Centers for Disease Control and Prevention
EARLY HEARING DETECTION AND INTERVENTION
Ad Hoc Group - Teleconference

Agenda for March 6, 2001

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JUNE HOLSTRUM: Hello, everyone. This is June Holstrum at the Centers for Disease Control and Prevention. Welcome to the March teleconference on Early Hearing Detection and Intervention. Thank you for joining us. Please remember to mute your microphone when you're not talking. Today's conference is being recorded, and a transcript will be available on the Internet. Before we begin our scheduled program, are there any announcements or comments from the listeners?

If not we'll move right on into announcements, and first we have Lee Ann Ramsey from CDC to talk about the help line.

LEE ANN RAMSEY: Hi there. I just want to share with you a phone number that we would like for you to use in your programs. It's a help line transcript that's put out by the AT&T health line. And folks can call in ?? and let me give you this number first; it's 1-888-232-6789 ?? and they can access the early hearing loss detection and intervention line by punching a number that they will give you once you dial in. And what it is is it provides the public with information about the EHDI programs, how to get their children tested, different sign language techniques like gestural sign language, American Sign Language, the differences, how to get into an individual family service plan, and just is an all-around general information for parents and professionals alike. So we'd like for you to use that number yourself and give it out to your programs.

JUNE HOLSTRUM: Marcus Gaffney who has a couple more announcements

MARCUS GAFFNEY: Hello everyone. I have two announcements. The first is that CDC/EHDI is anticipating hiring a second senior epidemiologist with expertise in planning, designing, and implementing state-based tracking and surveillance systems in the near future. If announced, the position will probably be at the GS-13 or 14 level.

The second item is we're pleased to announce that the EHDI Web site has just been updated. The new Web site includes 1999 DIPS data, program summaries from the 15 states with CDC/EHDI cooperative agreements, and a copy of the Year 2000 CDC Program Announcement, which can be used for references by states. The EHDI Web site can still be found at the same address, which is http://www.cdc.gov/nceh/cddh/ehdi.htm.

JUNE HOLSTRUM: One more announcement from CDC. The American Academy of Pediatrics recently released a model legislative bill for newborn hearing screening, and this has been sent to all the state AAP chapters. If you're not already working closely with the AAP chapter in your state, you may want to contact the executive director of your state AAP chapter. A copy of the bill can be found on the AAP Web site, and their Web site is www.aap.org, O-R-G, slash, policy, P-O-L-I-C-Y, slash, M as in Mary, 970, dot html.

First we'll have Karl White talk about the genetic and etiologic analysis project, and then that will be followed by Linda Goetze, who will talk about the cost analysis project. Go ahead, Karl.

KARL WHITE: Thank you.

Also, for those of you who didn't get the Web site to the AAP model legislation, you can get it off of the NCHAM Web site, www.infanthearing.org, under the legislative link.

And that bill has also been sent to all of the EHDI state coordinators, so they will have a copy of it as well.

Now to the item that June asked me to discuss. As a part of the cooperative agreement that the State of Utah has with the Centers for Disease Control, we are conducting a study looking at the epidemiology of hearing loss, of congenital hearing loss.

That study is under the direction of Dr. John Carey, who is a geneticist with the Division of Medical Genetics at the University of Utah. Cooperating with John are myself and John Eichwald at the Department of Health and Ken Ward at the DNA laboratory at the University of Utah. Dr. Carey couldn't be with us today and asked me to do a brief summary of the project. As you know, about 1 in 300 infants have congenital hearing loss, and it's estimated that genetic causes account for at least 50 percent of these hearing losses, and that about 90 percent of genetic hearing loss is non-syndromic with autosomal recessive inheritance representing the most common etiology.

Interestingly, mutations of the connexin [inaudible] are estimated to represent about 50 percent of all receptive hearing loss.

Proceeding, then, if the estimates I've just given you are correct, we would estimate that about 20 percent of all congenital hearing loss would be due to mutations of the connexin 26 gene. There are about 70 different disease genes that have been connected with hearing loss and have either been mapped or cloned. The gene for connexin 26 is perhaps the most important because of its frequency, but there are several other genes that are related to ?? causally related with syndromic hearing loss such as those associated with Waardenburg Syndrome and some forms of Usher Syndrome.

The goal of this project is to provide a better understanding of the etiology and pathogenesis of genetic hearing loss which could lead to better prevention or therapy strategy. This will be done by evaluating all infants who are identified through the Utah state newborn hearing screening program with congenital hearing loss, and inviting their families to participate in the study. Based on similar studies done here in Utah, we are estimating that we will be able to get at least 70 percent and hopefully more of those families to participate.

For every child who is identified with a hearing loss and whose family chooses to participate, an analysis will be done to determine the etiology of that hearing loss. The first part will be determination of the phenotype. This includes examining records, documentation of the pedigree, and physical examination of the child to determine whether there's a syndrome involved.

Once we've established whether the child has an acquired cause or a recognizable syndrome, or they're put in the category of having no evidence or cause of a syndrome, then an analysis will be done to look at the genotyping, and all of these families will be offered a connexin 26 analysis.

If connexin 26 shows no mutation, then the lab will proceed to test mitochondrial mutations associated with non-syndromic hearing loss. Cases due to acquired hearing loss will also be offered DNA testing, and blood will be drawn in parents as well so that other DNA tests can be done if determined that it would be appropriate.

As a result of these analyses, all of the children who are participating in the study, those

children identified with hearing loss through the newborn hearing screening program, can be classified according to whether the hearing loss is an acquired loss or a genetic loss, or whether it's due to mutations of these various genes. The frequency of connexin 26 mutations and any other gene mutations will be determined.

Since previous studies with the connexin 26 and mitochondrial genes have been done with older children, the results of this study will provide new information on congenital hearing loss, and hopefully will aid us in providing better management and treatment for these children.

We anticipate beginning to collect data on children in April or May of this year, and are estimating that we will be able to collect data on about 70 children, 70 to 80 children per year, over the next four or five years. And this should give us a significantly larger sample size than has previously been available to look at these sorts of issues. So if there are questions I'll be happy to try to respond to them, although John Carey's a better person to respond, I'm sure.

KIM OLLER: What's the difficulty, or how easy are these tests to apply, and how likely do you see us in the near future to be utilizing these kinds of tests on a more routine basis?

KARL WHITE: The tests are relatively simple to apply if you have a lab who is used to doing this type of genetic testing. And virtually any medical school would have those sorts of facilities as well as lots of other places. The tests are relatively inexpensive to conduct. Whether it becomes standard, I think, depends on what the data from projects like this and other projects tell us as to how frequent these things really are, and then what the information is provided that would allow prevention or therapy. And most of those things are, of course, down the road years.

DEB LOCHNER-DOYLE: I shouldn't have to ask this because John Carey's an excellent geneticist, but can I assume that genetic counseling will also be provided to the parents?

KARL WHITE: Yes. It will be. And it's a great question.

DEB LOCHNER-DOYLE: I asked because I'd be interested in knowing if there will be any data collected (from the Utah study) in terms of the impact of the EHDI screening on the existing genetics clinics.

KARL WHITE: I'm not sure exactly what you mean. The impact of newborn hearing screening on the existing genetics clinics?

DEB LOCHNER-DOYLE: Right. In terms of if it's going to be perceived by the genetics community as a potential burden. Here in Washington, we regrettably have a few of our clinics that currently have a two-month waiting list for families to be seen. There has been some concern expressed that once universal newborn hearings screening occurs, it will greatly add to this waiting period.

KARL WHITE: Yeah, I'm sure that is a possibility, and it's similar to some of the concerns that Part C programs have and other people have as the universal newborn hearing screening programs get implemented. I believe that demand drives supply in

these sorts of situations, and that as we identify these children and add to the workload that will give us the opportunity to seek additional resources to expand those clinics or Part C programs or whatever.
Here in Utah we don't have those sorts of long waiting lists right now, but I'm sure there could be some of that impact.

DEB LOCHNER-DOYLE: Yeah, and I agree with you 100 percent. I guess that's why I'm hopeful that you will be collecting some data in terms of whether or not there is an impact so we can maybe proactively start advocating for increased resources to support our existing clinics.

KARL WHITE: It's a great suggestion. I hadn't thought about it in quite that way, but we will certainly do that.

IRENE FORSMAN: Karl, this is Irene Forsman. We had a contractor do a review of Medicaid EPST policy. They have analyzed the written contracts, state by state, and they are now at a stage of follow-up telephone interviews. There will be a report, which we will be able to disseminate within the next couple of months. The contractor also plans to do some work with some private insurance carriers and some MCOs over the next six to eight months.

KARL WHITE: John will be the key person, but there is a staff of genetic counselors and others there who will be involved with him. Okay, if there are no other questions I'll turn the time to Linda Goetze, who is also here at Utah State University, is an economist who is responsible for the second part or the second study we're doing as a part of this cooperative agreement, on some cost analysis issues related to EHDI programs.

LINDA GOETZE: Good afternoon, everyone. I'm glad to see that economics entered even in the genetics discussion. Resources are certainly an important factor, and that's one of the reasons why we've included them as part of this study. I'll begin by saying that we design a cost study to fill in gaps that we thought existed in the current literature on cost of newborn hearing screening and diagnostics. And as a result what we saw as some of the areas that weren't comprehensively done in those studies, issues like the cost method, there's been some weaknesses in some of the previous studies. We like, we really prefer the ingredients method, which is a well tested, comprehensive approach to measuring the complete resources and cost and prices used by a program, and that's the method that we'll apply here. Many studies have not done that. They've often not based cost estimates on real data [inaudible] resources and the prices of those resources used for screening.

They often exclude also parent resources, and parents ?? that can really affect how you perceive a program. If parent resource contributions are really high, then it may be a barrier to effective screening or effective diagnostics. And identifying those parent resources is an important way to understand those barriers and overcome them, and then try to address barriers. So we think that's really important as well. And also they haven't addressed issues related to cost or resources used for diagnostics, which is a real

challenge.

Our approach uses the ingredients method. We also have included methods to estimate both parent and provider time in the cost estimate. We're going to be doing parent interviews, combining a mail/call routine. We're going to use personnel time tracking forms, and they're going to be [inaudible] sampled. And we're going to begin to look at the cost of diagnostics over the life of the project.

And in fact, our sampling plan will include eight hospitals throughout Utah that will be stratified by size, and 360 families will participate in the study over a three-year time period. These families will include 105 who failed the in-patient screen but passed the outpatient screen. They'll include 105 who failed both screens but passed the diagnostics; and then 150 who failed the screens and failed the diagnostics. And we will break out resources according to the categories of service ?? screening, rescreening, screening management, time management, patient management, scoring, those sorts of areas.

We're doing this because we think it's important to understand how not only to describe cost, to describe cost [inaudible] technology used ?? the screening technology, the diagnostic technology ?? but then you can look at it in more depth. It begins to describe the various resources that are used, to staff time, who are the types of personnel in different hospitals who are doing this screening [inaudible] the full equation of cost; and then also family perceptions about the screening process, because we're going to ask families a few questions about how the experience was for them as well, the screening process and diagnostics. It will also describe the type of staff, staff time. It will also reflect differences in prices that can be really important in affecting overall costs ?? local price variations which might reflect shortages of personnel, regional differences, and so on. So overall we think that it's an important component in understanding the complete picture of early detection and treatment.

So basically that kind of outlines our plan. And if anyone has any questions ?? let me also say if anyone wants to talk about this individually afterwards, the methods we're using, or provide feedback, I do have a toll-free number I could give you. Linda Goetze ?? I do a lot of cost studies ?? it's G-O-E-T-Z-E, and I'm at 1-800-887-1699. So are there questions?

PENNY HATCHER: Linda, this is Penny Hatcher in Minnesota. Unfortunately, we got disconnected through part of your presentation, so I don't know if you addressed this. But we're looking at, especially like with the parent surveys and related to the parent resources, are you including some of the cultural differences, both amongst ethnic groups or religious groups, given that Utah is predominantly Mormon? We're just curious about that.

LINDA GOETZE: Well, we are going to ask some basic demographic questions of families who participate. And it's interesting, because I did a couple of screenings at a hospital and one of the nurses said to me ?? it's really interesting that you raise this question ?? she said, you know, the Hispanic babies are more likely to fail the in-patient

screen. She said, I think that their tube is constructed differently.

I mentioned this to Karl afterward, and I thought, well, there are lots of reasons why this can be explained other than a difference in biology. And one theory for that is that in fact we know that they don't stay in the hospital as long if they don't have insurance because of the high cost of care. And so I think that those are important issues, that they may not have had as many in-patient screens and as many opportunities or times to pass the in-patient screen. And so it goes down as a failed in-patient screen because they had, one, there wasn't as much time for the ear to clear, and that ?? and sometimes it can be harder to get those families back as well.

So we are going to look at that, and we're going to look at the time to ?? one of the really important factors is time of patient management, getting patients back into the hospital, and what are the issues related to that, and trying to identify what are some effective ways to get hard-to-reach families back in, and to what extent is it parent resources that are a barrier ?? amplification costs, for example, or lack of transportation -- and what can we do to overcome those barriers.

ADAM ROCHE: Linda, this is Adam calling from Atlanta, and my question has to do with the number of in-hospital screens. Are you all keeping a record of that?

LINDA GOETZE: Yes. Karl, are you still on? Karl may have hung up, but yes, that's in ??

SUSAN FREIDMAN: Karl handed me the phone. This is Susan Freidman. Hi, everybody. He had an emergency call come in, so I'm here to help you in any way I can.
LINDA GOETZE: That's in the Utah database, number of screens both in the hospital and outpatient screens. And that's how we're going to be polling our families. The sample plan is based on that EHDI database in Utah. And that's how we came up, too, with ?? we tried to come up with a sampling plan too that was reasonable. We had to develop this based on the number of infants that we would expect we'd recruit in those categories based on real data that we had from before ?? for example, the 150 that we planned to recruit who failed both, we believe that that's a reasonable number to achieve over a three-year period in Utah, based on the data that we've collected in the past.

HALLIE MORROW: Hi. Are you going to ?? what we're finding is that there are a number of no-shows for outpatient screening. Are you going to look at that issue as well in terms of cost?

LINDA GOETZE: No-shows are such a critical issue, both with respect to this and in early intervention. Yes, we will, because we'll be tracking the time of personnel. And we'll include the time spent ?? one of the big questions with respect to no-shows is whether staff can allocate their time to some other productive task when there is a no-show. And so that issue will be addressed in our personnel time tracking form.

In early intervention programs, I don't know if you're interested, but in the literature

there is some evidence that's starting to come out that the shift toward natural environment may actually, even though home visiting is more expensive per hour, the cost is higher per hour, the real cost of delivered services decreases a little bit if you take into account the decrease in no-shows that result from having a sort of captive audience when you go to the family's home. They're much more likely to be present. The no-show rate appears to be a bit lower. And so at least finding out what the no-show rates are, and then starting to say, well, what can we do to overcome that.

And I was also talking to Christine from Colorado, and she was talking about going over to the Netherlands where the nurses ride their bikes with their little newborn hearing screening packs, and go from place to place. So there may be issues like that that can help overcome the no-show ?? if we end up with no-show rates among certain populations then we may want to address them with other technology or other staff patterns.

JUNE HOLSTRUM: Any last questions for the Utah group? We now have an update on the CDC tracking and surveillance plan. And Marcus Gaffney's going to give us that update.

MARCUS GAFFNEY: Hello again. In the fall of 2000, CDC/EHDI awarded 15 cooperative agreements to states to promote the implementation/enhancement of EHDI tracking and surveillance programs and to encourage the integration of EHDI state-based surveillance and tracking systems with other disorders detected by newborn screening.

A condition of this award was that states would be responsible for creating and implementing a state surveillance and data tracking system to minimize loss to follow-up. And to help the 15 states accomplish this task, CDC/EHDI is working with state health officials to prepare a state-orientated guidance manual. This guidance manual is based on a draft by Dr. Roy Ing of CDC, and will endorse current screening recommendations and clinical guidelines that have been adopted by CDC, HRSA, and the JCIH. The manual is being designed for both states that have an existing EHDI program and states that are planning to implement a new program. Its primary function will be to help state health department officials plan and evaluate EHDI programs in their state.

To help with the planning of a new program, the manual will offer suggestions and recommendations on establishing program goals and measurable objectives, identifying sources of data relevant to EHDI tracking systems, and collecting uniform data items. Items to help states evaluate their current program will include an analysis of existing state tracking systems and recommendations on adopting standardized reports to help track infants through the screening, evaluation, and intervention process.
Working drafts of the guidance manual have been distributed to the chairpersons of seven EHDI committees. Members of the committees, such as Data Sources and the Reporting Systems Committee, are currently working with members from CDC/EHDI to review and offer suggestions on this manual.

Complementing the progress on the guidance manual, the EHDI committees are developing recommendations on ways to implement the five EHDI national goals. The

goals were decided upon after the EHDI Executive Committee collected ideas from various committee members and reviewed current screening recommendations that are endorsed by CDC, HRSA, and other agencies. The ideas were then narrowed down and organized as follows:
Goal one, all infants will be screened for hearing loss by one month of age;
Goal two, all infants who screen positive will have an audiologic evaluation by three months of age;
Goal three, which states all infants identified with a hearing loss will be enrolled in appropriate intervention services by six months of age;
Goal four, all infants with a hearing loss will have a medical home;
Goal five, every state will have a complete EHDI tracking and surveillance system that will attempt to minimize loss to follow-up.

Most EHDI committees have each been assigned one of the five national goals. Each committee holds a teleconference each month to discuss factors and ideas related to how to implement their assigned goal. They also have the responsibility of developing program goals and measurable objectives for each of the national goals. From the measurable objectives the data items and their definitions will be developed.

The first goal of ensuring that all infants will be screened by one month has been assigned to the Populating the Database Committee. The Reporting Systems Committee is working with goal two, which states that all infants who screen positive will have an audiologic evaluation by three months.
The third goal of enrolling identified infants in appropriate intervention services by six months is being addressed by the Family Issues Committee. And ensuring infants have a medical home, or goal number four, has been undertaken by the Data Sources Committee. And the last goal, number five, which proposed that all states will have a complete EHDI tracking and surveillance systems, is being reviewed by the Data Items and Definitions Committee.

Based on the committee discussions, they will develop recommendations on how these five goals can best be accomplished. When completed, these planing and evaluation guidelines will be available to all states. And that's my update on the tracking and surveillance plan.

JUNE HOLSTRUM: We will go to Colorado this time, and Colorado will tell us about the Level II project out there.

BILL LETSON: Hi there. I guess this will amount to a slight shifting of gears. Our Level II Project is really oriented toward attempting to coordinate activities between newborn hearing screening and newborn metabolic screening. And metabolic screening being those kinds of things wherein you screen babies at birth for PKU, hemoglobinopathy, cystic fibrosis, congenital thyroid disease, things of that sort. And it varies quite a bit from one state to another as to just what's screened for.

What we're doing for starters is designing data collection and information systems that

will collect information that will be used for long-term follow-up to try to monitor the outcome in a variety of fashions for different diseases ranging from congenital hearing loss to, say, sickle cell disease, for example.

And all of these modules are being developed in a way that they can be ?? data can be entered at central subspecialty clinic sites, for example, for sickle cell disease, and then downloaded to a common information platform at the Colorado Department of Public Health and Environment. And that information then will be fused with information coming from a birth defects surveillance registry.

So we hope to have all of this information captured in a common place electronically. It looks like it's going to be done largely through the use of Access. It turns out the existing databases in the inherited metabolic diseases clinic, the sickle cell clinic, as well as the existing database for our newborn hearing screening program are all Access databases. So that would sort of ?? lucky happenstance, makes it a little easier for us to accomplish some of this.

The point of all this is then to have these modules designed and use them to try and determine what's happening to the kids that have been identified beyond just the immediate newborn period. What we do in follow-up currently in Colorado is we identify positive tests, whether they be for newborn hearing screening or for some of the metabolic diseases, and then we attempt to make sure that those infants who have positive tests get diagnostic tests and get into the appropriate care. At least that's the case for metabolic diseases.

We are ?? and we have an individual whose job it is to do that. With the EHDI grant we're creating the same type of short-term follow-up for newborn hearing screening, such that an individual will actually track any positive tests to make sure that a child identified with congenital hearing loss will then get appropriate diagnostic procedures and referrals, just like the metabolic kids do. But that's really quite limited.

What we hope to do with the overall program is take those short-term follow-up pieces and extend it over years. By information exchange with the various clinics and even up to medical homes that deal with these kids once they've been identified, we hope to determine on a yearly basis whether those kids are getting whatever standard evaluation is appropriate for them on a yearly basis. For example, with sickle cell, whether they are having a yearly check-up with the sickle cell specialist in Denver or not, and if we know who and where their primary medical home is.

The place where you might anticipate the problems with this, where we're certainly anticipating problems, are in circumstances where kids have a fairly rare diagnosis and they are not living in one of the population centers, and in Colorado those all happen to be along the front range of the Rocky Mountains. And we've got a good deal of the rest of the state which is quite rural, and some of these kids with hearing loss and other diagnoses don't live in the population centers. And they're, quite honestly, more difficult to track.

So what we've designed into our follow-up system is this common data, electronic data

platform that I mentioned that will receive the information on all of these kids, is designed in such a way that it can actually be used as a case management tool by public health nurses out in the counties. And what we intend to do is have public health nurses use this data platform and this information to check up on kids with specific diagnoses that are being followed on a yearly basis, and then feed that information back to us so that we know something about what's happening with those kids and can do further follow-up if need be.

In a nutshell, I think that captures the nature of the project. I may have left some things out, and I don't know if Vickie Thomson is on the line, whether ??

VICKIE THOMSON: I'm here.

BILL LETSON: You may have something to add, remind me of what I've forgotten to say.

VICKIE THOMSON: No, that sounds just about everything. We're really excited about our EHDI database in terms of we keep adding these fields to it. We can monitor, for example, the types of hearing aids that [inaudible]. One of the struggles we're having in Colorado is, probably as in most states, where only if you qualify for Medicaid do your hearing aids get paid for. Most insurance companies do not pay for hearing aids. So we're really trying to push that legislatively, which we will next year.

And so we'll be able to look at the types of hearing aids that people, that infants are being fit with. Interestingly, most of our infants are now being fit with the digital hearing aids. So when we go to the legislature we want to make sure that there's appropriate funding for this higher technology.
That's just an example of what we're collecting. We're also collecting information from the audiologists in a follow-up report to look at the types of diagnostic testing that they perform. We have guidelines in Colorado from our Colorado Infant Hearing Committee, and those guidelines include the types of assessments that audiologists should be doing.

For example, they should be using auditory evoked response with tone bursts as well as bone conduction and diagnostic OAE. So we want to monitor whether or not infants are getting appropriate follow-up, because we have some infants that have been misdiagnosed because they've only had, for example, behavioral testing below six months of age. So that's just something that we want to monitor as well, and be on the screening programs.

BILL LETSON: And you've given me enough of a breather to remember something else I was going to say, but that I was actually reminded of in the earlier discussion between Karl White and I think Deb Lochner-Doyle from Washington.

We had originally intended within this particular EHDI grant to connect all of the kids who are identified with congenital hearing loss to our statewide genetic counseling activities that is done through a contract that the state has with a group of clinical

geneticists at Children's Hospital in Denver. Unfortunately that portion of our grant application wasn't funded, but in the way that Karl was describing sometimes once you get an idea things begin to happen anyway.

So we are intending as a part of our process to try and see that kids identified with congenital hearing loss in the same fashion that the kids with metabolic diseases are referred for genetic counseling, that the hearing kids get referred in as well. The problem is one of funding, and we do anticipate that it will increase the load on the genetics clinics, and it could very well lead to an increased waiting time.

Since we didn't get funding through this mechanism, we're looking for funding through another mechanism to basically beef up the current genetics counseling funding that the state passed out to the folks of children to try to make this happen. So that's sort of an ancillary part of what we're doing, but I wanted to mention that just given the earlier conversation, because we've certainly recognized that that's very much an issue.

And we'll be fascinated with the results, I think, of the Utah project vis-a-vis connexin and all the rest, because I think in the long haul we would also love to get into looking at that if we can figure out how to do it. Any questions?

PENNY HATCHER: Bill, this is Penny Hatcher in Minnesota. We're curious ?? we're very, number one, pleased to hear about the role of public health nursing to assist in tracking and follow-up, which is something that we're doing here in Minnesota. But our concern is how do we support financially public health nursing as a ??

BILL LETSON: Right, right.

PENNY HATCHER: We are adding one more task already on their long list of tasks that they [inaudible].

BILL LETSON: Exactly. But the issue is very much the same issue that I was just talking about and that was raised earlier, with regard to adding one more burden on the geneticist who actually, in most cases around the country, receive most of their funding from the public sector, it turns out. And the issue is very much the same with public health nursing. The way we're dealing with that, that there was not an opportunity to attempt to enhance funding through this grant. But we may have found some other ways, through some other grants and opportunities, to go a little bit beyond what we're doing within this grant. And I think we may be able to find some ways to literally fund the public health nurses' activities in this regard.

But we're ?? it's sort of like the genetics clinic. We're doing it through a different mechanism that doesn't come straight from EHDI. But I can tell you we certainly have indeed recognized that that's a problem.

PENNY HATCHER: Bill, this is Penny Hatcher again. What role are your health plans playing in this? Because this is ?? I don't know how it is in your state, but the majority of these children are their clients, too. And there is some level of reimbursement depending upon certain tests, but how are they involved in your project? That's one question. And

then I do have another one, but I'll let you answer that one first.

BILL LETSON: You know, I think ?? I may be getting into a little bit of trouble here, and I don't think that Cathy Waters is with us. Cathy Waters is our person that is the acting director of the children with special health care needs section in our MCH block, and she's actually done a lot of work negotiating with health plans around a variety of issues that relate to special needs kids, with mixed success, I have to say. That's kind of an ongoing process, and the extent to which we deal with managed care organizations in the context of this project depends as much on some of the success that Cathy has in some of her negotiations with them. There at the moment is not a direct link between the MCOs and this particular project. But there is the potential to link things up in a better fashion, sort of depending on how the overall picture develops. Does that make sense at all?

PENNY HATCHER: Yes. And Cathy Waters spoke, I think at the last one, or some other ??

BILL LETSON: Yeah, could be.

PENNY HATCHER: I am aware of some of her activities, so thanks, I appreciate that.

BILL LETSON: Okay.

HALLIE MORROW: Actually, I have a question. This is Hallie Morrow from California. Well, actually I have two questions. The first is what are you doing about getting consent for all this data sharing that you're doing in the follow-up activities, and the second question is how are you getting the data reported from your outpatient providers?

BILL LETSON: The first is sort of the 800-pound gorilla, and we've really had a lot of internal debate about informed consent. And this is how it's rolled out: When we got to the point that it was very clear to everyone considering that question that we were doing long-term follow-up, we all agreed, given our statutes, et cetera, that we were going to have to do informed consent for this entire process. So that's going to be one of my tasks in the not-too-distant future, is to run this through an IRB process and develop the consents.

What I think we're going to do, though, is we're going to aim our consent process to the long-term follow-up piece. We actually have the ability to do the short-term follow-up on kids who are being screened on the basis of some our statutes that relate to the state epidemiology functions that allow us to do that without consent. It's the long-term follow-up piece that we have to have consent for. So that means that can be limited to the kids who have a specific diagnosis. We don't have to deal with everyone that turns up with a positive screen somewhere. We'll only include those that have a confirmed diagnosis. Did that answer the first part?

HALLIE MORROW: Yeah, I think so. When you start thinking about that you can run

into all sorts of other kinds of issues, because you're talking about a whole bunch of data sharing, even if those people aren't doing ?? you know, contacting families and stuff. But this will be very interesting to see how it all rolls out.

BILL LETSON: Yeah. We think that the families are going to have to understand that we intend to kind of check up on them and make sure they're getting what they need, and they're going to have to agree to that. I think frankly that is not going to be a huge issue. I could be wrong, but I think most families will consent to that. We'll just see.

VICKIE THOMSON: This is Vickie. Hallie, in our brochure we do let families know that the results are going to be sent to the health department and to notify the hospital if they do not want those results shared. So it's kind of a ?? what would you call that ?? a negative informed consent. So only those families, which are very few, that either refuse the screening or do not want the information to go to the health department sign a waiver, a release.

BILL LETSON: And that exists now, but we are going to go beyond that, a formal informed consent for anyone with a diagnosis that falls into this system. We've really decided that that current negative ?? what is it?

VICKIE THOMSON: A negative ??

BILL LETSON: Yeah, negative. It's an odd concept. But anyway, whatever it is, we've decided it's not adequate for these long-term purposes.

VICKIE THOMSON: Any child that is identified with a hearing loss currently does get an authorized informed consent from the family. So we have that in place for hearing.

BILL LETSON: And your second question? I think I've lost it in the discussion here.

HALLIE MORROW: How you would get all this follow-up information from your outpatient providers.

BILL LETSON: Ah. Well, you're in California, right?

HALLIE MORROW: Right. Does it show?

BILL LETSON: Well, the reason I mention that is it's one of the advantages of being in a relatively small state. We don't have multiple institutions competing with each other for patients' dollars, et cetera. We have one medical school, period, in the entire state. And for most of these diagnoses, particularly the metabolic diseases, they've got a pretty good handle on those kids, even the ones that live in the rural areas. So we think that about 80 percent of our information is going to come from the clinics at Children's Hospital. Now hearing gets a little more dispersed, and we do recognize, as I mentioned earlier, that there are going to be some kids, even with sickle cell disease, that are going to turn up in some small, out-of-the-way place. And it may be quite difficult to get that information.

That's where public health nursing comes in. They would help us capture some very basic follow-up information that will then allow the specialty clinics to follow the kids in more detail, keep track of them.

KIM OLLER: This is Kim Oller in Maine. I have another question about this follow-up and the informed consent issues. Are you particularly concerned about the follow-up because of the fact that there might be research done on the data that are obtained in the follow-up? Because when you say that you're going to submit this to an IRB, I'm a little puzzled by what the motives for that would be. If it's purely clinical information, do you really need it?

BILL LETSON: We have designed our long-term follow-up module so that, yes, there could be research done as a result of this. And our follow-up modules for inherited metabolic disease and sickle cell, for example, will actually get information that's quite detailed, getting right down to things like acute JES [phonetic] syndrome occurrences and things of that nature.

KIM OLLER: So it is because there would be research done potentially on these data that you feel you need the IRB approval for follow-up?

BILL LETSON: Well, yeah, that would probably be why we need IRB involvement. We feel that we need informed consent simply because this is long-term follow-up, and even fairly basic information, at least with our statutes, our state epidemiologists felt that long-term follow-up goes beyond what our epi statutes cover. Now in Colorado, the way things have developed, that just in and of itself might require an IRB pass-through. We're getting to be quite ?? there's a lot of sensitivity of what should go through an IRB, and it seems to be more and more things are going through our IRBs that might not have previously.

JUNE HOLSTRUM: Thank you, Bill and Vickie. Are there any last questions for Bill or Vickie. Our next speaker is from the National Early Childhood Technical Assistance System, and she's going to be talking about the connection between NECTAS as the hearing screening programs. Cindy Oser was not able to be with us today, so Jo Shackelford has graciously agreed to take her place.
So go ahead, Jo.

MARTHA CARMEN: June, it's Martha Carmen with Congressman Walsh. I'm going to have to hang up in a second, unfortunately, because I have to go to another meeting. But I can either do a real quick thing on the caucus or wait till next time, but I'm going to have to hang up.

JUNE HOLSTRUM: Why don't you say something quickly.

MARTHA CARMEN: Very quickly, and I'm sorry I'm messing up your schedule today, Congressman Walsh was approached to be one of four co-chairs of a newly formed bipartisan Congressional hearing health caucus. The other members are Lois Capps,

Carolyn McCarthy, and Jim Ryun.
We were approached by the Deafness Research Foundation and its National Hearing Health Campaign. It's an educational caucus so that members of Congress and relevant health staff can be better educated about hearing health issues from type of communication to diagnostic things and everything in between.

We did have our first meeting February 8th of last month, and it was sort of an intro college 101 level course, introductory hearing health, and the topic was what happens when hearing loss is diagnosed. And we had an ENT to give the medical perspective, an audiologist, someone with experience with hearing aids and cochlear implants, somebody representing deaf culture, and then another participant to talk about educational options.

And it went very well, and the next caucus meeting will probably talk about lack of reimbursement for hearing aids and cochlear implants. We hope to bring in members of the insurance industry, somebody representing managed care, somebody from HCFA, from the Medicare/Medicaid perspective, and somebody representing the [inaudible] fee for service kind of plan. That's a very quick overview. I can take two quick questions, and then I'm really going to have to run. I'm sorry.

UNIDENTIFIED: I have a quick question for Martha. Is there any way that someone could participate in one of these or observe it? I think it would be very interesting to hear what they have to say.
MARTHA CARMEN: Sure. Where are you located?

UNIDENTIFIED: I'm in Washington, D.C.

MARTHA CARMEN: Oh, sure. Let me give you my e-mail address really quickly, and send me a note and I'll get you on the list.

UNIDENTIFIED: Okay, great.

MARTHA CARMEN: It's Martha dot Carmen, C-A-R-M-E-N, at mail, M-A-I-L, dot house, H-O-U-S-E, dot gov, G-O-V.

UNIDENTIFIED: Okay, great. Thank you very much.

MARTHA CARMEN: Somebody else? Okay, thanks so much.

JUNE HOLSTRUM: Thank you, Martha. Jo, are you ready? Sorry for the interruption.

JO SHACKELFORD: This is Jo Shackelford substituting for Cindy Oser. I was asked to describe NECTAS and how we might assist with the newborn hearing screening. NECTAS. For those who don't know us, NECTAS stands for the National Early Childhood Technical Assistance System. We have a federal grant from the Office of Special Education Programs in the U.S. Department of Education. The coordinating office of this grant is in the Frank Porter Graham Children Development Center at the

University of North Carolina, and that's where I'm located. But we have five other partners, the Federation for Children with Special Needs in Boston, Georgetown University Child Development Center, the National Association of State Directors of Special Ed, Zero to Three in Washington, DC, and the University of Hawaii at Manoa. Our role is to provide technical assistance to all the states and territories as they implement the early children programs under IDEA, the Individuals with Disabilities Education Act. Our primary clients are the state coordinators of the Part C program or the Infants and Toddlers with Disabilities Program, the state ICCs, the state coordinators of the preschool three-to five-year-old program, and early children discretionary projects that are also funded by OSEP.

We support these programs through a variety of strategies including consultation, workshops and conferences, print products, audio and video teleconferences, and electronic communications such as our listservs and our Web site that has a searchable database capability.

As part of our work scope we're prepared to help with collaborative efforts between the early childhood programs and the Early Hearing Detection and Intervention programs. Cindy Oser, who is with Zero to Three, and I are the liaisons from NECTAS to the EHDI program.
We can disseminate information on early hearing to our clients, and we're also collecting information from state programs on how they're working with early hearing screening. For example, we have guidelines for service providers and we have family information, manuals, and brochures. You may know of one of our recent NECTAS/EHDI efforts. Last December we had a Web enhanced teleconference on early hearing detection and intervention for our clients, in which there were presentations by Karl White, June Holstrum and Brandt Culpepper, Mary Beth Bruder from the University of Connecticut, and Kristina Gonzalez, a Connecticut parent of a three-month-old infant with bilateral hearing impairment who was identified on newborn hearing screening. The Web-enhanced portion of that teleconference was PowerPoint slides which participants could view on our Web site as they listened to the teleconference by phone. These slides are now accessible on our Web site at www.nectas.unc.edu. Look under What's New at NECTAS on the right side of the home page, and it's the very first item. So that's a brief description of our work, and I can take any questions if we have a few minutes left.

LINDA GOETZE: Hi, Jo. This is Linda Goetze from Utah. I'm wondering how often some of the finance issues have come up with you all from states, and whether ?? the NTRM out of Office of Special Ed Programs calls for new, possibly new responsibilities for service coordinators with respect to financial case management and helping parents understand the costs related to early intervention and some things like that. Have you looked at that as it relates to some of the newborn hearing issues? We've been really struggling with additional Child Find and funding those –

JO SHACKELFORD: These are issues that we address. We continue to work with states on funding issues for Part C and putting together the blended interagency funding required in that program. We also have helped states with the financial case management

for individual families. However, I don’t believe we have had specific requests from states around the newborn hearing issues.

LINDA GOETZE: Yeah. And so I'm wondering, and it ties into some of the EHDI issues, so I'm wondering if you all have helped provide technical assistance to states in addressing those issues.

JO SHACKELFORD: Not as yet.

LINDA GOETZE: And what some of the strategies that states are using to blend funding to help families.

JO SHACKELFORD: Okay. I'm making a note of that as we speak.

IRENE FORSMAN: Linda, this is Irene Forsman. We had a contractor do a review of Medicaid EPSD policy. They looked at ?? these are people who do this all the time for us. They have looked at the written stuff, and they're now in a stage of doing some follow-up telephone review. There will be a document and there will be a report which we'll be able to disseminate probably within the next couple of months. They also plan to do some work with some private carriers and some MCOs over the next six to eight months, just FYI.

LINDA GOETZE: Great. Is that McManus [phonetic]?

IRENE FORSMAN: Yes.

LINDA GOETZE: Okay.

JO SHACKELFORD: That might be something that we might want to let our clients know about.

IRENE FORSMAN: You're welcome to do that.

JUNE HOLSTRUM: Also, we did have one more announcement, and that's that the new RFA for EHDI should be out either at the end of March or sometime early April, we hope. It's up in the Grants Management Office now. It will be very similar to last year's, and we will send out announcements through the e-mail as soon as it's actually out. We're running a little late, so I won't even ask for last questions. We will see you on May 1st. Thank you.