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

Friday, January 27, 2012

Morning Session–Part 2

11:15 a.m.–12:30 p.m.

Park Hyatt Hotel

Washington, D.C.

CHAIRMAN BOCCHINI: So we'll reconvene, and next on the agenda, Dr. Brad Therrell is going to present the results of the data that he's put together at the request of the committee.

Dr. Therrell is director of the National Newborn Screening and Genetics Resource Center, and he's a research professor, Department of Pediatrics at University of Texas, Health Sciences Center, in San Antonio.

Brad?

DR. THERRELL: Thank you, and it's pleasure to be here again.

This is actually a report that began over 2 years ago, and it came from some deliberations in the Follow-up and Treatment Subcommittee, which were initiated because of this concept that all programs are able to match up the babies that have been born with the babies that have been screened, which is not the case. So here's a little bit of the brief background.

We brought forward a report from the subcommittee to the Secretary's Advisory Committee

on January 22, 2010, and we had a number of discussions. Basically, the committee thought this was a great idea but wanted to have a little more data. And there were actually some discussions about whether or not more than just the serial number of the newborn screening spot should be collected on the birth certificate. For instance, should the data from the screens be there? I'm not going to get into that part again, because we sort of beat that one about and decided that maybe we put that one off, so. But we were asked to develop as a next step a short white paper on the recommended changes to the birth certificate and what was available today and why we needed that. And that's what we've done.

So just as an introduction, newborn screening is defined as a core public health program by the Association of State and Territorial Health Officials, and you all know the Secretary has endorsed the panel, which now has 31 recommended conditions.

All the states have laws that require

some sort of newborn screening and they all have laws that require some sort of birth registration. The trouble is, those two programs don't necessarily interact. And so while state health departments are generally responsible for both, they sometimes exist in two different silos. And so now that we're into more and more electronic health record information, it seems an ideal time to maybe address this problem of programs not being able to tell you how many babies were screened in their state.

So electronic recordkeeping for both activities is there in all the states. And those states that don't have electronic birth registration are almost there.

Serial numbers for newborn screening blood spots exist in all states, although they may differ a little bit in their format. And hearing programs also have a responsibility to monitor how many babies are being screened, but they don't necessarily also connect to the birth certificates. And so there's a chance here to get sort of all

these programs combined.

And there are some requirements now coming down in the form of recommendations for 2020, for states to be able to tell how many babies they screened and that there is an improvement in the number of babies being screened. And right now that's difficult for states to do because they don't link to birth certificates.

So the records from newborn dried blood spot and newborn hearing screening records, they don't always contain the same name or the identifying information. Birth regulations don't always require that the final completion be done quickly so that they are available for checking. But it is true that sometimes the blood spot screening and the hearing screening are co-managed within the health department, but not always. And management of birth registration programs is usually completely separated and may not have this on their agenda. And that's where the big problem lies.

So what about solutions to this matching?

There's basically two ways you can do it. You can do it manually, or you can do it electronically. Manually, as you can imagine, is a big headache to try to match all the newborn screening blood spot forms to the birth certificates, but it is being done in some of those smaller states, believe it or not. I've actually been in a state where there's a person dedicated to this all day long.

Electronic matching can take sort of two forms. One is called deterministic matching, and that's where you look at an exact match with something between the two things you're matching, like a name, for instance. Unfortunately, newborn screening names don't always match.

So probabilistic matching is more often done, and that's where you pick some part of the field and combine it with another part and another part, and you get some probability that this is the baby you're talking about. And so it comes up as a sort of statistical probability, this is the baby, but just in case it isn't, here are a couple more you might want to look at.

So it's difficult to do a deterministic match on baby's name, as you can imagine, but it's not so difficult to do it on a number if there was a number there. Some states don't allow birth registration -- don't require birth registration to be so quickly, and so that's something we need to talk about separately.

So as a result, newborn screening programs most often use is probabilistic matching that I'm talking about. Sometimes that's a program that takes minutes to run, sometimes it's a program that takes hours, sometimes months, dependent on how many items you look at and how good you want your probabilistic matching to be. So the higher your bar is, the longer it takes, basically. So that's very difficult.

So maybe the solution is to record initial newborn dried blood spot serial number on the birth certificate and link the two databases. I mean, this is the simplest thing. People are doing it; it works. It's just that we have to convince people that this is the thing that needs

to be done.

So the payoffs in this sort of a linkage, the dried blood spot programs can confirm that a specimen was collected or not on all the newborns. The hearing screening programs could also have a link, if they collected the serial number. And birth registration databases could also utilize this to check their data because right now it's entered by somebody, and that becomes the birth record. This would allow another way to look at some information that's entered and see if it matches. So there's some benefits that way as well.

There are some external things to think about here. The Clinical Laboratory Standards Institute has a standard on blood collection and filter papers. It's been around for about 25 years. And for 20 of those years, it's contained a suggested format for states to use as a serial number, so that if we had these in our databases and babies move between states, the field would be able to capture the same information from state to

state.

There's an organization called NAPHSIS, which is the organization that the state birth registrars belong to, and that's the group that advises the National Center for Health Statistics on what they should be obtaining from the states in terms of vital records. And so the National Center for Health Statistics actually resides within the Centers for Disease Control. And then HHS, in addition to sort of overseeing all of this, has national efforts ongoing to improve electronic records. So there are all these things coming into play here.

So, currently, about 96 percent of states have electronic birth registration. Eleven states reported into us that they have a field on the birth registration or in the birth registration that collects the newborn screening serial number. Four others had plans to do so in the near future. And of those states, four reported that this is a required field.

So on the birth certificate or in the

birth registration, some states will designate certain required fields. Now if you designate a required field, it doesn't necessarily mean it's going to get filled out, but there's a higher probability that it's going to be filled out. Without that, then you've got a high probability that it's not going to be filled out in most states, because it's extra work and it's not required.

We also were asked at one point to look at how many states are actually trying to do these sorts of linkages with any kind of database, and we found out that about 66 percent of the states are trying to do something. Thirteen states reported that they have no linkage, and four states didn't report into us. And again, the matching time varied from hours to months.

So all of that came into play when we developed some recommendations from the committee. Originally, these were fairly stiff recommendations asking the Secretary to do this, the Secretary to do that. We were asked last year to modify those

and to bring to the table the people that might be affected by this, which was basically NAPHSIS and National Center for Health Statistics. And so we had some conversations with both groups.

We circulated this white paper that's in your material to those groups for comments and changes. We've also circulated it to the Association of Public Health Laboratories and others. We've gotten all the feedback we think we can get. And everybody is pretty much in tune with this.

The question remains as to where it is on everybody's radar. And so the feeling is, among the newborn screening community, that if this were to come to the attention of the Secretary's Advisory Committee and the Secretary, it might get better play in the states and there might be a better chance of getting the sort of linkages that we need.

So there are I think four recommendations that you can talk about. These are things that we came up with as a committee, ran by these two

groups; they agreed with.

So the first one is that the Secretary's Advisory Committee should encourage state newborn screening programs to utilize a unique serial number on each initial newborn screening specimen collection device to aid in electronic tracking and identification.

To facilitate harmonization, the format of this number should follow that that's recommended by CLSI, which as an option includes something called the checksum character. This is a character that's put at the end of a number that is mathematically arrived at, which checks the numbers that are previously reported in that number. So you can either, for instance, if you're typing a number, you might make a mistake, but if you have this checksum number and you got to the checksum number, it would tell you, you made a mistake, go back and do it over. Okay?

Second recommendation was the Secretary's Advisory Committee should work with NAPHSIS toward a goal of including the newborn screening serial

number on the birth certificate to facilitate confirming access with all newborns at the time of the newborn screening and to provide an external mechanism for evaluating certain demographic data records on the birth certificate, and use these data for improving electronic health information service quality.

Third recommendation was that the committee should work with National Center for Health Statistics towards a goal of including the serial number in the next revision of the U.S. Standards Certificate of Live Birth. Now that's something that comes out from NCHS periodically and states use as a model to what their birth registration would look like. It's not changed so often that there's a routine. It's changed when somebody, some higher official basically, asks them to look at it and consider changes. And this is that sort of a higher official, in our minds.

And if there's a choice of including it as a required field or not, it should be a required field. And the reason is, we've already had the

experience in states that don't require it and it's not being filled out, and states that do require it are having it filled out.

And last, state birth registrars and state newborn screening program directors should be encouraged to consider ways in which electronic data validation of the demographic information collected on two activities can be used for cross-validation and data quality improvement.

So they're pretty much no-brainers, in my mind, but how we implement this and how it takes place at the states is the issue.

In terms of cost, we actually went to the states that have implemented it and asked what their cost was for implementation, and in all cases, believe it or not, there was no cost because their birth certificates had just been updated and they took this as an opportunity to increase the fields. And so they didn't charge for it.

Now I went to NAPHSIS, and I asked them to look at some other people and they did. And they found that a couple of people said, well, if

you put a field in our database, it's probably going to cost you about $25,000 or $30,000. So we really don't know what the impact would be. It depends on the sophistication of the database that you're talking about, when it was last updated, what the agreements are with the vendors, and that sort of thing.

So that's it.

CHAIRMAN BOCCHINI: All right. Thank you, Brad.

All right, this presentation is open for discussion.

Don?

DR. BAILEY: So, thanks, Brad. I'm just curious, are these data only going to reside at the state level? Are any of these data amalgamated up to a national level? And what about families that move from one state to another, would this help in a situation like that?

DR. THERRELL: Right. There is no national database; there is no plan for a national database. It is kept at the state level. And if

you look in the paper, there's actually a section in the paper that talks about concerns about privacy.

DR. BAILEY: Right.

DR. THERRELL: And the point of that paragraph was to sort of alleve people's fears that this was going to be used for some sort of national tracking database. We've got 50 or 51 programs here; they're all different. It's highly unlikely that at any one point in time they're all agree on anything. And so having a national database or even having an interoperative national database of some sort is pretty unlikely.

Now we're asking about the field size because it is possible for people to move from state to state and actually programs hand people off from state to state. And so this would be a way for them to put in their database that person and not have a negative effect on the data.

CHAIRMAN BOCCHINI: Jeff and then Dave.

DR. BOTKIN: I'm looking at our new matrix of levels or nature of support. So if this

is approved, is this something that would go forward for the Secretary to act on or would this be informational only? Most of this is occurring at the state level, but is there secretarial action, HHS action, that's associated with the recommendations?

DR. THERRELL: Of course, that's your debate, but in my mind, I think it should go forward to the Secretary, with a recommendation that the Secretary do these things or share these things or do them in the form of a letter, if nothing else, to the states to make them aware of the issues and the possibilities. But again, it's for you to decide.

CHAIRMAN BOCCHINI: Dieter and then Stephen.

DR. MATERN: What if you have birth records or certificates where there is no numbers, so basically the screen did not happen. Is anything going to happen then? Or do we just record that it wasn't done?

DR. THERRELL: Well, so that's the point.

The hope is that programs, as they get into this mode of checking, would be able to say in a fairly quick basis that baby hadn't been screened, let's go figure out what happened and let's get him in for screening. Right now, that's not happening.

DR. MATERN: And then you add that later to the birth certificate if the screening actually happened?

DR. THERRELL: Yes.

DR. MATERN: And if the parents refused?

DR. THERRELL: Well, if it were a mandate of the state that this number were on the registration, then there wouldn't be this sort of issue. It's the same thing with the birth certificates required, newborn screening is required.

DR. MATERN: But in some states you can opt out. In some states, such as Minnesota, you can opt out after the screening was done.

DR. THERRELL: So there would have to be some sort of mechanism to handle that. I mean we could say opted out or whatever.

CHAIRMAN BOCCHINI: Let's see. We have Stephen and then Alan.

DR. MCDONOUGH: Yes, it would appear that we would be voting on recommendation one, because it does ask the Secretary to have the National Center for Health Statistics to do some stuff, right?

DR. THERRELL: That's what I would hope.

CHAIRMAN BOCCHINI: Alan?

DR. GUTTMACHER: I may be raising a point that doesn't really need to be raised or isn't worthy of raising, but is there any wisdom, Brad, do you have any, maybe, Jeff, others, who have some expertise in this area, any feeling about -- going back to Don's earlier presentation and how much we need to be alert to anything that may impede the public avidity for newborn screening, any thought about how this might have any impact whatsoever on those who have concerns about government having data on their babies, et cetera, et cetera?

DR. THERRELL: Yes, I mean my experience would indicate that there's always going to be

somebody somewhere who doesn't like what you're going to do. And it's an educational thing, I think. We still have to pay attention to the fact that these are programs where we don't know if every baby is getting screened, and this is for the benefit of the baby, not the parent necessarily, and this is a way to check and make sure every baby is getting the services that's their due. But I'm sure there will be somebody somewhere who doesn't see it that way.

DR. LOREY: Brad? Brad?

DR. THERRELL: Yes.

DR. LOREY: It's Fred. I just wanted to comment that for us, we've been wanting to do this a long time, and we did do it manually, we can get the tapes and do matching. But we've met with vital steps a couple of times, and they're the ones that are resistant. So if there could be some sort of recommendation, it would help us.

CHAIRMAN BOCCHINI: Okay. Freddie?

DR. CHEN: I am concerned about possible implications also for undocumenteds, and I mean, at

the end of the day, it's still the state having a new number for every birth, whether it's national or state; it's still government. So we should be well aware of those implications, and certainly the Secretary will be.

DR. THERRELL: Yes, some people had made the point that the number is already out there; it's just a matter that it's not being recorded. And while people may be moving in and out who might not have had screening, most pediatricians would try to have them screened if they go to a pediatrician. So, yes, I'm aware of it.

DR. LOREY: We have a law against that, but I bet Arizona doesn't.

DR. COPELAND: I have a couple of technical points about these recommendations, one of which is the advisory committee can make advice to the Secretary. That is all they do. So the recommendations where the advisory committee does X, Y and Z are problematic, and so I think we need to look at this very carefully. I would ask you to look at them very carefully and see if there's a

way that we could frame those so we're still within the scope of what an advisory committee does.

And also please keep in mind the sensitivities that Freddie raised about where we'll put the Secretary in terms of public perception and consideration. It's one thing to ask her to say that, for those states that want to do this, it's a great idea; it's another thing to ask her to say that all states should be doing this.

DR. THERRELL: So I don't think the recommendations actually say that all states should be doing anything. It just says they should be aware of, they should work towards, that sort of thing. And like I said, originally we had some stronger wording, and we've modified that wording at the request of the executive committee before. And we have worked with the National Center for Health Statistics and NAPHSIS, and they are in agreement that this is something that should be done. But they're also in pretty much agreement that it's not on their radar unless somebody brings it to their attention. And we could do that

through this committee or we can go individually state by state, try to get a registrar, try to convince a registrar that this is something worthwhile and so on.

CHAIRMAN BOCCHINI: Alexis?

DR. THOMPSON: Is there any indication that funding is a significant barrier to states actually utilizing or coming online with, for instance, going with a serial number? You mentioned that only 11 states and you mentioned about a figure on how much at least for one state it costs for them to actually add a field -- or one organization to add a field. In general, is the -- do you have a sense of, for those states that have not gone to it or would like to but are having challenges, that funding is an issue?

DR. THERRELL: Funding was brought up as an issue by NAPHSIS, and we took a look at that to see whether that was an issue. And my feeling is it's not that big of an issue because most of the time the state's not going to do it until they make a change anyway. They're not going to go to the

trouble for this one thing to go make a big change. The exceptions to that were some states that said, well, our database is easy to change and it's going to cost us $20,000 or $25,000.

Now, I'm from Texas and I worked long and hard to get this put on the Texas birth certificate years ago. It got put there when they went to electronic birth registration. But last year it was taken off because nobody was putting data into it, and they wanted to use that field for something else. Now I'm told that there's been some conversations back and forth, what would it cost to put it back on. And they're saying, oh, well, this is a going to be a major change and it's going to be $300,000.

So it varies, depending on who's interested. And if you get somebody who's interested who thinks this is a good idea, it's not going to be very much money. If you get somebody who's resistant, because they got other things they want to do, it's going to cost a lot.

CHAIRMAN BOCCHINI: Jeff?

DR. BOTKIN: Can we put the recommendations back up? I'm not sure I understand Sara's point, so I want to see what they say.

DR. THERRELL: They're also in this paper that should be in your notebook.

DR. BOTKIN: We should be able to get them back up.

DR. THERRELL: We're working. Okay.

DR. BOTKIN: Thank you.

DR. THERRELL: So there is the first one. It talks about encouraging state programs to use serial number on each newborn screening specimen form that complies with the national recommendation from CLSI.

DR. COPELAND: So this is where wording is really important. Is it the advisory committee -- you're asking the advisory committee to encourage or are you asking the Secretary to encourage? Because it's a significant difference. If the advisory committee thinks it's a good idea, we can send it as an FYI. If we're asking the Secretary to encourage, it's asking her to take

action. And these are some nuances that we need to have clear, and that's why we have the nature of support and the different levels.

DR. THERRELL: You want to see the -- what do you want to?

DR. DOUGHERTY: But the advisory committee doesn't have the authority to advise the states independently, right? It has to advise the Secretary.

DR. COPELAND: Correct, but we could say that the advisory committee supports this as an option if you guys voted on that, and then send it as FYI to the Secretary. There's two different options.

DR. THERRELL: So this wording actually arose from conversations we had with the previous committee and were changed because the previous committee wanted this kind of wording. Now that's fine with me. I mean, my main goal is to get it done, and I don't care how the wording is. So change the wording however you need to change it. You want to see the second one?

DR. BOYLE: Maybe we need to first decide.

CHAIRMAN BOCCHINI: Before we get to the second one --

DR. COPELAND: Just a minute. You're going to have to repeat what you just said, because your microphone wasn't working.

DR. BOYLE: So I was just going to say, maybe we can decide what action we want the Secretary to take, whether we want this to be an FYI for her or we want this to be an action for her to be more active in. And then we can reword it accordingly. That's just my sense of --

DR. COPELAND: Do you want to take that recommendation by recommendation or all six of them together?

DR. BOYLE: Well, I --

DR. COPELAND: Or four.

DR. BOYLE: Four. We can bundle some of them, in my mind.

DR. COPELAND: Yes.

DR. BOYLE: I don't know what others feel

about it.

CHAIRMAN BOCCHINI: I think that's a reasonable suggestion, and so if you want to -- if there's additional discussion that we need to have about the benefits and the role this might have, we can do that. But if not, why don't we entertain a motion, based on Coleen's comment about whether this should be something that the committee should advise the Secretary to consider or whether we ask her directly to contact the states with the recommendations.

Michael?

DR. LU: Hey, Joe. I don't know if I have enough information to make a recommendation related to what Alan and Freddie raised about the concerns about the perception of government intrusiveness. I don't know how this might or might not impact on that. Do we have any information to guide our recommendation?

DR. THERRELL: Not really.

CHAIRMAN BOCCHINI: But we do have 11 states that are doing this.

DR. THERRELL: Yes.

CHAIRMAN BOCCHINI: Is there any concern in those 11 states?

DR. THERRELL: Those states have not expressed any problem with it, so.

CHAIRMAN BOCCHINI: One out of five states are already doing it.

DR. LU: Kind of pre and post, they haven't --

DR. THERRELL: I haven't asked that question. I can go back and ask that question. But when I asked for the information coming from the states, and I gave them open-ended questions that they could relate to, and there was never that comment made. No comment.

DR. MATERN: Which states are doing it? Maybe there's someone in the room who could comment from that state.

DR. THERRELL: I don't have all the data, but Colorado, Michigan, New Mexico, New York, Oklahoma, Oregon, South Dakota, Utah. Utah. Wisconsin is another one.

DR. FEUCHTBAUM: This is Lisa Feuchtbaum from the California Department of Public Health. I just wanted to point out that first part of the recommendation about having a universal number used across state. I understand and appreciate the importance of that. But from a program evaluation perspective within each state, it's not critical to have that common number, quite frankly.

DR. FEUCHTBAUM: If we in California would like to find out how many babies were in fact screening instead of coming up with an estimate, which is what we do now, we would just need to have that number on the birth certificate. It doesn't have to be the same number that other, you know, the format doesn't have to be universal. So that's why I think it's important to maybe separate some of these recommendations.

CHAIRMAN BOCCHINI: Yes. Then we'll go back to Don.

UNIDENTIFIED PARTICIPANT FROM MASSACHUSETTS: In case it's helpful to have a few anecdotal from the states. So, in Massachusetts,

it's not incorporated into electronic birth certificate information. My comments would be exactly as Fred's. I met with him a number of times, I would love it to be there, it's just resistant. It's not because of concerns about privacy; it's not really stated as concerns about privacy. It's more like a lot of people want things and we have to be very careful about what's included, et cetera, et cetera. This just doesn't seem to get high enough. So it would be helpful to have some kind of a thing that's beyond us from a national recommendation.

On the privacy thing, personally, I'm one who tends to be very concerned about privacy issues. I'm the one that gets the calls from the parents and it's -- this particular issue, I'm not concerned about it nearly as much as some other things. I think the electronic birth certificate already exists as a government database. Fill the paper, the number is already in our database. There is always a danger in linkage, but I think just anecdotally again, I would say that for me

personally, it's not one of the things that I get concerned about so much, about the privacy concerns, even though I am very concerned about that on some other fields. It's just an anecdotal piece for you.

CHAIRMAN BOCCHINI: Okay, we have Don and then Alexis.

Oh, I'm sorry. Let's get another state experience.

DR. BOWMAN: Thank you. I'm Bob Bowman, I'm the director of genomics and newborn screening in Indiana.

I've had some discussions with our registrar about this issue, and I've actually spoken with some hospitals directly about this. Really the biggest thing is it's going to impact the vital records program a lot more than it's going to affect newborn screening. I think that's one of the key things.

In terms of the number, the actual format of the number is not as important to us as the number itself, and I think that alleviates the

privacy concern on our side, because every card has a number. And we are aware of that number as a newborn screening program. So from that standpoint, as long as we don't necessarily have to mandate a certain number, it's not as much of an issue.

In terms of what issues, you know, how will this impact vital registry, I think it's important to recognize that we are not all communicating with the same people at the birthing centers. So when we did speak to the birthing centers, what we heard was there was concern how they were going to get this information, the individuals who were actually entering the information into the birth certificate.

There's also concern about transfer babies and babies who had religious waivers. How would that be addressed?

I'm trying to think of some other issues, because it's been a while since we had that discussion. But I think those were really the main concerns that we had. And that's why making it a

mandatory field was really questioned.

CHAIRMAN BOCCHINI: Thank you. Any other state experience?

Okay. Don?

DR. BAILEY: So I think I know the answer to this, but, Brad, remind me, what's the problem we're trying to fix here? Is the problem that there are some babies that might not have been screened and so we want to -- we want some mechanism in place so there can be a cross-check between the screening program and the actual birth record?

DR. THERRELL: Basically, that's right. In addition to that, there are some requirements coming down to the states to be able to tell how many babies were actually screened in their state, which they cannot do. And this facilitates that. But it's mainly the reason you said.

DR. BAILEY: Right.

DR. THERRELL: Yes.

DR. BAILEY: Yes. So maybe I'm completely off-ways here, but it seems like this

might be getting down to a level of specificity for states that's unnecessary, and that what we ought to be -- that what we could do as a committee is say that every state ought to have a policy in place to assure that there could be a check between the birth and the screening program, and there are different ways to do it and this would be an example of one of them.

But again, you've really been in this a lot longer than I have, but it just seems to me, if we're not trying to create a national data set that we could harmonize in that kind of way, what you're doing I think is trying to harmonize some kind of reporting process or procedure. Maybe there were alternate ways to do it, I don't know.

DR. THERRELL: If you read through the paper, you'll see some discussion about ways to do it and ways not to do it. The big problem is that if it's not on the birth certificate, then some other -- if the number's not on the birth certificate, then some other mechanism comes into play that gets the same information off the birth -

- doesn't get the same information, but gets the information off the birth certificate, and it's usually like the first two letters of the last name, the first letter of the first name, third number of the birth date, and it gets bigger and bigger and bigger, depending on which state you're in. And then that data may not be run until all birth certificates are in at 6 months or whatever. And so it's not very good at checking to see if a baby got screened in a timely manner so that if he didn't, you can get him screened and they can get treated. And it's so simple to put the number there and just connect the programs.

But the trouble, like you're hearing, is that the state registrars, this isn't their program. Their program is birth certificates. And they've got people coming to them wanting everything on the birth certificate.

The reason this one seems to fit better is because it's a state requirement that every baby be screened. I agree there are some issues about those babies who might refuse, but I think there

are ways to get -- I mean, in lots of cases, those babies get a number anyway, and that number carries with it the refusal. But some may not do that. But there are ways to address that, so.

CHAIRMAN BOCCHINI: Alexis?

DR. THOMPSON: I just want to sort of explore perhaps a slightly different issue in addition to the one Don mentioned in terms of wanting to fill in the blanks in the early newborn period. Another area that's become increasingly problematic is people asking about their sickle cell trait status. And that the vast majority of states at this point do actually detect trait and that sometimes that question isn't actually asked in the newborn period; it's actually requested years later. And the opportunity to actually be able to tie one's trait status over a lifetime, we're finding there perhaps are health implications for trait status.

And in this way what you're describing in fact may be a very intriguing way not just for research purposes but for clinical management to

actually in fact be able to tie back. The alternative is what we use right now, and that is simply actually retesting people who unfortunately we know were already tested.

DR. THERRELL: Yes, you're right, that's been a huge problem lately with people trying to match you up names and their name was different or is spelled different or whatever. So, yes.

CHAIRMAN BOCCHINI: Jeff?

DR. BOTKIN: Well, I would just go back to I think Brad's earlier comment, which I very much agree with. This is just a no-brainer, and I think Brad has done a nice job talking to the relevant groups and agencies to find out whether we're stepping on toes here, and I think the answer is no, that folks -- everybody supports this and thinks it's a good idea, and it sounds like the states would like a little bit of encouragement to bring this a little farther forward on the stove.

And so if we can craft language in a way that doesn't overstep our bounds -- we're not telling states what to do. We're simply saying

this is a really good idea, you ought to think about it. That doesn't sound to me like it's overstepping.

Otherwise this whole committee is going to be handcuffed in trying to deal with state-based newborn screening programs if we're too sensitive about that particular issue.

Now, exactly how the language ought to play out with the Secretary I think is a different question for the one recommendation that I think is more relevant to her authority.

CHAIRMAN BOCCHINI: Andrea?

MS. WILLIAMS: I think we can address the privacy issues by having the number not be related to disease, not linked to disease, so it's just linked to the test, that you actually had a newborn screening, not to go any further and say what your results. Do you know what I mean? So it's just a number and not related to a disease at all.

CHAIRMAN BOCCHINI: Okay. All right. Additional comments? All right.

So I guess the two issues are, one, the

set of four recommendations and the view of the committee. This will require a vote, so there would need to be -- so we'll need to make a motion.

But then the second is at what frame do we want to place it in terms of our level of support for what goes to the Secretary. I'm sure we can put together a letter that reflects the wishes of the committee as to how to approach the Secretary.

DR. BOTKIN: Could we see again the recommendations, and specifically the one that relates to the Secretary's authority?

CHAIRMAN BOCCHINI: Okay. So we're going to go back to the four recommendations, and I think we've already indicated that the committee cannot work with the states, that we need to recommend that the Secretary consider X, Y and Z.

DR. BOTKIN: I guess it's the first one.

CHAIRMAN BOCCHINI: Coleen?

DR. BOYLE: I was just going to say the same thing. I think they need to be reworded in light of that.

CHAIRMAN BOCCHINI: Okay. All right.

DR. COPELAND: So from a programmatic standpoint, we need to know what level of support and what you're asking for in order to reword them, or else it'll have to wait till the next advisory committee meeting to be voted on.

CHAIRMAN BOCCHINI: We can stop there. That's the one, right there.

DR. BOYLE: So I would make a proposal, and that is that over lunch we reword them and then come back. Does that sound like a reasonable thing?

CHAIRMAN BOCCHINI: Okay, if everybody is in favor of that, that sounds reasonable.

DR. COPELAND: I ask that the Federal ex officio members, if that will allow you enough time to consider this?

Alan?

DR. GUTTMACHER: It probably needs a lawyer who's sitting in there.

DR. COPELAND: But it is not a trivial question, because they are expected to represent

their agency.

DR. KELM: Are we talking about action of the Secretary or are we talking about --

DR. COPELAND: Yes.

DR. BOYLE: We haven't talked about that.

DR. KELM: Okay. Because I don't know if we need to get a sense from entire group on what way we're going to take it, before we start wording it.

DR. THERRELL: So Sara had asked me earlier how I would see this going down. And I said, to me it's a letter, you know, this one, this particular one is the Secretary says to NCHS, you need to think about -- you need to put this serial number on the standard certificate of live birth.

The other three are basically a letter from the Secretary to the states, saying these are important issues and you need to be addressing these in your state. I mean to me, that's what -- that would be what I would see the Secretary doing.

DR. COPELAND: So you would say this would be a recommendation that the Secretary take

action on all four?

DR. BOTKIN: But that action would only be to raise the profile of the issue at the state and not to have any sort of administrative or legislative action.

DR. COPELAND: Exactly.

DR. BOYLE: So speaking for my agency, since one of them does involve our agency and we have already talked, but we haven't briefed the directors, so I would have to clear that.

So I would say that we revise these accordingly with your guidance and present them to you either before next meeting for your comments. But now at least you're all briefed on it.

CHAIRMAN BOCCHINI: Okay. If that sounds reasonable, then we would then revise them, distribute them, and postpone a vote until next meeting.

I'm sorry, Brad.

DR. THERRELL: Yes, we'd also like permission to move forward with this paper because every time I do it, it's old data again. So we'd

like to go ahead and get something out.

DR. COPELAND: What is the title of the paper? Because that's --

DR. THERRELL: The title of the paper is Improving Data Quality and Quality Assurance in Newborn Screening by Including Blood Spot Serial Collection Device -- Serial Number on Birth Certificates, whatever.

DR. COPELAND: As long as it doesn't reference that it's the Secretary's recommendations, then you're okay.

DR. THERRELL: It's not recommendation, right.

This is a committee product though, it's not just my product. It's Coleen's product.

DR. COPELAND: So then you'll have to go through CDC clearance, so as long as it doesn't say it is advisory committee product --

DR. MATERN: So this paper is in the documents that we -- on the server or -- I can't find it.

DR. THERRELL: It should be in the

briefing book.

DR. COPELAND: Tab six.

DR. DOUGHERTY: It does say it's from the long-term follow-up subcommittee of the Secretary's Advisory Committee, so then --

DR. COPELAND: Yes, that's problematic. That can't be in the title until it's been voted on at the very least.

DR. DOUGHERTY: But weren't we going to vote on it, wasn't that the vote today, to vote on the paper?

DR. BOYLE: It has to be postponed.

DR. BOTKIN: So where are we with this now? We were going to revise this over lunch and bring it back?

DR. COPELAND: But the ex officio members need to run it by their agency heads. So we will revise it, and we will have you vote on it, but it just won't be done today because of the revisions and the fact that it has substantial implications.

CHAIRMAN BOCCHINI: All right.

DR. THOMPSON: Or would it be useful for

us still to do the revisions today so that the different agencies that are requesting know exactly what they're requesting? Does it work, still doing the revisions today, even if we don't vote on them?

CHAIRMAN BOCCHINI: I think if you want to discuss, I mean I think it's going to take a little time to do the revisions, so I think that maybe it would be best to do the revisions offline and then send them to the committee members for their review and response, and come to a consensus, so that then we can go to the Federal partners and have them specifically work with their agencies for approval? That sounds fair? Okay.

DR. BOTKIN: I'm still confused. Do the other agencies have to approve this for publication purposes or do they have to approve it prior to the time that this committee could make a recommendation?

CHAIRMAN BOCCHINI: Well, I think we're talking about two different things. One is making recommendations to the Secretary that have this potential impact before the agencies can decide on

whether to come in. I would guess based on what we have, that the agencies could vote on recommendations as they stand. We've decided that we're going to modify those, the recommendations, and therefore they need to see the modifications and consider those with their agencies before they would have the opportunity to vote.

Is that correct, the way I'm stating that?

DR. DOUGHERTY: There's an elephant in the room, I think.

When the Secretary gets the recommendation, she turns it back to something called the interagency coordinating committee on whatever, newborn screening or whatever. So then it comes back to the rest of these agencies here to try and tell the Secretary whether she should follow through. And if she's going to follow through, some options for how she does that.

So the recommendation has implications for us, the ex officio Federal agencies here.

DR. COPELAND: The other option is the ex

officios would have to abstain. And there is enough people otherwise to vote if you want to go forward and vote on this.

DR. BOYLE: That is the other option.

DR. COPELAND: Yes, that is the other option from a procedural standpoint.

DR. DOUGHERTY: And are there enough people?

DR. COPELAND: Everybody's here.

CHAIRMAN BOCCHINI: Steve?

DR. MCDONOUGH: It seems to me that the language change is just a formality; we're just changing the Secretary for our committee, which is appropriate if we do that. But that general concept I think we all understand. And if we send a recommendation for the Secretary, she can either accept it or not based on what people think. So I don't -- if we postpone this to May, we're just setting it back another 4 months, and to me it doesn't make much sense.

DR. THERRELL: Yes, I would agree with that. This is actually coming from the

subcommittee, therefore, it says, the SACHDNC should. If it comes from this committee, the next step would be the Secretary should.

CHAIRMAN BOCCHINI: I would just need it in the form of a motion to accept this with modifications as -- go ahead.

DR. BOTKIN: I would second. I'll second.

[Laughter.]

DR. MCDONOUGH: I will move that -- I'm comfortable level one and all four.

DR. BOTKIN: Second.

CHAIRMAN BOCCHINI: All right. Is there any further discussion?

DR. LU: Let me just, you know, I'm new to this, but I just think that if we're going to be assigning a national ID to every single -- I know our agency would have a lot of questions about the potential impact on privacy. I just want to make sure that there's enough strings around issue, especially for certain subpopulations, undocumented immigrants, racial/ethnic subgroups which weren't -

- I don't think have been adequately addressed.

So, yes, I think if we're doing that today, I don't think I could adequately represent my agency.

DR. THERRELL: So my comment would be it's not a national number, it's a state number, and it's a state number that already exists.

CHAIRMAN BOCCHINI: And I think the recommendation is that the Secretary make the states aware of this and so that they can consider this as a method.

DR. THOMPSON: Michael, can you clarify the -- I'm trying to envision exactly the scenario that you're raising. Why would adding this number, assuming that this number is not tied to actual results, there's already a birth certificate that already has been generated for that baby, why would adding the number cause additional concerns for someone who's undocumented?

DR. LU: Well, you're adding a kind of ID number to a dried blood spot --

DR. BOYLE: So the number is on the blood

spot that you put on the birth certificate.

DR. LU: So the proposed action was putting it on the birth certificate which could then be traced back to the newborn.

DR. THERRELL: See, right now, in every state, there is a database of some sort on the newborn screening specimen which has a serial number. And in some cases, it may even have, as we've seen lately, the Social Security number. And so the issue has been on the listserv, what do we do with these states that are using Social Security number? This is a way out for those states in a way because they can use this serial number and not have to use the Social Security number, although some states just use the last four digits.

DR. COPELAND: But I think that it underestimates the concern about residual blood spot because I think that there is still -- there are other issues, as Dr. Lu pointed out. It's not simply a matter of a number and birth certificate linking, and Dr. Lu is saying that he's concerned that there are other implications that we're just

not aware of.

And anyway, I understand what this concept is, and I understand where everybody is coming from, being a former medical director, but I think that Dr. Lu was just raising a concern from his point of view, that there are probably unanticipated consequences.

DR. THOMPSON: All right. I just want to understand what -- I'm trying to do the scenario where that would be a concern and just for educational information. I just wanted to understand what kind of concerns have been raised about this.

DR. LU: Right. And really all I'm asking for is kind of more information. The perception of certain parents and certain subgroups, they may be particularly sensitized to this issue.

MS. WILLIAMS: Is there a way to use a number that's not related to the blood spot? I mean we're actually --

DR. THERRELL: See, that's what's

happening now, they're using probabilistic matching which sort of creates another number in a sense, maybe alphanumeric or whatever. And that's what happens, that you create that and then you try to do those kind of matches, and it's difficult to do. And this is the simple solution. And the number is there. I mean, every blood spot has a number on it.

The bigger question is, what about those babies get two and three? And so if you read this paper closely, it says take the initial number, not the second and the third. I mean those may be linked somewhere down the road but we really want to know initially, was that baby screened and whether they're screened timely and is there anything we need to do if they wasn't.

CHAIRMAN BOCCHINI: Okay, we have two from the audience, Nancy and Anne.

DR. COMEAU: People seem to be getting hung up on numbers, and the reality is, is that the birth certificate has a name and the newborn dried blood spot has a name, but those names are often

not matchable. And so people I think we could agree that names tend to be more identifiers than some random number.

And so this is really about facilitating that match. And whether it's a number or name, I don't know if that helps you to think about this. The birth certificate has a name, the dried blood spot that comes in has a name. We try to make sure that every baby with a name on the birth certificate -- in the vital records has a blood spot, and the only way we can do that is by matching names, and names and addresses and things like that. And when you try to read the printing on the blood spot, when you see how people misspell names, it gets kind of crazy. So it's really a number. I don't know if that helps.

CHAIRMAN BOCCHINI: Nancy?

DR. GREEN: So, Brad, you've obviously done a lot of work with NCHS and with NAPHSIS, and I'm just wondering whether it might be helpful in the committee's deliberations, and their potential concerns, if there's some sort of official

correspondence from each of these other agencies with which you've worked to understand their position, because really we're recommending part of -- as a part of their function.

DR. THERRELL: So, initially, I met with the executive director of NAPHSIS who was getting ready to retire. He was in favor of it. So then we waited till he retired and met with the new one, and in the meantime, he's sent it to the board and the board sent back a message that it was fine. Then the new director came in, she didn't know he'd sent it to the board. She sent it, requested to the board and the board says we already saw this, and we thought it was fine. So we didn't -- they offered to send us something if we really need it.

So, at this point, Jeff and Coleen and I were on the phone with them actually talking about this.

NCHS, as well, they said they really didn't have a concern. If we thought we needed it -- and we thought, maybe naively, that the conversation that the three of us heard would be

enough to satisfy you. If it's not, we can get those letters. It's not going to be difficult to do. And if you feel like that's something that you would like to have before it goes out of here, we can handle it.

CHAIRMAN BOCCHINI: Carol, did you have a question? No?

Oh, I'm sorry, we have one more here.

MS. BUJNO: My name is Lisa Bujno, I'm from New Hampshire. I oversee the newborn screening program there. And we've been doing the probabilistic linkage for I think 5 or 6 years now. We're a very small state with under 15,000 births a year, but we do it every day. And it does take a little bit of work to match.

So, on the one hand, having the number on both of the documents would be helpful in terms of staffing resources to make that linkage easier. On the other hand, New Hampshire is the live free or die state and known for heightened concern related to privacy, and I have had conversations with some folks that have expressed, while they're fine with

that kind of linkage, I think having a number that link the two and make any future kind of connections easier might be a greater concern to them.

CHAIRMAN BOCCHINI: Thank you. Carol?

DR. GREENE: Two questions. One is probably for later that has to do with the process, and it's very interesting to watch the dynamic and the effect of a vote on anything going to the Secretary with the ex officio members voting. I have been on one -- I've actually been a member of one other committee, CLIAC, and the ex officios don't vote, and I was staff for SAGUS and the ex officios don't vote. They're there to provide -- anyway just a topic for future discussion.

What I wanted to say about the privacy issue is I have a close link to some members, there's a very -- there's actually a privacy community. And therefore, when I first heard about this and thought that it was really scary, I took it back home and was told it's really not an issue, because it's all information that is already

existing. It's not a national identification.

I got an earful about how the Congress has shot down an attempt at a national identifier, but when I talked to some of the people who were involved in that process, they just -- this is different from perception, it's different from what we just heard about New Hampshire, and what's been raised, but the true experts in the privacy community think this is a non-issue.

I shouldn't say I'm actually speaking for them. I'm interpreting what I heard.

[Laughter.]

CHAIRMAN BOCCHINI: Denise?

DR. DOUGHERTY: So maybe I've been watching too many presidential debates and reading too many other documents about what can happen with retained dried blood spots. And they can be used for law enforcement purposes.

So depending on how the immigration debate goes, and it just -- maybe I'm paranoid, but I'm tending to lean -- I think -- I guess what this is coming out to is that the paper perhaps needs to

go into the pros and cons of doing this.

No? Okay.

CHAIRMAN BOCCHINI: Okay. Let's go to Carol, then Jeff.

DR. GREENE: I think perhaps it might be possible to point out, Denise's comment made me realize that link can always be made. Okay? Having the number makes it easier and faster, so that you can monitor newborn screening. It doesn't change the fact that, and we did this in Colorado because we actually had to answer the question, are all the babies being screened? And we did it, no matching deterministically, and then we did it probabilistically, and then we did it by hand. That link can be made.

Nothing changes the fact that the link can be made. We got names, we got addresses, we got birth dates, we got lots of stuff. Putting the number on there doesn't mean that the link can be made; it means that the link can be made in a timely fashion to monitor newborn screening. The link can be made. This doesn't create the link.

CHAIRMAN BOCCHINI: Thank you. Okay. Who else? There was one more -- Jeff.

DR. BOTKIN: I just see this as a way of improving the efficacy and efficiency of health departments, and to a certain extent, if we don't like health departments are doing, that's a concern about privacy. But if this is a good set of activities we're doing, then I don't think the privacy issues are even on the page.

And I guess I don't understand the connection with the dried blood spots. I see that really as a very different issue. I mean they're being saved or not saved independent of whether we can do this kind of matching in a more effective way. So we shouldn't link it. I mean we want to stay away from that because --

CHAIRMAN BOCCHINI: Okay. So I think we have to keep in mind that this is something that is being done at the state level, and I think Don's comment earlier is appropriate, that as we think about this, each state might have a different solution, but if we go with this as a

recommendation for this as a potential solution, that makes sense.

And I think that's the modification that we're talking about.

So we have a motion on the floor, a second, and we've had our discussion. So I think if there's no other questions and discussion, we'll go move to a vote.

So, first, is there anyone who is planning to abstain? So we have. Okay.

So let's start in the middle this time.

DR. COPELAND: Fred Lorey?

DR. LOREY: We're voting yes on number one, and is that how it goes?

CHAIRMAN BOCCHINI: We're looking at all four together, is what's on the table. Let's vote level one. Level one, I'm sorry.

DR. COPELAND: The motion is to amend all the recommendations to say, instead of the advisory committee should, that the Secretary should, and do all four of those with the idea that there will be action taken on all four.

DR. LOREY: I vote yes.

DR. COPELAND: Okay. Steve McDonough?

DR. MCDONOUGH: Aye.

DR. COPELAND: Charlie Homer? Charlie?

[No response.

DR. COPELAND: Dieter?

DR. MATERN: Yes.

DR. COPELAND: Jeff Botkin?

DR. BOTKIN: Yes.

DR. COPELAND: Joe Bocchini?

CHAIRMAN BOCCHINI: Yes.

DR. COPELAND: Cathy Wicklund?

MS. WICKLUND: Yes.

DR. COPELAND: Alexis Thompson?

DR. THOMPSON: Yes.

DR. COPELAND: Andrea Williams?

MS. WILLIAMS: Yes.

DR. COPELAND: Don Bailey?

DR. BAILEY: Yes.

DR. COPELAND: Charlie, are you on the phone?

Dr. HOMER: I'm here. I need to abstain.

Thank you.

DR. COPELAND: Okay.

So there's no "no" votes, so the ayes have it. It will go forward.

CHAIRMAN BOCCHINI: All right.

Okay. And so we'll modify the wording and have the committee review that.

DR. COPELAND: Actually there's no mechanism for that, so I'll --

DR. THERRELL: So question. In the paper, can we modify the wording and now put this out as a recommendation from the committee?

DR. COPELAND: Yes, you can.

DR. THERRELL: Thank you.

CHAIRMAN BOCCHINI: All right. Thank you all.

All right, so we're going to now break for lunch. We're a little bit, behind but we still need to get back here at 1:15 so that we can get through the agenda on time, so people can catch flights. So, 1:15, we're going to reconvene. Thank you.

[Recess.]