes.

DR. KELM: He actually was the lead author on the 2009 CCCAP -- was it guidelines?

CHAIRPERSON HOWELL: It was a policy statement, yes.

DR. KELM: At the time it only recommended tertiary care. Now he was definitely positive about moving it to newborn screening at the meeting.

CHAIRPERSON HOWELL: I did not bring this out, but early in the meeting Alex Kemper reviewed the evidence that was presented to this committee. So he went through the evidence document with the group that was gathered there. Again, as Kellie pointed out, Bill was one of the -- he was the lead author on this policy statement.

DR. KELM: One more quick thing. I thought it was really interesting. Even though most people were not traditional newborn screening people, one of their key issues that they kept coming back to was reducing the false positive rate and a way to do that and a way to make the algorithm such that we could minimize the false positive rate. It was interesting; it was something in parallel to what we talk about here often.

CHAIRPERSON HOWELL: Along that line, Andy Ewer, who spoke from the U.K., the senior author of the document you have before you, has a great deal of experience in trying to set the cutoff value so that they don't miss anybody, because their system is such that they know who is out there that they might have missed, and at the same time actually minimize the number of follow-up studies that have to do. They've gotten that down pretty darn good.

Coleen and then Mike.

DR. BOYLE: I was just going to make a couple quick points. First, I think it was interesting the evolution and experience among the cardiologists in picking through the complexities of false positives. Going back to Ned's earlier point about being very conservative about setting the threshold for screening and the idea of trying to do more good than harm, I think that overnight when they were thinking about it they actually -- or at least Bill retracted in his mind and came back to being more conservative in the initial cutoff. So I thought that was actually an interesting evolution in thinking, seeing the process work. So that was one issue.

I do think that, from a short-term and a long-term follow-up perspective, beyond this initial screening, I did feel everybody thought it was a lot of complexities in the system. So even though I think they were all positive about it, I do feel like there weren't any easy answers, and I think that's one of the reasons the cutoff value for a positive screen was rethought overnight, basically trying to minimize the potential impact on the system.

I forget what the third point was.

CHAIRPERSON HOWELL: Mike.

DR. WATSON: When the committee looked at it, it was single pulse, and now you said -- is it a mixed model, then, where 94 percent on upper or lower extremity, or is it a differential, or a combination?

CHAIRPERSON HOWELL: I'm sorry, I missed your first part of your question.

DR. WATSON: When we looked at it, it was single pulse.

CHAIRPERSON HOWELL: Yes.

DR. WATSON: Just a single oximeter.

CHAIRPERSON HOWELL: That's right.

DR. WATSON: Now it's apparently dual.

CHAIRPERSON HOWELL: Yes.

DR. WATSON: And it's supposed to be the differential between upper and lower. So is it a mix of 94 percent somewhere gets you there and then the differential adds on?

CHAIRPERSON HOWELL: That's correct. For instance, there is a specific cutoff that will get you a follow-up. But if there's a differential of 3 percent between the upper and the lower, that gets you a follow-up.

DR. LLOYD-PURYEAR: And you're doing three screenings.

DR. WATSON: Okay. That's good, because each one misses some things.

DR. BOYLE: Maybe I remember incorrectly, but I thought it was greater than 95 or 94.

CHAIRPERSON HOWELL: Yes, it is.

It's interesting, there has been a considerable amount of email since the meeting with the U.K. people that they continue to look at their numbers. But the exact figure I think is probably going to be around 95, but I think that's beyond the scope of this group here. But that needs to be looked at to be sure you're not missing anybody and that you're lowering the false positives. They have been extremely sensitive to that, as Coleen points out.

DR. WATSON: Then I had one other quick kind of question, comment. Getting things into the registries that NIH or NHLBI has ongoing will accomplish something, but if we don't get it integrated across newborn screening it's going to be confusing, because we're going to be -- the SCID screening is going to be picking up the DiGeorge patients or the interrupted aortic arches and TETS and truncus and a lot of things that are going to also be detected in critical congenital cyanotic heart disease.

I'd hate to replicate hearing screening, where we get a phenotype and never get to the etiology. The genetics of this stuff is really hard. A lot of the transcription factors, you can use them at one level, but they're awful for prediction. But there's a fair bit of genetics. It's very hard to tease out of the literature because of the way the literature presents things, and nobody's presented it as sort of the outcomes from starting with this population and screening.

CHAIRPERSON HOWELL: Let me make one comment and then Michele has something. The thing is is that I don't think anybody had any clear idea that this would be necessarily placed in an NHLBI

registry. But there was a discussion about how those registries could relate to that. But everybody is extremely sensitive to the points you made of how the data will be handled.

This is the problem with the point of care testing, and it's a big issue.

Michele has a comment.

DR. LLOYD-PURYEAR: On the genetics, currently the registry that's used for the cardiac surgeons, every infant receives genetic testing. That's part of it.

DR. WATSON: Well, from a diagnostics perspective, you do deletion 22 and stuff like that. But NKX2G and Gadda-4 and Gadda-6 all clearly have -- from research, they clearly are involved in development that leads to some of these cardiac congenital heart defects.

CHAIRPERSON HOWELL: Well, we'll have a great opportunity to look at some of the recommendations that come out of this group.

DR. WATSON: Nobody has treated those diagnostically --

CHAIRPERSON HOWELL: I think the group is very sensitive to how the data, how will the data be handled, how will it be managed, and so forth. And we'll have to see about this.

Chris.

DR. KUS: I thought the point that the outcomes of this -- I guess from my understanding of birth defects registries, and particularly from New York State, that is not something that they regularly do. I'd be interested, was there any discussion about that, because it just seems like that's out of what they do.

DR. LLOYD-PURYEAR: There was discussion and there wasn't agreement one way or the other. There was discussion. Phyllis Lawyer raised some of the same concerns you did. We brought, or CDC did, or we helped bring, the birth defects person from New York and Utah. Actually, Coleen can talk about this, but sort of the ideal birth defects program is in Utah and they are very much more than just surveillance.

DR. KUS: But what I'm talking about is capacity across the country with that.

DR. LLOYD-PURYEAR: No, that doesn't exist.

CHAIRPERSON HOWELL: There was discussion, I think it's fair to say, of the ideal registry, which is in Utah, and the response to that is that that's absolutely wonderful, but that does not exist wildly. So that did not go unknown. Although the folks from Utah thought it would be great, and I would agree, if we had that throughout the country, it doesn't exist at the current time.

DR. KUS: What did the person from New York say? I mean, I know the person. I'll talk to her.

(Laughter.)

DR. KUS: Never mind.

CHAIRPERSON HOWELL: She said Dr. Kus is really a nice guy.

(Laughter.)

DR. LLOYD-PURYEAR: I have a bureaucratic thing to say. What we will be doing -- if you remember, what the Secretary said is that they will be -- she will be looking at a review from the federal agencies on this recommendation. So that the federal agencies that

were there -- NIH, FDA, and CDC and HRSA -- will be working on a report for the Secretary, that will be about the recommendations that came out of this meeting.

CHAIRPERSON HOWELL: Are there further comments or questions?

DR. BOTKIN: This is Jeff Botkin. I've got a question.

CHAIRPERSON HOWELL: Great.

DR. BOTKIN: It's encouraging to see all the collaboration on this and the momentum. But it raises a question about whether and how we would acquire some baseline data about current practices. It seems to me it would be helpful to try to figure out what the current state of universal screening is within birthing facilities, maybe with some sentinel states or some such mechanism.

Was there discussion about baseline data acquisition to help us determine the efficacy of the implementation of the screening?

CHAIRPERSON HOWELL: Do you have any comments about that?

DR. LLOYD-PURYEAR: Well, with Alex Kemper's aid, we're in the process of doing a survey of nurseries. But to be specific, I'd have to answer no. We don't have that baseline data. We have a sense from various institutions, but it is -- but not across the country.

DR. BOTKIN: It just might be useful to think about whether there would be a good targeted way to get some baseline data at this point, before this process gets too far going, just in terms of what percentages of nurseries of different types are already doing screening, what availability they might have with different pulse ox technology, a few simple things like that.

CHAIRPERSON HOWELL: Those would be very, very worthwhile. I think that the cardiology group may have a good bit of that information. They seemed to know a lot about what is happening. But that has not been collected is the thing.

But again, it's perfectly clear that we will need some pilot type studies done that will implement it. Of course, we have the available data from the two very large experiences in Europe that were informative.

Coleen.

DR. BOYLE: Someone made the recommendation earlier about having a representative from a national hospital association. I was just thinking of trying to answer some of these questions and thinking about the implications and impact on the system. I think it would be great if we could perhaps make that as a formal recommendation, if we need a formal recommendation for liaison members. But at some point the need for that expertise --

DR. LLOYD-PURYEAR: On this committee?

DR. BOYLE: Yes.

CHAIRPERSON HOWELL: Do you see any problem with liaisons to the committee?

DR. LLOYD-PURYEAR: Right now the problem is numbers of organizational reps on the current committee. The committee has the opportunity to rethink its current organizational representatives and whether or not that current list of organizations gives it the expertise that it needs as it goes forward. They can decide to remove an organization from this committee and bring in another organization.

Just let me know.

CHAIRPERSON HOWELL: Alan has a comment back here.

DR. ZUCKERMAN: Alan Zuckerman. I was a member of the work group. One of the complexities and one of the probable needs for better baseline data that came out during the meeting was that a significant number of these children are diagnosed prenatally through other technologies and that that number changes and has been varying. So this is going to be an unusual newborn screening condition in which prenatal ultrasound will identify a proportion of these children and this may be an issue we want to include into evaluating the effectiveness of screening.

The Society of Thoracic Surgeons does try to capture that data in their databases.

CHAIRPERSON HOWELL: That was discussed during the meeting. However, nowhere near all infants are detected currently prenatally.

DR. BOYLE: So that's where the birth defects program come in, because they do capture -- again, not all cases, but they do capture children diagnosed prenatally. And they will also capture children what are false negatives, who are missed by screening for whatever reason.

CHAIRPERSON HOWELL: Mike.

DR. WATSON: Thinking about bringing the AHA on board, I would make sure we were paying attention to the Joint Commission's side, piece of this, at the same time, because we went to the Joint Commission about getting standards for hospitals around newborn screening and they required me -- basically, the AHA is loathe to have

any more standards imposed on them by the Joint Commission on Hospitals. So they made me do the complete liability analysis of all cases in newborn screening and whether there were costs to hospitals. And there's huge costs to hospitals.

I haven't been able to get the guy at the Joint Commission to respond to my reinvigorating our discussion now that we've got all the liability analysis done. But we should make sure that we've got the two pieces in play at the same time so we don't bring on a group that's very resistant to the standards before we get the standards in place.

CHAIRPERSON HOWELL: Well, obviously that's a point of discussion.

Is there anything else about this meeting?

was a (No response.)

It was a very good meeting and I think had some very good plans to move forward. We'll expect some documents coming back from the group doing the white paper.

Let me also remind you -- Alaina has just reminded me -- the folks who have the health technology assessment document at your place that came from the U.K., each of those things has your name on it. We handed it out with the absolute commitment that they will all be returned. If you do not turn it in, when you get to the airport the TSA will confiscate you.

(Laughter.)

So if you go through and they say, we're not letting you through, you'll know why.

DR. KUS: This is adding to the TSA screening process?

CHAIRPERSON HOWELL: Yes, we have added this. Look for HTA reports in the luggage.

I think we'll move along. I'm going to go back on something I promised earlier, that I said we would not go back to the organizations that wanted to make public comments because they were, none of them, were here. But we'll make a quick go-back and see if Kelly Leight would like to have a few words now that she has arrived late from lunch. Kelly, you will have three minutes to talk and two minutes for questions, and then you're out of here. But other than that -- she's a lawyer; she's tough.

(Laughter.)

MS. LEIGHT: First of all, my deepest apologies that I was not here promptly at 1:00 o'clock. I'm sorry.

Thank you, Dr. Howell and committee members, for allowing me to address you today. As the parent of a child with a genetic disorder and the coordinator of Preserving the Future of Newborn Screening, a coalition of parents, health care and public health professionals, corporations and other interested individuals passionate about newborn screening and newborn screening education, I urge the committee and the Secretary of Health and Human Services to promptly approve and implement a national program to educate the public about newborn screening.

I also urge that sufficient funding be appropriated to ensure the sustainability of educational efforts and so that a broad-based communications strategy can be implemented. In particular, we

must make sure that any strategy can reach our non-English-speaking populations and those without access to the Internet or cellphones.

Based on the testimony we have heard today and discussion in the Education Committee, there is an urgent need for prenatal education about newborn screening. Providing information in the hospital after birth is wholly inadequate. Mothers are not able to absorb information about newborn screening when recovering from childbirth. Right now, this is when information about newborn screening is being provided, if it is being provided at all.

Moreover, groups with political agendas have been spreading disinformation about newborn screening and about the safety and security of newborn blood samples and infant screening information. Unfortunately, news headlines like "The government has your baby's DNA" are becoming more and more common. Some parents are developing distrust of the newborn screening programs and the entire newborn screening process as a result of bad information.

The solution is providing accurate information during the prenatal period about the newborn screening process and its benefit to our children, along with information about each state's storage and use policies. I strongly urge the committee to integrally involve prenatal caregivers, such as the American College of Obstetrics and Gynecology, the Association of Women's Health Obstetrics and Neonatal Nurses, and the American College of Nurse Midwives in the process to ensure buy-in from them and obtain their cooperation in providing educational efforts.

As a final point, I would like to ask that our coalition

and its members be considered for inclusion and-or consultation during phase one of the educational efforts. As a group, we have a strong interest in and have given a lot of thought to the issue of prenatal education about newborn screening and we may be able to provide a specialized viewpoint in the planning of an educational campaign.

Thank you very much.

CHAIRPERSON HOWELL: Thank you, Kelly, for being succinct. I think you mentioned one group of health care providers that we have not heard a lot from and that's the nurses group. Of course, the nurses are the primary informer in the world we live in about health care, and there are millions of nurses, so I think that's a group that we do need to hear from. I thank you for that comment.

MS. LEIGHT: Thank you very much.

CHAIRPERSON HOWELL: Our next person on the list is Jim Bialick. Is Jim back? Jim is back from lunch also. You must have had a wonderful lunch somewhere. Jim Bialick from the Newborn Coalition.

MR. BIALICK: Thanks very much for this opportunity the comment. I'm Jim Bialick from the Newborn Coalition. We were lucky enough to be involved in the congenital heart defect working group before this and saw the great consensus that was reached by many of the professionals in the community as well as some of the amazing projects that are under way nationwide and in some major centers that can be great examples of what we're working for.

I'm going to speak directly to my expertise, which is more on the technology and policy side. I want to talk about the

recommendation and about some of the nuanced policy measures that are taking place and how we can work within the recommendation to make sure that the needs of many of the states that are sometimes held up by legislative nuance can be moved forward.

Adding to the core panel, the states through their own language can mandate the level of follow-up that takes place on the state level. Dr. Howell showed in his presentation that the follow-up in the short term actually takes place at the point of care and that is on the provider, and that has always been on the provider. This is not shifting it through legislative change, but this is expected; this is a normal part of the process.

We're not saying remove public health from the process at all. We're just saying revise this role when it's not a blood spot. We're talking about something different here.

The addition of the newborn screening panel can be called an examination at point of care and evaluation for the purpose of the recommendation. So we're talking again about the nuanced difference between a screen and an evaluation at point of care. I think it's a very interesting issue and a very important issue to discuss when it comes down to again the nuanced language of state law.

Augmenting existing terminology does alleviate some of the issues, but it is not a catch-all. Indiana was brought up yesterday as an example where some of the things that were added as the screen are required -- are then required to be looked at under a different lens than if it was a point of care evaluation. There are many states that are like that and I think bringing this up as something that is

slightly different, again, it's part of the newborn screening program, but it's not a blood spot, and so treating it differently.

Organizationally, we're working in short order to develop briefing and educational material to show the difference between a metabolic screen and a point of care exam. We think this is something that, with the permission of the Advisory Committee that could be circulated, that would show that there are some differences that would quite easily alleviate some of issues we're dealing with on a state by state basis, but as well drive the clear distinction that we're discussing here.

We look forward to working with the committee further and working with the subcommittee around congenital heart defects.

CHAIRPERSON HOWELL: Thank you very much, Jim.

Then the final person on my commentator list is Annamarie Saarinen. Annamarie, did you have a few words to say?

MS. SAARINEN: Thank you, Dr Howell and the committee, for welcoming me to Minnesota with this cold weather. I feel like I'm at home when I come here any more. It's not supposed to be like that.

Actually, I wasn't going to say anything today, but I realized I didn't send you all a thank-you letter after September. So I wanted to thank you for your diligence in your process and all the hard work that happens in this committee to look at critical congenital heart disease. It's not an easy one. It's different and it change the paradigm a little bit, so I'm grateful for that work.

I'm also grateful for the Implementation Workgroup allowing my participation and that of Jim and other kind of health IT geeks who

are trying to find our way through this process and make it actually easier on everyone, including the state department of health folks, who by the way I have the utmost, utmost respect for. I've worked on a dozen projects over the years with these fine people, and I think their role is going to be so critically important. It's the first call I made when I wanted to see if this was a possibility to do a statewide screening program for critical congenital heart disease was to our state department of health and their newborn screening folks.

The only other thing I just wanted to try to keep in mind through all of this is that I think in the title of your committee it doesn't include the words "metabolic" or "genetic," and I know that's the work you do, much of the work you do. But let's recognize that there are other things that affect newborns and children that are critically important and I believe are the charge of this workgroup that fall outside blood spots.

So if we can maybe remember that moving forward and know that not everything's going to fit into the same box, but there's still good collaboration and great work being done.

So thank you again.

CHAIRPERSON HOWELL: Thank you very much, Annamarie, for your comments. You can take this weather back to Minnesota with you.

(Laughter.)

We'll let you through TSA with the weather packed in your bag.

COMMITTEE DISCUSSION

CHAIRPERSON HOWELL: We have -- let's see what else we have

on our thing that we need to deal with. We're coming to the end of the day, but I wanted to -- where's my thing about the dates of the upcoming meeting, which I don't seem to have before me right now.

Here we are. We have an upcoming meeting in May, here somewhere in my notes. Do you have the dates of the meeting?

I wonder if there are any other items of business that need to come before the group before we leave today.

VOICE: May 5-6.

CHAIRPERSON HOWELL: I'm sorry?

VOICE: 5-6, May 5-6 is what I have.

DR. LLOYD-PURYEAR: Yes, that's it.

CHAIRPERSON HOWELL: Here we are.

MS. HARRIS: It is May 5th and 6th.

CHAIRPERSON HOWELL: May 5th and 6th, and then we have a September meeting.

MS. HARRIS: That's the 21st and 22nd.

CHAIRPERSON HOWELL: Great, we have found the sheet I'm looking for. The May meeting is indeed May 5th and 6th. We have then September 22nd and 23rd. I think, as usual, we would like to have any agenda items that you would like to see. We have a number of things in the mill already that have come up today that will obviously be on the thing, but if you have any agenda items please let Michele know.

Are there any other items of business that should come before the committee?

(No response.)

Silence. Can I have a motion that we adjourn?

VOICES: So moved.

CHAIRPERSON HOWELL: Second.

(Show of hands.)

CHAIRPERSON HOWELL: Thank you very much, and we'll see you in May.

(Whereupon, at 1:41 p.m., the meeting was adjourned.)