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INTERAGENCY AUTISM COORDINATING COMMITTEE

SUBCOMMITTEE FOR
BASIC AND TRANSLATIONAL RESEARCH

STRATEGIC PLAN QUESTION 7 PLANNING GROUP

WHAT OTHER INFRASTRUCTURE AND SURVEILLANCE NEEDS MUST BE MET?

THURSDAY, SEPTEMBER 20, 2012

The Strategic Plan Question 7 Planning group convened via a conference call. Thomas Insel, *Chair*, IACC presiding.

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PROCEEDINGS:

Ms. Gemma Weiblinger: Hello, everyone. My name is Gemma Weiblinger, and I am temporarily acting as designated Federal official for Dr. Susan Daniels, who is currently out on maternity leave.

Welcome to IACC's conference call to discuss the update to Question 7 of the IACC Strategic Plan: What other infrastructure and surveillance needs must be met?

I will now turn the meeting over to Dr. Thomas Insel, who will lead the discussion.

Dr. Thomas Insel: Thanks, Gemma. We should find out who is on the phone with us. So here in Bethesda, we have?

Ms. Weiblinger: Gemma Weiblinger.

Dr. Elizabeth Baden: Elizabeth Baden.

Mr. Dan Hall: Dan Hall.

Dr. Roger Little: Roger Little.

Dr. Insel: And myself, Tom Insel. And I heard Alison Singer.

Ms. Alison Singer: I am here.

Dr. Insel: Who else do we have?

Dr. Catherine Rice: Hi, Cathy Rice is here.

Dr. Insel: Hey, Cathy. Good to have you. Anyone else?

[No response]

Dr. Insel: Okay. We're missing -- so we're missing -- so we know that Geri Dawson, who is also on this group, has a conflict and is not going to be able to attend.

Donna Kimbark, who would be our organizing person, is not here, but that's okay. We'll go ahead without her. And the only other person -- and I think that is it. I think we've got a full group. That is great.

And we have got -- again, this is a call that is open to the public. So it's part of our FACA approach to make sure that everyone has a sense of what the process is for updating.

So, in the absence of Donna, let's go ahead and kind of rock and roll on this particular question. Let me start by saying that the IACC has as part of its reauthorization of the charge to give an update every year. That would mean we have to have an update by the end of December. So for those of you who are our external advisors, which

would be Cathy, Dan, and Roger, we had -- the IACC met in July and decided that to do this update by the end of December since this was our first meeting since being reauthorized. And we are a little bit behind the curve.

We are just going to focus on two parts of each of the seven questions: the part that has to do with what do we know and the second part on what we need. And we would just essentially use this update to capture the big findings, what happened, and in this case what may have been built or developed since January of 2011, when we did the last update. This particular question was added to the Plan a little late. So it wasn't in the original version. Parts of it were. And then it got added. And it was a little bit of a "reorg" that has put several things together.

So this one is a little less dramatically organized than some of the earlier ones, but I think you will see as we go through it that we can quickly tackle some of the main pieces of it. And the three of you as our external folks are going to be very helpful covering most of that. I think

there are a few pieces that we are going to have to maybe reach out further to get information about.

Our hope here, just to be really concrete, is that we put together a brief summary, "brief" being maybe 1,000, at most 1,200, words on what do we know and what do we need, so two separate sections. That is based on what is in the Plan, takes into account an update that was done in 2011 because this was addressed already last year -- I'd say technically almost two years ago, but it was published in January 2011 -- and gives a broad audience a feel for where are we currently. And we will be making progress on where are the continuing gaps. Well, what are some new opportunities that may have emerged in the last couple of years?

And to the extent that it's possible, we want this to be quantitative. We want to actually hear about what has been done. So if we are talking about biobanking -- how many brains, how many cells, how many DNA samples -- just, you know that level. Where are we in October of 2012?

We will as a group put together a document that provides this summary. And then we want to take that to the October 30th meeting of the IACC Subcommittee for an airing -- you know, let them hear what we have put together. They will make some comments back to us about where it works, where it doesn't work, what is clear, what isn't. They may have some additional ideas or know about other things that we didn't cover. We'll incorporate those comments. And then our work is mostly done. It goes to the full IACC thereafter, have a few weeks to make final corrections, and then we have done our update. So that is the basic process.

Let me see if there are questions or, Alison, if you have anything to add about what the task is here.

Ms. Singer: No, that was an excellent summary.

Dr. Insel: Okay.

Ms. Singer: The question I had was just a general question -- that we have been calling this the 2012 update -- but is it actually the 2013 update? Because normally when we publish the Plan

in January, we publish it for the new calendar year. Have we been referring to it as the wrong year?

Dr. Insel: Well, let's see. You're right. I mean, the 2011 update of the Plan was actually published in January of 2011, wasn't it?

Ms. Singer: Right.

Dr. Insel: Yes. But we wanted to have this submitted by December of 2012, partly because we didn't want to lose a year, although technically we lost all this time in the reauthorization process.

But what we will be covering will actually be all of the new information from virtually the entire year of 2011 and almost the entire year of 2012. There will be things I'm sure that will happen in November and December that we might miss.

But, for that reason, it feels to me like it's the 2012 update, but you are right in the sense it is probably not going to be printed until 2013. So maybe what we will do is kind of recalibrate. When we do our update for next year, it will be the

2013 one.

Ms. Singer: Okay.

Dr. Insel: But, Cathy, Dan and Roger, any questions about what our task is?

Dr. Donna Kimbark: Excuse me. This is Donna.

Dr. Insel: Oh, great. Welcome.

Dr. Kimbark: I was in listen-only mode. I apologize. I couldn't get on as a participant.

Dr. Insel: We have thought that might have happened. We have had problems with that in other calls. So would you like to take over from here?

Dr. Kimbark: Sure, sure. I'm not exactly sure what was going on because I was frantically trying to get on as a participant, rather than a listen-only. So I apologize if I repeat anything or anything. I thought that you were talking about when the year is and all of that as far as that is concerned.

Dr. Insel: Yes. So what we have done, Donna, so far is to run down what the task is, --

Dr. Kimbark: Right.

Dr. Insel: -- which is what has to be done before October 30th. And, essentially, all we have

said is that this is an update of the two sections -- that we could be rewriting the plan itself but just doing -- we are trying to capture what has happened since January 2011, especially anything that is truly substantive and that we would like what we put into the update to be quantitative so that when we do the next version of this next year, you can see if there has been movement or not.

Dr. Kimbark: Right. That sounds like a great idea. So let me just get my thoughts together here. What we have already discussed, I think, is that we are updating, rather than revising. So I had sent out a little bit of that information as a Word document just so people could take a look at it and get an idea of what has been published in the past, as in the Strategic Plan in the past.

Now, one of the things that [Inaudible comment] I took part of that Strategic Plan and kind of bordered some of you in some of the points that the Strategic Plan itself is, of course, the document that you should go to as the most recent that is there.

But if you look at the summary document as well, you see what the initiative for it in the past and what the identified gaps were as well.

And that was done again in 2011 overall as far as the updates were concerned. So has anyone taken a look at that and gotten an idea of essentially where we are now as [Inaudible comment] goes and how we should go forward?

Dr. Rice: This is Cathy. I have looked at it and have the advantage of having worked on it last time. So I may have a few questions and others.

Ms. Singer: Same with me. I was going to comment that in this particular chapter, I think there is actually good institutional memory here. Cathy and I wrote the original section. And then last year, we wrote the update.

Dr. Kimbark: Can you tell me who you are, please?

Ms. Singer: Oh, this is Alison. Sorry.

Dr. Kimbark: Thank you.

Dr. Rice: And Cathy Rice.

Dr. Kimbark: I didn't know if you were going to be able to make the call. Okay.

So there is good memory on it -- so when you look at where we are now, you know, in our scientific advancements and community advancements overall and you look back at the question and what was identified as what we need to do, where would you like to go next? I think that's one of the things that it's the next 2012 update really has to identify because in the past, it identified two to three areas under -- you know, each one of these areas under like biobanking and data-sharing biobanking, surveillance, and information and communication dissemination. So do you want to go through them one by one, these issues, and see if there are issues there, or do you want to do something else?

Dr. Rice: I guess a quick question. If I understand this right, we should be thinking about writing it as a separate section again.

Dr. Kimbark: Right. It's not going to be merged in with the rest, from what I understand.

Dr. Rice: Right, okay. So we may, in essence, be saying some of the things that are still needs that were noted in 2011?

Dr. Kimbark: Yes. I mean, we can approach how we write it so that it's not repetitive. We can just say in 2012, these are still areas that have research gaps and whatnot.

Dr. Rice: Um-hmmm. So I mean, I am wondering, with the expertise on the Committee, if we should divide up and take different sections and --

Dr. Kimbark: That is what I was thinking would be the best, but I also wanted to do a tiny bit of time to brainstorm if there's anything else that should be added to this section before we just suddenly start, you know, doling out the responsibilities, because it would be nice to know if there is something else that also has to be added to those responsibilities first.

Ms. Singer: Well, the only thing that I would say -- this is Alison -- is that, you know, I think the way this chapter is laid out actually really lends itself well to updating because it is really written in very distinct chunks. And I think there has actually been clear movement over the last two years in each one of these areas. So I think this chapter might be one of the easiest

to update.

The one thing that came up yesterday -- and, Cathy, you were on this call as well -- is we had the Services Subcommittee call to start planning.

And they started to talk about services research infrastructure, which is something that had never been included in Chapters 5 and 6. And while they were talking about infrastructure, I was sort of thinking, "Well, should their infrastructure needs, would infrastructure needs for Chapters 5 and 6 be included in Chapter 7 so that it is sort of seamless?" And that is something that we only touched on briefly when we talked about research workforce development.

We talked a little bit about training. But we might want to try to bring someone from that Services Subcommittee onto this Chapter 7 to see where it makes the most sense looking at the Plan overall to include infrastructure needs for services research.

Dr. Insel: Alison, this is Tom. I think that is a really good idea. There is a much broader conversation going on nowadays in the research

community about how we move from, for instance, claims data to the data that's linked to electronic medical records. This isn't with respect to autism but across the board. And we have had some barriers in being able to do that.

It is not so simple. And we might want to think about how in the section that deals with data-sharing gaps or data needs the importance of getting beyond our current state, which at best is claims data.

I know that, for instance, David Mandell, who, is on that services group, has been thinking a lot about could we create a national Medicaid waiver database that would allow somebody to not have to go state by state to get a sense of what is going on. That may be largely claims data. And if you could think about how you could link that to medical records, you would have a very powerful platform for interrogating what actually happens to people with an autism diagnosis. So that may be something to build into this that we didn't think about last time.

Dr. Rice: Yes. This is Cathy. I would

definitely agree with that and the efforts of not only, like you said, getting beyond the claims database of trying to increase the consistency and quality of what is put into medical records. You know, SAMHSA recently did a review of trying to come up with autism screening clinical indicators and concluded that, really, at this point, as we could have guessed, there is not a short enough, well enough validated consistent screening tool for autism that could be recommended to be a standard clinical indicator as in screening for drug and alcohol abuse, for instance, or depression screening.

But there is definitely interest in that, but there is emphasis on developmental screening in that we may be further ahead there. But thinking about how inconsistent the use of instruments are, the collection of those, there is a lot that could be done in terms of the infrastructure on that clinical indicator part as well.

Dr. Insel: Right. And, just to take that one step further, Cathy, where we are going in a lot of areas -- from *The New York Times* this morning,

in fact -- there are common data elements in creating these standardized platforms for how we define various clinical indices. That has happened in pieces of the autism community but not broadly.

We have been talking about is this place where it is time to actually put in the kinds of common element structure that allows for much better screening, much better diagnostic standardization, much better follow-up so that you can compare across many different sources to be able to aggregate data in a way that makes more sense.

So you know, we have a whole thing in here about data-sharing initiatives, but if the data are not interoperable, if they're not in the same format or standardized in some way, doesn't matter how much you have. You still may have difficulty aggregating it.

Mr. Hall: I do think we made progress in that area in that, you know we require all of those that –

Dr. Insel: this is Dan Hall.

Mr. Hall: -- all of those that are obligated to share their data through the National Database

for Autism Research. We have a standardized data dictionary out there that they need to harmonize to. And we have a lot of capabilities for bringing all of that data in and validating it all. And, you know, we have also rolled that out with our partners of Autism Speaks and Simons. We are now working at the Simons Foundation to incorporate their data definitions in.

So I think we are really there. You know, we have defined over 400 measures, which equates to about 40,000 specific data elements being captured in the field or now defined, and it's out there online in our data dictionary.

Dr. Kimbark: Dan, this is Donna -- I want to ask a question about that, but those are mainly for people that are doing research, right, that's funded through certain organizations. Is that correct?

Mr. Hall: Yes. It's the NIH Autism Speaks and the Simons Foundation.

Dr. Kimbark: Oh so, we have actually, the DOD actually, made a requirement for our CTAs, our clinical trials, to actually go into NDAR as well.

But the one thing that I want to point out, though, is that those defined points that you make a point about, I mean, those definitions are great and all in your dictionary and all of that. That is all great, but will it be translated to what we were talking about before, common data elements for across state and for more privatized types of diagnosis and validation?

Mr. Hall: Umm. You know it is extensible to include any definitions. So you know we do support others that come up with a new measure, a new assessment -- to find that and incorporate that.

You know, we can incorporate, you know, services, potentially, services-based definitions as well. You know, we haven't done that.

We have really -- you know -- our objective in this question was to share 90 percent of all data, research data, out there. And this is how we are doing it. So that 90 percent, which we are making very good progress against, does have definitions defined. And when new research begins, we negotiate that with the researchers to give us those definitions so we can work toward one

harmonized standard.

Ms. Singer: Let me just add this. This is Alison. Your team does a great job with that. Gretchen works directly with our grantees when they begin to get that all loaded in right from the start.

Mr. Hall: Yes. And, you know, so we -- I guess in the update section, we expect and have very specific terms for data sharing. And they must conform -- the researchers must conform, to those definitions to bring that data in. And we think we have a pretty good way to harmonize and have harmonized across a number of data sources.

Dr. Insel: It sounds like we are getting into the first part of this data sharing. Donna, can we go ahead and plunge into that section?

Dr. Kimbark: Sure, if you want to. Sure. That sounds fine. I am taking notes as we go along. Okay. So you want to go into the 2011 update that went into the AIC as setting of a goal of accelerating scientific discovery by making informatics tools and sources and resources more useful and usable and --

Ms. Singer: I'm sorry, Donna. Could you move closer to the phone? It is really hard to hear you.

Dr. Kimbark: Sorry, sorry. Hold on. Let me try to get rid of some of this background.

So we have been talking about the consortium, that could be informatics consortium and the current members, and we were charged with identifying information to acknowledge these solutions, major informatics frameworks, and developing standards in the field. And then we end our update. And I think we just got an update right now from Dan. So I think that that's good.

So does anyone have anything they want to say about the consortium or where we should go further with data sharing?

Dr. Insel: This is Tom. I guess that if the original short-term goal from 2010 was to create mechanisms to support the contribution of data from 90 percent of newly initiated projects, it would be good to know where we are at with that.

Mr. Hall: Sure. So we've instituted a program here at the NIH, where there is nary a grant that

goes out that does not have specific data-sharing terms in it. I think we are up to 130 human subjects grants that have explicit terms which are available. We can send out the link in our Website what those terms are and when that data is shared.

We are up to now, at least at the NIH, we are up to data on 25,000 research subjects, which is a pretty significant amount. We have a release coming in November that is probably going to put that up to about 35,000.

We are federated, which means you can go into NDAR and query into the NIH data as well as the Autism Speaks AGRE repository. Those that have consented in IAN, I think, were over 9,000 subjects there -- the Autism Tissue Program. And we are now working with the Simons Foundation to federate with them. So all told, that is about 45,000 subjects available today. So that data is out there and "queryable," oh, and we did an interface where the public can see in summary that data. If they go to the NDAR Website, they can look and query against it. And we are continually updating and creating new tools to make access to

that data here.

Dr. Kimbark: So do you have any ideas about respect -- with respect to -- You said you about 40 to 45 thousand subjects who are within the database and that is with respect to how many of the population of research subjects that are out there as well as, are these all standardized according to your definition?

Mr. Hall: Yes. All that data is harmonized to that data definition. You know, I won't --

Dr. Kimbark: Okay, so do we know how many are still lingering out there that you should be -- to be -- that are being placed within this realm?

Mr. Hall: Yes. Well, as the NIH funds more grants, those terms come in, and we bring them into the pipeline. So you know, essentially these are five-year grants. So it takes five years to get the entire NIH portfolio with these terms in it to ensure that that data does come in, but I think we are well on the way.

Dr. Insel: Donna, are you asking, of these --

Dr. Kimbark: I’m asking what the compliance is, actually.

Dr. Insel: Okay. So out of the universe of research subjects with an autism diagnosis, how many are in NDAR?

Mr. Hall: Ummm.

Dr. Kimbark: It was in the one, you know, you can do this data sharing with. I mean, I know that you can't do it like overall, everybody in the world, but --

Mr. Hall: Understood.

Dr. Kimbark: -- the ones that you had some control over with the granting process. Are they all compliant, or what is your compliance?

Mr. Hall: Yes. So you know it’s a difficult number. You know, on the grant application, we get a targeted enrollment. And so you know our targeted enrollment is about 70,000. So we're probably about 50 percent there. And that number, you know, over the next five years, certainly will get to that number and likely far exceed it. So right now in the NIH, you know, the target enrollment is what the -- when the grant application comes in, how many subjects they expect to enroll. And that number is about 70,000.

Ms. Singer: So Dan, this is Alison. I am wondering if you think that at this point in NDAR's life cycle, it would be appropriate, in addition to reporting about data contributed to NDAR, for us to start to report on use of the data in NDAR more than outcome focused and the input focused.

Mr. Hall: Understood. And we are certainly focusing on that. You know, we have had, you know, some of the data that is -- you know, I mean, some of the publications that are coming out now will, you know, reference back to NDAR. We have a paper out, and there are a few papers that are in progress on those findings. But we can reach out and update the group on those topic areas.

Dr. Kimbark: That would be good because maybe that is one of an initiative. You are at 50 percent, and you are hoping to get a higher percent of compliance within the next years or so. I mean, that could be an initiative to see that NDAR is actually used as a resource.

Mr. Hall: Absolutely. And we are doing a number of things, you know -- NDAR as well as all

of the other repositories out there. And we are doing a number of outreach efforts to facilitate that, but certainly educating the research community to use this resource is a major part of our mission. And, you know, we --

Ms. Singer: But in terms of the update, I think that is where we need to really focus now --

Mr. Hall: Yes.

Ms. Singer: -- so that it is not just a repeat of -- you know -- it is not more and more data in, which isn't that great, but, of course, it is great.

Mr. Hall: Sure.

Ms. Singer: But now we have to start to focus on the value of the data, particularly for NDAR since it's the publicly funded base.

Mr. Hall: Absolutely. Absolutely, and you know, I guess one of the things that I wanted to bring up in this meeting is on the research workforce development, which is a part of the Plan –

Dr. Insel: Why don’t we get there later because I don't want to get us too far off the

track -- just so as we round this off, but in terms of the data sharing, the other piece besides talking a little bit about the output. So anything you can put in there -- for instance, --

Mr. Hall: Sure.

Dr. Insel: -- from what you know about the use of the data -- would be great. But I think it would be useful to get a little more specific about what data are actually there.

What are we talking about is it clinical data, genomic data, imaging data? What did we have in January of 2011? And what do we have in October of 2012? So you can very quickly -- within one paragraph and maybe even a little table -- just summarize how far we have come and then also give people a sense of now that this is built, already in the last 18 months or 19 months, whatever it is, what has been used. And if there are any publications or new analyses or anything you can point to and outcomes of having built this, that would be great.

Mr. Hall: Okay.

Dr. Insel: Are there any other issues around

data sharing, Dan that we aren't thinking about that need to be included in an update, something that has happened since January of 2011?

Mr. Hall: Yes. I mean, we have a facility now, and we are trying to encourage the researchers to use, to associate the publications with the specific data. And we have a capability in sort of the data that drives from PubMed right to the data. And we are trying to encourage the scientists to use this facility for result replication and a more specific understanding of the results, because the data would be right there. And we have that capability now available.

Dr. Insel: Okay. And that actually addresses this business about the need for replication studies. Though, we don’t have -- as far as I know, we don't have a funding mechanism for that, it is good to know that we have a tool that can address it.

Anything else, Donna, on data sharing that we need to be thinking about?

Dr. Kimbark: The only other thing that I heard while we were talking for the data sharing was Dan

said something about other repositories, should we address that or not? I mean, we're talking mainly about NDAR, but we are not talking about anything else as far as data sharing is concerned.

Mr. Hall: Ummm.

Dr. Kimbark: I mean, should we consider that, okay, we have NDAR, should we be networking out to other repositories?

Ms. Singer: Well, I think this is where we should include what Tom was talking about before with regard to the electronic medical records and the new opportunities that have emerged to move beyond cleaned data. And a gap area that we should focus on is, really, as you were saying before, to look at the possibility of creating a database that would consolidate all of the state Medicaid data into one useable database. So I think that is where that could go, is in the data sharing.

Dr. Kimbark: Right. Okay.

Mr. Hall: Yes, and I agree. To connect those types of things, those databases together, would be idea. We, actually, you know, are connected to Autism Speaks, Simons Foundation. We are receiving

data from the State of New Jersey, Autism Science Foundation, Department of Defense. So you know, when we say NDAR, NDAR is really a portal to all of these other repositories. And it's not clear on our Website yet, but it soon will be that, at least for research data, it is quite -- you know, it incorporates many different repositories.

Dr. Insel: I wonder if this should maybe be put into a table for the update, just to show granting now because, as I recall, in 2011 or '10, NDAR was a silo. It wasn't really a portal at that point.

Mr. Hall: Correct.

Dr. Insel: So it might be useful to clarify this as just an entryway to get into all of these other data sets and to also describe the ontology that has been built that allows that to become useful.

Mr. Hall: Absolutely.

Dr. Rice: and actually -- the last update did also include other, like the Simons. And to see, be able to see, what the linkage to NDAR is would be really helpful and what other efforts may be

out there that are not yet linked to NDAR.

Something that comes to mind that will be in the future is the ICARE Network. I don't know what they were calling that in the application, one of the ACE networks, which is a multi-country registry, which has really been advanced since the last update of trying to harmonize many of the registries that already exist and increase sample size. That could be included here as well as I was wondering about the effort to make national surveys more accessible.

There is a data resource center now that can help with analyzing the national data sets, like the National Survey of Children's Health, National Health Interview Survey. And so that is more accessible and available, I think, and would be good to include also.

Dr. Insel: Yes. So anything like that that’s a great idea, I mean, any other opportunities there that could be linked in. I think what the original vision was, was that we would be able to tie together the universe of research projects.

And then what I am hearing from Alison is that

when we get to the gap, we should also think about other kinds of data sets that maybe wouldn't be in NDAR but we want to make available, particularly for people who are looking at the utilization of services or who want to do the science of implementation and dissemination.

Dr. Rice: And Department of Education is investing in linking early intervention and special education data sets and outcomes research, the type that Paul Shattuck has used those data sets. So you know, maybe thinking broadly about education, including education, too.

Dr. Insel: So Dan, are you comfortable in pulling together a paragraph for us that will kind of capture where we were, where we are, and where we could go with these two or three additional gaps that we are talking about?

Mr. Hall: Yes.

Dr. Insel: Anything else that Dan ought to put into that section?

Dr. Kimbark: I think that the next section, if anybody has anything else, I think the next section is the biobanking.

Dr. Insel: Right. Roger, do you want to take us through --

Dr. Little: Sure.

Dr. Insel: -- what is the state of tissue and samples?

Dr. Little: Sure. Can you hear? Okay. This is Roger Little.

Dr. Insel: Yes.

Dr. Little: Can you hear me okay?

Dr. Kimbark: Yes.

Dr. Little: Okay. So outside of the ATP, the largest collection of autism samples I am aware of is at the University of Maryland National Child Health and Development Brain Bank in Baltimore, Maryland. And they have about 42 samples there of brain. And then they have additional samples, about 19 others, in autism. They are categorized as autism related, so things like autism/Rett syndrome, autism/unaffected relative, autism/ -- let's see -- epilepsy, et cetera. So there's about 42 that are characterized as ASD and then these additional -- perhaps 19 or so -- with autism and then some other phenotype, including a suspected

or unaffected relative, one each of those.

Beyond that, I can say a few words, Tom, if you would like me to, about what is happening at NIH that directly bears on this that is new since January.

Dr. Insel: Well, so I think before we get there, if it would be helpful -- I don't want this to be NIH centric. I think to the extent we know about ATP, I mean, I would think that for the update, you would certainly want to mention the freezer failure that occurred --

Dr. Rice: Absolutely.

Dr. Insel: -- how that I hope sensitized the community to how fragile this collection was and how shallow this pool is.

Dr. Little: Yes.

Dr. Insel: A freezer failure in one place and the entire world of autism tissue banking is in jeopardy.

[Inaudible comment]

Dr. Insel: So that is a pretty amazing -- I mean, we are not in that situation for most other diseases that we study. So that tells you that we

have to do something very different than where we have been.

I would think that in the update, you would want to light a fire here, say, "We've got a problem." And wherever we were in 2010, we're probably worse off.

Dr. Rice: Yes.

Dr. Insel: Because of this freezer failure, we have to think about how to respond to this. You know, it is just astonishing that we are talking about a neurodevelopmental disorder. And, yet, the world's collection of tissue for the organ affected is so tiny; it's just amazing.

Ms. Singer: And this is the one area where we have regression. We have actually moved backward.

Dr. Little: Yes.

Dr. Insel: So I would capture that in this update and figure out a way to raise a flag here and say, "This has got to be a place where we would do something very different going forward."

Dr. Kimbark: So perhaps we should phrase it like something in an emergency response initiative or something like that, because I know that when

talking to my integration panel and when they were discussing what they should do about it, there were real questions about whether or not certain grants should be funded or not because of this issue.

Dr. Insel: You mean because the tissue wouldn't be available?

Dr. Kimbark: Yes. That is like a domino effect.

Dr. Insel: Yes. And then the other issue that we have heard from our grantees is that, even if, for instance, within the ATP, the tissue appears to be there, the quality isn't sufficient to be able to answer the main questions that people have.

Dr. Kimbark: Yes. I've heard that a lot, but I've heard that throughout the years, actually. So, there should be some type of, kind of, responses that we have gone backward, that we should go forward with talking about standardizations of bio-banking as well as getting more samples.

Dr. Insel: So Roger, what can we say? Has

there been any progress on that front?

Dr. Little: So yes. We are developing an initiative here at NIMH along with the Neurology Institute and Child Health to actively reach out to the public. And we have identified this as a serious gap and a need to educate the public about the need for donation. We're working on how to message this.

It is obviously a very delicate issue, especially when you are talking about a pediatric population. And we intend to -- in terms of increasing accessibility to these issues for investigators -- we are federating the brain banks that we currently support. So that there will be an essential IT Website for people to go to -- both investigators and the public -- for the investigators to put in a request for the issues for the public to learn about why we do this and what the need is and provide education about tissue donation for research.

So that is a main thing that we are focusing on that front. In terms of standardization, we are switching from a grant mechanism to contracts that

support our brain banks so that we can have greater control of how brain banking is done, tissues collected, processed.

I led a workgroup over the summer that included many of our instrumental brain bankers that developed a phenotyping standard for control subjects so that subjects that are characterized as control at different brain banks across the country will have a uniform way of being characterized so that a researcher getting controls from those different sites can have a fair degree of confidence that what they're getting has been similarly characterized and they can have high confidence in that tissue.

[Pause]

Dr. Kimbark: Is there a publication on your list?

Dr. Little: We have a white paper in draft form. And we are working on getting that out probably in the spring to coincide with our outreach and brain bank repository contracts, which will be first funded in fiscal year '13.

Dr. Insel: When we talked about this within

the IACC, there was an idea that this would be an ideal place for a public-private partnership with the advocacy community really spearheading the campaign and increasing awareness. Where are we with that?

Dr. Little: So I have been talking informally with Alison, who is expert, obviously, in communicating on these topics. And we are working together to kind of in a complementary way get out this message and reach out to the public on these issues.

Ms. Singer: Now, we are going to announce on October first that we received a two-year grant from the Simons Foundation to do a major recruitment, brain tissue awareness/donation project. It will be mostly done online, but there is also a print and radio component. It is really going to be a serious push.

I think there has been sort of a delay in wanting to do this because of issues with regard to standardization, but I think in light of the loss of tissue in Boston and basically the advocacy community sort of feeling that if there

were more brains being donated, it would put pressure on the scientific community to come up with the standardization protocols more rapidly.

So we are going to be launching this pretty quickly. I am actually going to be meeting with Roger. We are going to meet on Monday to talk about this a little bit. And what I would really like to focus on is how we can make the best use of these resources, but I think the advocacy community can really focus on speaking to other families and work on the recruiting piece and then have the NIH really focus on the issues of collection and processing and standardization of the tissues. And it all sort of feeds back into a loop.

I don't think families want to donate brain tissues. They don't feel like it is going to be useful. I think there was just devastation among the donors whose loved one's brain tissue was lost. And that really can never happen again.

So you know, I think there is recognition now that this has to be a major push. There is now funding to put against this, and we really want to

move quickly on this.

Dr. Insel: Just a couple of things to add, especially with reference, Alison, to your point about how the tissue could be used.

[Background noise]

There are two I think breakthrough areas that are emerging, one being the possibility of somatic new patients as a cause of autism, something that is suggested by the high rate of de novo mutations in germline. That suggests that children with autism may be even more likely to have variations in DNA structure in particular cell groups. And those could be in the brain. We have now the first reports of neurodevelopmental disorders to demonstrate that, not for autism but for other disorders, like hemimegalencephaly that was reported by Chris Walsh about four months ago as an example of that. So that you will only know by having the tissue that you can interrogate.

The second piece is something that we funded. Just -- actually, the notice of grant award went out yesterday for an entirely new approach that is actually transformative to do very precise

neuroanatomy and post mortem tissue with a tool that is called CLARITY. It is being developed by Karl Deisseroth and his colleagues at Stanford.

And I think this will rejuvenate and really transform the field of human neuroanatomy in a way that hasn't happened in decades. This is not quite ready for prime time, but it is certainly ready for people to begin to see the potential.

And I think, as you and others go out and talk about the importance of tissue donation knowing that these kinds of tools are now available for a three-D reconstruction, you don't even have to do a reconstruction. It is actually a three-D method to look at individual neurons in real space, in the real tissue. It is pretty extraordinary. The images are amazing.

So there is a lot happening on the science side in terms of how the issue could be used. What we don't have yet is a really clear pathway to collect additional tissue. And I think what would be good to do for the document -- for the update -- is to say specifically, "Where are we in terms of how many brains are currently available? What

is our best estimate of their value? And then where do we want to be? What should this field have if it is going to be able to make the kinds of discoveries that we need?”

So, again, I want to push us to be as quantitative as possible as we do these write-ups. In this area of the Plan, more than in the other questions, we should be able to actually say, "Do we have 160 or 150 brains available? And where are they? And how has that changed since January of 2011?"

So Roger, can we look to you to pull that together and give us a really good sense of what is there?

Dr. Little: Sure.

Dr. Insel: We didn't talk about this for the previous section on data sharing, but for bio-banking, do we want to include a Rett, fragile X, TSC, related syndromes, or is it just going to be autism strictly defined?

Dr. Little: Well, I think we want to get whatever donations we can, because if those tissues are available, our researchers can ask

different questions. And so as long as the tissues are annotated appropriately so that the researchers know what tissue is available, they can ask the questions based on their hypotheses. And they may need some of those tissues for even controls or to have an investment plan.

Ms. Singer: I think for the section on bio-banking, we also need to include an update on what has happened with stem cells. Really, the technology for skin fibroblasts has exploded over the last two years. And that should really go into this section as well.

Dr. Insel: And that might include a reference to the [Inaudible comment] syndrome paper from the --

Dr. Little: Oh, yes.

Dr. Insel: And then there has been an enormous amount happening recently with IPS cells. So we want to make sure we capture that literature. Some of that may be summarized elsewhere in the Plan, but it would be good to know, for instance, what is the current collection of stem cells or fibroblasts before transformation. So what do we

have that is banked?

Also, I think in this section, we ought to have the most up-to-date figure for DNA banks as well. What do we have in the way of DNA -- anything that is useful for RNA and then cells themselves?

So, Roger, if you could, again, let's make this very quantitative. Actually, we may want to put it into a table, actually get us the numbers. That would be helpful. The original Plan was kind of more process than substantive to establish and maintain an international network of bio-banks for the collection of tissue fibroblasts for IPS and other tissue or biological material by acquisition sites that use standard protocols for phenotyping collection and regulated distribution of limited samples by 2011. So we need to respond to that to say where are we and where do we still need to go.

Dr. Little: Yes.

Dr. Insel: So can you get that together for us?

Dr. Little: Sure.

Dr. Insel: Alright. What is next?

Dr. Kimbark: Surveillance is next.

Dr. Rice: Okay. I can say a few things about that. This is Cathy. So the ADDM Network has continued to collect and release data with a new abstract earlier this year. Also not yet released but in process is including younger children at age 4.

We have also developed a framework out of a workshop for evaluating changes in ASD prevalence. And multiple studies are happening in terms of looking at identification changes, whether it's methodological or community changes, versus risk factors with some publications, particularly on perinatal risk factors and very limited impact on prevalence, despite the change in the population of these risk factors.

We have also had some additional supplements. So the South Carolina site that is doing record-based surveillance is also doing a screening study as well, adding screening to that component to look for missed children.

We have had a lot of advances in international studies. And certainly we're aware of the South

Korea study but also international networks and reviews of international studies. And there are lots of projects that are in the hopper there that we could talk about briefly, I think.

I guess other -- in terms of surveillance, it's not directly surveillance -- but another thing I was thinking about was the NIH-HRSA collaboration to follow up on the National Survey of Children With Special Health Care Needs to better understand the difference between children who were reported to have ever been diagnosed with autism and those that currently have autism, that there was a sizable proportion of children who were said to once have a diagnosis but not at a later date. And so those data are in, collected, are being analyzed.

I think in terms of the future, we talked about some of the things in infrastructure, like with clinical standards and EHR and the need to, I think, link surveillance to some of these infrastructure updates as we have a better coordinated data system. Hopefully, that will move us toward more real-time data in terms of

collecting a lot of information on population changes, although it doesn't solve the problem of unidentified people, but it certainly may help speed things up. So those are some of the highlights I can -- you guys have more.

Ms. Singer: So, I would add that I think over the last two years, what we have also seen is more of an emphasis on surveillance of the adult population and a focus on estimating the prevalence in adults. I know there was Federal funding for the -- I think it may be called the Autism Women's Network or the Autism Center that's -- I can't recall off the top of my head -- that's really focused on adults. I think that shift should go in here.

Dr. Rice: Right.

Dr. Kimbark: So, we all have the numbers as far as the prevalence and all of that, but when you talk about some of the stuff you were just talking about as far as infrastructure update and your real-time data, it doesn't solve the problem of your unidentified people with ASD. So how do you wrap that all up? And what do you say -- Tom

said we want to go quantitative. We all hear the numbers, but how can we wrap up some of the other information and some of the efforts that you just talked about more quantitatively?

Dr. Rice: So I guess I am not exactly sure what you mean in terms of just providing summaries of some of the things that have been reported.

Dr. Kimbark: What I am saying is that I think everybody has heard some of the numbers. There are questions about what those numbers actually mean.

And I think that -- you know, I don't think that the report is actually the place to actually talk about that but what those numbers actually mean. And what I am hearing is that you are talking about how to solve the problem of those people that have ASD but they are unidentified.

What do you think that that segment of the population is? Is that a large segment, or is it a smaller segment? I mean, we have seen it, as far as the diagnosis, grow considerably over the years.

Dr. Rice: I think it's an increasing segment, but then that also depends on what your data

source is. So within the CDC-collected data we have seen since we have begun autism surveillance, it was about 40 percent of the kids that we identified that did not have a diagnosis on record. Now it's down to about 20 percent.

But we also know that, although our surveillance system is very specific, it is not as sensitive as we would like it to be in that there are still -- we are still looking at an at-risk population. We are not completely looking at the general population.

And so if you were to go further beyond that, which is an example of the South Korea study or the process study of South Carolina adding screening in the general population to records-based surveillance, we will get a better estimate potentially in a U.S.-based population, although very small in that pilot, but that is a start in trying to see what the gap may be in the general population.

So still we have some indication, but that is an important area of future need to better understand.

Dr. Kimbark: Well, I think that that was something that we could address. I mentioned sensitivity in all of that. I think that is something that we could address as well, right?

Dr. Rice: Yes, yes.

Ms. Singer: And I think when we think about what has changed over the last two years, I think we could start to talk about the fact that we now not only look at just collecting a number, but we are looking at the drivers of the changes in prevalence.

Dr. Rice: Um-hmmm.

Ms. Singer: If you could talk a little bit about Peter Bearman's work and other instances of trying to dig a little deeper and understand the levers of change?

Dr. Rice: I think that characterizing functioning, although that's --

Ms. Singer: Right, exactly. And we could talk a little bit about the upcoming *DSM-5* here.

Dr. Rice: That's true, the impact. That is certainly going to be a big area of need.

Ms. Singer: Right.

Dr. Rice: We have already done some work -- impact. And others have as well. But that can have potentially huge impacts on both research as well as clinical identification.

Ms. Singer: And although we don't know what the impact will be yet, we should certainly acknowledge that it will have some impact.

Dr. Rice: Right.

Dr. Insel: Cathy, I think you have given us a lot that you can talk about in terms of providing the numbers from the most recent ADDM report. So that is great. And the idea that you are doing the population-based study and including the South Korea data as a predecessor of what you are doing in South Carolina is really, really important to note here.

One thing that I have found helpful in talking to people about the ADDM project is to put that into the context of how things have changed. So you can say that there is a 23-percent increase since 2006 and roughly 78 percent from the 2002 data. But to remind people that, even with the report that we had earlier this year, that those

are children who were born in the year 2000. So if in 2012, we're talking about -- if people want to know what the prevalence is in 2012 -- one would have to make some kind of an extrapolation from the cohort that was born in 2000, and if you go backwards, it does look like there is about a 10-percent increase in prevalence per year.

I don't know that you want to say this in your summary, but I would try to put this into context to remind people who are reading this in 2013, that the data that we point to from ADDM is -- is kids who were born 12 years earlier. And the actual prevalence currently could be considerably higher. That's why having the study of the 4-year-olds will be helpful to capture this a little bit earlier in time.

Ms. Singer: This is something that --

Dr. Rice: I was going to say just the importance of building up the infrastructure so we have consistent-quality data that are being used clinically but that could also be the springboard for having better, more consistent information sooner.

Dr. Insel: Do you think that we should have something that looks like an ongoing surveillance report that we have for a lot of infectious diseases so that, every month or every couple of months, you would get a report out about what is -- you know, how many measles cases have there been in July and August in the United States. I can get that information quickly online from CDC.

But when we asked about the autism cases, it's a 2008 cohort – [Inaudible comment] was born in 2000. So we are really many, many years behind relative to where we would be for infectious diseases.

Dr. Rice: Yes. And I think that's because, of course, you know, the nature of what we know about infectious diseases and how we can diagnose is quite different. And so you know, the same way with any behaviorally defined condition, we could have weekly reports of anxiety, depression, you know, many mental health and developmental disabilities that we don't have very good biomarkers for, but the question is, what goes into getting that information and then what is the

meaning of it?

So I am not sure -- in the case of autism -- that it is really the amount of resources that it would take to have a standardized reporting system for a very wide range of diagnosed ages of cases that would then also be a vast underestimate.

We worked with the State of West Virginia, who had a statewide -- they have a statewide autism registry and found compared with how it went, they identified in their reporting registry versus their earlier ADDM data. And it was, you know, less than 5 percent of the kids they actually identified in the registry compared to actively going out and identifying them.

Dr. Insel: Hmmm.

Dr. Rice: So that is the challenge. Until we have a very clear diagnostic standard and test that is being applied consistently in the community, I don't know that what reporting cases in that way would do because what would the response be to that because it is still going to be a massive underestimate to get that type of data from special education reporting on their

annual counts.

And really, that just tells us who in those systems were classified in that way, but it really doesn't tell us anything about etiology. It tells us much more about service disparities, which is very important.

So if the point is to get to etiology, I just don't think it is realistic.

Dr. Insel: I am just thinking. So in the original plan, this was one of the -- it was to develop a Web-based tool that provides population estimates for states based on the most recent prevalence range and average identified by the ADDM Network by 2012. I mean, essentially what we are doing here with the update is we are responding to the short- and long-term goals that were set out in either ‘09 or ‘10.

And at the end of the day, we are basically going to be saying to the public we have done it or we haven't done it. So I am trying to figure out, or in this particular area, where there has been an awful lot of activity. How much of this can we say we have done?

Dr. Rice: I mean, I think we have done a great deal in terms of that, that particular issue. I think the way I heard you frame it first was different from how I read that objective in that having a real-time reporting system versus having access to the current data on the Web and the current data, you know, as we know is not as current as we would like it to be. That is how I read.

Ms. Singer: To me, the way I think we could maybe express this for the purpose of this project is maybe to put it in communication information dissemination in that there has been progress in terms of surveillance. But I think where there is still a disconnect with the general public is in understanding how the data are collected and what the data mean.

And I think that we could identify as a need or a gap the need to improve the communication of the surveillance data if we want to call it the surveillance data specifically to the general population so that there is an understanding at the level of how many cases of measles are there

and among the general population of what the prevalence is, what the changes are, and what they mean and what we mean when we say, "prevalence among 12-year-olds" and why data are collected for 12-year-olds and just maybe identify it as a communications need.

Dr. Insel: hmmm. So, but what I was trying to do and not doing it well, I'm afraid, was to look at what's in the list because it's amazing how many of those original objectives are around the ADDM Network. And I think some of them we have done.

I mean, certainly it seems to me that the South Carolina study that you talked about is a really good response to a request for a population-based surveillance approach, which we have never done in the United States. And you're doing it. And I think that ought to be really clear that it is underway. But we ought to link it to the specifics here, which was to have five hypothesis-driven analyses about what might be the driver.

So, all I am suggesting is that we go back to

the original language that the IACC put out for us as a guidance to say these are the things that must be done in this order; these are our priorities. And so many of them have to do with ADDM that we ought to look at how we have responded and identify where we have delivered and where we haven't.

Dr. Rice: Um-hmm, um-hmm.

Dr. Insel: And that is by way of saying I think actually, we have delivered on some of these things quite well. And then, as Alison says, I think there is also a need to communicate what this does not accomplish and where the gaps remain.

Dr. Rice: Right, right. Sounds good.

Dr. Insel: So do you think you can do that in one paragraph?

Dr. Rice: I can certainly give it a shot and then --

Dr. Insel: If you need two, I think on this one, we can give you a little bit of leeway.

Dr. Rice: Okay.

Dr. Insel: Like these were two things --

Dr. Kimbark: Okay. Do we want to move forward to the implementation and dissemination? We have talked a little bit about that already.

Ms. Singer: I would put the communication piece in here, Cathy, so that we are not just calling out the surveillance data specifically on this. I think it's generalizable.

Dr. Insel: Um-hmmm.

Dr. Kimbark: So you want to get rid of the information and communications section and just --

Ms. Singer: No.

Dr. Kimbark: -- No surveillance or --

Ms. Singer: No, no, no. I'm saying what we just mentioned about talking about the need to improve communication of --

Dr. Kimbark: Right.

Ms. Singer: -- data are and how they're collected. Include that not under the surveillance but, instead, under this communication --

Dr. Kimbark: Right.

Ms. Singer: -- and information.

Dr. Kimbark: Okay. That's what I thought. That's what I thought at first. Okay.

Dr. Insel: And Alison, if you look at the original objectives, how many of them dealt with communication and --

Ms. Singer: I don't think any of them.

[Laughter]

Dr. Insel: I couldn't find anything here --

Ms. Singer: I don't know.

Dr. Insel: -- that really addressed this.

Ms. Singer: Yes.

Dr. Insel: So it seemed like we recognized it as an issue, but maybe it was because we didn't think it was a research issue. It never --

Ms. Singer: Right.

Dr. Insel: -- got elevated to having a strategic objective.

Dr. Rice: I recall we had batted them around, but I think it was dropped for just the reason you mentioned.

Ms. Singer: Yes.

Dr. Rice: Yes. So I mean, there's -- the first need is we should come up with a clear --

Ms. Singer: But you know what we can say? We can say that the Simons Foundation is now funding

a communications project around research, recognizing the need to improve communications about methodology and use and outcomes of research so that this may be an area where we can try to focus on the future.

Dr. Insel: And also the communication effort that you just talked about that you are about to roll out around participation --

Ms. Singer: Right.

Dr. Insel: -- and increasing participation. It is kind of striking, you know. We are at 90 percent for most childhood cancers, but I think we are below 10 percent for autism in terms of participation in research. I don’t actually know what the number is, but if that's --

Ms. Singer: I think 10 is high. It was five when we looked two years ago. We should look again.

Dr. Insel: Yes. It would be good to know how we compare it to cystic fibrosis or childhood cancer.

Ms. Singer: I think we stink.

Dr. Insel: Okay.

[Laughter]

Dr. Insel: And then on the dissemination side, Elizabeth was just reminding me that there is a piece of Question Number 5 that will address that. So we may not have to do a lot here. We will have to find out what they are saying about it. It is in the Plan as a specific objective for methods to improve dissemination, implementation, and the sustainability of evidence-based intervention. So they will hopefully – hopefully, the Question 5 group will address that.

What about training? Alison, can you help us on the communication piece? Could you draft something?

Ms. Singer: Yes.

Dr. Insel: Cool. Okay. And then --

Ms. Singer: I don't know that much about what is going on at AHRQ, though. Is there anyone who knows what is happening there, their grants and stuff?

[No response]

Their grants and stuff? Alright, I will try to find out.

Dr. Insel: And you know, as we draft something, it will get circulated to the whole Subcommittee. And there will be someone from AHRQ who can look at it and say, "Oh, you know what? You left out this huge project that we're" --

Ms. Singer: Okay. Good. That's good. Excellent.

Dr. Insel: So workforce training, that's another -- that was an issue in here.

Dr. Kimbark: One of the things that I would like to ask is -- and I think this is a prevalence problem throughout science -- is that we have a tendency to fund predocs and postdocs and then we fund, you know, established investigators is that yes, there are always transitioning postdocs to an established investigator.

Dr. Insel: You mean like an early state investigator award?

Dr. Kimbark: Yes.

Dr. Insel: That would be a great thing for a foundation to take on. Alison, I think that was meant to be a pitch.

Ms. Singer: I was scribbling furiously about

what I had to include in the communications section. So say that again.

Dr. Insel: So Donna was just saying the need to have some mechanism to help investigators as they transition from postdoc to independence.

Dr. Kimbark: And this is like a gap, I think, in a lot of the biomedical sciences that there's like a wall that a postdoc just can't get over. It's very difficult to get over that wall because, in many instances, you need to have your own funding before you can shop around for that job for your first assistant professorship. So it is very, very difficult to get an early-stage investigator or career development type of award in this day and age. It is very, very difficult.

Ms. Singer: What is the amount of those awards?

Dr. Kimbark: It depends. I mean, I do know in some areas, the amount of the awards goes for around -- it's not very much. I think it's like 300,000, something like that. And that’s direct cost. It doesn't include indirect cost. I know it's been twofold. It's 240. It's 300. And that

would be not 300 per year. That's like 300 over a 3-year period.

Dr. Insel: So, this section, would it be useful again for us to collect who is being supported, either on training grants or on K awards through the NIH, across all of the institutes for research that is related to autism?

It is always tough because they are not coded that way.

Dr. Kimbark: Um-hmmm.

Dr. Insel: And if somebody is doing, you know a study of Neurexin-1 in developing a Neurexin-1 knockout, it could be enormously significant for autism research, but that may not be identified as an autism project. But we could try to do something like this: We could try to capture what the number of people are that are in the pipeline for autism.

Mr. Hall: You know, if I could add to this? You know, as we talked about data sharing, we have a tremendous amount of data available. And Alison rightly brought up, you know, what are the results? You know, there is opportunity to do

secondary analysis and target those types of individuals, the computational biologists of the world, to come into autism to tap into the resources that we do have available. It's a difficult sell sometimes to the established investigators, but for this audience, I think there is an opportunity.

Dr. Insel: So the objective was to encourage programs and funding mechanisms that expand the research workforce and have interdisciplinary research training and recruit early-career scientists by 2013. Maybe the way to respond to that is to kind of capture the number of individuals that are in the pipeline in each of those areas.

I think both what the Autism Science Foundation does, Autism Speaks, some of the efforts at Simons, some others there, and then throughout NIH, we could probably come up with a rough number of what that pipeline looks like and see, for instance, about training within the ACE centers, you know, all of those different sources.

Dr. Rice: Although small, some of the efforts

by NSAR are related as well, may be good to ask.

Dr. Insel: You know, it's funny the way that the language was originally framed. It was to encourage programs and funding mechanisms, rather than to say 212 investigators by 2012 or something, you know, to provide something that is a little more -- so you'll know when you've done it in this case. It's easy to say that we can encourage programs and funding mechanisms without ever having to be accountable to that. So maybe we can try to fix that vagueness by in the update providing some actual milestones of what has been done.

And I might try to tap somebody in our training program to help us with that so we can get, at least on the NIH side -- Alison, can you get us a roster of early-stage awards that you have done?

Ms. Singer: Yes. That is no problem. I was also going to add we should put something in here I think about the result of losing the ARRA funding.

Dr. Insel: Yes. Good point. Good point because

that is --

Ms. Singer: That is a reduction in workforce.

Dr. Insel: Yes, or at least a reduction in support. So the problem is we have a lot of people who are coming into the workforce who are going to find a more limited pool of funds to tap into compared to where we were in 2010 -- big issue.

Dr. Insel: We have only got about five minutes left. I am just looking at -- so, Alison, maybe you and I can work on this piece together and --

Ms. Singer: Okay.

Dr. Insel: -- just push numbers back and forth. And I'll see what I can get from Simons and Autism Speaks as well. Geri can help us.

Can I -- there are a bunch of other issues in here like state of the states, issues around centers for vertebrate and invertebrate model systems that aren't captured in the four categories we have just talked about. How do we want to deal with those for the update?

Ms. Singer: So, I think, actually, some of these things were discussed by the Services Subcommittee when they were talking about

infrastructure. So I think this is a conversation that has to take place maybe between you and Geri and Denise and David about how to handle some of these services infrastructure questions, --

Dr. Insel: Okay.

Ms. Singer: -- because I think they want to take on the state-of-the-state issue and they want to take on some of these.

And I don't know if it is best placed in Sections 5 and 6 or whether Chapter 7 should be infrastructure for both services and basic science.

Dr. Insel: I think where it gets confusing is whether you are talking about structures or infrastructure for services science, services research, or infrastructure for services and their sort of surveillance about what are the service needs and what is being provided, which is a different topic than actually, well, what do you need to be able to do the best science in this area?

Ms. Singer: Right, right, yes.

Dr. Rice: Yes.

Dr. Insel: Looking at -- there are several -- It is kind of interesting. When you look at the 15 or whatever it is, 20 different objectives that fall under Question 7, a lot of them really are not in the four buckets that we just talked about, but they have to do with other topics. So I do think we are going to have to figure out how we will address those, especially the issues around creating center mechanisms or looking at networks of clinical research sites offering clinical care in real-world settings. So we have done a lot of that with the --

Ms. Singer: The ATN.

Dr. Insel: -- Autism Treatment Network. The ATN has done that. And it would be a shame not to call that out in the update because --

Ms. Singer: Well, maybe when Geri is back on the call, she can handle these pieces.

Dr. Insel: I like that idea.

Ms. Singer: I mean, ATN is her project.

Dr. Insel: Yes. So we can volunteer her for something.

[Laughter]

Ms. Singer: That's what happens when you don't get on the call.

Dr. Insel: Yes. So we --

Dr. Kimbark: Do you want to go through those and at least bucket them to where they should fall in those major topics?

Dr. Insel: That would be great. And then what we may want to do when we do the actual write-up -- again, we don't have a huge amount of space here, but at least leave a little space for the topics that don't fall neatly into --

Dr. Kimbark: Right.

Dr. Insel: -- data sharing, biobanking, surveillance, and communication, or workforce. Okay, anything else?

Dr. Rice: Did you want to --

Dr. Kimbark: Yes. Are we going to get a suspense date for when we want to have like a draft of what we're doing right now?

Dr. Insel: Right. So we have to have a --

Dr. Kimbark: We have to have a suspense date.

Dr. Insel: -- final draft.

Dr. Kimbark: So we can then have another

teleconference, you know, like have a draft to one another and then have another teleconference.

Dr. Insel: Right. So I was going to say final draft, but that sounds like an oxymoron.

Dr. Kimbark: Yes.

Dr. Insel: But the draft --

Dr. Kimbark: I wouldn't want to do a final. I would want to do like an initial draft --

Dr. Insel: Yes. Let me just finish --

Dr. Kimbark: -- so everybody can get a feel for things.

Dr. Insel: The draft that goes –

Dr. Kimbark: and then have a teleconference, discuss it, what we have, what we put together, and then finalize what we want to put together and then have another teleconference, put our stamp of approval on it.

Dr. Insel: So we should work back from October 22nd, which is when we have to have something to the full Committee.

Dr. Kimbark: Right, right. So I think that we probably should -- I know Geri -- is Geri out the entire week next week?

Dr. Insel: I don’t know.

Dr. Kimbark: I think she is. I think that is what I heard.

Dr. Rice: Okay.

Dr. Kimbark: When we were trying to get the teleconference ready, she said she couldn't make it next week. I thought it was next week, but maybe it was this week.

Dr. Insel: What do you think --

Dr. Kimbark: You know, about in two weeks? Is that too soon or too long?

Dr. Rice: I'd say later on the side of two weeks. Are you thinking like the fourth or fifth?

Dr. Kimbark: I'm thinking about the fourth or fifth to at least send an initial draft out. And then we'll have a teleconference early the next week.

Dr. Insel: Sounds good.

Dr. Rice: Yes. Okay? I'd prefer the fifth if possible.

Dr. Kimbark: We'll do the fifth, then. That's fine. That's fine. I want to try to put together a teleconference for the week of the eighth,

preferably earlier in the week, rather than later.

Dr. Insel: Okay.

Dr. Kimbark: Okay? And I scribbled some notes. And a lot of it will be even I can't read them, but I will try to type them up and send them to people so that they at least have something to go on.

Dr. Rice: Right.

Ms. Singer: Right. Thank you.

Dr. Insel: Thanks much.

Dr. Kimbark: Thank you.

Dr. Insel: Okay. Bye-bye.

(Whereupon, the conference call of the Strategic Plan Question 7 Planning Group was adjourned.)