

MCHB/CSHCN DIRECTOR JUNE, 2004 WEBCAST

June 11, 2004

PETER VAN DYCK: Good afternoon, everyone. This is a monthly Internet webcast. I'm Peter van Dyck, director of the Maternal and Child Health Bureau and we've put together an interesting program for today. Before I introduce today's speakers I would like to review some of the technical information about the webcast. Slides will appear in the central window and should advance automatically. The slide changes are synchronized with the speaker's presentations. You don't need to do anything to advance the slides. You may, however, need to adjust the timing of the slides to match the audio by using the slide delay control at the top of the messaging window. We also encourage you to ask the speakers questions at any time during the presentation. Simply type your question in the white message window on the right of the interface, select question for speaker from the drop-down menu and hit send. Please include your state or organization in your message so that we know where you're participating from. The questions will be relayed on to the speakers periodically throughout the broadcast. If we don't have the opportunity to respond to your question during the broadcast, we'll email you with the answer afterwards unless we just don't know the answer. Then maybe we'll make something up. But again, we encourage you to submit questions at any time during the broadcast.

Now on the left of the interface is the video window. You can adjust the volume of the audio using the volume control slider and you can just access that by clicking on the loudspeaker icon. Those of you who selected accessibility features when you registered

will see text captioning underneath the video window. At the end of the broadcast, the interface will close automatically and you'll have the opportunity to fill out an online evaluation. Please take a couple minutes to do so. It helps us greatly. Your responses will help us to plan the future broadcasts in this series and improve our technical support.

As always, Chris DeGraw is here acting as the technical guru and will be the interface between you and your questions and the speakers. And on my right is Michele Puryear, the director of the genetic services branch in the Division of special healthcare needs to the Maternal and Child Health Bureau and Michele is going to speak today, as well as a guest whom she is going to introduce. Michele.

MICHELE PURYEAR: Hello. Our first speaker today is going to be Dr. Brad Therrell the director of the national newborn screening center located at the University of Texas, San Antonio. The center is funded through a cooperative agreement with the Maternal and Child Health Bureau.

DR. BRAD THERRELL: Thanks, Michele, Dr. van Dyck. What I want to do for the next few minutes is sort of bring you up to date on what is going on in the world of newborn screening and then I'll leave some time at the end for Michele to talk about some of the activities that HRSA has related to newborn screening and genetics. First let me begin by saying that newborn screening can refer to a couple of different programs at most state health departments. Sometimes it refers to traditional biochemical testing that we've been

doing for the last 40 years and sometimes it refers to the newborn hearing screening programs which have just recently started up.

In this presentation I'm for the most part going to be talking about the traditional newborn screening, biochemical testing. There are multiple ways of defining newborn screening but basically it ends up being an essential public health program that prevents catastrophic problems from occurring. It's a complex system. It has more than laboratory and more than follow-up as you'll see in a minute. And it certainly is a public health prevention strategy that I'm sure most of you are aware of and it has been most successful over the last 40 years. Screening can -- is comprised of a number of different aspects including the public health laboratory people, the follow-up people, administrators, specialty care providers, family members, policymakers, kit manufacturers and other interested people including state legislators and perhaps in some cases those are the most important.

Now just for a little refresher, we've been doing sort of the traditional newborn screening since the 1960's, the early 1960's when Bob Guthrie reported his method for detecting P.K.U. At that point it was the program began in the public health departments with pressure from parent support groups and some help from HRSA, actually. Back then it was called the Children's Health Bureau, with funding from the Children's Health Bureau and pressure from parents legislators began to understand the need for these programs and began instituting had programs in place by the end of the 1960's or 1970's. State

legislators decreased the state funding and asked these programs to pay for themselves. I'm sure you're aware of that as well.

Today most programs have a fee-for-service. There are still about eight that do not charge a fee-for-service and pay out of the state coffers. All states have a law that can be cited as a basis for newborn screening but there is a lot of variation in the way newborn screening occurs from state to state. Newborn screening is a system and that system generally is considered to be five or six components. Those components must function together seamlessly if we're really to have a functioning and efficient and effective newborn screening program. Now, given the history of newborn screening over the years I want to talk for a few minutes about the system and what the states are doing and where we might be going from here.

The flow schematic I'm sure you're most aware of that should be on your screen now shows that the baby starts -- if you look in the upper left-hand corner starts at the hospital. Screening occurs both blood spot screening, the traditional method and hearing screening and in many cases these data are reported together to a central database. Sometimes on the newborn screening form. And many times they are also connected up to birth certificates. The data flows into a central facility to do the laboratory work. Laboratory testing occurs, reports back into the systems. Sometimes follow-up hearing screening occurs and reports back into the system and that data is available for other database is. It is also used by the screening program to track the babies that need follow-up because of positive test results and to report back the routine negative test as well. So that if there is

a positive test there is usually a coordinator who tracks the baby down back through the hospital and into the private care provider and tries to make sure that that baby is in a medical home and is having the proper confirmatory testing done. It is not always as easy as it seems. The information about who the provider is going to be is not quite available yet when the baby leaves the hospital. You can see that's a pretty complex system.

The next slide should show you the components of the system. Put them together as a possible. If you start in the right-hand corner is screening. Screening has the laboratory testing and results. The follow-up where the results come back and somebody makes sure the baby gets in for confirmatory testing and if there is diagnostic testing necessary the baby gets into the diagnostics aspects of the program and usually referred to a specialty provider. And if a disorder is diagnosed, the baby is then referred in for management and along with the management I've listed there management of specimens as well. There is residual blood that remains and that specimen has to be managed along the way and many ways programs are managing specimens today. In order to complete the system we need evaluation so that we're sure we have a quality program so we look at quality assurance, outcome evaluations and cost effectiveness.

Tying all of this together is education and actually the thing that really ties it all together is sort of money. And the last slide in that series shows you money where this is the same that ends up being the decision making factor in many programs. Now, with that system in place, there is a lot of concern these days about where we're going and what we're doing and why there is not equity across the systems. And you can see on the next slide

there is interest in Congress right now and actually a year or so ago there was a hearing by Senator Dodd's committee to discuss why it was there are so many differences among the program and such variation exists and such equity doesn't exist across the country. And from Senator Dodd's interest and Senator DeWine's interest the G.A.O. was asked to submit a report of what is the status of newborn screening in this country today. And that report is now available and it's available through our website as well. I won't go through that report except to emphasize a couple of things.

One is if you look in take report you'll find out that everybody has a program in place and three of those programs, and only three, actually, require consent at this point. So that everybody else requires a dissent of some type. In some states dissent is not even allowed. There are eight programs that mandate two screens, that is one screen before the baby leaves the hospital and one screen at about one to two weeks of age. And there are eight programs as I mentioned that don't charge a fee and those that do, the fee varies anywhere from \$10 up to \$70. It's not related to the number of calls but related to a number of other complex issues. The amount of medicate reimbursement varies widely across the country. In many cases this is part of the thing that drives the program. The number of babies on Medicaid in this country is a third of all the births. And again, as I mentioned earlier, the storage of blood specimens varies widely from program to program.

If you look at the next slide I have a bar graph which tells you graphically the number of disorders that are being screened across the country state by state where I've listed 51 as the total of 50 states plus the district of Columbia. And you can see on the left there are

three conditions screened by everybody now. P.K.U., Hyper Thyroidism and appeared other things. Three states don't have sickle cell. You can see that about 30 of the states do Congenital Hyperplasia and 30 do others. Until you get down to the right side where you see only a couple of states do Toxoplasmosis and H.I.V. And if you look to the far right you see the number of states that are actually using the latest technological advance in screening programs. 35 states have the capability. 33 of which actually have mandated MCAD deficiency.

If you go to the next slide you see there are a number of different service models for laboratories across the country. There are public health laboratories within the state providing only state services and some public health laboratories that provide services to multiple states and you can see from the slide that the states that are using the same laboratory I have in the same color so you can see in Oregon, for instance, provides services to Hawaii, Alaska, Nevada, Idaho and Oregon and Massachusetts provides services to all of New England and so on.

Now, if you go to the next slide you'll see another model which is superimposed. That's the model of now we're getting into private laboratories as well. In California there are eight different private laboratories contracted to the state. South Dakota has one contracted laboratory, there are a number of states which are now using Pediatrics Laboratory in Pennsylvania as a contracted laboratory. So the point of these two slides is to show you there are a number of different models that are working for laboratory service provision.

Now, the next slide shows you those states that now have the SPECTOMETRY available. Those that are colored actually without a star have the potential and have the ability to offer it; they just don't naturally have the laboratory in place in their state. In the next slide you'll see a number of arrows that show you where the states send their samples. The point of this slide is to show you that we're not just constrained by a laboratory within a state or a neighboring state to provide these sorts of services. There are a number of states that have demonstrated that you can mail the samples across the country and still get reliable test results in a reasonable amount of time. Now the next series of slides just shows you the number of different states and which states are actually offering the different tests so the first one is congenital hyperplasia. Those states in the darker lavender or purple color have mandated testing in place. Those that are cross hatched have -- either have a pilot in place or been mandated to do the testing and they're trying to set it up at this point. The next slide shows you cystic fibrosis and a couple have had it mandated but not quite set up yet.

The next slide shows you the number of states that are doing things other than the routine testing. Infectious diseases, H.V.I. and toxoplasmosis. The next slide shows you the number of disorders being screened in the different programs to reemphasize to you that there is still inequity across the country. You can see from this slide that the largest number of mandated disorders right now is in Mississippi where there are 40 disorders that have been mandated and named in the law and the regulations. And then there are a number of states that have greater than 30 disorders where it becomes sort of an exercise

in futility to try to name -- to try to count the number of disorders because of the differences in the way people count. Sometimes people will count two types of one disorder as two tests. Sometimes they'll count it as one. So we've gone to just calling it greater than 30 when you get up into the higher numbers. As you can see, the least number of disorders that is mandated is still three in one state. We've gone back over the last -- over a ten year period of time from 1990 to 1999 and looked at the data that's been submitted to the state and asked the state to validate those data so that we could look across the country and see what the national incidence of some of these disorders are.

And you'll see from the first slide in this series that sickle cell diseases actually is the highest incidence disorder that we're screening for and that includes S.S., S.C. and other things. It's about 1 in 2000 babies have a positive test for sickle cell looking at the population as a whole. Hypothyroidism is one in three thousand. Cystic fibrosis. If you go to the next slide you'll see I've started at the top as PKU which is one in 19,000. Just under that is clinically significant anemia sometimes counted like PKU by some programs. If you put the two of those together you get the clinically significant anemia PKU is one in 14,000. Classical CH is about one in 19,000. And so on until you get down to the 1 in 350,000. We don't have on these slides disorders like MCAD and some of the organic acids because they're too new in data collection and still collecting what the incidence of some of those disorders are. If you talk about projected incidence, keep in mind that we really don't have those data yet. It's just too recent and too few cases to say reliably what the instance of those disorders are.

Now if you look at the next slide or on to the next couple of slides you'll see we get into this question about how do we decide what is going on in the newborn screening program? And for the most part that is done by state legislative authority and sometimes that authority goes to the state health officer, sometimes it goes to the board of health, sometimes it goes to advisory committees. A number of ways those laws are written. Ultimately it resides with state legislatures to decide what states do in the newborn screening programs. In terms of how the decisions are made over the years they've mostly been made because of public and professional interest. Although sometimes there has been political interest which has driven addition or deletion of disorders from newborn screening programs. Cost benefit has been a consideration and then scientific evidence has often been a consideration but not as often as we would like.

Nowadays we're looking more and more at evidence-based justification for newborn screening. We still tend to use the traditional criteria for newborn screening that were created back in the 1960's by Wilson and Younger. There are about ten different aspects to the criteria that they suggested. These mostly have to do with incidence and availability of testing and cost benefit and those sorts of things. They don't really take into account like multiplicity of tests that could be done from one instrument or one sample of blood. So Michele will talk about this more in a few minutes but there has been a HRSA contract with the American College of medical genetics to take a look at these traditional criteria and see what needs to be done in terms of updating those.

This contract and this consideration actually came out of some meetings that were held back in 1998 and 1999 by the American Academy of pediatrics who was funded by HRSA to develop a task force to look at newborn screening issues and that task force was chaired by Ed McCabe and co-sponsored by a number of different agencies to try to get consensus as to what we were going to be doing in newborn screening. Federal agencies. From that task force came a report which was published as a supplement to pediatrics in 2000 and if you don't have a copy of that and need it, just give me a call and I'll be happy to send you one. This report -- it's very comprehensive and has a good deal of reference material about what has been going on and where we should be going in the future.

Basically this task force report was based on five major principles about newborn screening in terms of there should be benefit, there should be public health agencies that oversaw newborn screening. There should be standards and guidelines developed, greater uniformity and everything should link up in the end to a medical home. So with those considerations in mind the task force developed some recommendations basically in four different areas where the report goes through and outlines where the deficiencies are and where we should be going in the future and defines the role of state and federal agencies in this respect. This task force report came forward with an agenda for action where it actually defined what the responsibilities were for the state agencies, talked about modeling regulations for newborn screening, talked about developing minimum standards, modeling guidelines for professionals, looking at models of care from infancy forward.

And designing strategies that needed to have input from the general public and funding demonstration projects to evaluate technology, quality assurance and health outcomes. As soon as the task force report came out, since it didn't go into what disorders should actually be screened for across the country in the different states, the March of Dimes did come out with an agenda that listed nine different disorders including hearing screening that should be a part of every newborn screening program and since that time they've actually come out with one more and that's the MCAD deficiency. They now recommend ten in every screening program. Parent support groups have used these ten disorders as sort of a yardstick for evaluating state programs and there has been a lot of press across the country in terms of whether or not individual states were meeting the ten recommended tests by the March of Dimes.

Now, there is, as I mentioned earlier, a lot of Congressional interest in newborn screening. Some of this Congressional interest led to committee challenges to -- and committee assignments or direction to federal agencies, including HRSA and CDC and NIH and AHRQ and those are listed, those actual wording from some of those bills are listed here on this slide. Now, newborn screening is still a variable program across the country. We're beginning to move forward with a lot of programs that are being funded by the federal agencies in response to this agenda for action. And some of those things we've been involved with here at our center, of course, were funded by HRSA as a cooperative agreement to serve as a focal point for newborn screening and genetic activity.

Some of the things we've been doing to help the states we've been looking at providing training support for newborn screening since states were not very well equipped to get into the -- we have developed courses at Duke and Baylor where a state health department laboratory personnel can go for hands-on training and state follow-up people can go for hands-on training as well. These courses are small numbers of students so that there is a lot of time spent between the instructor and the students. We're offering them only at two institutions right now so we get pretty uniform way of handling the training and you can see on the next slide there are some pictures of some of the people going to these courses. You probably know some because we've already covered just about every state that had an interest in the procedure. We're continue to offer these courses as long as there is an interest and looking at ways to go to the next level now and offer refresher training and perhaps some training to physicians who are having questions about what these disorders are and need some refreshers in that aspect of screening. We also have provided consulting reviews to state health departments.

It started in 1987, having outside persons come in and evaluate their program. Give some suggestions to the state as to how they can improve their program and move forward.

This began with funding from HRSA in 1987 and over the years these reviews have covered about 26 or 27 different programs. Some of those have been actually covered a couple of times. So that since 1999 when the national newborn screening and genetics resource center was funded we have now taken over those reviews and go through three or four states a year. We come only at the invitation of the state and ask the states to provide us in advance issues and questions that they would like addressed by an outside

review team. The team includes expertise in laboratory, follow-up, administration, medicine, there is a couple of federal people on the team. One from HRSA and one from CDC looking at quality assurance and so at the end of a review there is an oral exit interview in by most of the questions are answered verbally and then we report back with a written report a couple months later. And the evaluation of these reviews has been done on a limited basis and in every case that a review has been done and evaluation has been received there has been a very positive response of the state in terms of their -- the information they got from the reviews and the way it was used to improve the programs.

If you look at the next slight you'll see a map that shows the number of states that we visited and the stars sort of indicate whether there is one or two visits. The gold stars indicate there have been a couple visits to those states. These are available should you desire to have a review, you can contact our office. We have a little application form that you fill out. We like a formal request and questions and issues and then we schedule a review and come in. It's about a three-day review. As I said most states have found it to be a very positive influence on their program. We -- there is a couple of pictures there of some of the reviews. A picture of the review team visiting in Missouri and one in the laboratory in Louisiana. A lot of other federal support and interest. Michele will talk to you in a few minutes about what is going on with HRSA. So I'm not going to talk about HRSA so much as I will mention that CDC has a program for quality assurance of the laboratories. Without this quality assurance program, I think the laboratories would be in a lot of trouble.

This is something that started off with some funding from HRSA a long time ago and over the years HRSA supported this and eventually HRSA money was sort of partially supporting it and now CDC is supporting it full time. And the picture there that you see should show you the blood specimens that are being prepared and sent out and the circle around the head of the group and is Dr. Harry Hannon. It provides quality assurance materials for programs outside the U.S., including about 50 different countries, 53 or so different countries. 64 domestic screening laboratories and over 350 laboratories around the world that use the materials coming from CDC. So in summary, let's just remember that newborn screening is a program that works. There are about four million babies born every year and 4,000 are detected with some disorder and another 1,000 could be detected if all the programs were offering the maximum amount of screening that could be offered.

There are -- I'm sorry, I can't see what I've got on the slide. There is a lot of different things going on in the programs. There are still a lot of inequities. There are still a lot of babies that are going undetected depending on where you live. So this is a problem if you live in one state and across the street happens to be another state, then sometimes you get five disorders in one and 30 in the other. And this is something that we're looking at right now and the new secretary's advisory committee is looking at this and so is AC & G contract and there is still a lot of interest in expanding programs. A lot of interest coming from parents and the state health departments themselves. Over the next couple years I think you'll see a lot of expansion in newborn screening and we hope we'll be there to help out. If you look on the last slide you'll see a listing of our website. I invite you to drop by

and take a look at it. It's got linkages to a lot of different newborn screening resources around the country and around the world. We also have list serves available so that we discuss issues in newborn screening. If anybody is interested in being on one of our list serves let me know and we'll add you. I guess that's really about it for now so that Michele has some time to talk to you. Thank you for your attention.

MICHELE PURYEAR: Thank you, Brad, very much for a very comprehensive discussion on the history and where we are going in newborn screening. Remember, folks, you can type in your questions any time. We have no questions at the moment that we're going to take but please type them in and we'll get to them after Michele's presentation. So now we'll go to Michele and hear about the current activities in the bureau.

PETER VAN DYCK: Good afternoon. I'm going to go ahead to slide number 8 so that we have time for questions at the end. And I have focusing slide number 8. And I want to focus the rest of my discussion on those activities in the newborn screening arena. Thank you. The bureau's vision for newborn screening has been focused around a systems approach with defined public health roles at state and national level. The presence of quality assurance both for the laboratory and for the program. The rest on public and private partnerships for that systems approach and a comprehensive and efficient care and management system. And then finally, but most importantly, a program that rests on equity for families. With that vision in mind we've undertaken several activities to address issues around equities, family and provider education, quality assurance and most activities have just started.

First we -- and -- two years ago we asked the American College of medical genetics to convene an expert panel to review the available information on newborn screening. And we wanted that to be based upon analysis of the best scientific evidence. We wanted them to address model policies and procedures and minimum standards for state newborn screening programs by creating a model for a matrix for changing newborn screening panels and for developing a uniform panel of conditions for screening. We are also developing newborn screening educational toolkit and this is based with two projects. One funded at UCLA that was looking at the policies and procedures for the informed consent process that is used in state programs and the second and separate project that's funded at Louisiana state university. With this project we're developing a sample newborn screening educational toolkit.

The process on the next slide shows that we're convening and have convened a number of listing groups both parents and providers to evaluate one or more options for an educational process for parents on newborn screening. We've developed a preliminary toolkit and we're conducting pilot testing but we've learned, though, thus far is parents want to learn from their pre-natal providers and they want to know all about newborn screening and states have -- we've had -- states have not been doing the job that they probably should have been doing in this area, at least according to the parents. Based on our work with parents, we've learned that -- this has come out with the newborn screening task force report. Parents want to learn about newborn screening at the time of the pregnancy.

We've developed a partnership with the American College of Obstetrics and Gynecology and the association of family practice physicians and are creating educational tools for training prenatal providers and also for them to use with their patients. Finally we started a new program based on legislation that was contained in the child health act of 2000.

There are three parts to that act. The first part is the grant program. Or the first two parts are the grant program and the third part is an advisory committee which is called the advisory committee on inherited disorders and genetic diseases in newborns and children. The grant program provides for funds to states to establish or expand or improve systems of programs, for services to reduce mortality and morbidity and to provide information and counseling on available therapies.

The advisory committee has been set up to provide technical information to the secretary with the development of policy and priorities for the administration of grants under the section 1109 or the first part of this act. And also to provide recommendations and advice or information as may be necessary to enhance or expand or improve the ability of the secretary to reduce the mortality or morbidity in newborns and children from inheritable disorders. These slides are -- the next slides provide the kind of expertise that should exist on the advisory committee. And on the slides 19 through 22 I've listed the advisory committee members that you can look at later. Please note, though, there are four federal agencies that are considered members of this committee and are actually voting members of this committee and the agency for health research and quality, CDC, health resources and Health Resources and Services Administration and NIH.

Peter van Dyck is the health resources service administration representative to the committee and the committee is administered by the Maternal and Child Health Bureau. The committee met this past Monday and Tuesday of this week and identified many issues, including making recommendations for a uniform panel of conditions to be screened for in all newborn screening programs. They're interested in looking at how blood screening programs are financed. What are the states capable of after recommendations from this advisory committee.

What science and technology is evolving to promote further expansion and the need for parents to be informed about newborn screening programs. We received 01:18:46.660 million this year to begin this program. We matched these funds and have delegated about \$4 million to begin funding the regional genetic service and newborn screening collaborative. This is in slide 23. The focus of these collaboratives is to enhance the support for genetics and newborn screening capacity of states within defined regions. We've defined the regions in our application guidance. These programs are expected to undertake a regional approach toward addressing the distribution of genetic resources in states. And I certainly hope that many of you are involved in the application process. These are coming in at the end of June and if you have any specific questions on these and especially if you're not involved because that's actually a requirement that -- that the Maternal and Child Health Bureau directors, direct the programs, and they're -- the applicant is required to involve you all in these projects. We want to know if that's happening in your states. And I will end there. Thank you. Any questions?

PETER VAN DYCK: Well, Chris, do we have any questions yet?

CRIS DE GRAW: We have one question. This one comes from Kansas and is directed toward Brad Therrell. Is there a fee charged for the state newborn screening reviews that you mentioned are available for the states?

BRAD THERRELL: Nope. That's included in our budget and so if you're interested in that, we take care of all the expenses here. It's included in our budget. The only expense on your end would be trying to help organize who we visit and who we see and who might, you know, be coming to see us and that sort of thing. In terms of the people who come in and where we go we take care of all those expenses.

CHRIS DE GRAW: We have another question coming from an MCHB staff person. How do the southern regions correlate with the ten HRSA regions?

MICHELE PURYEAR: There is some correlation but not complete correlation. There is some similarity. If you go on the HRSA website, you can look at how the regions were defined.

CHRIS DEGRAW: We have another question from Florida. Can you provide more information regarding the newly created advisory committee?

MICHELE PURYEAR: We have a website which, if you again go on the Maternal and Child Health Bureau website, you can link to that. If you go to Maternal and Child Health Bureau, go to programs, go down to genetics, there is a link to that website and that website describes the charter, the roster, along with biographical sketches and also will give the agenda for the first meeting that we had on Monday and Tuesday.

CHRIS DEGRAW: That's all the questions we have at this time. Now would be the time to submit questions if you have any further questions.

PETER VAN DYCK: So, folks, again if you have questions type them in the question section and press send and we'll collect those. If you have continuing questions or think of questions after the call ends, then you can send them in by email. And we'll answer them over the next several days. And again, if you need to know the email address, it's INFO @ MCH com.com. Well, Brad, thank you very much for being on from Texas.

BRAD THERRELL: My pleasure.

PETER VAN DYCK: Michele, thank you for updating people on the bureau's involvement. Want to thank all of you for participating in our monthly broadcast. I would like to thank the contractor at the University of Illinois School of Public Health for making everything work and patching in Brad from Texas. Today's webcast, as with all webcasts by the bureau cooperatively with the University of Illinois are archived and available usually

within two days or so on the website www.mchcom.com. We encourage you to let your colleagues know about the website and hope they'll find it useful. While I've been talking a couple of you had quick fingers and submitted a couple more questions. We'll pause for a minute and take those.

CHRIS DEGRAW: How do you define equity?

MICHELE PURYEAR: Well, Dr. Therrell spoke and showed you the great disparity between states and what conditions states screen for. In the very least I would think that any child born anywhere in this country should be allowed a minimum core of conditions to be screened for at birth. Every child -- a child born -- African-American child born anywhere in this country should be screened for sickle cell disease. It shouldn't be an accident of birth of what you're screened for. This is a big issue that parents have come to us also and this is also fueling a lot of the Congressional interest is the differences between states and if that difference is not based on good science, then I think there is a problem.

PETER VAN DYCK: As director of the bureau I feel some pressure in the equity issue. If I think those of you in states who provide only a small number of tests. Certainly parents ought to have the ability publicly or privately, to be told and have access to a full complement of tests. At the same time, I feel a responsibility towards having equity in the follow-up for those tests and equal access across the country to the experts that are necessary in that follow-up. As we begin screening for more and more rare diseases, one

in 350,000, there are other diseases in that category of rarity that can be detected. There may be only one or two experts in the country qualified to treat that condition. We need to provide in some national referral pattern or regional to regional referral pattern equal access to a child or family anywhere in the United States to those two or three experts. It is not just equity in the screening, it's equity in the screening and the follow-up and the equity in access to clients that I really feel a responsibility towards implementing and I feel that the development of this regional system will help us get to that point.

CHRIS DE GRAW: One final question. Are there state representatives here that --
[inaudible].

MICHELE PURYEAR: They did not specify organizations or representatives of organizations per se except for those handful of liaison organizations that you saw. And so the representation is broad in nature and I think the legislators thought they had representation from state directors through the bureau and through my representation. Saying that, I think it would be important for you to look at the website, to be in contact with Michele, and if you have issues you would like to have discussed, agenda items you would like to have discussed, if you would like minutes of the meetings after the meetings happen they'll probably be on the website. But you need to stay in touch and keep in constant contact with us and we'll try to be a conduit for your questions. Is that all, Chris?

CHRIS DE GRAW: That's all the questions.

PETER VAN DYCK: OK. Thanks for all those questions, folks. Again thanks to the presenters and again we want to make these webcasts responsive to your needs. So please suggest topics that you would like addressed in the future on the www.mchcom.com and mail info to www.mchcom.com. Thank you for joining us. We look forward to your participation next month. Have a good rest of the day and a good weekend. Thanks very much. Goodbye.