Transcript: Morning Session – April 19

Please stand by for real time captions.

Good morning everyone. This is Dr. Joseph Bocchini, on the chair of the Secretaries Advisory Committee and I want to welcome all of you to the 30th meeting of the Secretaries Advisory Committee on Heritable Disorders in Newborns and Children. This is our second teleconference type meeting so welcome to all of you. Before we start the webinar, I want to go through a couple of housekeeping notes. For committee members, sound will be coming through your phone lines, so please make sure you have your computer speakers turned off so that reduces feedback. Hold questions and comments till the end of each presentation and when invited to speak, please state your name each time and speak clearly to ensure proper recording of the transcript and minutes. If you have any problems with your phone line, press star zero and you will get some help. For the members of the Public, sound will be coming through your computer speakers so have them turned on.

The first order of business for this meeting is roll call. And I'm going to go through the roll call sheets. Don Bailey?

Present.

Jeff Botkin? Jeff had not confirmed for the meeting so he may not be available. Colleen Boyle?

Here.

Debi Sarkar?

Here.

Denise Doherty?

Here.

Alan Guttmacher?

Here.

Charlie Homer?

Here.

Kellie Kelm?

Present.

Fred Lorey.

Here.

Michael Lu.

Present.

Dieter Matern?

Here.

Catherine Wicklund?

Here.

Andrea Williams?

Here.

For the organizational representatives, Fred Chen? Beth Tarini? Michael Watson?

I am here, this is Beth.

Michael Watson? Nancy Rose? Susan Tanksley? Chris Kus?

I am here.

Department of Defense? -- [Indiscernible]. Ed McCabe?

Here.

National Society of Genetic Counselors, I just received an email from Cate Vockley, she is unable to attend.

Carol Greene?

I am here.

Thank you for being on the line at this meeting. The first order of business is administrative business. This will require a vote by the committee. Are there any additions or corrections to be made to the minutes of the January meeting that were sent out to you in the agenda book? If everybody was comfortable with the minutes, I will ask for motion to approve the minutes.

So moved, Charlie Homer.

Denise Doherty, I signed in.

Did you want to second the minutes as well?

Yes.

This is Coleen, I will second then.

We will go through a voice vote for the acceptance or approval of the January 2013 meeting minutes, and I will go in alphabetical order starting with Don Bailey?

Approved.

I vote yes, Dr. Botkin will be absent. Coleen?

Yes.

Denise.

Approved.

Charles?

Approved.

Kellie Kelm?

Approved.

Fred?

Approved.

Alan Guttmacher?

Approved.

Andrea Williams?

Approved.

Before I go into the discussion of the annual report, I would like to move to allow Dr. Lou to get an update on the committee and of the committee business. Michael?

Good morning everyone. I would like to join Dr. Bocchini in welcome I'm all of you to all the -- to this meeting. I want to thank Joe and the committee members for your continued leadership and service. I have two pieces of good news to share. As you know, the legislative authority for this committee is scheduled to expire on April 24. In order to continue the work of this committee I'm happy to announce that secretaries -- the secretary has decided to create a discretionary committee to carry out the function. Several logistic steps will have to be completed, including issue of a Federal Registry Notice. We are taking the administrative steps to have the committee in place, with time to review meeting materials prior to our next tentatively scheduled meeting on May 16 and May 17. As soon as we get more information, we will share those with you.

The second piece of news is Debi Sarkar is that the Designated Federal Official for this committee, taking over for Dr. Sarah Copeland. Most of you have met Debi. She has been staffing this committee for the past year. She is a public health analyst working with the Division of Services in the Genetic Services Branch. She has a Masters of Public Health with a concentration in child health from the University of Alabama in Birmingham. She is the project officer for the follow-up in newborn screening initiative, the Newborn Screening Clearing House Technical Assistance Center and data repository. She has worked at HRSA since 2006, and was previously in the HRSA Office of Health Information Technology.

Thank you and good morning everyone. I wanted to say we are really excited about the discretionary committee, and my team and I are working hard to get that set up. I hope you find today's meeting informative. We have great presentations lined up and I hope you will have some good discussions.

I also want to add my gratitude to Debi. With Dr. Copeland’s departure, Debi came back early from maternity leave in order to minimize disruption to the work of this committee, so I want to thank you very much for your dedication. I want to welcome all of you to this meeting and on behalf of the Secretary and the department, I appreciate your leadership in service with this committee and all you do for heritable disorders in newborn children. Back to Joe.

Thank you very much. And of the committee is appreciative of your efforts and a very pleased with the Secretary's decision to establish the discretionary committee so we can continue to do our work, and hopefully we will be right on schedule and we look forward to the additional information as it comes out. We appreciate everything you have done. We also want to recognize the support we have gotten from the community, from the various organizations, that support the work of this committee as well. I would also like to welcome Debi officially as a DFO. I think we have all had a chance to work with her and we are pleased she will take on this role in an official capacity and we look forward continuing to work with her.

Let's now go to the discussion of the annual report. You of all seen it in the agenda book and I'm going to summarize what is done but I also want to thank the staff because I think they put together a very strong report which indicated very nicely the breath of the work achieved by this committee in 2012.

The report summarizes the advisory committee's mission, provides an Executive Summary and the Secretary's advisory committees accomplishments, organized according to the requirements of the legislation, and included is a future forecast organized into the three categories we have developed for the subcommittees that bring information to the full committee—that is education and training, laboratory standards, follow-up and treatment—and that is followed by a conclusion. A couple of highlights to remind you of the accomplishments of the committee in 2012: the committee approved the condition nominations for Pompeii disease and for review by the CRW. Developed and enhanced discussion and ten descriptions for the home and strategies to improve linkage to the medical home for children with heritable disorders. Supportive activities related to the harmonization of newborn screening quality indicators in case definitions across the country, and that is a process still ongoing. Revised the condition review matrix to serve as a tool for categorizing and assigning value, based on a scale, for conditions nominated for possible inclusion under the Recommended Uniform Screening Panel and added an assessment of the capacity, feasibility and readiness of state newborn screening programs to implement population wide screening for a nominated condition.

There are reports the committee submitted to the Secretary, one on *Implementing Point-of-Care Newborn Screening* and the second on *Improving Data Quality and Quality Assurance in Newborn Screening by Including the Bloodspot Screening Collection Device Serial Number on Birth Certificates*. The committee supported CDC and APHL in the planning and organization for the 50th anniversary of the Newborn Screening Campaign for this year, also approved the report on *Insurance Coverage of Medical Foods for Treatment of Inherited Metabolic Disorders* which was developed by the Follow-up and Treatment Subcommittee. The future forecast is

indicated on this slide and I think rather than go through this in detail, since we will get reports from the subcommittee, they will bring us up to date on these. But I would like to recognize the extensive work that has been done by each of the subcommittees, in the input the committee has had in guiding those subcommittees to move forward in a number of areas that I think have either come to fruition or will do so in the next year or so.

The conclusions are that the committee continues to provide recommendations, advice and technical information to assist the Secretary in her efforts to reduce the morbidity and mortality in newborns and children having, or at risk of, heritable disorders. The coordinated efforts of the Secretary's committee and the stakeholders, including policymakers, state public health agencies, providers and the public will continue to ensure newborns and children have universal access to high-quality screening, follow-up and diagnosis, and disease management and treatment which may prevent the potentially devastating consequences of disabilities, life-threatening diseases or death.

That is the summary. The committee members have had a chance to review the report. Are there any additions or corrections or desire to modify any of the content of the annual report of the committee? I will open that for discussion. All right, on hearing no comments, is there a motion to accept the annual report as written and distributed to the members of the committee?

This is Don Bailey, so moved.

Second?

Steven McDonough, second.

We're going to go through another voice vote for the approval of the committee's 2013 Annual Report. Don, do you mind starting again?

I approve.

Colleen Boyle?

I approve.

Denise?

Approved.

Charles?

Approved.

Kelly?

Approved.

Approved.

Michael? Dieter?

Approved.

Steve?

Yes.

Alan?

Approved.

Alexis?

Approved.

Catherine?

Approved.

Andrea?

Approved. That will conclude the administrative business portion of the meeting.

This is Steve, I have a question. First of all, I agree with everything you said about the community and appreciate the work that has been done. I have a question on the main meeting, is that going to be virtual or in person?

At this point it will most likely be a virtual meeting. This is still a little bit up in the air until everything goes through the process for establishing the discretionary committee, but the expectation is it will be a virtual meeting again. Debi, to have anything to add?

That is it. As soon as we have the discretionary committee set up we will notify you of the details for the main meeting.

Thank you.

At this point, we are a couple of minutes ahead of schedule. We now have a presentation and update on the RUSP conditions. Chris Kus will provide a presentation on lessons learned from early hearing detection and intervention that may be applicable to critical congenital heart disease screening. He is Associate Medical Director of the Division of Family Health within the New York State Department of Health. He provides leadership for New York State Child and Adolescent Health activities. He worked in child development and public health in both New Hampshire and Vermont before coming to New York in 1993. He is a board-certified pediatrician and fellow of the American Academy of Pediatrics. He is past president of the Association of Maternal and Child Health Programs. Please, we can turn this over to you.

Thanks everybody. This is kind of coming attractions in the Follow-up and Treatment Subcommittee. One of the charges was to look at lessons learned from the early hearing detection intervention effort that may be applicable to critical congenital heart disease, and we have had several meetings and have produced written material. What I'm going to do is go over some of the major points we intend to report on and then we will be flushing that out with some examples and references, with the idea that out our next meeting we will most probably have a finalized paper for the committee to review ahead of time and to vote on. With that in mind, the other thing I would highlight for folks is to remember that in the December 2012 issue of *Genetics in Medicine*, we did put out a document called a *Framework for Key Considerations* as a starting for point- of-care screening of newborns. A bunch of us were involved in putting this out and that is a good background document. Within that document it talks about one of the things of the roles and responsibilities of different parties, particularly healthcare providers and public health agencies, when we talk about point-of-care screening so that will be a background document we refer to as we put out this paper.

As background, the EHDI program -- before the infant is discharged. Hearing screening and CCHD screening are different in timelines and further follow-up. Hearing screening follows up as an outpatient, while CCHD screening necessitates follow-up in the hospital because delay may result in morbidity or death of the infant. When we looked at it, there were things we saw in the EHDI experience that has some applicability to CCHD screening. The first major lesson we're going to talk about is the idea that state CHEAR in newborn but spot screening programs are not often well integrated with each other, and as we add new point of care screenings, we need to strive to have the public health newborn screening programs be better integrated. I think what you're going to see in the later document that the EHDI program, because of the electronic way you can conduct the hearing testing, has some similarities to CCHD and as you get more point-

of-care screenings, those would be things that could be integrated that, often times when people are talking about newborn screening, they generally mean blood spot screening and we're putting out to foster the idea that people start thinking in totality about what universal newborn screening is.

The second point listed is state health departments should play a leadership role in implementing Electronic Data Systems that utilize standards-based messaging to reduce errors and enhanced timeliness in data reporting. This gets into the idea of the public health role to report if infants are being screened and what is happening to them and take advantage of the developing electronic technology in order to transfer information. In some sense, EHDI has served the model in electronic information exchange between clinical care and public health programs. There are national data elements standards developed in collaboration with EHDI. They have been accepted by CDC, the agency for healthcare research and quality. The idea would be state programs would be advised to leverage the extensive work currently underway to facilitate the electronic exchange of newborn screening results. There are state programs that have been funded relative to the blood spot and hearing screening to facilitate electronic transfer of information in the case of blood spot screening from the data that comes in to the lab from the primary care Dr. And vice versa. That is one of the things we wanted to emphasize.

What has been critical, and this is one of the things we've been talking about in terms of implementation that as you add new tests, appropriate financial support will be needed to develop the screening system. From the experience of EHDI there have been ripped ported concerns as to ongoing funding if that is not carved out in some way or -- about the idea it will continue. I think this gets into the idea of stating what your newborn screening program is about because we are getting reports and hearing screening is viewed -- may not be viewed as critical a follow-up as say blood spot screening. The message we want to get across is you need to support the systems and you need to make the case of the importance of them, particularly with the primary care physician and with EHDI. CCHD may not be as much at issue in the sense the follow-up will be in the hospital and it will be a critical one. What we have seen is, as states have been implementing CCHD, many states are not implementing it and the response has been because the funding is not there. States have gotten funding to do the implementation are moving quicker in that area.

Screening programs should require child level data for quality improvement efforts. What we found with the EHDI program is some programs initially reporting population -- and didn't have the individual patient information that allows people to do quality improvement and follow-up. The blood spot screening does allow you to do that. We want to say that in order to be able to

report on how well newborn screening is doing, we want to say are we getting to all kids with regards to hearing screening and with ongoing CCHD screening. The public health role being able to say kids have been screened, and what has happened to them afterwards and one of the discussions will be long-term follow-up with regards to CCHD as it has been EHDI. EHDI has been more of the idea of the outpatient, although one of the things we find is follow-up is hard to come by, and there have been variable success across the country.

The last major point is appropriate financial support, federal and state, will be needed to integrate CCHD screening into existing data systems or enhance interoperability among newborn screening systems when integration is not possible. New York State has one of the grants to do the electronic transfer of information. We found it slow going and need to take the benefit of federal and state dollars to work on integrating the information so we are able to provide an overall report on what is happening with newborn screening, and particularly trying to strengthen the idea of being able to say what is the outcome of newborn screening and realizing long-term follow-up has traditionally not received the kind of funding it deserves and that we need to proceed with.

The next slide is just saying the major points here going to be reporting on. As I said, we're going to be adding some information about good examples, in this case some references to this and hopefully be ready for presentation to the full committee at the next meeting. I'm going to stop here and see if people have questions or comments or things we might want to emphasize. Do you agree with the points and things like that?

This is Carol Greene. Chris, when you said next meeting, I know we have been working on a plan for this and then we said next meeting, we were thinking September, we were not anticipating having this ready for May. Carol, I have lots of the information. It is probably fair to say the idea is we would have it for not the next meeting, but at the September meeting to have a polished document and the committee time to review.

This is Fred Lorey. It is a nice report and I agree with most of it but again we have this issue of specifically relating to the integrating of the hospital-based testing and the laboratory testing. This is not possible in every state. In California, for example, they are in different departments. Laboratory screening is a public health and hearing screening and the developing of heart disease screening is in another department. Since the beginning, they have not wanted to share data or cooperate with us in any way. Along with that, not every state public health laboratory, myself

included, necessarily agrees these hospital-based tests should be integrated with newborn screening. We're jumping from blood testing we are doing ourselves, we are quality control and there is a big issue. On the other hand, we're looking at hospital-based testing where we have no control over the data. It is a totally different group of people and I'm still not convinced they should be together. That is just my opinion and I agree with all of the funding issues, but the one point I would make is it really depends on the state, whether there can be cooperation or integration or data sharing no matter what the recommendation is.

Fred, we have heard this comment. In some ways I think that's going to bring up that discussion. Later today we're going to have a discussion with CCHD and what is happening with it. That is an issue within the committee I would like to hear comments. Both of these programs, although in different places, are in the New York State Health Department and in some sense, my thought is when we report about newborn screening, we should report in an consistent fashion and report on all newborn screening. As far as the actual integration and what that means in terms of data, there is probably going to be more integration of the point-of-care screening but on the overall report, I still think the idea of states reporting on their total newborn screening program as this committee talks about what should be the screening come out of this committee, I think that is kind of where we're going. I think we probably agree with this. How we write it up is an important part, but I thank you for your comments because we have heard that.

This is Charlie. I think there is a question of the role of the committee, our committee and what do we want to set? It seems to me what we are saying in this report is that the public needs to be assured all children are appropriately screened and all those children who need follow-up and appropriate intervention are getting it and we have a mechanism for monitoring and assuring that. I think the committee's role is to articulate that and say there are lots of different kinds of newborn screens, nonetheless there is an overarching public health interest to make sure those are done correctly. Different states may choose to implement them, depending on their culture and organizational structure, in different ways but it is nonetheless a public health function or a public function, if you want to take out the help part. Resources need to be allocated and again we could go on further to say and it does seems to make sense that with the implication across different agencies that that is moving a little bit into state agency function.

I think that as well put and Charlie, you were part of our writing group, I think that is the message that should get out and the committee as a whole should support.

This is Joe Bocchini, do we have an idea of how many states are what, to what Fred indicated exist in California, where there is a separation?

We actually did this survey as we were going through this and we can add that to it. Again, anybody can chime in, but I think in the development of hearing screening, there was the idea it was not closely related to blood spot and it was related to the early intervention program and so that led to the two different areas and I think there is variability about how states collaborate on that. I think that is something we could put in the report, to flush that out and give people more of a sense on how that is. I think a lot of people in our discussions are reporting that you are within the spectrum; we don't want to talk to each other and share information and try to work together on these issues.

My second question is, based on what you have gotten back, does this seem to be any overlap in the administrative structure that could potentially be a cost savings if things were combined in a different way?

That is a good question, one of the questions for me is whether it would be a cost savings because one of the areas is the ongoing follow-up, and given that there are mechanisms, pretty strong mechanisms for blood spot screening for follow-up, could newborn hearing screening take advantage of that and would that be a more efficient way of doing it? In terms of cost savings, since long-term all of hasn't really been funded, I don't know that would result in cost savings but it would be hopefully more efficient and less expensive model, but that is some of the pluses about taking advantage of different ways people follow-up. Other comments from people on the phone?

I know the committee members' lines are open. Are all of the organizational representatives' lines open as well for them to comment or ask questions?

This is Debi, all of the lines are open except for the public.

Any discussion or question or comment from any of the organizational representatives?

This is Beth, I have no comment.

This is Coleen. Thanks Chris and everyone else who has given us thought. I was trying to think of a good way to say, with a question, that Joe put forward about the administrative savings which I think is a very important issue, particularly in these times when we are asked to be doing more with less, and I noticed too if you had to do with appropriate financial support for different aspects of the implementation of CCHD screening and clearly recognize the importance of that. I guess I'm thinking of when you were going forward with the white paper being developed, you may have said this and I apologize, but is there a way you can look at state models, maybe not showing how potentially long-term follow-up or integration first and long-term follow-up could happen? I'm just going back to Charlie's idea of the role of the committee and how do we help facilitate the integration and uptake of these new conditions as we move forward? Tweaking a system that perhaps is a little entrenched because it has worked well and now there are changes to it.

I think that is a critical point and hopefully what we're going to do, there was a review of hearing screening programs to learn about some of this. I think what we are hoping to do under these areas is maybe highlight models that have shown nice collaboration, to give people an idea of what you might do, and there are a few states out there that specifically when you talk about hearing screening, there are states that have done somewhat enter in long-term follow-up than other states and seeing whether that kind of lesson can be used for CCHD and also state that have strived to do some integration on electronic transfer of information. I'm hoping we can tell a little bit of that story.

This is Joe again. Is there enough data on the cost in the individual states that you could link some of the cost per patient? I don't know if there is enough data.

I don't know about that. I do know and I think from the CCHD study, the way the grant went out, there was a significant effort to try to collect cost in that study which I don't bank has been done for other hearing screening, but I may be wrong. That emphasis as you talked about is probably something we also want to go forward with. I don't know the reason updated to look at that.

This is Carol Greene. I just had an interesting thought from this discussion, thinking about how much further the ramifications of some of these questions could go. First I would say that Fred

Lorey would point out that cost would be very different in different states. States that have some plan already for how to integrate data in newborn screening, no matter where it comes from, will look at cost differently than states that might have to build a different system to bring that data together. I think we are talking as in terms of the long-term follow-up, in babies that had a normal -- in the context of the heart, had an abnormal -- and the ultimate outcome and then if we talk about the long-term follow-up which is perhaps, but I'm not sure, what Colleen had in mind, she did a lot of work on the long-term as chair of this committee before Chris and I took over. The numbers are going to be a lot larger. If you put together all of the babies with the condition we have been talking about before, except for thyroid which nobody has been following up at all, and maybe that is not in this committee because most of it is not hereditary, but then we get into the questions about the babies that have heart defect that was a picked up by the screen and wasn't supposed to be because it wasn't a critical heart defect. In most of newborn screening if we find -- not picked up by the newborn screening were trying to improve our screening process and track back, this could get more complicated because were also talking about if we start to include all of the heart defects, were talking in one of hundred babies. I think we need to be thoughtful about how far down the process we want to think about long-term data in the heart defect population, and how do we tie that to the screening question?

This is Chris. It would be interesting, there is that presentation so we will get some sense of what people are thinking in that area. I think what we're doing is shedding some light on things and probably enough for questions that are going to need more thought as we go through this.

All right, any additional questions or comments from committee or organizational representatives? I think you can see on the left of your screen one public comment.

You're talking about the public comment about the public of input with regards to doing these?

It is a comment by Kimberly Pieper, I think another lesson learned is this condition of CCHD was recommended for addition to state screening panels without examination of the capacity of the state to implement the screening, very different from the established processes states already use.

I think the health infrastructure was added to when we are reviewing new conditions. I think we have learned, and her comment is correct, and retrain to get that as best we can on going.

That is correct. Okay. Additional comments? If not, I want to thank Chris and the subcommittee for its work. I think this is coming along very nicely and I think the input you received today is also going to help sort of brought the strength of the report, so I think that is great.

Dr. Bocchini, this is Debi. I think we should open the lines for the public to see if they had any questions.

Okay.

Operator, it if you could open the public line and let people know they can dial whatever it is they have to dial.

If you would like to ask a question, press star 1.

We are using our time efficiently so you will have time left over.

This is Susan Tanksley, I must've dialed wrong because you couldn't hear me when I was trying to call earlier.

Good to have you here. I wanted to mention that New STEPS is collecting information about the overlap between EHDI programs and blood spot screening programs so that information is collected.

And that will be available to the subcommittee in the timeframe this report is being worked on?

I am certain they can make it available then.

Thank you.

At this time I show no further questions.

Thank you for your input and Chris, thank you and the subcommittee. We will go on to the next update. This is from Beth Tarini. This is on assessing the impact of the NCAA sickle-cell trait screening on state newborn screening programs. The presentation will be by both Beth Tarini and Anne Azrak. Beth Tarini is an M.D. MS and fellow at the American Academy of Pediatrics. She is a member of the committee on genetics. Her research focuses on the communication process and the health outcomes associated with genetic testing and pediatrics. She is interested in pediatric population -based screening programs such as newborn screening. Dr. Tarini seeks to optimize communication about genetic testing between parents and providers in an effort to maximize health and minimize harm. Anne Azrak is a project coordinator and research assistant in the child evaluation and research unit at the University of Michigan, where she works on projects that examine the impact of policy on health care service delivery through state newborn screening programs. She received her BA in biology from Kalamazoo College and conducted global health evaluation in Kenya and Ecuador. Thank you both, and I will turn it over to you for your presentation.

Thank you everyone for being here today. This project is part of a two-part contract with genetic alliance and HRSA to assess the policy impact of non- disordered related recommendations on states. You will probably, at the next or following meeting, see that the second project we are working on touches long-term follow-up.

Some background, this recommendation from the committee was given about the NCAA sickle-cell trait mandate. It was decided to the Division I legislative Council. In here you have the proposal and amendment bylaw referring to it, it was approved April 3rd team, 2010 and went into effect August 2010. That mandate was for division II athletes, that a pre-participation medical examination shall include a sickle-cell solubility test, must document the results of a prior test have been provided to the institution or the perspective student at -- [Indiscernible]. The history for the mandate came from, just to give you some background, on September 24, 2006, -- collapsed during football practice. On June 28, 2009 -- from that a lawsuit ensued from the family which included numerous other stakeholders, including NCAA. The lawsuit was settled June 28, 2009 and the result of that settlement was an agreement to screen athletes in all universities for sickle-cell trait. In 2010, the NCAA approved the proposal to add the mandatory

solubility test. In October 11, 2010, SACHDNC published its recommendation. That recommendation was discussed at this very meeting.

[Captioners Transitioning]

This evaluation testing happened within the medical home and includes counseling as well as privacy of genetic information. We see medication unsafe practices on heat-related illnesses. And that the secretary of HHS instructed -- to work with the Sickle Cell Disease Association of America and others to develop guidelines and educational resources.

And that the National Institutes of Health do a study?

The major thrust of the recommendation is that genetic testing should not be a prerequisite for participation in sports unless deemed medically necessary.

So, after this recommendation was published in 2011, the NCAA moved from mandating testing of Division I athletes to Division II athletes and, recently in January 2013, they approved a mandate for screening of Division III athletes.

That’s interesting, some background. This was slightly different in that it included a waiver stipulation that, prior to signing a waiver, which is a possibility for the athletes to defer testing that the institution provide the athlete with education regarding the implications of using this waiver and that student athletes would contestability.net have concerned -- confirmed result documented or have signed a waiver be provided additional education regarding the risks and impacts Amber cautions associated with sickle cell trait.

The next question -- for all of us sitting here -- most of us working in areas related to newborn screening, well, as a part of this mandate was the stipulation that the testing at the universities can be done -- should be done unless documented results of a prior test are provided to the institution or the student signs a waiver and declines the test.

Here you have a posting from a university in California that direct the athletes to their state as well as the medical home to look for previous results from, phrases, newborn screening or any testing that would shoulder sickle cell trait status.

The question is -- what has the impact been on the state given that sometimes explicit direction from others -- athletes seek these testing results from the state?

With that, our objective was to assess the impact of the objective on the newborn screening programs and address the issues of what is in the demand placed on program resources, have changes been implemented, and what of the band? What is been the variation in impact across programs? You also see on the slide a note that this is not an issue up to committee vote. This is a presentation to the committee of work that is being done in his newly completed and, of course, looking for input and comments from both the committee and the public at large.

The methods for this project have been phone and written surveys. We started in February. We are still finishing up the last of the surveys. The recruitment has been a snowball sampling method. We started with stakeholder interviews director that laboratory directors and personnel and follow-up directors and personnel. From that, identifying and surveying the people for additional assistance in contacting others who might also have useful knowledge.

We also included hematologists and genetic counselors and sickle cell community-based organizations in our sample. The states were considered complete after speaking to laboratory and follow-up representatives. The reason is that as we interviewed the hematologists and genetic counselors, it seemed to be that while some have seen things in the clinic -- for example in the follow-up, much of the effect, if there is one, of the mandate has been directed at the follow-up directors and laboratory directors of the programs.

After we collected each state profile, we summarized it and send it back to those who participated in the survey and asked them to validate it and comment if there are any to scrap or if it is accurate.

The domains assessed for the history and procedure of newborn screening for hemoglobinopathies, particularly what is in the laboratory procedure in history? We think this is

important because sometimes a response is -- well, sickle cell screening has been in place, phrases, four, phrases, for 20+ years and these athletes can clearly go back to their state and get these results done. That is not always the case, especially since some of the athletes were born at certain times in certain states that may not have been screening at that point time. So, the history is important.

The availability of the results if they were done -- the sickle cell trait results may not be available. Whether or not -- and how the state is reporting them. As well as the direct effects of the mandate in terms of the volume and nature of requests and the procedures for reporting such results. We have a qualitative assessment of programmatic impact of this mandate.

Here is a map showing participation to date. We have about 88% of the states that have been contacted and almost 2/3 have completed. This map is a little old. Even in the last week, some states have contacted us and I would like to take a moment to thank you. I know you get a lot of surveys. Those that work for the states -- you have a lot of work to be done to keep the programs moving and going. I appreciate your time.

To those of you who have yet to be contacted, if you are willing and able to provide us the information, we would be mostly grateful.

For the results -- these are preliminary results. We are continuing to analyze them, but I felt it would be useful for the committee members as well as those involved in SACHDNC to see these.

The history and procedure -- we found that the mean year for dosed -- most dates screening for hemoglobinopathies was in the 1990s in that range from 1975 to 2005. There have been a number of methods used -- isoelectric focusing, liquid chromatography, DNA testing, and electrophoresis. These methods are used in different ways. 14% of the states that we surveyed so far for single testing come up with the vast majority two step reflexive testing.

In terms of availability, this is interesting. Many assumed that if the state tests for sickle cell during the time the athlete was born, clearly these must be available. That is not the case. This assumption should not be made.

In the first figure you will see the assumption that if the state started in 1995, that was the date that most of the athletes would be looking for -- given their birth year -- looking for the results -- that that would be the case. However, the states have a number of challenges in terms of these availabilities -- there could be changes in data storage as you see here. Move from 1995 and sometimes up until the present is when there was a change in the storage of the results.

Sometimes with the change in storage, those databases from prior years are inaccessible. Sometimes you will see that while the databases simply don't exist anymore because of law and regulations. For instance, in some states every five years the previous records have been destroyed.

You will see here -- the population with the results of states and how they described availability of results. Minnesota is highlighted because they have had a change in process. They have treated this as prior and not as at the recent change.

The final figure here -- screening for hemoglobin was able minute after 1995 -- sometimes the screening was not universal. There was not screening of everyone or it was targeted in some way and -- or the data was scored only -- stored only for positives. Those with a clinically negative result cannot find the negative result.

We are going to look at the availability of results since 1995. These are the states in which it is possible to disclose results if the state is willing and able. Here you have a map of the states with available results -- 43 we have contacted and have the information from -- 23 have available results. 20 have no available results. Here is the distributor. States in white we have no data from. Not yet.

Of those -- these are the states currently providing results. There are 19 states providing results, and currently there are 20 not of the 39 that we have.

Of those results, not everyone is providing the same results while the majority of states, I would say 15/39 states are providing the entire newborn screening results. There are some states

highlighted in orange which are providing -- when someone calls about this mandate in needs results, they are only providing the hemoglobinopathy results, and you can see those in orange.

We don't have a quantitative assessment yet. As I said earlier, this is preliminary analysis. But, the qualitatively listing the concerns that they might prevent the newborn screening programs from providing the sickle cell trait results -- concerns about privacy of genetic information, the policy of the program, the cost to the newborn screening program of providing these results. There were concerns about the accuracy of being able to match the record to the individual, given the time has passed. The time since the result was taken. Also, the accuracy of sickle cell trait as a diagnosis. This is, numerous times. Newborn screening is a screen, not a diagnosis. These traits results were not intended to be diagnostic. They came as a part of the screen and they may not have ever been confirmed because the intent was to screen for sickle cell disease.

Some concerns that it would result in athletes and managed to not exist. Inconvenience retrieving the results. And, of course, it does take resources -- both people and time.

In terms of other concerns, this is a flavor of some of the discussions. Providing sickle cell trait results is not a worthwhile public health initiative this is not the mission of the newborn screening program. Of course, that is an opinion, not representative of a state position or program position. Another concern from one of the participants -- public trust in the program would be undermined if people found out that we were sharing information collected when you were a newborn.

The next question -- if you were doing screening, if you have those results available, for sickle cell trait, and you are willing to share them or provide them, the question is -- who the states provide them to? My understanding is that in most states, at least in Michigan, the primary care provider or the healthcare provider to the individual with documentation can have access to newborn screening results as the point of care of the patient. The question is, what other stakeholders -- who else can get these results? That is what we asked the states.

Interestingly, there are states -- seven of 39 that provide results directly to athletes with appearance. Seven states are providing the results to athletes or parents. We will see here -- for states -- 4 states provided it to the departments directly.

Some states – 8/39 – that we have data for provide results to the team physicians. Sometimes the team physician is considered by some states to be a healthcare provider for that athlete, so it comes under the same responsibility. And, no states provide results directly to the NCAA.

Finally, the effect of the mandate. In terms of volume -- you will see the number of requests per year reported to the state -- by the state program. I want to clarify first that -- this does not include Web retrieval -- record retrieval through web-based portals. These are states that have been contacted directly by an individual for results. The individual could be an athletic department contacting 430 athletes or one individual contacting for that person's own results. So, the results we have range anywhere from 0 to 6000 requests per year. Not surprisingly, most requests were received between the month of May and August fire to the initiation of training for the scholastic year.

The burden on the program -- this was reported by the programs themselves. 24 programs reported no burden regarding this mandate for time or money.

Seven states reported that there has been a time of burden and -- time burden alone. None have said that it is only money and 5 had set it is a burden of time and money. To some degree this is a perception -- time is money. To some people, it is time and some it is money. We did not get into the issues of trying to deconstruct this. In some cases, it was simply resources like printers and fax machines and things like that.

The reason that North Carolina is circled is because you might have noticed that North Carolina was not one of the states that were providing results, yet it has felt a burden of time and money. So, this is interesting to point out -- even if you are not providing the results, you have had an impact of the mandate itself.

One might ask -- is the burden related at all to the prevalence of sickle cell disease in that state population? You can see some correlation. The figure on the last with dark colors -- these are the states with the highest prevalence of sickle cell disease. On the right, the states that are blue and red report a burden of time and time and money and for instance, Florida has a high prevalence, but does not report any burden.

What kind of burden -- we have information on that. For money -- some examples that they shared -- we would hire someone just to handle these calls but we don't have the resources. Or, since our system is backspace, we are killing our fax machine. We don't have the funds to buy office equipment. In terms of time -- they recorded that all of the requests come in a narrow time. In the early summer and it is like cramming 40 weeks of work into a 25 week window. And, providing information to a NICU were one of the treatments -- new birth is in treatment is a high priority in this is what we try to spend our time.

Someone else said we spent so much time explaining to the parents what the screening is for and why they are required to get this information. Or, I could have a little tape-recording to explain where to go to get these results because I have to give that speech so often. There are retrieval issues and delivery issues and the fact that the state becomes an intermediary and has to explain to parents what is going on.

Programmatic changes -- from a qualitative nature, we found that this has affected the procedure for reporting results in some states as one participant said -- we were not used to providing results of individuals. We had to make a new forum for individuals to request a newborn screen.

State had to visit their policy on request of information -- who can request and ensuring that they had adequate policy and documentation of students' athletes consent for release of results.

There have been issues about retention as I noted earlier. Some states don't retain the results. Some states say that if they have retained them and they have not had to destroy them by policy requirements, they may not be able to functionally access them. One said that the mandate pushed the debate to destroy samples older than five years to the brink.

There has been the review of educational materials as noted in the previous slide. In some instances, they are responsible for explaining the results to the families. And there have been staffing changes and re-assignment of duties an additional four [indiscernible]. Interestingly, there has been positive changes. I think they are positive in terms of IT. One participant told us that the influx of requests have helped us to make a stronger case for an online portal system for the newborn screening results in general.

Then, there are questions about procedure and policy and philosophy of what the provision of results over time will be. How long should we be keeping the results for sickle cell? If we keep them for sickle cell, why not all other diseases? Should there be an age limit or should we keep these records for a lifetime?

In conclusion -- based on what we found, we conclude that not all states are capable of providing sickle cell trait results to student athletes. The assumption that because sickle cell disease is screened for, as a part of the newborn screening program, that these athletes can go to the state programs to get these results. This is not an assumption that should be made. States have varying practices on sharing of sickle cell trait results. Even among the states willing and able to give the results, they have reported variable impact of this mandate raging from no impact to significant impact.

In closing I would like to acknowledge the state programs for their participation as well as the hematologists and genetic counselors and the sickle cell organization as well as Mike collaborators on this project. Of course, the funding from HRSA and Genetic Alliance to make this possible.

I will now open up for questions.

Thank you. Let's go ahead and open the lines for the committee members first -- committee members, then organizational representatives and we will take questions or comments from committee members first.

This is Catherine Wicklund. I was wondering -- did you get data on the number of requests before the mandate or was it simply the number of requests that they had since the mandate?

I will let Annie answer that question.

We only collected the number of requests received for year since the mandate was past, but in follow-up questions, one thing that we asked every state -- was this an increase in the number of requests they were receiving every year, and what year did they notice the increase beginning?

With the exception of one state, all of them reported that this was an increase in the number of results they have ever received for sickle cell trait results and that the trend was that the increases it started in 2010, but some states didn't receive an influx of requests until 2012 when it was passed in Division II.

Thank you.

This is Andrea Williams. I would like to know what type of educational information they were sending out with the results.

Some of the states responded that when they received a request, whether or not they have the records to provide, they would send out the brochure. The brochure they would send to any family that received a diagnosis of sickle cell trait. With information about sickle cell trait as well as where they could get more information. That generally correlated with their normal reporting procedure for newborn screening. Some states referred them to where they could get more information and some states did not provide any additional information.

Also, one of the first states interviewed -- some of the states were happy and willing to partner with athletic department for the NCAA in terms of helping to create an educational program, but depending on the states, it was not something that came to fruition. The University or NCAA felt they have their own educational program. In some ways, this project shows -- I can't remember who said this -- but someone on the committee -- when you see one newborn screening program, you only see one newborn screening program. So, it varied across the states.

This is Alexis Thompson. I have a number of concerns. My first and foremost -- I would love to understand exactly what the purpose of the review is in terms of where this is going. It seems to be inconsistent from my interpretation of what the document was that the advisory committee prepared. The committee did not, for instance, necessarily say that the screening of the population-based screening as far as the trait was scientifically based at all.

Moreover, I am a little concerned in that -- if our obligation is to the general public and is certainly there are ample reasons why individuals in the general public would want to know the carrier status, I am not sure why we are focusing on the NCAA when there really is a false

premise that someone who is a student athletes in fact needs to know their status in a way that the general public does not.

I completely agree. Perhaps I did not set this up as clearly as I should have. This presentation in no way is a comment on the medical necessity of the NCAA mandate for the medical legit is in the -- legitimacy of it. It is not meant to portray the recommendation as endorsing it or its medical legitimacy or the decision of the NCAA to have the mandate.

This presentation -- this project came out of the question that as part of the larger issues of public health impact that have accompanied the effect on the committees defloration regarding [indiscernible] in their impact on state newborn screening programs, the issue of the NCAA mandate came up for discussion and recommendation was put forth and went to the Secretary and the Secretary responded. That being said, since it was deliberated by the committee, the committee's resources were used to discuss it in the question was on some level -- this is an issue that is touching newborn screening and also topping -- touching the public health programs. It would be helpful for the -- from the HRSA perspective to understand the impact of this issue at the programmatic level. Not to determine whether or not the mandate itself -- not to debate the medical legitimacy of the mandate or its necessity.

I also completely agree that on some level this raises a larger question of -- this mandate came forth and because it came forth from the NCAA it has now had an impact that does not mean from an ethical or moral perspective that one should not pay attention to having the duty or visibility of providing results to all carriers both going forward and education and backward, or for non-carriers results going backwards from the states. I think this provides a first step in examining a larger issue and that first step has been done because this was a deliberation of the committee. I believe the Dr. is on the line and I would be happy to give her the floor. She was part of HRSA when this project was conceived.

I think when we opened the -- the public commentary it -- I think when we open it up for public comment we can get -- when we do that.

Before you do that -- this is Andrea. I am thinking -- as we are talking about this, I am thinking about how we have always focused on unintended harm. Right now, I think for the purpose of overseeing on the effects of this on the stage programs, have we really thought about the effect

on the individual -- the student athlete when all the education is haphazard right now from what I am hearing, every state is doing it their own way and there is not a way to follow what the unintended harms are and that probably didn't even come up -- wasn't discussed here. I am concerned -- I am a lot concerned that we have taken on something that we clearly said was a position and now we are in deep in this presentation. I feel like the student athletes themselves they or may not have received information on their genetic information and what is means and how it should be protected. Did they even discuss this? There are a lot of applications here that should've been taken into consideration.

I appreciate that. I respectfully disagree with the idea that we are in deep because the states -- when they have given results, giving education, and the education -- is my understanding -- usually follows the protocol they have done in terms of sickle cell trait in general. If I gave the impression that they were simply handing out results, that is not the intended purpose. Although as an aside -- if we want to have a larger discussion, any physician in a web-based portal system in a state can access an individual's results and that individual would get the additional information from the primary care physician.

Putting that aside, I think your question about the harm is an excellent one. The question of what is the educational status that is occurring for these athletes -- I think that given the vastness of the screening -- the majority of the information being relayed to athletes on their test results is actually not being relayed -- I don't have data for this, but I think I can deduce this from what we have. It is not coming from the states. It is coming from their institutions or to whatever means the institutions -- University NCAA is getting in. The issue of harm and/or appropriate education is an important one and I think it is one that should be addressed. I think the bulk of that problem, if it does exist and to what extent, is something that needs to be looked at within the universities and the athletic department themselves. That is where the bulk of this is happening. I think that our data shows some of the states are feeling a burden of resources and time of giving these results, but the vast majority of athletes are getting this testing through other means other than the states.

This is Cathy -- this demonstrates that when an outside body makes this mandate -- the two impact that this can have on the state and the responsibility of the state Department of Health. Is it their responsibility or not? Again, the number of resources is maybe taking away from other things that are necessary for the state to be doing -- to me it is like a way to look at this issue. If you look at the prenatal round -- women come in who are at risk to be a carrier of sickle cell trait -- you are not going back to the states requesting their status necessarily. That test is read done automatically in the OB/GYN office. Whether that is right or wrong is another debate. I find it

interesting the impact that it has on the department of public health and all of the states. Again, is that really the role of the department?

I appreciate your comment. I think that is an important point -- that the programs were not responsible for the mandate, but they will feel the effects. Just by [indiscernible]. The larger issue -- issues of what is optimal counseling and what does it involve is a larger discussion, which I think is an important one. And, who is qualified and what does it entail? What is optimal? Had we minimized the harms? And what harms exist? I will let any speak more about this.

One thing we mentioned at the beginning of the presentation -- in the snowball sampling method, we also asked for hematologists and sickle cell community-based organizations and genetic counselors. Through our conversations with different states, we have gone into other topics that didn't end up in this presentation today because it is indeed very preliminary. Some of the topics we discussed with them -- what is the genetic counseling offered and what is the typical procedure for putting the families who have a sickle cell trait result through genetic counseling? What is the involvement of the organizations in this educational effort? Then, getting more information about discussions that hematologists are having with individuals of this age -- the age of the student athletes. So, there is a lot of other data that we have which is preliminary to present right now, but we're looking into it and we did not feel it was the time to put it into this presentation.

This is great. I have the bigger question of the idea -- our committee put out with invitations that were -- would hopefully talk about good science, and the NCAA came out with a policy ahead of time which is not based on good science. Does this committee have a further role to say -- why continue this?

That is a good broader question. I would like to have some discussion about that, but I think Sara Copeland is on the committee line now. Are you there, Sara?

Hello?

This is Ed McCabe. Maybe you mentioned this and I missed it -- I apologize -- do we know the sensitivity and specificity of newborn screening for newborns sickle cell trait? Does the CDC have this kind of data from their quality assurance program? I am concerned that the information being given out -- I don't know the quality of the information.

I don't have that for you, but I can tell you that qualitatively from our discussions with the states that there is -- to me it seems there is a great attention to how certain they are about these results before they give them out. In many cases, even if they have them -- regardless of the testing -- if they have the results, they are hesitant to get the results to an athlete unless they are certain that the results were done at an appropriate level of test. I don't have the numbers for you, but there are always discussions with the states paying attention to the fact that they will not give up the result unless they are pretty certain it is in standby. I don't have the numbers for you -- they differ according to the screening mechanism was used. I want to make it clear that the states, by and large, there are more. That said, I don't feel comfortable giving out these results because I can't really stand by them. I did not get the sense in this project that the states were handing out results just because they have them and they could take them out of a box. That was not the way I interpreted. It is from the states and their activities. This is Susan Tanksley, can I make a comment? As newborn screening programs -- we try to stress this all the time -- newborn screening is not a diagnostic test. It is a screening test. Without diagnostic confirmation, you can't be absolutely sure. In the case of transfusions, for instance, you may or may not know that the baby was transfused. The transfusions would interfere with [Indiscernible] -- isoelectric focusing or result.

Yes, and those issues -- correct me if I'm wrong -- if we were talking about today -- about a patient of mine -- you would ask me to confirm those results, right?

Yes.

As a qualitative note -- some states mentioned that providing the result -- also with a cover letter expressing that this is only a screen. The newborn screening program recommended that it be interpreted it as a screening and not as a diagnosis of the individual for whom they provide the results.

This is Sara Copeland. Can you hear me?

Yes.

Thank you for letting me talk, even though I am not official. To get back to the underlying request -- the fact that she is taken it so much for the -- this is nothing less than what I would expect from her and her abilities. The idea was -- what impact does the advisory committee have without these policy statements? And is there any utility to doing them? It sounds like there may have been some kind of amelioration of the NCAA recommendations. They do have education on the exercise. It doesn't sound like they listened to us at all when it came time for recommending everybody be screen. This isn't meant to endorse or support or condemn what the NCAA put out there, but rather looking at what the impact had been from the committee and can the states use what the committee has come up with to say this is one of the bodies that we look to for advice and this is what they are saying. I don't know -- Annie or Beth -- have you heard from the states in terms of -- the Advisory Committee did not think this is a good idea? Had they been able to use that as a tool to maybe back off on any of this?

I will go first. I think that the states are in a bit of a pickle in that regard, because while the federal committee has issued an assessment of recommendations, the state may have an overriding policy on release of results. So, while it depends on the level we want to get to -- I am not sure -- if you are in a state that says we have a state law that says these are public records and if someone requests them and we have them and we can give them and we believe them valid -- albeit with a caveat saying, as Susan pointed out, that these are screenings and not diagnostic, I am not sure it is a recourse of the state to say we can give them. Of course, the state could say we don't feel as part of a larger community for which the recommendation was issued that this is optimal -- FYI -- this is our stance. But, I don't think it can be rationale for not providing the result especially if in some states there is state policy overriding this. These results have to be released to the individual requesting them.

Go ahead.

I think that is an important point. It comes down to the state level. What the advisory committee can do is support the states as much as possible and provide them with tools, resources, and guidelines. Ultimately, there will be other factors that impact what the states can and cannot do. I think you have nicely pointed out that the impact is from an outside group that really technically should not have much impact on the newborn screening program. But, it really has.

I agree with you and others who opposed this question -- the thrust of the recommendation was one thing. It had its stance. It came from a body of a federal committee that was deliberating an issue. The task I undertook was to say having had that occur -- the deliberation and recommendation, the states are existing now with potential burdens and resource requests and requirements that I think, as a larger issue, merit at least acknowledgment or awareness of, even though this may not be endorsed by SACHDNC, but the states feel it and the states will operate in a milieu in which they will have to negotiate how to deal with these requests. And, that gets back to my initial point -- I give you a task and you take it and not only do you do well, but you do it further. I think you have come up with some good points. I think it does point to some of the issues that the states deal with. I like Cathy Wicklund's [Indiscernible] -- the state is expected to report for pregnant women -- how this is another venue that the states could look at.

This is Alexis Thompson. I wonder, as you talk to the states and they are proposing solutions for the influx of requests that come from the NCAA, how much of the problem-solving or strategies really relate to how this can benefit the public overall?

I recognize this is an anecdote and I will let Annie speak to this -- the actual numbers -- but, I can tell you in the conversations with the states that the states really do feel, from my perspective, a responsibility to make sure they are doing the job the right way. And that many more is that the states have tried to partner with the athletic department to set up a program. They know it will take resources, but it is the right way to do it. Let us help you -- the athletic department and NCAA. I am not trying to tarnish them. I don't know the details of the conversations. But, more often than not, it is not like these days are swatting at flies, so to speak. The states, in my opinion, have been true to their duty to help the public. Not simply to follow marching orders of giving out requests. In cases where it hasn't worked, it has not been for the lack of the states not trying.

But, your response, to me, is quite concerning because -- and athletic director is not the public and not for the public good. I think that is troubling. I don't think that anyone on the call is persuaded by this notion that when you sign a waiver -- if it is a waiver -- of liability against an institution, that that reflects someone having, as a primary interest, the health of a student. So, in that sense, the notion that we are looking at solutions that facilitate for an athletic department as opposed to, say, a woman who has a pregnancy and has a baby at risk for sickle cell -- something that most of us can easily see is quite relevant for the public domain to consider. I guess it troubles me that if we are looking at solutions that can't ultimately leave me to something that will benefit all citizens, -- ultimately benefit all citizens, I don't think it is useful for the states to have to respond to a private entity.

You raise a good point. On the heels of this project -- after the project was started -- as this came to be, I have been a discussion with reaching out to other members of -- other stakeholders involved -- athletic department and the NCAA. In an effort to say and to the NIH as well -- to say that this is not necessarily -- this may not be optimal. This policy -- this policy came as a result of litigation, as Chris pointed out. There is some concern of the medical legitimacy that is not resized. Not robust.

I share your concerns. Because of that, Alexis, I've reached out to the stakeholders in the CDC and NIH and NCAA and the athletic departments in trying to marry a fractious union of -- can we all work together to find a way to educate these athletes in a way that everyone is comfortable with, that is for their best interest, and not simply to check a box on a policy? As you might guess, these are contentious issues. Trying to have the porcupines mate, if you will, is challenging. I am trying to do my best as the next step to address exactly what you say -- given these results to the institutions and not having any attention to how they use them and how they educate the students is not optimal. However, these are private entities in some instances. How to get them on board is in a discussion as a challenge, but one that can be done. I completely agree with you.

I raise this only -- if we are looking at solutions that are really to facilitate the response to this mandate and we are doing that in an environment of restrictive for resources, that could be used to help the broader communities for evidence-based purposes. It concerns me that -- we are not supporting this to benefit the broader community, are we not necessarily, then, perpetuating the notion that it is important for student athletes --

---

Are you saying, then, that there is one thing about optimizing it for the athletes, but if you are going to optimize it for the athletes, the public should come as well?

If we are looking at solutions -- mentioned in some states they were proposing improving or establishing portals that the public or primary care physicians could access. Clearly, those kinds of things -- you could see how the larger public would benefit from that as well as the student athlete that has a medical home. But, anything short of that -- other solutions -- I think these are concerning.

You are speaking -- to make sure I understand -- to the larger issue of the challenge of comprehensive and adequate carrier dictation of the public?

Correct. That would extend beyond sickle cell testing.

I look at the glass half full -- I in no way think we should do it for the athletes, let me clarify -- and that should be the end of it. I think to make lemonade out of lemons, that this instance they offer the opportunity for us to say this has happened -- this is a reality now, this mandate. These results are being released. Is there a way to create a model or paradigm of education that can be broadly disseminated or used for, phrases, sickle cell trait counseling they can get at what is been a struggle for so long, which is comprehensive coverage and adequate delivery of counseling. I think that in some ways this could be a model. In fact, the NIH is not interested in funding the study for the NCAA, but a study involving the NCAA or a project can then have broader ramifications for the newborn screening programs, and for their conflict regarding the trait, is something that is the lemonade that could come from these limits.

Speaking about the long-term follow up committee -- the membership doesn't overlap, but I am wondering if the work overlap -- there is also some thinking about what will happen when we move toward DNA screening and to what extent could some of this be an issue for long-term follow up for any carrier that is found? Whether it is sickle cell or, depending on how people are doing screening, is this something where we need to be thinking about not only the role of the states, but where we find a limit to the role of the state because the state can't take on everything.

This is Andrea. While we wait for that to happen, what is happening to the thousands of people that are receiving these results? That's the issue. While you were waiting on this larger thing to exist, there are things happening that seemingly we are saying one thing and doing another.

This is Chris. The other comment I would have -- I don't know the context of this. We talk about somebody collapsing who had sickle cell trait. How many athletes collapse because of practices and the way things are implemented now for the greater population? Our recommendation was that this was not evidence-based. I agree with Alexis. I have trouble with that.

Chris, I agree with you. The sickle cell trait is one of a number of possible reasons for which athletes can collapse and possibly die during intense conditioning. I have been a supporter of not simply mandating screening, but mandating treatment because I know I am preaching to the tribe -- but -- the choir -- but it is not completely successful.

Again, the legitimacy of the mandate was beyond the scope of this project. But to the extent that Dr. Bocchini and others in the committee have had these issues, and dealt with them to create this recommendation as a response to the mandate, I endorsed the discussion. But, it was not a part of my solution or my task.

Got you. I agree. I hear you.

This is Joe -- Dr. Bocchini. Based on the conversation we have had -- I think the key points are, as Chris raised earlier, the role of the committee at this point. Then, as Dr. McCabe indicated, this is a screening test. It might be under the purview of the committee to reiterate our position on routine screening of athletes, but also raise these new issues that have now come, locating the problem of allowing data to be given without proper education, inadequate evidence of appropriate education, and follow-up, and maybe misuse of preliminary screening data. This adds to the problems that this has created. I wonder whether, subsequent to developing the results of this survey, that additional efforts could be made to put something together to highlight the additional problems developing. Does that seem to be a reasonable way to go with the data that would satisfy the concerns -- legitimate concerns -- that have been raised by many members of the committee?

Joe, I want to point out -- before this discussion -- results are preliminary. This is not the final report. But, I agree that your question is important and valid. I don't know that they will change greatly the final results, but these are not the final results.

This is Colleen. I think Joe's suggestions are right on the mark. I would caution us to make sure that the survey we have can actually address these questions so that we are actually adding to the evidence base.

I have a question, Colleen.

Do you mean the responses that we gathered?

Either that you gathered or we have not seen yet.

Okay.

How much time do you think you need for review of the rest of the data and coming up with a final data set for discussion?

Probably -- we could -- if we try to get 100%, I would say by June 1. The effort is in getting the complete data and the rest is in condensing what we have -- analyzing what we have. I would say June 1 seems reasonable.

That timeline would potentially allow us to review the data, and at a September meeting make decisions about how to move forward and put together another set of information from the committee, highlighting the additional problems that this mandate has created and perhaps be able to use that information to advise the various state public health departments on how to address issues this might raise, in terms of accurately indicating the information they are giving and what it means and what needs to be done and that might at least improve the use of the information.

I think that is a great idea. Specifically, I feel much of the discourse in the public policy arena has been around [Indiscernible]. Or don't do it. There are harms or no harms. There has been -- the states are caught in the middle of this with the arguing bodies and the stakeholders. Something that reminds the other stakeholders and points to -- the core elements at the base that need to be addressed and understood in the process and this would be helpful. I think that would be a nice follow-up to the recommendation. The recommendation was in place to float out there and to -- have a follow-up that is concrete and direct and meant to improve this process and assist the states.

The only problem that this survey doesn't address is the potential negative effects to the individual -- the actual negative effects of the individual athletes.

That is correct. It is difficult to get access to the output.

Any additional questions or comments?

This is Cathy -- Alexis, you may want to comment on this. We just had a student -- they did try to access students last year. I can have Brittany send some of the data that you found. It is hard to determine if actual harm is done given that the majority of people are negative. There was not a large number -- only two individuals that she was able to identify with the trade and also get the response rate, in particular from the ballplayers. It was only one football player that responded. The data is hard to get. At that age, I am not sure that they are thinking about this in the same way we are.

This is Chris. Also, we think about harm -- we have talked about use of resources in other ways. That is harm to the public, in my mind.

Good point.

Dr. Bocchini, this is Debi. I know we are a little behind schedule but I wanted to acknowledge Rachel Montgomery's public comment.

I see. Let's go ahead. I think everyone can do that -- she indicates she's a public health representative listening and regarding education -- we collaborate with our states committee-based sickle cell organization to provide education since they have the resources available. That is part of what [indiscernible] indicated in the study. In some states, this was happening. Thank you for that comment.

If there are no further comments from the committee, maybe we could have the operators see if there are any questions on the public line.

Please press star 1 if you would like to ask a question.

While we wait for that, toward the end of the morning's segment, can any organizational representatives who was on the call after I did roll call -- indicate that they are on so I can give you credit for being here this morning?

At this time, I have no questions.

Okay, and I have no additional organizational representative response.

If there are no additional questions from the committee or organizational representatives, this will conclude the morning session. What we will do now is -- since we are 5 minutes behind schedule, we will meet straight up at the hour. If you are on the East Coast, that will be 12 noon. -- Sorry – 1 pm. Sorry -- I am mixed up with central time.

Straightout, that is 1 p.m. Eastern time. -- One o'clock Eastern time.

Any comment before we close for lunch?

This is Debi. I need the committee members to stay on the line.

Everyone else -- please sign off for the moment. Then, we will leave the committee members on the line for Debi.

Thank you.

[The 30th Meeting of the SACHDNC is on lunch break until 1:00 pm Eastern Time]

[End of morning session, Part 1, for April 19]