

Financing Genetics and Newborn Screening Services

September 6, 2005

MIKE WATSON: Hello, everyone. This is Mike Watson at the American College of medical genetics welcoming you to our second teleconference. We have a couple of very interesting speakers to talk about financing and services today. I'm hoping it goes as well as our first teleconference which was very well received and for which we've gotten a number of favorable comments. I want to give you a few of the pieces of information, some ground rules to the process and introduce the speakers. First of all, let me say that I'm on a different screen than everyone else watching this from the outside. The screen that you are looking at, the slides appear in the central window and they will be advanced automatically by the folks running the teleconference. The slide changes are all synchronized with the speaker's presentation. You may want to adjust the timing of the slide changes to match the audio. Please pay some attention to this. This is something that came up a number of times during the last teleconference. What you want to do to change the -- if you find that the audio isn't running with the slides, then you can adjust the timing of the slide changes to match the audio by using the slide delay control that is at the top of your messaging window. As far as questions for the speakers, you can submit them as the audience at any time during the presentation.

We'll collect them, consolidate some of them where they're similar. You can do this by typing your question in the white message window on the right of the interface. Select question for speaker from the dropdown menu and hit send. Include your state or

organization in your message so that we know where you're participating from. The questions will be relayed onto the speakers periodically throughout this web broadcast. If we don't have the opportunity to respond to all the questions during the broadcast, we're going to get those to you afterwards. We'll share them with the speakers after the conference and we'll post all of those or any answers that are too long to do on the web conference, we'll post those in the archive that will be available through a website of the call. You'll notice on the left of the interface that you're in is the real audio player window. You can adjust the volume of the audio using the volume control slider which you can access by clicking on the loudspeaker icon. For those of you who selected accessibility features when you registered you'll see text captioning underneath the real audio player.

At the end of the broadcast, the interface will close automatically. You'll have the opportunity to fill out an online evaluation and we would appreciate if you did that. Your responses will help us to plan future broadcasts in this series and improve our technical support. When we move to questions and answers we'll do those at the very end after both speakers have delivered their material. It should improve the context and whether directed at specific speakers I'll read them that way. If they're general I'll leave them open to the two speakers to respond to. So time to get moving.

Let me introduce our two speakers for today. Coming up first will be Kay Johnson for the past 20 years she's served on the child health policy as an advocate, consultant and researcher. A research assistant professor in the Department of pediatrics at Dartmouth, college. Serves as president of the Johnson Group Consulting firm which conducts

analyses, facilitates meetings related to MCH policy and programs. Her expertise is perinatal care, and many other things and services for children with disabilities and other special needs. She's staffed the National Task Force on newborn screening, convened numerous workshops with state legislatures on genetics and child health and recently completed a study of state finance strategies for newborn screening programs which is what she'll discuss today. She previously worked as a researcher staff scientists at George Washington University September for health policy research. She served as a national policy director for the March of Dimes in senior health staff positions at the children's defense fund. A past chair of the maternal child health. Served on the boards of national perinatal association. All kids count and an advisor to numerous maternal and child health initiatives.

After Kay speaks Deb Lochner Doyle will be speaking. She's the state genetics coordinator for the Washington Department of Health. She has a masters degree in human genetics and genetic counseling from Sarah Lawrence college. She's certified by the American board of genetics and genetic counseling. Prior to joining the Department of Health in Washington Deb served as a technologist with memorial Sloan Kettering cancer research center and senior genetic counselor for the Jones institute for reproductive medicines. Women and infants hospital in Rhode Island. A national leader serving as a founding member on the economics of genetic services committee of the ACMG. Has served as past president of the NSGC and a founding member and past president of the coalition of state genetic coordinators. So I welcome you to the teleconference and our first speaker is Kay Johnson.

KAY JOHNSON: Hi, I just would like to begin by thanking Mike Watson and Judith for asking me to share some of the results of my recent work on newborn screening financing and also to say thank you to Michele Puryear who was then the project officer for this work and will be a co-author of the article that will be summarizing this work, as well as Lauren Raskin from the association of state and territorial health officials who served as -- served to offer guidance for the part of this work that I'm going to talk about in terms of case studies. The states authorities and challenges is a way to begin to think about framing this. And I think we can't talk about financing and how it is proceeded with regard to newborn screening without talking about states' roles and their authorities. And as you can see on this slide there is a quote from Tony Holtzman at Johns Hopkins university and long been an expert in newborn screening and thinking about its policy framework in saying that only public health agencies with their authority could implement systems that would mandate screening for all infants, ensure the quality and availability of testing and provide follow-up care on a population basis. So in that framework with the state public health authority, which is unique in our country, these agencies have taken on those mandates and now are faced, as I'm sure you all know, with the challenge of financing newborn screening systems that have additional tests and equipment, that have staff skilled in the new technology, and that have more effective follow-up with families as more families may be affected by the additional results of the additional tests.

So what was the analytic approach for my work and further discussion about how I framed the question of financing? So the slide what needs to be financed? I started with the goals

from the National Task Force. I think they're useful today for our thinking about this and the National Task Force on newborn screening recommended that financing be adequate for screening, short term follow-up and diagnosis. Essentially they said states should just make sure that money is available to cover those three core functions of newborn screening. And then that there be funds made available, typically outside of newborn screening programs for comprehensive care and treatment for all those who had identified conditions and that there must be money for quality assurance and evaluation of these programs if we hope for them to succeed in reaching our goals.

I have a diagram here about the flow of funds. I don't want to spend a lot of time on this, but I would encourage you to try to think about your state's newborn screening financing system in this sort of context so that you either have at the top are you collecting newborn screening fees, yes or no, do you have state general revenue appropriations for newborn screening, yes or no and if you're collecting fees, who is paying the fee? Is it directly paid by some third party payer, insurance, Medicaid, state children's health insurance program? Is it being paid by the birth facility? Paid directly by the family and figuring out what happens to those collected fees and do they come directly into the budget or do they go back up into the state general revenues? I think following some kind of diagram like this can help you understand how your flow of funds for newborn screening works in your state. The other thing is different -- those are variations, but at the same time we have some sort of consistent themes that I call the myths about newborn screening finance.

The first myth is that newborn screening programs are fully funded by fees. In reality, we know we have five states in the district of Columbia that are not collecting fees and that they're only covering the tests of the lab costs. In some states that's changing but that has traditionally been the case. The second myth is tax dollars fund newborn screening. I've worked around the questions of financing a lot of different kind of Maternal and Child Health services. Mike read all those in my introduction. What I would say is if we're using fees as a source -- primary resource for newborn screening financings we need to continue to remind public officials that's the case. When you to go a state legislator you have to remind them you aren't always just talking about a direct increase in the tax dollar getting it from state general revenues, or having it come from a public source. That where it is a fee it is not necessarily a public dollar, even though it's managed through a public program. And some have estimated that as much as 2/3 of the financing for newborn screening is ultimately coming from private dollars.

And then the third myth is that newborn screening is paid for adequately by third party reimbursement. What we know from my work and the work of the U.S. general accounting office, the work of the national newborn screening and genetic resource center, that the fees are not always covered by insurance or Medicaid and that particularly in the case of Medicaid reimbursements they've tended to be below the actual cost or fee level of the program. The next slide shows you the distribution of funds by the source of funds. We don't routinely collect data about the nationwide sources of funding for newborn screening. These are data that were collected by what was then the U.S. general accounting office, now the government accountability office, still known as GAO. This is the distribution as

they collected it in 2001 and what you can see, which is fairly consistent with what we know from today, is that the majority of the dollars came from fees, that a small share came from the Maternal and Child Health Bureau Block Grant.

A larger share from Medicaid. State general revenue dollars and other federal funds such as the prevention Block Grant and some other resources. There is no direct source of federal funding for state newborn screening programs today. There are these federal funds, the other and in particular the federal share of Medicaid and the Maternal and Child Health funds that are used. The extent to which the percentage of births that are being screened with the new technology is changing. You can see here what was going on by HRSA region in 2004. The percentage of births and the other thing that is changing is the percentage of births financed by Medicaid changed dramatically over the past decade. So that you see here the darker the tan or going toward brown, the greater the percentage. Virtually all states -- well, virtually all states are above 25%. The majority of states are above a third. And if you can see how many states have the darker brown, that would be the color of a South Carolina, Mississippi or Texas, more than 44% are clearly pushing up toward half. So the role of Medicaid in financing all of this changed also. So I'm going to talk to you about two sources of data, and segment them a little bit just for clarity in this presentation.

The first is a set of case studies that I conducted on behalf of ASTO with funding from the Maternal and Child Health Bureau and just in order to get a look at how states were adapting to all of these changing conditions. Our study questions were how did states

address these recent challenges. They were all having budget shortfalls. There was increasing consumer demand. The rapid technology change we've talked about and the pressure to privatize. How were they sustaining in the face of all of this? We selected a number of states for particular purposes. A very deliberate sample with these qualitative case studies. And we were looking for geographic distribution. You'll see this number of other factors reflected as we go along. I'm not going to read all of these right now. You can see there was variation in the screening panel. These are the states that we chose. If you're not good on your two state abbreviations it is California, Maryland, Minnesota, Mississippi, New York, Oklahoma and Oregon and you can see that they were test -- there is a check that is something that the state was testing for in 2005.

The next slide is going to show you a blowup of what they were doing in terms of financing. You can see that between 1997 and 2004 there were substantial increases in the fees for all of these states except New York, which does not collect a fee. So there are 45 states at this time that use a fee approach and we'll talk a little bit more about the change later on. What were they using those fees for? So again, the 2004/2005 fee level in the first column there and then the -- the sources of funding, were they collecting fees, were they using state general revenues, were they routinely using the Maternal and Child Health Bureau health Block Grant dollars. Would that not include special one time projects or some things you may know your states have done with regard to genetic planning. This is whether or not they're routinely using the Maternal and Child Health Block Grant dollars as part of their budget. Three of these, a different distribution were using Medicaid directly for that core three elements of follow-up and diagnosis.

Looking then by state, the financing approach in California, they're paying for the program up to the point of diagnosis. At about \$60 per baby and they do allow their hospitals to keep a portion of the charge as their -- to cover the cost of collecting the blood. The challenges that they reported to us in these changing times, that as they began to add new tests and began to go much more widely with the spec tomorrow -- they have a half million births in California and changing a system for that many infants was a substantial challenge in their view. They had a delay in expanding their test panel because they had a particularly hard time with the California state budget for a number of years.

I'm sure you've all heard about that on the national news but they were now able to have success in doing their expansion. Their core approach to this is that they have public health management, which uses, through contract, their private lab capacity, particularly thinking about it almost as a regional approach for the different segments of California. In Maryland, their financing approach is that the fees cover the lab costs and use their Maternal and Child Health Bureau health Block Grant funds for short term and long term follow-up. They had particular challenges. One, they were actually in competition to the company Pediatrix which now owns something that used to be called NEOGEN. They have a requirement for informing and consent and getting the new consent forms developed has been a substantial challenge. They are one of a number of states that does two screens and how that affects cost we'll see a graph on that a little bit later. They felt that the follow-up for many more families was an enormous challenge for them. Budget pressures were there but not at the top of their list.

In Minnesota, they told me that they hit the restart button. They were trying to finance a new approach with their fee increase, not just do things the same old way. They wanted to really focus on the family as a consumer as they went about expanding the number of tests. Through a new public/private partnership they had the state lab doing the initial screening. The Mayo Clinic lab doing the tandem screening and the University of Minnesota being responsible for a lot of the coordination of the newborn screening follow-up, as well as specialty care. They have also made a very deliberate effort to provide structured linkage to the medical home or the primary care pediatrician for each child in engaging them much more in the system. And the interviews there suggested that they were having some success with that approach.

In Mississippi, this is some months ago now, as we know Mississippi is particularly, along with other Gulf Coast areas, really challenged right now but they also took a much broader view at what they could be doing in newborn screening and had their legislature mandate that they would provide comprehensive screening. The finance approach was based on a fiscal analysis that suggested that they would have to double the fee. They added more in the way of insurance in Medicaid payments in the process of doing this, they were under enormous political pressure to change both from their Genetics Advisory Committee, as a professional set of recommendations as well as through parents and some of their legislative leaders. They had not previously had their own state lab capacity. They had been in alliance with Tennessee.

Tennessee was not moving quickly toward an expanded panel of tests and so Mississippi found what they wanted at the price they wanted to pay, but through the contract with Pediatrix they went to the public sector purchase and guaranteed in their contracts they would get a portion of those funds back to do the follow-up and evaluation and quality concerns for their program itself. At the same time, they were one of the states that I think had an important vision about the need to add more public health follow-up staff. They did it by each of their health districts. Recognizing that there were going to be additional responsibilities in those areas. New York is not a fee-based program. They have -- they, too, had a lot of advocacy by parents, March of Dimes, academy of pediatrics who all got to the governor and legislature and began to move that ball forward. They also have a large number of births, about a quarter million, and they estimated a substantial load with additional number of positive screens. They have figured out how to make that change, done a more gradual transition. They have a very strong centralized approach to the lab. In fact, the lab personnel run the program in New York and they have their own way of just approaching it through the state public health budget as a regular part of the state public health budget.

In Oklahoma, their finance approach was again to do a fee increase to do more tests. They deliberately went after Medicaid and private insurance billing and they had legislative changes to back that up. The legislature was very committed to helping them put together a financing plan. They were also very clear, the staff of the program in Oklahoma, about the fact that the HRSA grants had really helped them plan for innovation and that they had used the opportunity with small amounts of funding from the Maternal and Child Health

Bureau to move their ideas ahead. They substantially expanded their test panel and implemented it this year, and simultaneously added more public health staff to keep up with the follow-up.

Oregon was our example of a regional lab as a vendor supplying testing services for five states, Alaska, Hawaii, Idaho, Oregon and Nevada. And they articulated the geographic access challenges that you have, particularly in places like Hawaii and Alaska where you have more remote areas or have to move samples by airplane and so forth. But they felt that the regional approach gave them economies of scale. Oregon itself expanded their screening but they did not, while they encouraged, not all of the states in the region have. The regional lab is still not leading, but providing capacity that will be there as other states select to use it. As a result of this set of case studies, it became clear that there was more to learn. So we used these case studies to guide a survey. Let me quickly run through for you what we learned in the survey.

As you can see here, I've put a lot of information, probably too much in this slide, on the left in the bars that have more purple color in them, those are the sources of funding for the state newborn screening program. And on the right the bars that have more blue, those are the uses of funding and we asked states to tell us about the four general types of sources of funding which would be fees, Medicaid, state general revenue, Title V and other. Then we asked states to tell us about how they were using those funds, whether they were primarily for the lab service, the initial follow-up, follow-up and some case management, administrative costs and other. What you can see is not surprising that the

majority of the funds are coming from -- majority of the states are using fees and the majority of those funds are being used for the lab services themselves.

What you see here is the number of states, but if I could say it to you in terms of percentages, 84% of the states in the survey were using -- were -- had fees as their primary source of funding for the Medicaid and the state general revenues, that was 30% of the sample. Title V was being used in 57% of the sample and other sources of funds in 24% of the states responding. On the right for the lab, basically all of the states were using 31 who responded, 70% were using their resources for initial follow-up. Drops down to 47% if you think about follow-up and some kind of case management services to the family. More using it more administration and then other things, a lot of the purchase of formula foods and so forth would be in other. Here are the survey results about the changes in the sources of financing. And what you can see from this one is that a majority of states reported that their newborn screening program funding increased between -- we were asking them about the period between 2002 and 2005. And you can see that the majority of those who reported increases had increases in fees and to a lesser extent to Medicaid, ten states Title V and general revenue funding increases in three states. 20 states reported no change in the level of Medicaid or Title V fiscal support and 23 states had no increase in state general revenues. There were very few states that had an actual decrease in funding overall, or in any one of the sources of funding.

Moving to the next slide, it's hard to see the trend. There will be in the article hopefully will be published of this, a table that shows all of the states. It is hard to show in a slide. I

selected a group of varied states. These are the states where the fees cover more than one screen. So most of these states have mandatory two screen, those these fees would cover that. What you can see is the high degree of variation both where they started and the degree to which they increased. So you can see, for example, Texas with a red line which started with no fee and went up to almost \$40 for the two required tests.

You can see a similar range of increase in Delaware, which started around \$40 and went up to around \$65 but you can see less increase in a state, for example, like Utah that has little Xs in it where they went from \$21 to \$32. So the variation is really quite substantial among the states and it to a large extent depended on the capacity they had at the beginning and just how far they saw themselves moving ahead. So what are the factors enabling states to expand and sustain financing for newborn screening programs? I think the most important thing to say is that this is a huge paradigm shift. And that states were experiencing a great deal of change in the climate in which they were doing this work. I would also note that if I were writing a paper about newborn screening financing a decade ago, or probably even five years ago, it would not have been interesting to anyone and probably not been published in a journal if it hadn't included something about cost benefit. Yet we've moved from an era of cost benefit studies to an era of consumer demand and private sector competition being driving factors in how newborn screening financing happens and at the levels it occurs.

What are the states doing? They're focusing on systems, not just on the tests. They're investing the state-of-the-art tests and equipment and financing more follow-up, which is, I

think, a very interesting trend and one that we should all follow and observe how those variations play out. They are engaging both parents and advisors in their process of change and they really are trying to manage this from a quality perspective as well as protecting privacy and doing informing of families as they go along. I think the factors affecting newborn screening financing in the future, as one of my interviewees said -- as goes genetic science, so will go newborn screening to a large extent. And finally, the other third factor that I think is very important in the way that it affects the newborn screening financing in the future is introducing profit. That really does change everything. What does it mean when a private lab takes funding but does not take the public health role? And there aren't residual dollars for the public health agency to follow through with its accountability around data and quality and follow-up? And I think that this is the kind of change I observe when managed care agencies took Medicaid financing and really shifted the role of public health in so many areas of the country. And what we learned in Medicaid managed care was that it really required oversight both by state officials in the executive branch and then the legislative branch, and it required creative thinking on the part of public health agencies to get the funding to hold up their accountability for these systems.

The political pressure against increasing healthcare costs is very widespread. I'm sure we all know that from reading the newspaper and listening to the news. And there are places, I'm sure still, where legislatures would say it is a nice idea, we can't afford to do it. Or say to a public health agency that is a really great idea, go ahead and do your expansions but we aren't going to give you any more money. You have to find a way to do this. I think much to their credit in the states that I've described to you from the case studies, the

legislatures did not take that approach. They were an active partner with the genetics advisory board, with the families who were concerned about these issues, and with the public health leaders who were part of the guidance for reshaping these newborn screening programs. The states also have thought more about how health insurance plans and Medicaid will play a role.

There has not been much resistance of them yet. But as the costs go up I suspect we'll get negative feedback. What we definitely know is that fiscal constraints drive policy. I would note here, however, that for the past 40 years now, we have been improving newborn screening programs and we have found ways to cover the costs of doing what we think is important and what we think is right. And it is not like the WIC nutrition program where we have waiting lists or the state children's health insurance programs in many states now have waiting lists. We have not moved away from the basic accountability and I would just argue at the end of this to say I think we still have a set of shared goals for newborn screening and we've made a commitment to date to finance them and that every newborn regardless of where born should be access to tests that meet national standards. I think we're moving with the work of Mike Watson and his colleagues and HRSA's leadership, and the leadership of the secretary's advisory committee toward understanding what it would mean to have national standards that were meaningful to all of us and that every child deserves screening, diagnosis and treatment and new tests meet criteria and newborn screening programs have quality programs and we need to be sure we have the resources to meet these goals. Let me stop there.

MIKE WATSON: All right. Well, thank you, Kay, that was very informative. For those who joined us late, let me just update you. That was Kay Johnson, she is participating in the financing genetics and newborn screening services from the national coordinating center, a project that is funded by Maternal and Child Health Bureau of HRSA. I want to move on now, as I said previously. We're going to hold responding to the many questions being submitted until the end of the teleconference. I want to get our next speaker in now, though. I've already introduced Deb Lochner Doyle. She is with the Washington State public health department. Deb.

DEB LOCHNER DOYLE: Great. Thanks, Mike. I would like to thank you and Judith for offering me an opportunity to present some of the early findings of work that we've done as part of a health resources services administration or HRSA grant entitled the genetic services policy project and I want to thank Kay for doing a great job of highlighting for people some of the big picture considerations when it comes to financing healthcare services.

If we go to the next slide, what I hope today to do is in some ways expand upon Kay's remarks but with a focus more on genetic services beyond newborn screening. For example, pre-natal services and others. Like newborn screening there is a variety of sources of funds that come into clinics. When I say clinics I'll use it as a very general term for where genetic services are provided. We know that clinics receive fees, that they bill for to third party payers both public and private. Medicaid, Medicare, Blue Cross-Blue Shield etc. Many clinics have contracts with community resources. State and federal

support including grants like the Maternal and Child Health Bureau health Block Grant and the institutional support category which can mean any number of things including the categories I listed earlier. How these are allocated to the clinics nationwide is really anyone's guess. I thought I would start by providing a very brief historical perspective so we can all understand how we find ourselves in our existing circumstances.

Next I want to make sure that everybody appreciates the realities of the data I'll be sharing, especially since what I'll be sharing represents a snapshot in time only and the data are compiled from existing resources. Unlike the case study Kay presented we did not solicit new data to answer specific questions but compiled existing data to see if we can describe the existing healthcare delivery system. This methodology has its benefits but also limitations. The benefits being it is cheaper. The limitation is that we're trying to use data that were collected for perhaps a different purpose other than the questions we're trying to answer. Then I'll share some state to state comparisons in an effort to try to explain the findings but also to solicit any ideas that you on this webcast may have for explaining what we're seeing. Finally, I'll end with some suggestions for further studies that I think may be helpful in describing the financing and service capacity levels even further.

Why should we bother to do all this exploration? Well, I mentioned the genetic services policy project at the onset. For those not aware of the project it is a federally funded project with one of the goals being to describe the existing genetics healthcare delivery system in the United States, evaluate the cost effectiveness of current models of care and

propose alternative models for future study. This is a cooperative agreement between the Washington State Department of Health in partnership with several University of Washington researchers as well as HRSA, Maternal and Child Health Bureau, genetic services branch. It's probably not a surprise to most of you why those of us working on this project felt such a keen interest. No doubt because we're facing some of the exact same issues you are. For example, in the State of Washington, we maintain service utilization data why from all genetics clinics in the state.

We've noted as the scientific and technological advances have occurred such as even DRCA1 and 2 testing we see more and more families seeking services for that advancement. We haven't seen gains in funding for services in either the public sector such as in the Maternal and Child Health Bureau Block Grant or state support for services or changes in state policy that would allow redirection of some of the existing funds even into newborn screening fees. Nor have we seen any increases in the private sector. I have to say we have seen perhaps more services being covered, the level of comprehensive coverage and certainly the level of reimbursement from third party payers has not increased and that has been true for the last ten years. It creates longer waiting times for certain types of patients particularly adults and children for whom a diagnosis has already been made. Furthermore, as states increase wait times it creates border issues.

Since patients from other states who are capable of traveling will tend to shop around for a clinic where they can get an earlier appointment even if it means going out of state which places additional purchase dense on the state system. All the while we're watching

institutions or facilities trying to deal with shrinking resources and choosing to prioritize services. So this is the situation we find ourselves in. But how did we get here? For a bit of a historical perspective first it's important to recognize that unlike pediatrics or other subspecialties, genetics is a relative newcomer to the field of medicine. Although we may try to argue that 30 plus years isn't so new, the reality is that geneticists are just now over the past decade been invited to sit at the tables with decision makers of organizations that are really critical in establishing the practices and procedures that are instrumental in financing healthcare services. That's not to say there haven't been public policies that affected the genetic healthcare system for indeed there were and are probably the earliest was public law 94278 enacted in 1976.

For those of you that have been around in the field for a while you may recall this law was prompted by well meaning politicians hoping to make public policy as successful as they perceived newborn screening laws to be but also were trying to take advantage of scientific advances particularly in the area of pre-natal diagnosis. The intent of this law was to push states to figure out a way to make genetic services more readily available to residents. Up until this time most were limited to large academic facilities only. Now around 1989 it's my understanding that the funds for this particular law were wrapped up into what we now know as Maternal and Child Health Block Grant.

I think most people on the call are familiar with that grant associated under the Social Security act or Title V. Every state receives these Block Grant funds based on a funding formula dependent on population size. The Block Grant, what some of you may not know,

is extremely flexible. By that I mean it's -- states can choose to spend the funds with very few strings attached but somehow the funds are to affect mothers, infants and children. Influential public policies have shaped genetic services. There were also many federal grants used for genetic services. More genetic clinics billed patients because they had historically been covered by research grants. As the resources began shrinking in the 1980's. Suddenly clinics realized they lacked the mechanisms for billing for patient services both institutionally in terms of practices and procedures but also nationally by way of lack of adequate CPT codes.

The medical genetics community began addressing these issues in the 1990's. I don't say it as a criticism but simply as a reality. The genetic services policy project we wanted to understand the global historical aspects so we could more accurately describe the existing system which we heaped was going to be quite varied across the country just as we found with newborn screening and to further understand the current system we decided to construct state genetics profiles. These are some of the data that I'll be sharing with you today.

Let me first describe some of the data sources. As I said earlier I want everyone to understand what data we had access to versus those we did not or that we didn't have access to yet. We have some ideas in mind and I'll talk about those briefly later. These are data that were readily available but not necessarily compiled for the purpose for which we were using them. We standardized the elements throughout states. For some elements the month or year of the data collection may be off. Particularly from those data that were

gleaned from state-run websites. Much of what I'll be presenting today comes from the American board of genetic counseling, the American board of medical genetics and state and federal websites. If I refer to other sources again I'll do that at the time that I mention them. So to populate the state genetic service profiles we wanted to understand the socio-economic and political variables. Service capacity variables and legal and regulatory variables.

You can read the slide as well as I can. We were looking for specific data elements that would address these topics. Ranging from population size, percent of the population under 200% of the federal poverty level. Medicaid expenditures. I have to say also that Medicaid data specific to genetic services is only found in three states, Texas, Mississippi and Washington. We also looked at various genetic providers per capita. Medical schools, whether or not a state has a medical school in it. Genetics training programs. All the newborn screening information which I'm not going to cover since Kay has done a great job of doing that and the full time equivalent or percent of employees of a state genetics coordinator, their background, etc. Again for legal regulatory variables we looked at privacy statutes, laws specific to genetics and mandated benefits and today we're focusing on financing of services.

While it is true as I hopefully illustrated earlier public policy can certainly impact financing of services. I'll primarily focus on differences in capacity of services. I've done so for a couple of reasons. Not the least of which is we're just finished compiling the data why in August and we haven't had time to mine all the data elements in our database which is in

excess of 250 pages. Since we don't have access to third party payments for services nationwide I'm using capacity as a proxy measure for financing. In other words, my assumption is that those states with the greater capacity for providing genetic services likely have policies and procedures in place that allow them to access better financing and best support the services. And I hope that makes sense to people. So if you go to the next slide, I'm showing the genetic service providers per capita. We calculated genetic service providers per capita by using population size that was obtained again from the state web sights and genetic service provider data were estimated based on certification data provided by the American board of genetic counseling as well as the American council for nurses and genetics.

These represents certificates and not necessarily people. Some people might be certified in more than one area. Some people may be certified and have moved. Maybe certified and died, stopped practicing and we have people who aren't certified practicing but it's our best estimate. Furthermore while we have the data broken down by different categories, for the purpose of this discussion I've added all of the varied certificate categories to generate what I'm calling a total genetic service provider rate. We're dealing with certificates, not people. Some individuals may be certified in more than one category but again, I think it's a fair overall estimate for our purposes. What I hope you can appreciate here, if you're scanning this map is that the majority of the states have basically 0.5FTE or full time equipment to 1.25 equivalent per hundred thousand residents.

Somewhat interestingly if you go to the next slide the different measures or categories of providers of genetic capacity, if you're looking at a clinical geneticist, molecular geneticist were correlated with values and all with significant P value. The same correlation was not seen for categories with combined specialties. Nor were they significant for the nurses. Now I'll state it a different way if it's not clear. You're more likely to see an increase in all provider types given the presence of one with the exception of nurses or combined NB certificates. It may be a reflection of early low numbers of the particular provider types. I thought it was interesting and some ways speak to the team approach that we typically see in genetics.

The next slide needs a bit of explaining. The data are derived from the same sources as the map I presented earlier but I wanted to dramatize the differences between the states of the highest level of capacity compared with those of the lowest level. I want to be clear this in no way invites quality of services. To the left you have the states with the greatest number of providers per capita. Maryland taking the lead. To the right the states that have the lowest number of providers and again, this is a dramatization cherry picking, if you will. I want to emphasize as the original map showed the vast majority of states fell between these two levels. I also looked at the political party of the sitting governor from all of the states and I wanted to demonstrate some way there was really no significant difference. I did this by in this slide by illustrating that it is the same in terms of Republicans and Democrats for both sides. If you look at all the states, there were no significant in terms of the political party. I want to caution against anyone who wants to often jump to the conclusion that being a rural state predisposes it to having a lower capacity. I know it's

tempting given that the bottom ten states represent rural areas. They have additional barriers in delivering healthcare services in general, let alone specialized services. When you do the analyses with all states, this rural variable really goes away.

What can we learn from looking at the states with the highest capacity? And again not all of our analyses are complete. But one of the things I'll be very curious to see if there is the presence of a medical training facility and whether or not that plays a role. Immediately I think of Johns Hopkins, Harvard, Yale, etc. We'll need to take a look at that and whether or not it affects capacity within a state and it also might affect in terms of advocacy of services, that general desire to keep services within a state and that quote, unquote, institutional support. If we go to the next slide I want to share with you about the only significant findings that we did find other than what I just shared was we did some linear regression to look at the percentage of the maternal and child health Block Grant -- although the 2004 Block Grant expenditures are available. When we began compiling the data the 2003 data is what we used. I wouldn't expect a shift in the data anyway.

On the next slide you'll see we compiled the data from forms 3, 4 and 5 of what states must provide the Maternal and Child Health Bureau annually as part of their Block Grant determination and what they spent on pregnant women, infants and administration. The next slide the results showed the percent of the states Maternal and Child Health Bureau Block Grant allocation on children was significantly positively associated with the total genetic service providers' per capita rate. The allotment was spent on administration was inversely -- now the latter figure shouldn't be a surprise to anyone. The more you spend

on administrative function within state government the less money gets out into any services. But I was rather surprised that the amount of money spent on individual categories such as pregnant women, children with special healthcare needs alone did not reveal significant findings. In other words, it was the total amount spent on children which included infants, children with special healthcare needs, children that you've got a positive finding.

Again the next slide simply shows the same information in a graph. The states with the highest capacity rates also spent more money. For those of you who are providing services to clinics and who are not receiving some of your states' Block Grant resources you may want to explore this relationship a bit further. I think that although I'm showing you the only significant findings we found so far, the other point that I want to make is again early on I alluded to the fact it was compiled an enormous amount of data for each of these states and yet we're not finding a whole lot of information that is statistically significant. I think that's telling in and of itself. It kind of suggests that just like newborn screening states in terms of how services have evolved have done it rather uniquely. So it's a patchwork quilt with not a lot of overlap. There is clearly a lot more work to be done. Not to mention finalizing the analyses once again, the wealth of data we've compiled but we're anxious to identify representative clinics we can follow more closely in the trends and service practice as well as reimbursement levels. As I said earlier we have some case studies that we have begun to work on and we hope that given the current new S codes. For those that don't know what they are they're temporary codes requested by payers for billable services. There are S codes for genetic counseling and more codes for cognitive

services to allow us to better track clinical services just like we're able to better track testing services largely thanks to Mike and his colleagues efforts to get appropriate CTC laboratory codes. Before I close, I just want to reiterate my primary point. That is that financing of genetic services in the United States is very uneven. That shouldn't be a surprise to everyone but I think it needs to be stated just like we've done with newborn screening. There are no consistent variables that have been documented to explain the diversity, although the greater percentage in maternal child health Block Grant money towards kids is associated with genetic provider capacity. I hope it will lead to better opportunities to explore genetics expenditures.

Finally I would like to give credit where credit is due and acknowledge the many professionals who assisted with this work. Cindy Watstein, University of Washington and several people working with us within the State Department of Health as well as students working with us as well. And hopefully with that I have left more than enough time for questions. Thank you very much.

MIKE WATSON: All right. Well, thank you, Deb. And Kay as well. Thank you for very informative talks. I want to remind everybody to submit questions if you've got them. We've probably got enough surprisingly we're almost exactly on schedule with two 30 minute talks and 30 minutes left for questions and answers. I'll start walking my way through some of the questions. I recognize based on the last teleconference we did this is going to lead to those submitting questions, submitting more clarifications and as I said, we'll try to address. Any we don't get to today through the archive that will be available through the MCH website. Our first question has actually come in in at least two different

formats. One of the questions asks about how feasible it is for states to calculate costs and benefits that relate to both the cost and benefits that the state recognizes or accrues, as well as the private sector. I guess the question is whether or not we -- each state actually is able to capture the benefits of the private sector in their analyses and the related question both, I guess, for Kay Johnson initially is public/private partnerships have developed economies of scale with capital intensive expansion of newborn screening systems. There is some evidence that with these economies of scale the laboratory testing costs as a portion of the total cost of the system will frequently be less with partnership arrangements. This has allowed conservation of healthcare resource for other components of the newborn screening system such as follow-up and education. The questioner asks if you could speak to any objective data you are aware of or have collected on this point, or have you been unable to dissect out the laboratory costs from other program costs? Kay?

KAY JOHNSON: I think from the cost -- let me take the cost benefit piece first and just say that has not been done. It certainly could be done. And I think we know going all the way back into the 1970's and 1980's, a lot of work done on the cost benefit of newborn screening and those kinds of studies have continued to be done through more recent times. There are quite a number of studies if you do a literature search when we were adding here at newborn hearing screening a whole round of studies and I think the studies around technology have gone on in recent times as well. There is no question if you wanted to do those cost benefit studies they could be done and that they would look very different now than when we were looking individual condition by condition. I'm not sure

why you would do that right now. I guess if you wanted to make a stronger argument in an individual state you could find the economist to do it. But I'm not sure that those are the data that are of greatest benefit. I think the talking about the marginal cost of adding the additional test to a panel once one has the equipment is the better conversation to have from a sort of political and program point of view. Certainly from a research point of view an economist could do that study in virtually any state if you wanted them to.

On the public private partnerships and economies of scale, I have not done a specific analyses around the questions of economies of scale. What I would observe based on the case studies is that there are several ways that we get to economies of scale in this. One is through public/private partnerships. Another is through the regional lab approach we know economies of scale matter. I wouldn't limit it to public/private partnerships. The other thing in favor of public/private partnerships is using all the available resources. I've often thought that George Cunningham of California does a very good job of talking about the way they've used public health management and labs. I think now the Mississippi example is a good one. And the only caution is around really developing it as a partnership rather than a competitive environment. I think that's the real challenge for all of us.

MIKE WATSON: All right. Thanks, Kay. I have two, perhaps short answer questions for you as well. One is the survey data that you commented on, when was that data collected?

KAY JOHNSON: Those data were collected in the early part of this year. The first quarter of 2005. So they're fresh.

MIKE WATSON: OK. Another question which I'll add a little information to asks which billing codes are hospitals using to recoup newborn billing screening costs. I will comment this has been a difficult area on the lab side. Many states have come to the CPT panel asking for a CPT code for newborn screening. And the CPT code panel has always argued that there is so little uniformity among the states that they can't really describe what a newborn screening testing service is. We've had meetings with them already and have general agreements that as we move towards a more uniform panel of conditions being screened in the states, and begin to approach a standard that we'll be able to go back to the panel and have that standardized panel recognized for CPT codes and we'll be doing that perhaps over the next six months or so. Back to Kay, the specific question was which billing codes are hospitals using currently to recoup newborn screening costs?

KAY JOHNSON: I don't know. Your answer is a good one. They have made specific arrangements on a state by state basis for how those will be billed and I do not know. My hunch would be that they're using a code, unfortunately those are not, the B codes are not HIPAA compliant. It brings into challenge.

MIKE WATSON: The money gets shifted downstream so the state can sell the newborn screening card to the hospital and the hospital is the one to figure out how to recoup its cost and it's variable as to where in the system the buck stops in the states.

KAY JOHNSON: It goes back to my diagram about figuring out where your money is going and what is coming to what source and what level of efficiency.

MIKE WATSON: One last very short one, I hope. What is the State of Maryland's money being used to finance?

KAY JOHNSON: Quite a number of things. In Maryland it's a very different approach. As I said, they have much more active parent informing process because they have an informed consent requirement. So they call it a goodwill informed consent but give more attention to the process of affecting parent informing consent up front. They're paying for the two screens. They're doing more follow-up with families and they have staff that is actually getting in touch with families and really following up I think much more aggressively than the majority of states. They also have clinical services that they are supporting in the community for at least three conditions and I believe now have fairly recently added or believed they were going to stay in the budget for hearing screening but particularly for example in the area of sickle cell is one I can talk about from the top of my head that they have clinicians that they've supported in the community to do backup, follow-up, long-term care and care coordination for families of -- affected by sickle cell disease and they are giving attention to quality improvement in their ongoing process and long term data collection on how children fare over the years to adult hood is another kind of data collection they're doing that is not entirely unique but somewhat unique and it is a unique package that they have there.

MIKE WATSON: All right. Thank you. Now I have a question that is actually, I think, going to begin to bridge between your two talks and then I'll have a couple directed more towards Deb. The question that bridges is what is included in follow-up? We know that, you know, quite often genetic services are the follow-up component. And Deb has addressed genetic services and certainly much of what she talked about had to be patients who may have been identified initially in newborn screening and programs where the state doesn't assume responsibility for much of the follow-up so they're asking what is included in follow-up. Does it include comprehensive care in the metabolic clinic itself or follow-up only to the point of being referred to the metabolic programs?

KAY JOHNSON: Why don't I take the short term and Deb you take the longer term. Does that make sense? There really is a distinction here. I wish we had other words to use for the two pieces. We just get into using qualifiers. If you'll bear with me to talk about short term which is from the point of the test results to the point of diagnosis and referral to another service. In some cases, that component is not being financed through the newborn screening program or is seen in the majority of states it is today the short term follow up. You have the tests, you have a suspect results, perhaps a repeat or confirmatory test so the short-term follow-up is providing the information about the test results to the provider and/or the family. And that is the first area from my point of view where we have an inconsistent approach and we need to think more as a country about how that gets done. So in some cases the information goes directly to the family and other cases it just goes to the provider who was on record of the birth certificate and other cases

the state has the state and/or the local public health people or their contractors have money to actually find the right provider who is the medical home and connect them. And then is that family referred for diagnostic service and is the completion of the referral confirmed? Yes in a majority of states, not in all states. So to that point of getting the child to the diagnosis is sort of today's norm in a majority of states but even that much follow-up is not assured in every state.

DEB LOCHNER DOYLE: Then you have the long term follow-up. That is, you have the infant or child who has been identified with whatever condition, and again, from the diagnostic follow-up that perhaps the state has provided they need to be seen for clinical services. Whether that is for fitting for a hearing aid or cochlear implant or something else, what have you, that's where the genetic clinics come into play and the genetics healthcare providers and frequently with the hearing they come in at a later date. Certainly for the other screening tests, usually the referral goes to a genetics clinic. As Kay mentioned in her talk, you are just now beginning to see more and more states being able to use the newborn screening fees to offset some of those costs. Historically that has not been covered with newborn screening fees or to the level that it has been covered it has been limited. So, for example, in my State of Washington, the newborn screening fee can be used to help support the metabolic clinic only in terms of as it provides quality assurance back to the newborn screening program. It is very limited. Most of that support has actually come from the maternal child health Block Grant funds or other institutional support.

MIKE WATSON: I'll take this chance to insert one of the questions because you alluded to it. I assume that everyone, all states get MCH Block Grants. Do all states have advisory boards as to how that money is applied?

DEB LOCHNER DOYLE: No. Well, increasingly states are developing genetics advisory committees. Some of those committees are how do I say this? They have members of the state legislature on them. They become very aggressive in how they interact with state agencies. Other advisory committees are much more advisory in nature. In other words, they don't have any real decision making authority other than to suggest changes in policy or in how resources are allocated. Then there are some states that don't have any at all. Not all genetics advisory committees deal with newborn screening issues. Sometimes those are brought aboard specifically for newborn screening. In other words, a newborn screening advisory committee or task forces are created.

MIKE WATSON: OK. I guess this one also sort of addresses that bridge issue we talked about between newborn screening and diagnosis or the genetics services system and the follow-up component. This person asks how do other states fund genetic counseling of the such as sickle cell that arise in newborn screening. Is this the responsibility of the NBS follow up program?

KAY JOHNSON: I think in some states it is. In many states that -- Deb can talk a little more to this. In many states the way to do that is to provide a grant to genetics clinic or a specific group of providers who can offer that kind of support. And when you do the

support to that clinical provider, you are there by building the infrastructure for them to serve the family and it is not like it is just a Medicaid dollar that can only go to the child.

DEB MIKE WATSON: All right.

DEB LOCHNER DOYLE: I also kind of read into that question and perhaps I'm erring here but it sounds like there is an expectation there will be some follow-up for the carriers identified. That is not necessarily true. There are programs that have specifically decided that their role as a state agency is to provide follow-up for children that are diagnosed with these conditions and being a carrier is not necessarily considered and therefore they do nothing.

MIKE WATSON: All right. Thank you. Now I have -- there is at least a half dozen questions that relate to S codes. So given the number of questions and the nature of them, I guess it's going to direct this at Deb and ask her to give a few brief comments about codes. We know that at least at the level of national codes in CPT the local codes are gone. So I guess one of the general issues is the relationship between local CPT codes, S codes, hick pick codes which are largely Blue Cross, Blue Shield base codes and are not quite a same as our local CPT codes that were in existence fairly broadly and have now been sort of retrenched and are now beginning to emerge yet again. If Deb could comment on that background and then give us some information about where can people learn more about the S codes. Are there states in which they work well? A number

of people commented they have them but they don't reimburse anyway so it doesn't really matter. If you could give us some more information on the codes.

DEB LOCHNER DOYLE: I can try. The local codes were great. States used to have the ability to create their own codes, particularly when dealing with Medicaid. And that was I think an unintended but probably not too bad of a thing. With HIPAA coming in all the local codes had to go away. That was so there could be a national standardization of codes. The S code or the hick picks are codes that are typically requested by third party payers and you are correct, it is generally Blue Cross-Blue Shield although they could be billed to other providers. On average they tend to not be reimbursed. I don't know why. It's really very different. We have done a couple surveys across the country in terms of asking different people which codes they're using and again it's a patchwork quilt. So I have no rhyme or reason for why certain codes may be funded or reimbursed and others are not. The S codes are temporary codes. In other words, there is an expectation that the service is either going to away or receive a CPT code because it's becoming part of mainstream medical practice and again, it is frequently, although sometimes they're requested by someone but frequently it's the third party payer insurance company, Blue Cross -Blue Shield in particular that request them. Then you have the CPT codes. Three different types, categories, 1, 2, 3, the gold standard is category 1 CPT codes which is a description of the service being provided with a much better chance of being reimbursed. I hope that helps.

MIKE WATSON: I think you alluded to the fact that getting a code doesn't always track with getting reimbursed for the code. And I will for those who probably aren't aware, there hasn't been a lot of activity at the national level in moving decision policy to national policy but we're in the midst of doing this comprehensively across the area of die ago no, sir particulars now and looking much more at those things that justify a CPT code being reimbursed. That is something that's coming and I think it's safe to say I'll expand on what Deb said about genetic counseling. It's likely that we'll have CPT codes for genetic counseling in the very near future, very, very likely. I won't go any further than that at this point. Let me move to another question then which is, do either of you have ideas about what might be done through the regional collaboratives themselves to begin to develop the information we need to address some of the questions to fill some of the gaps that are going to be needed to really move financing of genetics and newborn screening forward?

DEB LOCHNER DOYLE: I'll share with you some things we've been thinking about. One of the frustrations in trying to get data about what is being billed, what is being reimbursed, is that frequently the genetic providers themselves don't have a grasp of the mechanism, the policies and procedures. Frequently don't even know who their billing people are in their own institution. We've proposed a couple different pilot studies in terms of have the hypothesis that pre-natal counseling is reimbursed and adult counseling is terribly reimbursed. How do you prove it? You have to get the data yourself. And when you don't have providers that are savvy enough to assist you in identifying who are the people within the institution who are doing the billing and then, you know, I can forge relationships with the third party payers but I need to have a set of codes I can go back and look to. Right

now I can do that for laboratory tests. I can't actually do that for the cognitive tests because the same consultation code that a geneticist might use is the same code any other healthcare provider might use. You have limitations. Two of them are we don't have the codes we need, particularly for the cognitive services. And then the other being we don't necessarily have a provider group that is in a position to really assist us.

KAY JOHNSON: I think that a larger level and to the extent that the regional collaboratives have some sort of finance literacy, if you will, Deb used the word savvy. To the extent that whether you like my diagram or you want to draw your own, we knew really how this functioned in each state it is very hard to capture in a survey. It is there are so many variations and the more we can get provider specific level source of studies, maybe a randomized audit about what people are doing in a region. Getting those studies that get the data and those folks in the regional collaborative can help us build common understanding so that when we talk about short term and long term follow-up, we know what we're talking about. We can all push on the gaps that there are. I think the other thing is really, as we're moving forward and like you mentioned several times, whether it's moving forward to try to get sort of national CPT codes or building more uniform standards, it is important that we can all talk about the conditions and the tests. But it is equally important that we can all understand how things are financed and share our common language. So to the extent that the regional collaboratives are the translators of all of this, I think it will help enormously. I don't know if that makes sense but I think that being a good translator from one state to the other will help.

MIKE WATSON: All right. Well, thank you. I'm not sure which is the good news and the bad news. There are no more questions so we get to end early. I want to thank everybody who has participated either through listening, submitting questions or being one of the speakers on this call. We would welcome any suggestions you have for other types of teleconferences that might be useful to the regional collaboratives to the public health programs or genetics providers. We would be happy to try to develop those and work with you. Feel free to email me at my office, Mike Watson and we'd be able to try to figure out how to integrate them into this program. So from the national coordinating center and the health resources services administration who funds the regional collaboratives and coordinating center, thank you for your participation and look forward to getting in touch with all of you at our next teleconference. We'll do these quarterly. The coordinating center will meet in two weeks. Submit any questions or comments and any recommendations for future conferences. Thanks. Bye-bye.