U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

SUBCOMMITTEE FOR PLANNING THE ANNUAL STRATEGIC PLAN UPDATING PROCESS

FRIDAY, NOVEMBER 19, 2010

The Subcommittee convened via teleconference at 8:00 a.m., Thomas Insel, IACC Chair, presiding.

PARTICIPANTS:

THOMAS INSEL, M.D., *IACC Chair*, National Institute of Mental Health (NIMH)

DELLA HANN, Ph.D., *Executive Secretary*, Office of Autism Research Coordination (OARC), National Institute of Mental Health (NIMH)

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ELLEN BLACKWELL, M.S.W., Centers for Medicare & Medicaid Services (CMS)

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GERALDINE DAWSON, Ph.D., Autism Speaks

LEE GROSSMAN, Autism Society

PARTICIPANTS (continued):

JENNIFER JOHNSON, Ed.D., Administration for Children & Families (ACF) (representing Sharon Lewis)

WALTER KOROSHETZ, M.D., National Institute of Neurological Disorders and Stroke (NINDS)

ARI NE'EMAN, Autistic Self-Advocacy Network (ASAN)

LYN REDWOOD, R.N., M.S.N., Coalition for SafeMinds

CATHERINE RICE, Ph.D., Centers for Disease Control and Prevention (CDC)

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PROCEEDINGS

(8:00 a.m.)

Dr. Insel: Good morning, everybody, and welcome to the Subcommittee for Planning the Annual Strategic Plan Update.

Let's start with a quick roll call. First, let's -- we can go around the room here so you can see who is -- or hear who is with us in Bethesda.

Dr. Hann: Della Hann, the Executive Secretary for the IACC.

Dr. Daniels: Susan Daniels, Deputy Director of the Office of Autism Research Coordination, NIMH.

Ms. Perez: Lina Perez, OARC.

Dr. Johnson: Jennifer Johnson, Administration on Developmental Disabilities.

Dr. Koroshetz: Dr. Walter Koroshetz, Deputy Director, NINDS.

Dr. Insel: And on the phone?

Dr. Boyle: Hi. This is Coleen Boyle with CDC.

Ms. Redwood: Lyn Redwood, SafeMinds.

Ms. Singer: Alison Singer, Autism Science Foundation.

Dr. Insel: Anyone else with us at this point?

(No response.)

Dr. Insel: Well, there are a few others who are scheduled to join, but I think we should go ahead because we've got a lot to do and I want to stay on schedule.

We also have lines open for "listen only mode" for the public. And let's start with just a quick run-through of the agenda. What we need to do is approval of the October 6th minutes, which you should have.

Then we'll do a quick discussion of the updates that have been sent in, starting with Chapter 4.

Five and six are not in your packet, and we'll have to circle back to those probably in a subsequent meeting.

And what we'd like to do today, though, is to get through four and then everything else except five and six, and see if there are any particular comments you might if we have time on five and six before we get to the finals, and then we'll plan for the subsequent steps.

Any questions about the agenda?

Dr. Boyle: I have a question. This is Coleen Boyle.

Dr. Insel: Yes.

Dr. Boyle: So we're not going to talk about the consolidation for one through three?

Dr. Insel: We're going to do that.

Dr. Boyle: Oh. Okay. Then I misunderstood you.

Dr. Insel: Yes. We'll cover it.

Dr. Boyle: All right.

Dr. Insel: We're just -- we're going to start with four, though, because we've been through those initial ones.

Dr. Boyle: Okay. Fine.

Dr. Insel: Or the first -- first draft.

Dr. Dawson: All right. Tom, this is Geri Dawson. I just wanted to let you know I'm on the line. I, somehow, went into the line that was the "listen only." So, I'm now in "speaker."

Dr. Boyle: And, by the way, that was what was sent out to us.

Dr. Dawson: Yes.

Dr. Boyle: So, that may be the reason why some people are having a hard time getting on.

Dr. Insel: Okay.

Dr. Boyle: I just happened to ask for it again and I got the other number yesterday.

Dr. Insel: Okay.

Dr. Boyle: You might want to have somebody send it out.

Dr. Insel: I'm glad you let us

know. We'll send out a quick correction so that everybody joins this line.

And I think what we'll do, you know, over the next few minutes I think there are a couple of other people who will be joining, but we have the quorum at this point.

Let's take a look at the minutes from October 6th, which you should have from the email, and let me know if you have any questions, concerns or comments about those.

Well, hearing none, do I hear a motion to approve the minutes as they have been submitted? Yes?

Dr. Boyle: I move to submit.

Dr. Insel: Okay. In favor?

(Chorus of ayes)

Dr. Insel: Okay. Unless I hear any opposition, they are accepted.

And let's move on, then, to number four, question four.

Dr. Dawson: Lee, did you join us?

Mr. Grossman: Yes, I'm here.

Dr. Dawson: I thought that was your voice.

Dr. Insel: Great.

Mr. Grossman: Yes. Sorry I'm a little late.

Dr. Dawson: That's fine.

Dr. Insel: Welcome. Good to have you.

Lee, I was just saying that we're going to start with Chapter Four.

Mr. Grossman: Right.

Dr. Insel: Because we've been through one through three, at least on a first draft. We are going to circle back to those after we get through the parts that are new.

Mr. Grossman: Okay.

Dr. Insel: And, Geri, were you the main drafter of number four?

Dr. Dawson: Yes, I was.

Dr. Insel: Could you take us through it?

Dr. Dawson: Absolutely.

Dr. Insel: Thank you.

Dr. Dawson: So it starts out by providing a list of studies and reviews that were published in 2010, and they range from studies on medications, the RCT of toddler treatments, some studies that are for adolescents on social skills and anxiety and then the review that was conducted on behalf of the Centers for Medicare & Medicaid Services is also included.

And then, moving on to the gap areas, we noted that this year there have been continuing new findings in the area of genetics which point to the idea that we need to be considering the use of genetics in our stratification strategies when we think about clinical trials and targeted therapeutics.

In addition, there were new data presented in 2010 from the Autism Treatment Network that provided some information about the prevalence of a comorbid condition, as well as consensus statements on assessment and

treatment of GI conditions which, I think, was a move forward.

And then, in addition, we noted the NIH Workshop on children with autism who have not developed functional verbal language and the gap that exists in understanding treatments that can address this population, and so there were a number of, you know, priorities and gaps that were identified as part of that NIH Workshop.

And then, finally, there were some important initiatives that have to do with adults with autism and insurance coverage for treatment for autism that were published this year, and really highlight the need to focus on identifying and addressing health research and treatment for varying populations and the existence of health disparities among people with autism.

In terms of objectives, we originally had many more than this, and working together, the subgroup tried to

consolidate and respond to Tom's mandate and the larger committee's mandate to not overwhelm the land with new initiatives, too many new initiatives or objectives.

And so, we settled on these. One was the need to conduct research that is community-based, and that could help really inform dissemination and implementation of best practices into the broader community, and there were a number of ways in which that could be done.

That could be done by looking at evidence-based medical treatments, by community physicians, by looking at the effectiveness of early intervention programs that are designed to be scalable and implemented in underserved and low-resource and low-literacy populations, including beginning to look at intervention models that are extensively used by parents such as TEACCH and DIR, but who -- for which there are not data, or there's not a lot of data showing

their effectiveness, and also community-based participatory research to identify disparities in the access to health care and treatments, including secondary conditions all along the autism spectrum.

And it was pointed out also, and we included in this objective the need to always assess not only the positive outcomes of different intervention strategies, but also to be vigilant and assess the potential adverse effects and harm that could come from an intervention.

The second objective was the need to begin to conduct multisite comparative effectiveness studies, and these really could be wide-ranging in terms of their targets, ranging from pharmacological, nutritional, behavioral, service provision, parent and care-giver training, medical and psychiatric comorbidities and so forth.

So, there's really a need now to begin to compare not only how different

subgroups respond to a given treatment, but also whether one treatment is more effective than another.

And then, responding to the issue that was brought up at the last IACC meeting, we wanted to make sure to include a specific objective that talks about kind of the personalized medicine approach, utilizing biomarkers to stratify individuals, to predict optimal response.

We could consider -- actually, I'm just thinking out loud here -- integrating that with comparative effectiveness because that would be a type of comparative effectiveness trial.

And then, two more. The next-to-the-last one was a very urgent need to focus on interventions for nonverbal individuals and there's a wide range of studies that could be done, everything from looking at service provision models, enhanced access to methods of alternative communication support, studies

of novel treatments, to facilitate communication skills and studies that assess access to AAC in children and adults.

And then, finally, the last bullet is to support two studies that focus on the prevention of secondary disability in ASD, and I thought this was a very forward-looking objective, such as prevention of comorbid medical and psychiatric conditions, quality of life, unemployment, isolation, homelessness and involvement in the justice system.

And so that summarizes it, Tom.

Dr. Insel: Okay. This is open for discussion.

Mr. Ne'eman: Geri, this is Ari. I think this looks -- this is looking very good. I only have one area of concern, and I apologize for not raising this before now. I've been fairly sick the past week.

I notice that we no longer have the ethical, legal and social implications objective. I think that's fairly important.

If memory serves, this was in Chapter -- question four previously. Feel free to correct me if I'm confusing it.

I'd really like to see it restored, particularly as we are talking about genetic research here.

Dr. Dawson: Well, I think that actually was in the one on causes, but I certainly think, you know, we could consider putting it into this one, although, you know, they're, perhaps, around biomarkers, but this really has to do more with the idea of using biological information to help target and stratify.

So, you know --

Mr. Ne'eman: And I'm looking -- I'm looking at my notes and you're right. That is in the one on causes. It may make sense to include it in the context of biomarkers, but that was my mistake. Thanks.

Dr. Dawson: Sure.

Dr. Insel: Other comments or

questions?

Ms. Blackwell: Tom, this is Ellen. I was just cross-referencing a couple of the new research opportunities with Chapter Five.

And, Ari, I know you've been tied up, but I think we might want to just make sure that we're not duplicating or we don't need to tweak something that's in Chapter Five, for example, the five CER studies.

There are some objectives related to looking at service provision in Chapter Five, and also, a little bit --

I'm not understanding, Geri. Maybe you could give me a little bit of information about the last objective two studies that focus on prevention of secondary disability.

I'm not quite -- are you saying that quality of life is a secondary disability or unemployment is a secondary disability?

Dr. Dawson: That's really --

Ms. Blackwell: It's a little bit confusing to me.

Dr. Dawson: No, I completely agree. As I was reading that I noticed that myself. So, I think all of those make sense, at least from my point of view, but you can correct me, except for the quality of life. I think we would say poor quality of life.

Ms. Blackwell: Well, I -- that's subjective. I mean, we are actually looking at tools to measure quality of life, and I think that there's -- there actually is some other stuff about that in Chapter Five, and perhaps also Chapter Six.

But I think you might want to look -- I mean, I don't like the idea -- I guess I'm just not comfortable with the idea of -- and you may need to rearticulate this last bullet and then think about it in terms of intervention and not a service.

Dr. Dawson: Actually, I would really look at calling --

Mr. Ne'eman: I wonder if it's possible to show clearly, you know, draw a

line between the two. I mean, I think the value of talking about secondary disability in question four is when we're referring to things like anxiety, depression, obesity, you know, and a wide variety of other things, the -- there needs to be a combination of some things that are -- are probably service-provision oriented in the context of access to health care and some things that may fall better within the construct of treatment in terms of, you know, the actual health care itself.

So, you know, I'm -- I do think there's a role for discussion of prevention of secondary disability.

Dr. Dawson: Yes. I agree. I think you just need to think about how to say it, perhaps, in a different way.

Dr. Johnson: This is Jennifer, and that was something I noted as well in that bullet. I just wasn't clear on how secondary disability was being defined, given several of

the terms, in that objectives, quality of life, unemployment, isolation, homelessness and involvement.

I agree with Ellen that those things, to me, are more indicators of how one is living their life, and how autism might be impacting those parts of their life, and I do think that's valuable research, but I don't see that being how I would define a secondary disability that's resulting from the autism spectrum disorder.

So, I think some clarity in that objective -- again, I don't question the merits of researching either secondary disability issues or quality of life issues, but I just think there needs to be some clarity in that objective to better convey what is meant there.

Ms. Blackwell: To me, it seems -- this is Ellen. It seems like an example might be screening for seizure disorder earlier so the person could receive treatment, for

example, for a concurrent medical condition.

Dr. Insel: Now, just to remind you, that's in the current plan from 2010 as the first short-term objective.

Ms. Blackwell: Okay. Well, the --

Dr. Insel: I think that we really don't need to repeat it here.

Ms. Blackwell: I agree.

Mr. Ne'eman: I could see some novel areas of prevention of secondary disability here. I mean, I really do think that the co-occurring conditions, what's referred to here as comorbidities are the area of promise in this context and I do not know that we have what we need in terms of prevention of obesity, prevention of mental health conditions and similar other things.

I do think there's a role for a new objective around that.

Dr. Insel: But I just want to be clear because the original objective said "Support of these three randomized control

trials that address co-occurring medical conditions associated with ASD."

So, that's been in the plan since actually 2009.

Ms. Blackwell: Then I would propose we just leave it as it is, Tom.

Dr. Boyle: Well, that's a little different. "Co-occurring" versus "secondary" conditions, and I guess I would -- this is Coleen. I would agree with Ari on that in terms of things like obesity and just other -- other health care related aspects that really are secondary to the condition but, you know, that are not co-occurring.

Dr. Dawson: Would it be possible to tweak the objective that's in here already?

Dr. Insel: It's possible to do whatever the subcommittee wants. At least you can recommend whatever you want. It's up to the full committee to decide whether this is worth including.

Dr. Dawson: So, it seems like --

Dr. Koroshetz: It seems to make more sense to, you know, as opposed to being redundant, I think if we look redundant, I think it doesn't look good for us in terms of adding objectives that people may see as something that was there before and it's not clear why it was added in.

So it might make more sense just to use different language for the initial objective.

Mr. Ne'eman: My concern there is that the context around "secondary" is different from the context around "co-occurring," particularly when you think about what we would be researching.

You know, a co-occurring condition could be if somebody happens to be born with a seizure disorder as well, and not something that's common -- a common co-occurring condition in regards to autism.

Secondary disability is as a result of lack of access to community mental health

treatment or lack of access to, you know, appropriate diet. An individual develops a secondary disability.

I think that's something that's much more relevant in the treatment context.

Ms. Blackwell: I would ask that we maybe look, Geri, at rewording what's already in Chapter Four to include co-occurring conditions and then maybe you could add some language that says, "including disorders that might, you know, appear, such as obesity, mental disorders, et cetera."

Dr. Dawson: So this -- let me -- just to -- I actually think that Ari has a really good point here which is, there's two kind of unique features about this. One is the concept of prevention and the other is the concept of secondary disability that isn't really captured in the other.

And I think there's sort of two strategies. Either we could have -- you know, we could enhance the first bullet, right, by

having a second sentence or adding the word "prevention." You know, either "treatment and/or prevention," you know, of -- or, you know, we could have a unique bullet but, you know, this obviously needs some work in terms of the way it's worded.

But I do think it isn't quite captured in the existing bullet and it's, like Ari was saying, I think it's one of the areas -- it's kind of the low-hanging fruit in the sense that we could really do something about this that could have a huge impact on people's lives, so we just want to make it's really captured.

Dr. Insel: So I have a question about this, Geri, because it does -- it feels to me like there's two concepts here that are a little bit confounded.

If you took the bullet as you've currently written it and you just take out the section that says "such as comorbid medical and psychiatric conditions," and you focus on

what Ari is talking about, which is the second disability to ASD that, you know, essentially issues that are the result of having ASD and not getting appropriate care.

Couldn't you provide -- couldn't you use the same language? It would just migrate into a different chapter. It's not really as relevant to Chapter Four, perhaps, as Chapter Five or Six.

And then, because if we leave it at the level where it is now, which is to have studies -- actually, there's two bullets. There's one from 2009 and one from 2010 that looked specifically at the treatment of co-occurring conditions.

One that's focused on RCTs for co-occurring medical conditions and one that's focused on the safety and effectiveness of medications commonly used in the treatment of co-occurring medical conditions.

Dr. Dawson: So could we, perhaps with the one that's -- you know, I guess the

difference is that, you know, when you think about co-occurring, all right, you're saying, okay, you have this condition. It's co-occurring and it's affecting a person's life, and how are we going to effectively treat that.

To me, that's a very different type of study and research than saying, you know, what strategies could we be using to actually prevent these. Like, for example, anxiety and depression, could they be prevented, are they because we have, you know, of the situations that we're putting people with autism in, which creates and exacerbates anxiety, or the issue of obesity and, you know, other even heart -- you know, heart disease.

So, it's just a little different emphasis. I think it could be, if by enhancing the one that you just mentioned, we could say, "as well as studies," right, "that examine strategies for prevention of -- of secondary conditions" or something. But

they're a little different, I think. Sorry to get you stuck on this. And I think it's pretty important.

Dr. Boyle: Geri, this is Coleen. And we sometimes talk about, in a disability context, we talk about, you know, improving -- health promotion and improving quality of life and prevention of secondary disabilities.

So, I mean, we could talk about health promotion opportunities, and that's the minimizing obesity and other sort of co-occurring disabilities, to really improve quality of life and promote health.

I mean, you could put it, perhaps, in that context.

Dr. Dawson: What do you think, Ari, does that capture what you were trying to --

Mr. Ne'eman: I think health promotion is definitely a big area of it. I would want to also see included something around access to disability, confidence,

mental health -- mental health, the treatments just in a sense that we all -- we have obviously secondary disabilities that are medical in origin, and also secondary disabilities that arise from mental health challenges.

But I do like the idea of putting a focus on health promotion, and I do think Tom is right, that some of these things could be placed into Chapter Five as well.

Not all of them. I still think there's a role for an objective around this, part of an objective around this in Chapter Four, but some of this clearly could play a role in Chapter Five, too.

Dr. Dawson: So I think what the planning committee needs to decide is whether we want to take this and try to build it into the existing bullets, perhaps the one that Tom mentioned in this chapter, as well as perhaps Chapter Five.

Or, do we want a specific new

objective on this. And, I honestly -- we could go either way, as long as this -- the concept is captured somewhere.

Mr. Ne'eman: So the advantage, I think, just to play devil's advocate here, to a specific new objective is that there has not been in the past the kind of focus on things like health promotion and, you know, recognition that, you know, even as we move away from a cure/treatment-oriented approach in the context of autism, there are a great deal of things that can be done to prevent secondary disability.

And having a unique objective around this might provide that focus. You know, now I can see the case to go in another direction, too, and I'm sure somebody here will make that case.

Dr. Insel: Susan has a draft that maybe the subcommittee wants to consider and see if this captures some of the discussions.

Do you want to -- can you --

Dr. Daniels: Yes. I can --

Dr. Insel: I don't know if they can hear you.

Dr. Boyle: Susan, you need to come to the phone a little closer.

Dr. Daniels: All right. Support at least two studies that focus on health promotion and the prevention of secondary disability in ASD impacting quality of life, employment, unemployment, isolation, homelessness and involvement in the justice system by 2013.

Ms. Blackwell: Hi, Susan. It's Ellen. I guess my -- my only objection to that is that I think there's a difference between secondary disability and those situational -- I mean, being homeless is not a disability.

So, I think that we need to clarify that a secondary disability could be obesity or seizure disorder, for example, but somehow you've got it -- we have to characterize that

this is -- these are, you know, negative -- these are, you know, a negative situational circumstances or -- I have to think more about how to say it.

But, being homeless or being in the criminal justice system is not a disability.

Mr. Ne'eman: So, maybe the situational circumstances belong in Chapter Five.

Dr. Boyle: I think they should be separated.

Dr. Johnson: Yes, I think they should because we can't say that these circumstances are just because of the secondary conditions that may be --

Dr. Boyle: Yes.

Dr. Johnson: -- just related to ASD. I think it's hard to combine it with the notion of secondary conditions.

Dr. Daniels: This is Susan. Would it help to have a parenthetical after "secondary disability" where you could list

examples?

Dr. Hann: Yes, and I'd be happy to work with somebody on that.

Mr. Ne'eman: Yes, that's just --

Dr. Dawson: I think what I -- I think we could probably just, you know, fine-tune this one. It sounds like we're getting some clarity and closure on it. So, maybe -- you know, I think it's just a matter of wordsmithing now. We could probably easily do that by email.

Mr. Ne'eman: The only thing I would add is, I think it's important to specifically call out mental health in this.

Ms. Blackwell: Yes. Yes.

Dr. Johnson: This is Jennifer. I would just suggest -- somebody mentioned earlier that the quality of life issues might belong under Chapter Five. Somebody might just table that for the Chapter Five discussion.

Ms. Blackwell: And I would also

suggest that we use the term "behavioral health," because that's what we're using here at CMS to cover mental disorders and substance use disorders."

Dr. Johnson: All right.

Dr. Koroshetz: So I would propose cutting them in half and maybe bringing in the comorbid medical and psychiatric conditions, if you'd like, and specifically put them into short-term Objective A, and then leaving the rest for question five.

That might sharpen short-term Objective A, which is kind of all -- I think, talking about co-occurring, it's basically this big world with everything in it and it sounds like people want to also bring emphasis to more focused areas, which are the comorbidities, so that might fit very nicely, as just a modifier in Objective A.

Dr. Insel: Coleen and Geri, can we get you to wrestle this one to the ground and come up with some new language?

Dr. Dawson: Yes.

Dr. Insel: You've got a -- it sounds like you have two or three options here.

Dr. Dawson: Yes.

Dr. Insel: We'll leave it to you to determine what -- what you want to take to the full committee.

Just as a point of clarification, and this will come up again later in the introduction. When we talk about something being comorbid, that implies that it's not part of the syndrome itself.

So, if someone has seizures and autism, is it appropriate to say that that's a comorbidity, or is that actually part of the syndrome that they have?

I just ask because if it isn't clear to me, it probably isn't clear to other people who would be reading this.

Dr. Dawson: Well, I think, you know, we don't know, you know, on some of

these, right? Like anxiety. You know, I think people believe there is a -- probably a biological vulnerability, but that, you know, others think that, you know, it may really be either exacerbated or even caused by, you know, the conditions in which a person with autism finds themselves in.

So, you know, it is a hard one to know.

Dr. Insel: I think it's important to sort of think this through a little bit, just conceptually. I mean, if we just use diabetes as a metaphor, is the vascular disease a comorbidity or is it part of the diabetic syndrome.

Because, if epilepsy is part of the syndrome, then it may help you to distinguish different forms of autism. It seems like it doesn't so far for anything that we've looked at, but I bring it up because, when you start calling these comorbidities, you may be actually restricting how we could begin to

stratify or how we could begin to think about what is already, we've said, a very heterogeneous disorder.

So, I'm not sure I have the answer here, but I just want us to be rather precise on the language because it does matter in the way you think about this.

Dr. Dawson: Yes. No, I understand. So, we'll keep that in mind and try to finesse that, if not actually, you know, address it.

I think part of it is just we -- you know, we don't know on some of these things. But, yes, I think that's a really important point.

Dr. Insel: Yes. So, Lyn addresses this in her revision in the introduction, and maybe what we'll do is, when we get to that point we can circle back to this and come up with the right language.

Because, what we could do in the introduction is simply address it, clarify it

and then use the same language all the way through.

Ms. Blackwell: Yes. I think that's a great idea.

Dr. Dawson: Yes, I do.

Dr. Insel: Okay. Other comments about Chapter Four?

Dr. Koroshetz: Can I ask, in terms of the biomarker one, the word is used very commonly, and sometimes not precisely, but I was wondering do people think that there are biomarkers that have been validated to the point where they're ready to stratify treatment?

The general biomarker goes through a kind of discovery phase and a validation phase, and then you test it in the real world in terms of treatment.

So there are things -- I'm just not aware of biomarkers that are already at this level.

Dr. Insel: Yes. I had the same

question, Walter. My sense is that this was a couple of years premature, but maybe there's something we don't know about that would lead people to think we're ready to make this kind of an investment.

Ms. Redwood: Hi, Tom, this is Lyn. I guess, when I think of biomarkers I think of many different things, and some could be biomarkers of disease and some could be biomarkers of the comorbidities that we've been talking about, and that there are some things that we have, you know, recognized that could potentially be targets for treatment.

I know one was low levels of cholesterol, abnormalities in methyl B-12 metabolism, functional B-12 deficiencies, those types of things that could be considered biomarkers for treatment, and also for monitoring progress to treatment. But we just need much more research.

Dr. Insel: So I would agree that there's the possibility for that. The -- I

guess I'm following up with Walter's comment.

The way we usually think about biomarkers is in a very hierarchal sense. So, the very first thing you do is the deep dive to demonstrate the power of the biomarker in terms of an association with disease or with a subtype of disease.

And the last thing you do before final qualification is stratification of a -- in a clinical trial which is usually about a $20- or $30 million enterprise.

You wouldn't want to do that with a biomarker you haven't really fully vetted. So, even in a case of breast cancer, for instance, where we've had biomarkers for about 15 years, we're only right now doing the I-Spy 2 trial.

The first really big stratification trial with biomarkers in the way this is described, and it took us 15 years to get there.

I think we're not anywhere close to

that with anything we have -- we certainly don't have a HER2 or any of the markers we have for breast cancer right now for autism. At least, if we do, I don't know about them.

Dr. Solomon: Tom, this is Marjorie. While it is, I think, a really important thing for us to be vocal about, given the population, we want to kind of get into the position where we can start to identify the biomarkers.

Is there a way you can think of or recommend that we could put an objective in there that we sort of begin to get a few new directions?

Dr. Dawson: I sort of think the objective, the way it's written now, does that, in that it says to use biomarker information to stratify individuals with ASD to predict optimal response to treatment.

Mr. Ne'eman: I guess my concern around that, I would be inclined to agree with Tom and Walter, just in the sense that, you

know, I don't know that we have an idea as to what these biomarkers are, how they would be utilized and I can see us exploring those things possibly in Question One or Two, but I don't know that this is quite at the point where it's going to result in any practical treatment implications or other implications for people's quality of life.

Ms. Blackwell: So an example would be a study that compares individuals with autism who have a mutation in the SMR gene versus those who are idiopathic in their response to arbaclofen.

Participant: That would not be viable.

Dr. Insel: Yes. So --

Ms. Blackwell: So, what -- what word do we want to use there?

Dr. Insel: It's a subtype of -- or actually what -- you know, and what I think the difference -- I think we're all wanting the same thing, but the language again is

different.

So for us the word "stratification" means something very different than what you just described. What I think the field is at what we would call the exploratory phase, the discovery phase where you're trying to find associations, and that's usually done retrospectively.

So, what you do is, you collect a lot of modifiers, a lot of predictors and -- potential predictors at baseline and that's the stage we're at. And then, after you've done the $20 million trial, you go back and you look at which ones were associated with response.

After that, you're ready to go ahead and do the stratification trial, if you have a big enough hit.

But, we don't have -- we haven't done that first part, so we're certainly not at the point of setting up a big trial to -- that is already stratified.

As I said, in almost every other area of medicine, you spend a lot of time and money on the exploratory phase before you set up the stratified trial.

Dr. Dawson: Okay. Here's another example, just to, you know, try to understand how the best way to phrase this. Would it be a study that looks at the presence of an abnormal EEG in absence of, you know, frank seizures, you know, versus individuals who might have seizures in their response to Depakote.

Dr. Insel: Yes. That would be --

Dr. Dawson: Okay. I'm just saying, the real -- and this is just off the top of my head. It's not, you know, I'm just -- I'm sure if we put this out to the smart world out there we actually could push people to start thinking this way.

I mean, one possibility would -- if we don't want to call it out, since it is obviously, you know, sort of forward-thinking,

is to fold it into the comparative effectiveness and say "Such studies could include the use of" -- and I don't know if you want to use the word biomarker, or, you know, something else.

Dr. Insel: Yes.

Dr. Dawson: "Biological or other information to stratify individuals to predict optimal response," how's that?

Dr. Koroshetz: So there's an objective in Question 2 that says, the old -- the new 2010 objectives -- going to do at least three studies which evaluate the applicability of ASD phenotype and/or biological signature findings performing diagnoses, risk assessment or clinical intervention.

Dr. Dawson: Well, that's not quite the same, but it's similar.

Dr. Insel: And there's a new objective from last year, convene a workshop to advance the understanding of clinical

subtypes and treatment personalization, what are the core symptoms to target for treatment studies, which is a little bit -- that's a meeting, it's not a trial.

And just -- launch five RCTs and interventions including biological signatures and other measures to predict response and monitor quality of life and functional outcomes in each of the following groups, and it lists infants and toddlers, school-age and adults.

Dr. Dawson: Well, that actually sounds quite good, that one.

Dr. Insel: Well, that's in 2010. I think what's going to drive the -- well, I know already, I don't just think this. The issue is going to come up at the full committee is, they're going to say we're just piling on here.

We've already got stuff that we did last year and you're just adding more of the same rather than really thinking about what's

there and monitoring our progress on what we've got.

Dr. Dawson: So the one that you just read, Tom, I think actually does it.

Dr. Insel: Okay.

Dr. Dawson: So I would be okay with removing this. I mean, the funny thing about this is -- I don't know if you remember this, but it came out of our discussion at the meeting where we said, "Oh, did we not actually include that?"

And so, anyway, it sounds like it's there, though --

Dr. Insel: All right.

Dr. Dawson: -- so let's -- I'm fine with removing it, given what you just said.

Dr. Insel: Oh, how does the rest of the team feel? Is it all right?

Dr. Dawson: Did you, Lyn, hear what -- the one that he just read which sounds quite similar?

Ms. Redwood: Yes. My concern -- can you guys hear me?

Dr. Dawson: Yes.

Dr. Insel: Yes.

Ms. Redwood: I guess my concern is when we look back through what's been funded, that -- and you guys can help me with that, because I don't have that information in front of me right now, when we talked about convening a workshop to look at biomarkers and to stratify treatment, that didn't happen that I'm aware of, in 2010.

Dr. Dawson: No, that was 2011.

Ms. Redwood: There was one you mentioned before that was 2010, Tom, when you were reading them off. I'm not certain which question, if that was back from Question Two.

But, I just want to make sure that these things actually happen.

Dr. Insel: Yes. I'm with you on that. I think that -- and I think that's what we're hearing from the full Committee is,

let's make good on what we've already put in the list rather than adding more things to the list.

Ms. Redwood: Well, if this is captured in other parts of the plan, then I'm fine with having this removed as long as there is a sense of urgency in getting that essential work done.

Dr. Insel: So, I have one other comment about the first two bullets, which are -- both talk about supporting at least five studies. One is community-based studies, the other is CER, or comparative effectiveness.

And that relates -- well, there are really two issues. One is, we have taken the tack throughout this plan of making the objective to support X number of studies. And maybe that's the best way to do it.

But as I began reading this I kept thinking to myself, is that really what we want or do we want answers? Are we just trying to support as many studies as possible

or do we really want to make objectives where we answer a question so it doesn't have to be studied any further?

And is there a way to capture that in the way that we have -- because they are, after all, called objectives, which means that reaching a goal of some sort. And if the goal is simply to fund studies, does that really get us to where we want to be?

So, that was the first question. The second is, in reading these, since we've just done a series of large-scale comparative effectiveness research studies which are much like what your -- what is in here, this is very different than many of the other things in the plan.

Every single CER study, it's about a $50 million undertaking, and those are somewhat modest. So, in these two bullets you capture basically, called for more than probably most of the rest of the strategic plan that's already in place.

And I just think the subcommittee should consider what these bullets are asking for, because this is an extremely high-priced item, which isn't prioritized. That is, it's not saying "If you could only do one thing in this arena, what would be the most important thing to do?"

It's really a long list that I think is going to be difficult for people to get their hands around. Just -- those are my thoughts in reading this and I'm not sure that's an argument for not doing it, but I wanted to toss that out there because maybe there are other people on the full committee that would have the same response.

Mr. Ne'eman: So, Tom, I definitely agree. Our objective here is, you know, to actually accomplish what we want to accomplish, not to engage in some type of researchers full employment act.

I guess my question here is -- is twofold. I think the reason why some of the

studies, some of these have mentioned more studies than others is that, you know, in the effort to combine multiple objectives that may have had some overlap.

There have been different areas of emphasis within this so, I mean, for example, looking at the first one, if we were only talking about one study there, then I think there would be a lot of questions as to, you know, whether it should be around the effectiveness of community settings and have evidence-based medical treatment protocols or CBPR, DIR, so on.

So, I mean, I think the purpose there is to indicate that we want all of these things to be studied. You know, if there's another way to indicate that, then I think that would be excellent because, you're right. The number is sort of arbitrary.

And I guess my other question is: What would you suggest as a way of prioritizing the various things that are being

mentioned within each objective?

Dr. Insel: You know, I think that would be something for the people drafting it to at least think about. And maybe -- and I don't want to be a whiner about this, so I'm trying to be careful about the way I think of it.

Maybe there's a way to frame these as questions. So that's what I kept trying to figure out was: how would you know when you had done this?

I mean, we could certainly imagine that there would be five such studies that would be supported, but what you really want to do, I think, is to answer a set of questions, and it wasn't that clear to me what the questions were here, other than -- so, you know, you could support a study to look at the effectiveness in community settings of evidence-based medical treatment protocols by community physicians, but is there a way to frame that so you'll know when you've actually

done it.

Or -- you know what I'm getting at? There's something about this that feels like it's open-ended and not entirely accountable, other than you could say, well, we've done this study, but that may not actually answer a question that will have the impact you want.

Ms. Blackwell: Tom, so would the way that they were written before, did they do that, what you're -- because I completely get what you're talking about.

I guess -- I think we were trying to model them on the way they had been written before.

Dr. Insel: Yes. Exactly. And this -- so this isn't anything unique to this revision. This is was there from the get-go.

Ms. Blackwell: So, this has the whole, you know, approach of revising the objectives to be more goal-oriented or more explicit in what it -- they're trying to accomplish.

Dr. Insel: Well, I guess for this -- I mean, I think I got sensitized to it because this -- these are such high-priced items. The CER is just incredibly expensive and difficult to do well, and it's -- you know, this is a -- most of these CER studies are four- or five-, or in our case, eight-year studies to do them in the right way.

The other piece was that the two -- these first two bullets, much of what we think about in CERs is really -- is around community-based participatory research and then effectiveness in community settings.

That's really often the way that comparative effectiveness gets played out. So, I wondered if there's a way to also blend them together because I don't see them as completely independent efforts.

Ms. Singer: This is Alison. I also want to add that I think where -- we may be confusing two issues, and I keep hearing, we need to add this objective, or we need to

change this objective because there were no studies funded that spoke to this, or you know, even though we had it in the plan there were still no studies.

And I agree, you know, it's disappointing to me to see that there were -- there were objectives against which there were no studies.

But I don't know that we can draw the conclusion that there were no studies against an objective because of the way the objective was written or because there wasn't a specific objective.

And I think one thing that the broader Committee, the full Committee may need to talk about is how can we do a better job of disseminating the plan and encouraging scientists to -- and act against the plan and apply against the plan, as opposed to making the assumption now that the reason that they didn't is because of the way the objectives are written or because an objective is

missing.

Dr. Dawson: So, Tom, you know, in terms of the idea of just, you know, trying to, you know, combine these, I guess one of the things I'm struggling with is -- and, of course, you may not be aware that this like 12 objectives that went into two or something.

Dr. Insel: Okay. Yes.

Dr. Dawson: So, you know, I think maybe -- I guess one question is the full issue of how many studies are suggested. Honestly, I put the five in there because it was -- it was a whole bunch of objectives, each one that -- and three.

And so I thought, well, how are we going to -- you know, what are we going to put here. I think the number's really arbitrary in some sense. I think the difference between the two, though, is the idea that we -- you know, we do have now some best practices, but they haven't really been tested in community settings or been forced to become scalable and

to look at the issues that would either promote or hinder their adoption in a community setting.

And so that's, I think, what the first one is. And it might not -- it might not be a comparative effectiveness trial, right? It might be taking one intervention and saying what if we looked to see whether we can do this in a community setting and how would we do it.

Dr. Insel: Okay. And, Geri, just -- when you were thinking about this, like if you take the first one, the effectiveness in community settings of evidence-based medical treatment protocols, what would be a good example of an evidence-based medical treatment, just so we're all on the same page?

Dr. Dawson: Well, so in the next -- in the next year the HRSA program will be publishing an evidence-based treatment for GI, and so -- you know, we could put best practices, because some of these are best

practices.

So the question is: How -- or, even if you think about -- you know, if we said treatment and diagnostic protocols, right, we have all these protocols for diagnosing children, you know, but obviously these tertiary care centers are not going to be able to meet the needs of the huge population of kids.

Somehow we have to have a way to have community physicians and clinicians, you know, use these out in their practice. And so far what it looks like is they're not -- they're not doing it.

They haven't adopted them and it's because, you know, they aren't scalable yet.

Dr. Insel: Yes.

Dr. Dawson: So, I know that in other areas of -- you know, I'm mostly familiar with mental health, but there's been a lot of work on this, you know, in teaching community physicians how to deal with

depression and anxiety.

You know, where it started out in specialized centers now you have primary care doctors pretty much handling most of depression, right? But, there was a lot of work on how you do that with, you know, different studies that were funded -- and I'm sure you funded them.

So I just -- we haven't done that work yet.

Dr. Hann: This is Della. I was looking through the existing plans and, in Chapter Five they have the first long-term objective is to test for methods to improve dissemination, incrementation and sustainability of evidence-based intervention services or in diverse community settings.

Dr. Boyle: Geri, this is Coleen. I would say exactly the same thing. You are really talking about dissemination and evaluating that dissemination.

To me, effectiveness is a very

different thing versus actually the dissemination of it.

Dr. Dawson: So, okay. So you're -- Coleen, was your point that it should say effectiveness?

Dr. Boyle: Well, I guess I think of the sequence of rolling out something. First is the -- thinking of efficacy. The second stage is effectiveness, within the context of a community setting.

So, the first stage is that the -- you know, does it work in the “Ivory Tower" world. The second stage, is it -- does it work in the real world.

Dr. Dawson: Of course.

Dr. Boyle: And then the third stage is actually, once you implement into practice, you know, does it work within the routine setting.

Dr. Dawson: Right.

Dr. Boyle: How you can continue to monitor that. So, I'm just not sure where you

are in that stage right here.

Dr. Dawson: Well, I -- yes. I think that that has -- it hasn't been thought through, I think, on that level.

Dr. Boyle: Okay.

Dr. Dawson: But --

Dr. Boyle: But it's the idea there?

Dr. Dawson: Yes. The idea is there. And on a -- I think it was kind of trying to pull all together these, you know, various bullets into one. And I think it does more refinement.

One question is whether it's captured in the one that Della just read, and perhaps it is because I didn't study that.

Dr. Boyle: Yes.

Dr. Insel: Yes. I think when we did this originally, the idea was that Chapter Four would be more around efficacy and Chapter Five would be more around effectiveness and dissemination. And maybe that's where the

mismatch is.

Ms. Blackwell: And Geri, this is Ellen. I would also suggest -- and I'll be happy to send you some information if you like, but that you take a look at our administrator, Dr. Berwick's goals for the Triple Aim, and I'll be happy to share that with you, because I think, as was just said some of the principles that we're looking at, safe, effective, person center care, timely, efficient, equitable. It could be integrated also into this plan.

Does that make sense?

Dr. Dawson: Yes.

Ms. Blackwell: Okay.

Mr. Ne'eman: So I have another issue around Chapter Four. It's relatively simple, but I wanted to bring it up. I was pleased that in our -- the first two new objectives we mentioned, we particularly call out, outcome measures should include assessment of potential harms, result of

autism treatments, as well as positive outcomes.

In the initial plan I think there are a few objectives where that could be appropriately added on as well. In particular, short-term objectives A, C, D and F, and long-term objectives A and C.

So I'd like us to consider adding them on to some of our existing objectives as well.

Dr. Insel: Ari, you know, since we're going to redo the revised -- not redo, but revise the introduction, what about putting some language in the introduction that will capture that concern.

So, just as with the comorbidities issue it can then travel all the way through the document.

Mr. Ne'eman: I think that's a good idea. My one concern here is, you know, there is value in calling it out specifically in the objective. I don't know how many researchers

sit down, read the entire IACC strategic plan and then, you know, decide how they're going to structure their study.

Their focus, most likely, is on the specific objective they're responding to. So, you know, I do agree with putting it in the introduction.

At some level I do think this is something that is so important and, unfortunately, so counterintuitive to many researchers that it requires an explicit calling out as well.

Dr. Koroshetz: Well, Ari, I would just say from the researcher's point of view, I'm -- it's something that seems to be ingrained in research and so, for instance, any kind of human studies goes through, you know, and IRB and the IRB is primarily looking at potential harm.

They don't really care whether the therapy is going to be effective. That's not their job. Their only job is looking for

harm. And then, usually, if there's an intervention, there's what called the Data Safety Monitoring Board that's set up that oversees, and their job is to look at adverse events and to see if, you know, the -- there's more harm than there's any chance of good.

So, I think in the practice of human research, the issue of harm is front and center. So that's -- just a thought in response to yours, it just didn't seem -- I mean, I think -- I think we're on the same page more than you think.

Dr. Dawson: This is Geri. Ari, I have to agree. I, you know, did include this here because I knew -- know that it was something that you -- you know, you really wanted to call out, and I completely understand why and why it's important, but it did cross my mind, the same point that Walter just made, which is that, you know, when you conduct a clinical trial, one does have to monitor and report harmful effects, and so

that's always been, you know, a very strong emphasis on -- in the -- at least in the work that I've been involved in.

Mr. Ne'eman: So, I mean, I think our concern is, is that, you know, I'm not sure to what degree that is always happening in the autism research context.

Dr. Dawson: I think it's required, actually. You can't get away -- if you have --

Mr. Ne'eman: But there are a lot of things that are required that aren't happening to the degree that they should be.

Dr. Koroshetz: Well, that's important.

Dr. Insel: How do other people feel about this particular issue? Because, that would require revising a number of other items -- a number of other bullets in the plan.

Dr. Solomon: This is Marjorie. I would weigh-in with the other researchers and

I liked your idea, Tom, of including a statement evident in the introduction or to include in the whole document, but you know, the people that are going to be doing the work are all very much inculcated along the lines of what Geri and Walter said.

So, I would view it as not necessary to call it out every time.

Mr. Ne'eman: So let me suggest that we place this in the introduction and we also place this in the "What do we need?" section of the narrative around Question Four. That way, we're -- we're calling it out throughout the plan.

We're avoiding looking around in the objectives, but we're also placing a special emphasis on it in the context of the section on treatments and intervention.

Dr. Insel: Yes. I like that idea and I would actually add to it, Ari, not only potential harm but I think one of the things that we need to keep in mind is that there's a

role for research showing that interventions are not effective as well as trying to come up with interventions that are.

And an important area for science here is to provide that evidence base. So, I think we should find some language in the "What do we need?" section to hit both of those points.

How about we move on to see if there are any other issues the objectives or any other part of Chapter 4.

Dr. Dawson: So, Tom, I just want to clarify what the consensus is about the first objective. That -- you know, that wasn't actually my -- you know, one of my only objectives that I added, so this represents a lot of different people's, you know, areas that they felt passionately about on the subcommittee.

So I just want to make sure that -- that I know how the larger group feels about that so when I go back, you know, I can

reflect that.

Dr. Insel: So I had, I mean, one question I had about that first bullet was around the disparities issue and whether that had already been captured also in other chapters of the plan.

I haven't seen the actual bullet, but my memory, which is never very reliable, was that we had a bullet that dealt specifically with disparities and access to health care and health care outcomes in a -- I think it was in Section Five, Chapter Five, or maybe Six.

Dr. Dawson: So I know that -- let's see. I think, Ari, you were, you know, interested in having the community-based participatory research studies. Do you -- would you mind, maybe, before we meet, just looking at the other parts of the plan and seeing whether you think it was captured there.

I think both you and Ellen were --

wanted to conclude that second part which is to study, you know, TEACCH and DIR and other programs that are currently being used in the community that don't have as much data.

So, anyway, maybe just think -- you know, think about whether that's been captured by other bullets or not so that, you know, when we -- because I'm not sure now what to do with the first one.

Mr. Ne'eman: I mean, I certainly will, and I'll take another look through the plan but, you know, my inclination is that these things most likely are not captured and require, you know, specific collaboration upon, just because, you know, we -- we have looked at the plan previously, and I think these are -- these are areas that require the additional focus.

Dr. Solomon: Didn't we reach a consensus, and we had talked a couple of minutes back about - I guess I feel a little bit like we're making the wrong shopping list,

and I'm not sure --

Mr. Ne'eman: I'm sorry. Could you speak closer to the speaker. It's very hard to hear you.

Dr. Solomon: Sorry. I guess I'm just sort of thinking back to a point that was made a few minutes ago about the format of the plan itself in terms of should we be trying to come up with questions that we're answering, or should we -- I guess when I was doing Chapter Two, I felt a little bit like I didn't have the context in which to say we'll need three new studies of this or five new studies of that, and so I'm just reflecting back on whether asking for five community studies is -- was done in a thoughtful way. That's all.

Dr. Dawson: I can tell you it wasn't that thoughtful. It was literally -- it seems like people are saying two to five and I combined something like, you know, eight bullets into one, so I thought I better put five, so that's the amount of thought that

went into that.

I'm happy to, you know, reduce it because these are very expensive. I just want to reflect the sentiments of the group.

Dr. Solomon: I understand entirely.

Mr. Ne'eman: To my concern on reduction, and I do agree if this is -- it is an issue of expense here, but my concern on reduction is we have combined a lot of objectives into one and, you know, it does seem to me that if we have four or five different sort of subpriorities within an objective, you know, to fund only two studies around it is going to create a situation where a lot of things that have been named as a priority are going to be left out.

Dr. Koroshetz: This is Walter. I was just thinking that, if you look at Question Four and you look under Research Opportunities, the first one seems to really hit both of those two bullets.

It's not as -- you know, it's not as detailed, but it talks about large-scale studies directly compare interventions and combination of interventions.

We have a pharmaceutical, educational, behavioral intervention to identify what works best for which people, and how much it will cost.

It talks about best practice models that are being used in community-based programs, clinical trials. Says safety and efficacy of interventions has not been rigorously studied, and studies in diverse populations.

It almost sounds like -- I think that the -- it seems like the gist of what everybody wants is in the research opportunities. The question is: Is there -- you know, if you look, maybe there's not an objective that really links to that, and maybe that might be the -- it seems to me that might be the way to kind of broach it --

Dr. Dawson: Walter, where are you reading from?

Dr. Koroshetz: Question Four.

Dr. Dawson: So this question?

Dr. Koroshetz: Yes.

Mr. Ne'eman: In the original document, the original --

Dr. Koroshetz: Original document, yes. And the aspirational goal, interventions will be developed that are both effective for reducing care, both core and associated symptoms, building adaptive skills and maximizing quality of life.

And then research opportunities. It's a more general term but it actually hits pretty much, I think, the main points.

Dr. Dawson: Right. But so is there an objective that captures this?

Dr. Koroshetz: Well, I don't really -- I think that that's the point I was making. I don't think there really is. So, it's one about medications. There's one about

sibling intervention. Effectiveness of medication, that's there, but --

Dr. Insel: You know, I think what happened -- I'm just trying to see -- remember the context of this. I think we really started on this Chapter Four with a focus on efficacy, on the discovery of new interventions that would be much more effective than anything we have now, and that's why there's this focus on 20 model systems that will allow the identification of specific molecular targets.

And then what we have in this -- in the new recommendations is much more on the comparative effectiveness end, which follows very nicely with the comments in what's changed.

It says, you know, we have the Affordable Care Act, we have CHPRE. We have a whole bunch of things that are calling for different kinds of information where there are changes in policies that now will make us ask,

"Do things actually work in the community? Is this -- are the interventions that are being used really broadly already worth paying for?" Those kinds of questions.

So, I think it is good to have something in there in response to the -- like the CER provision in the Affordable Care Act. I'm not just sure that what we've got here is exactly what the Affordable Care Act needs, which is -- I guess it's number -- in the first bullet, Geri, it's what you have as number two: scalable early interventions programs for implementation in a variety of settings in the real world to find out whether the things that we're currently doing are worth -- worth paying for. Are they effective, and if they are, for whom, and if they're not, who should have something else and what should they have.

That's kind of what the policymakers are looking for. And perhaps if there's a way we can shape this -- because

that was not in the mix when we originally did Chapter Four, and it is the new reality.

Ms. Blackwell: Tom, this is Ellen. I started working on Chapter Six last night and I -- you know, because I've assigned it now, to Chapter Six, I started making a list of provisions in the Affordable Care Act that I thought, you know, we should mention, and I was going to put them in Chapter Six because that's simply the chapter that I'm assigned to.

But, is there a better place to talk -- you know, maybe an overarching place where we should talk about those changes that's not Chapter Six?

Dr. Insel: Well, no, I think this is the place. I mean, these are intervention studies, so --

Ms. Blackwell: But there's more in the Affordable Care Act than just the intervention studies or the adult quality of life measures. There are other pieces that

are services options.

So, it's kind of -- kind of a stew here. I'm not quite sure what to do with it.

Dr. Insel: Well, I guess I don't see it that way. I mean, I think it's -- I think the team that worked on this did a great job in saying, you know, if you -- if you look in 2010 and say, what's really changed, it's around this issue.

So, we were very focused on efficacy and coming up with novel interventions that were better than the ones we have now in what we wrote in 2009.

We modified that a bit in 2010 to get at these questions of predicting response, bringing in biomarkers, making sure that the trials included adults as well as children.

And now in this new version, it seems to me it's logical that the question that's being asked is, "All right, does anything really work in the real world?"

So, if we take this from the

efficacy domain to the effectiveness domain, can you see -- are things scalable, are they practical, are they worth paying for? Those are the questions that are the right ones to be up.

I think the only question -- and I think that's part of what we're struggling with here is, are we ready to do that, do we have the interventions that are worth doing that for, and I guess the implication from what I'm reading here, and what's in the bullets we have that, even if the research isn't there, people are already doing this and paying for it.

So, we should really look at whether it works, whether it's scalable and whether it works in a real world setting.

Ms. Blackwell: Yes. I think that -- that we are ready for this, and I think the other -- the other part of it is that, by putting it in here, you know, people hopefully will, as Alison was saying, you know, respond

to this by starting the design studies with this in mind.

You know, I do think we need to get past, you know, if we talk about early intervention or, you know, some of the other studies that are looking at health care and health care outcomes, you know, we need to be starting to conduct these in real world settings.

And so I think this will really push the academic community and the clinical community to start designing these kinds of studies. And I think it -- the reason why -- I wouldn't necessarily fold it into comparative effectiveness is that, you know, we don't even have studies on effectiveness yet.

We only have efficacy studies on most of these things, right? So, the first thing I could imagine someone doing is, you know, not trying to compare two studies in their -- two approaches in their

effectiveness, but they might want to just try to scale, you know, one approach and see if they can show it to be effective in a community setting compared to, say, standard of care.

Dr. Insel: Right. So -- but given that, I mean, I guess it does, then, raise the question about whether the comparative effectiveness bullet is premature.

Ms. Blackwell: Yes, but I -- I think it is premature, but the only issue is that I think there's funds going to be out there, right, for it.

Dr. Insel: No. I was thinking the same thing. It's sort of opportunistic because --

Ms. Blackwell: Yes. I mean, I would -- then we don't want to have it not as a strategic plan if there's going to be funds out there and, you know, people stretch.

Dr. Insel: I know. I feel -- you know, I feel a little funny about this because

I also have the sense that it's -- to not include it in the plan would -- we may lose a moment here, and that would be real important.

Dr. Koroshetz: I think the other thing to say is a lot of comparative effectiveness -- there is a lot of comparative effectiveness studies on things that have never been proven effective so we're not the only ones out there doing it.

You have a line about effectiveness, is to test things that are being used. You know, once they're in medical use, then the medical system, you know -- it's already there, and so that's fair game for comparative effectiveness once they're in --

Dr. Insel: Yes, that's a great point, Walter. So those of us who have been on this Committee that oversees comparative effectiveness research across all of NIH, and there was a lot of debate about this point and originally we thought you had to have the efficacy really nailed down.

But we have decided, as a policy matter, that something like TEACCH or Floortime or something that is in broad general use is still worth including in a CER trial because, even without the efficacy there, it -- there's still an important policy question that needs to be answered.

Dr. Dawson: So I think the question, then, is whether we can combine these two bullets. The only thing I would say is that one would not want to require that it be a comparative effectiveness study in order to start looking at the effectiveness of a, you know, program in the community.

Dr. Insel: Right. Right.

Dr. Dawson: And so that was the -- that's the issue there.

Dr. Insel: Okay. Okay. Well, mindful of the time, is there anything else on this that people want to give as feedback to the group that's worked on this?

Dr. Koroshetz: I would just go

back and say that the language that somebody put together under research opportunities, large scale studies that directly compare interventions, blah, blah, blah, it's actually quite good language.

And to make an objective out of that research opportunity, I think, would probably be the thing that -- that might guide you.

Dr. Dawson: Can you send that to me?

Dr. Koroshetz: No, it's in the plan. It's in the --

Dr. Boyle: It's on page 26, Geri.

Dr. Koroshetz: Page 26 of the --

Dr. Insel: Of the original plan.

Dr. Koroshetz: -- up to 2010.

Dr. Dawson: Okay. That's what I was wondering. It's page 26. I'll find it, then.

Dr. Insel: Okay. And the only other comment I had was that I thought that

the -- this section on what gap areas have emerged since last year, you know, sort of giving the reader an update, was just outstanding, because it not only talked about some of the policy issues, but by highlighting the ATNs, it sort of sets up those objectives by saying, "Hey, we can do this. We actually have a network in the real world that's ready to go ahead and move some of this forward."

So, I think it's a very strong case for saying a lot has happened in the year since we did the last revision, and with these things in hand, particularly with something like the Affordable Care Act in front of us and PCORI now being set up -- I guess today is their first meeting; I'm pretty sure it is. -- that this is the time for us to be asking a whole new generation of questions, particularly about real world effectiveness and CER.

Della?

Dr. Hann: Yes. So I would just

like to review them, what I hear -- Geri and others work on this update. What I'm hearing is the points we need continue to work on, just so we're all on the same page. That efforts will be made to consider rewording and combining the first, under new opportunities and research objectives that have emerged, to combine those first two, and reword it and focus on effectiveness and/or comparative effectiveness, that the third area, the third bullet will be dropped, the fourth was not -- to my knowledge was not discussed today, so I'm assuming it stands.

And for the last bullet, that Coleen and Geri will work on the wording of that and Ari and Ellen will also consider how elements of that may be related to Chapters Five and Six.

Dr. Dawson: So, I just want to clarify. Is it true that you want us to combine the first two, or keep them separate?

Dr. Insel: Let's leave that --

what do people think?

Dr. Koroshetz: I mean, I think it's probably -- probably easier to at least combine it and separate it out.

Mr. Ne'eman: I don't know. It looks pretty hard to combine. This is of a significant size.

Dr. Insel: Geri, I'd be willing to work with you to try it, if we can do it with --

Dr. Dawson: Sure.

Dr. Insel: You know, if we can find the language. It has to be -- I think there has to be a logic to it and I think I can see the logic but I'm not sure we have the words for it yet.

Dr. Dawson: Okay. Well, any help you can offer would be greatly appreciated.

Dr. Insel: Okay. And, you know, the good news is this reflects a lot of progress. So, it's -- you know, it's kind of amazing to think that we're having discussions

here about effectiveness and real world interventions only two years after saying that we didn't really have anything worth testing. So, that's kind of a good thing to recognize.

Ms. Blackwell: This is Ellen. I would just like to thank you, Geri, for doing such a good job and being so patient and hammering away on this language.

Dr. Dawson: Oh, my pleasure. It was -- you know, it's been an enjoyable experience working with the group.

Dr. Insel: Can we move onto Chapter Seven. And, Ellen, were -- oh, Coleen. Okay.

Dr. Boyle: Oh, actually, I was -- it was Coleen and Geri on this one.

Dr. Insel: Okay.

Dr. Boyle: So, Geri as well. So I appreciate her -- her contributions.

And Question Seven is a -- really a composite question, focusing on infrastructure and surveillance needs. So, in terms of the

first section of what's new, we followed the format that was provided in Question Seven already, and that was -- we focused on data-sharing -- sharing, biobanking, surveillance and information that communication, dissemination, as well as the work force development, and that's -- it's actually the research workforce development.

So, Geri actually did the updating for the data-sharing and the biobanking. So, Geri, maybe I'll just turn that over for you, just for the updates, what we've learned.

Dr. Dawson: Oh, sure. Della, in data-sharing, I thought it might be helpful to include the new Autism Informatics Consortium that was formed this year, which is a collaboration among the Science Foundation, the NIH, particularly NDAR, and the Interactive Autism Network and.

And they had a meeting that was held this year in August and they identified objectives and gaps in terms of our need for

issues related to harmonization of data, best practices and really just ways of enhancing the ability for data-sharing among the scientific community at large in the United States. And those gaps are -- I kind of highlighted those down below.

Biobanking, I thought it might be useful to put in the new development for the Autism Treatment Network of beginning to collect biomaterials on patients in that registry, and funding for the collection of DNA, plasma and urine on four out of the 14 sites with a step towards establishing a bio repository for the ATN.

And I'm actually going with your -- Della, I'm looking at your screen so, I don't know if there's more. I guess I should have pulled up my own.

Yes. Okay. Thank you.

And then in the Autism Tissue Program, this year there was the -- they launched a program to sample tissue from the

brain, to have DNA isolated from brain tissue as well as the beginning of a -- a stem cell repository from brains.

So, tissue is being collected from brains and skin that -- from the donors that come into the Autism Tissue Program so that these can be used to develop pluripotent stem cells, and that's been funded by the NIH.

Dr. Boyle: Okay. Thanks, Geri, and then under the category, I highlighted the work by both the out-of-network and the National Survey on Children's Health in terms of the updated information about prevalence for children on the autism spectrum as well as the multiple studies that have indicated that the identification of risk factors and changes in awareness as well as diagnosis contribute to, but not fully explain the rising problems in autism.

Under the category of information, communication, dissemination, we highlighted, I guess, both new reviews on intervention

quality and effectiveness, as well as the CDC HRSA-sponsored state activities that have helped in terms of development of state plans for ASD and other DD services.

That's clearly begun to build sort of the resources and the services and linkage to early intervention.

I don't have anything right now under new developments for research workforce development so if anyone on the phone has some thoughts to what can be captured as -- as new in that area over the past year, I'd be happy to take it and to integrate it.

And I think, Geri, that you did highlight the gaps that have emerged, right? I don't know if you had anything else to say about those two areas.

Dr. Insel: Actually, before we go on to the gaps.

Dr. Boyle: Sure.

Dr. Insel: On the workforce development, is there anything that the

subcommittee knows about that ought to be included as a new development in 2010?

Mr. Ne'eman: I think this is an opportunity to mention a number of the stuff in the Affordable Care Act around workforce issues.

There was a tremendous amount of grants going out to build a stronger health professions workforce with a particular focus on closing disparities and it's going to be an opportunity to build on that.

Ms. Singer: This is Alison. I think this is also a place where we can talk about the stimulus money that went towards autism and the fact that many people were hired into autism research labs through the stimulus money and that there's some concern about what happens next year when that stimulus money goes away.

Mr. Ne'eman: Yes.

Ms. Singer: With regard to workforce.

Dr. Boyle: So are there concrete things that you can send me because, again, I'm not that -- that part I'm not aware of. I actually was going to tap into Peter van Dyck and HRSA which I didn't get to in terms of what they might have funded through ACA.

Dr. Insel: Well, so I just want to make it clear that I think it's the research workforce that we're focused on here, so --

Dr. Boyle: Okay.

Dr. Insel: -- this is really the number of scientists or the number of graduate students or post-doc's that are being supported in the research pipeline.

Dr. Boyle: All right. So we don't care about services piece of it then?

Dr. Insel: Not for this particular bullet.

Dr. Boyle: Okay.

Dr. Insel: But there is information, as Alison mentioned, though, we could take the stimulus package numbers where

we have at least a list of grants.

I don't know if we can get to the training part, but we can -- we should be able to get some information about the number of additional people that were supported in the research workforce.

Dr. Boyle: Okay. It's a -- is somebody help you with that?

Dr. Insel: We will get somebody here to pull numbers. That's not that difficult.

Dr. Boyle: Wonderful.

Dr. Insel: Excess in the -- and I would -- you know, Alison's point about this was a surge with a short-term stimulus package and it does beg the question, what's going to happen in 2011 or 2012 when that -- those funds are no longer available.

So, I'm not sure -- I'd have to -- you know, how much we want to say about that, but to not at least mention it here --

Dr. Boyle: Well, I definitely

will, and I could put it under the gaps -- the potential gaps somehow.

Dr. Insel: That's right. I think that would be great.

Dr. Boyle: Okay.

Dr. Insel: So, we'll get back with you when we've had a chance to look at the ARRA that is the Recovery Act list and we can get some kind of number that we can plug into this.

Dr. Boyle: Okay.

Mr. Ne'eman: Tom, can I just raise an additional issue around ARRA? So, one of the ARRA -- the areas of ARRA funding, not specific to autism research, but within NIH more broadly, was the NIH directors award to promote diversity in the scientific workforce.

And I do think there's some value in discussing that here. I wonder if we can make mention of possibly where we're already talking about expending -- bringing early career scientists into the ASD field and

expanding the research workforce, the need to ensure the recruitment of diverse populations, including individuals with disabilities and individuals on the autism spectrum.

Dr. Insel: Fantastic idea.

Coleen, if we give you the language, is that okay?

Dr. Boyle: Oh, that's fine. I think that's an excellent idea.

Dr. Insel: Yes.

Ms. Blackwell: Coleen, this is Ellen. Can I -- can we just reverse for a second back to the communication paragraph?

Dr. Boyle: Sure. Sure.

Ms. Blackwell: I was looking at it and I was thinking that I think it's more than just state plans for autism, and I would actually suggest you strike the other DD services because, I mean, our focus really is on autism here, but it's more than just state plans, it's what states are calling autism summits, commissions on autism, blue ribbon

panels and task forces on autism.

And they -- and so there's a lot of different names for what these plans look like, other than just the state plans.

Dr. Boyle: Sure.

Ms. Blackwell: But you might want to capture that in that paragraph.

Dr. Boyle: I can -- I can enlarge that.

Ms. Blackwell: Okay. Thanks.

Dr. Insel: And before we go on, you know, on the biobanking side, maybe there should be the addition of just putting a line in the sand here about where we are with DNA samples from the Simons collection as well as from the NIMH repository because if we want to use this to look back on in the future, it might be good to have those numbers.

I think Simons has just crossed the two thousand mark, and that includes not just DNA, but immortalized cells and they have huge amounts of other information that goes with

those -- that collection.

For the NIMH repository I'll get you the exact numbers, but it's in the eight thousand to nine thousand range, and it could just go into being added in with what's being said about the ATP.

Dr. Dawson: We should also add in the autism genome project data.

Dr. Insel: Oh, yes.

Dr. Dawson: That's -- that's, you know, well over three thousand now.

Dr. Insel: Okay.

Dr. Boyle: Geri, do you want to keep working on that one?

Dr. Dawson: Sure.

Dr. Boyle: Okay. Thank you.

Dr. Insel: And, Susan, if you could get with Thomas here, he can get you numbers about the NIMH repository, and we can add them all together.

The good news is that there shouldn't be too much overlap because we're --

everybody should have a GUID so we'll know that there are independent samples, and I'm sure that someone from Simons can get us the latest numbers about what's in their collection.

Dr. Koroshetz: I just had the sense that you didn't really explain the actual magnitude of success you've had in data-sharing and it would be worthwhile putting in the big numbers.

Dr. Insel: Yes. I noticed that -- I mean, that would be -- for neuroscience meeting and there was a couple of lectures given by Congressman Kennedy, and he used the autism community as the example of data-sharing that he wanted -- that he felt was a prototype for many other disease groups.

So, there's nothing wrong with celebrating some of the successes here. We might want to --

Dr. Dawson: Would we want to add, then, data from the, you know, NDAR, as well

as also talk about the data federation efforts between Simons, NDAR and AGREE, and ATP?

Dr. Insel: Yes. I think what you have is great. I think you've done that, and I guess the only thing I would add is maybe putting in a number of where we're at in 2010.

I think we're -- we've passed the twenty thousand mark and by the end of December it will be actually well beyond that. We can get you the current number. We can even just put in a number and flag it with the date, you know, so for November 19, 21,712, whatever it is that GUIDs that have been established in NDAR.

It's just part of, again, noting progress for where we are at the current time. I'd like, to the extent we can, it's great to be quantitative, but I think what you've done here is really great. I mean, it's -- it's a good summary, including the workshop to clarify that the community has really come together.

Dr. Boyle: Okay. Geri, I don't know if you wanted to say anything about the gaps.

Dr. Dawson: So just really quickly, the workshop identified, carefully, I think, some gaps and they're listed there, but they have to do with ongoing options for data federation, you know, meeting to have query and interface languages that can allow investigators to actually access some of these large databases in a flexible way.

There's a consensus that we need to build common data dictionaries and ontologies that the field can use, and also continue to promote the standardized GUID usage, and then also coming up with things like a common phenotype battery that would be promoted throughout the research community as well as coming up with procedures for how we collect imaging and genetic data that can be used more broadly throughout the community.

And then, in the biobanking, just

the need to establish repositories that, you know -- Sorry, I'm going to go over to my end so I can move it down here.

To have repositories in real world settings that can start to link information about biosamples, whether it's genetic or otherwise, to the treatment and longitudinal course of patients in real world settings or people in real world settings that are being served in clinics.

And this has been really critical to other fields in terms of moving forward. Progress is to have, you know, networks of community settings that are -- that are serving patients or individuals with a conditions and at the same time collecting biorepository information. So, that was what was tried to capture.

Oh, and I should also point out the last part about the need for high throughput screening tools to evaluate gene environment interactions.

That was a bullet that I think, Lyn, you put in, so you may want to comment on that.

Ms. Redwood: That came out of the workshop the NIEH has sponsored with autism --

Dr. Dawson: Yes.

Ms. Redwood: And that was one of the things that was discussed rather extensively, and that there are several systems now, but they need to be better developed.

I didn't realize, Geri, that you had put this in there, but that's great.

Dr. Dawson: Yes. I guess one question, looking at it now, is whether it really should go under biobanking or -- I do think that was included in the Question Two on, you know, what caused this to happen or, you know, looking at etiology.

Ms. Redwood: Okay. Along those same lines, Geri, we could also put in there -- I was reading over the comments from Linda

Birnbaum, too, in terms of needing more information regarding, what was it, bioinformatics and microbiome and those types of things.

So, I think, if it would be possible, to put that in there too, as infrastructure needs, that might be a good place where it would fit.

Dr. Dawson: Okay.

Dr. Boyle: All right. Just moving on to the surveillance capacity, that the issues that we highlighted in terms of gaps was better understanding how multiple identification and potential risk factors have influenced the changes in autism over time, and to be able to examine multiple data -- data sets to identify potential risk factors in the population.

I think that another -- I guess, another area that I didn't include that probably should be included is the issue of having more real time data for autism

surveillance.

I know we're driving towards that here at CDC, but we always seem to be a little bit -- it would be best if we were more current with the information that we're -- we're identifying and tracking.

In terms of the communication information dissemination piece, these two, both the workforce development and the communication information dissemination piece I think need a little bit more work.

You know, obviously, there has been, as I mentioned, additional information on intervention quality and effectiveness and there's -- as Ellen pointed out, there's fairly robust activity going on at the state level in terms of the ability to disseminate information about treatment options and services to the community.

So, highlighting perhaps -- better highlighting the gaps there, I think we do need to flesh this piece out a little bit

more.

So, Ellen, any help you have with that, that would be great.

Ms. Blackwell: Sure.

Dr. Boyle: And similarly with the research workforce development, the areas that we highlighted were health services research, translational research and research related to international collaborative studies.

Ms. Blackwell: Is there calling -- this is Ellen. Is there anything in here that we need to add about students, colleges?

Dr. Boyle: I mean, I think that would be great. I don't know, you know, what specific funding has begun to both postdoctoral or doctoral programs.

Ms. Blackwell: Alison, do you have any suggestions?

Ms. Singer: Well, I mean, I think one of the issues we struggled with when we were reporting in the portfolio analysis was should we report our grants under workforce,

since they are pre- and postdoctoral, or should we report them under their category areas?

So, I think we could go back and look at the grants reported and see how many of them address this issue.

Dr. Johnson: This is Jennifer. I'm just wondering if -- I know HRSA was mentioned earlier as a possible research and adjusting the research workforce development and I'm just wondering if we should indeed go to them because they do have funding for their leadership, education and neurodevelopmental disabilities grant --

Dr. Boyle: Right.

Dr. Johnson: -- specific to us, and a lot of students will do research related to autism or other disability issues, and so I think that is a workforce development resource potential there that we might want to better understand with what's going on within that network of programs.

Dr. Boyle: Okay. Well, I can follow up with Bonnie Strickland to get her thoughts on that.

Dr. Insel: There's one other -- one other piece to this which is not a gap, but it's actually just would fall under what's new in this research area for the research workforce.

And, Geri, you'll know more about this than I do, but at least two companies, two pharmaceutical companies in 2010 have opened up autism research divisions and there may be even more than that that will be happening before the end of December.

So, that's -- in terms of medication development, that's a -- that's never happened before, so --

Dr. Dawson: Yes. That's a really good --

Dr. Insel: -- it's a step forward.

Dr. Dawson: So you think -- where do you think we should capture that?

Dr. Insel: I put that under research workforce development, under what's new in this research area and what have we learned in this past year.

So, in addition to whatever comes out of the stimulus package, I think you can mention that -- what would it be, it's Pfizer and Roche, is that right, and maybe Merck.

Dr. Dawson: Exactly. Right.

Dr. Boyle: And Novartis also.

Dr. Insel: Which one?

Dr. Dawson: Sure.

Dr. Boyle: Novartis.

Dr. Insel: Novartis. Okay. So I don't know them but, Geri, can -- would you know which ones to plug in there?

Dr. Dawson: Sure.

Dr. Insel: Great, because I think that's, of all the things that have happened this past year in terms of therapeutic, that could be huge because they will put -- once they get engaged they can put huge amounts of

resources into high throughput screening and lots of other things.

Dr. Koroshetz: And they won't leave the field so quickly.

Dr. Insel: Yes. We can name them, we can shame them when they leave. Okay.

Dr. Dawson: Oh, I like that.

Dr. Insel: Strike that from the record, please.

Dr. Dawson: Okay.

Dr. Insel: Okay.

Ms. Redwood: Could we also -- Coleen, this is Lyn -- with regard to the area of surveillance in terms of what's for MapStar.

I know the parent community gets somewhat frustrated with the monitoring systems that we have in place now, in that they're not consistent, and because they're being re-competed -- re-competed every so many years it's -- there's no consistency in that data.

Also, it appears as though the number of sites have decreased --

Dr. Boyle: Okay.

Ms. Redwood: -- and that not all sites are able to get the same data.

Dr. Boyle: Okay.

Ms. Redwood: So we don't have access to educational data, which I think should be part of any of those sites if we're going to be funding them.

Dr. Boyle: I'll incorporate them all in. That would be a great idea.

Ms. Redwood: And we also don't have the data that actually breaks out the different subtypes of ASD.

Dr. Boyle: Okay.

Ms. Redwood: So, I think it makes it really, really difficult to plan for the future in services when we don't know what the level of ability and disability is of the individuals.

Dr. Boyle: Okay.

Ms. Redwood: So, if we could add some of those things in there in terms of gaps --

Dr. Boyle: Yes. That's right. So subtypes as well as level of functioning, something like that?

Ms. Redwood: Yes. Because, you know, some individuals with ASD are incredibly functional and brilliant.

Dr. Boyle: Correct.

Ms. Redwood: I think Ari is a wonderful example of that. And then, as we well-know, there's others that are not functional at all and will require 24-hour care and so we need to be able to plan for the future by knowing what the level of needs are in the communities.

Dr. Boyle: Okay. I'd be happy to --

Ms. Redwood: There is no breakdown. My understanding, in terms of whether it's Asperger's, PDD-NOS or DSM-5,

now, autism.

Mr. Ne'eman: So let's just be careful here. I think we want to acknowledge, and I do think we want data on the variability within the autism spectrum, and that's very important.

Yet, at the same time, I mean, first it doesn't really make sense for us to be collecting data by diagnosis because it looks like the DSM-5 is going to be consolidating things, anyway.

And second, I want us to be cautious about simply tracking this construct of functioning because different people are going to have different service provision needs and different areas of strength and challenges in different areas.

I'd be much more interested in tracking characteristics or service provision needs or things of that nature.

I don't know what exactly we're going to get in terms of utility if we just

say, "Well, this percentage of people are classed as high-functioning," or "This percentage of people are classed as low-functioning."

Ms. Blackwell: Yes. This is Ellen. I agree. I think that's kind of a slippery slope and --

Ms. Redwood: I have a question that, how do you know which -- in the future, how many group homes you'll need, if individuals are able to live independently without having some grasp on that?

Ms. Blackwell: That's a good question, Lyn.

Well, Ari, let me answer Lyn.

Mr. Ne'eman: Okay.

Ms. Blackwell: I think when -- if you didn't see the services presentation on that aid, but you might want to go back and look at some of the -- the early presentations in the morning that talk about, you know, how the country services system is set up and what

we expect to happen in the next ten years, I actually think that might help you because --

(Whereupon, the court reporter was disconnected from the telephone line at 9:49:17 a.m. and reconnected at 9:50:21 a.m.)

Ms. Redwood: -- how many group homes we have. It's already, so it's really about what each individual needs and what each state has decided that it can provide.

Does that make more sense?

Ms. Blackwell: Yes. I'm just wondering, in terms of planning for the future, though, how did you come up with that information.

Ms. Redwood: Well, so it's really -- I mean -- I mean, states make their own projections and decide, especially in terms of adult services what -- what they're going to provide.

Dr. Insel: But then why are you doing surveillance if it isn't to inform the policy?

Mr. Ne'eman: So, I mean, I have an entirely distinct objection here. You know, I just -- I don't know if by doing this we'll be getting useful data if we're just breaking down by high/low, and I supposed mid-functioning.

I mean, for one thing, the type of service provision needs are going to change, depending on best practice.

Lyn, you mentioned group homes. Well, you know, a number of states are moving towards less restrictive settings and, you know, there are different types of group homes, and one thing that's a going trend is to separate the real estate component of service provision from the service provision component to service provision so people have more choice.

So, there's a growing level of individualization and the service provision needs that one plans for are often just as much shaped by preference as functional need.

But, you know, going back to what kind of data we should be collecting, my only point here is let's collect it on the basis of actual characteristic of "functional need."

Let's know how many autistic adults or children or -- well, how many autistic adults are going to need some type of residential support. Let's know how many autistic adults are going to need some type of employment support.

Let's know how many people are going to have communication-related challenges. These are practical priorities. Simply classing people into high- versus low-functioning doesn't actually tell us very much as to what kinds of policy steps we're going to need to take.

Dr. Boyle: I'm sorry. I don't agree, Ari. I have to agree with Lyn here. I think, you know, we need to collect this data because, just as you're saying, Ari, the differences where, what do we need to do in

supported employment, for example, is very different for a person who's nonverbal, versus a person who has an above-average IQ.

So, I -- you know, I think --

Mr. Ne'eman: I don't think anybody is -- I don't think anybody's objecting to that. I certainly agree but, I guess my point here is, wouldn't it, then, make sense to collect information as to how many people are nonverbal and how many people have intellectual disability, rather than saying, you know, well, how many people are classed as high- or low-functioning --

Dr. Boyle: Sure.

Mr. Ne'eman: -- a category to which we don't have a clear definition of?

Dr. Boyle: I think -- yes, I think that's fine, but I think the point Lyn is making, and I think it's a good one, is that one of the reasons that we collect this data is so that it can inform the future so we can decide what we need to be getting ready for in

terms of service delivery so that we can accommodate those needs.

And I think, you know, if you want to call it nonverbal versus whatever -- as long as the data are informative.

I also think, you know, Ellen, with regard to the states sort of not needing this data because they can only do what they can do, I think there's also -- you know, the private sector has shown its willingness and interest in getting involved here.

So, for example, I think ten years ago we saw a number of parent groups opening schools, you know, and their kids were two and three and four, that's where a lot of parents' groups focused.

And now I think, as the kids are growing up, you're seeing a lot of parent activists and parent advocacy groups focusing on creating employment opportunities, and various methods of housing.

And I think that, in order for the

parent groups who are -- who are going to be doing a lot of this work, to be data-driven, we need to have the community be able to provide them with good data.

Mr. Ne'eman: Nobody disagrees with that. I think we are on the same page --

Dr. Insel: Ari, can I interrupt? This is Tom, and I want to make sure we don't get hung up on this question.

So, if we could just maybe put in language, Coleen, if it makes sense to you, that within the realm of surveillance, which is mostly now focused on administrative data for eight-year-olds, it sounds like the subcommittee wants to see more -- some deeper phenotypic information or something more about the features besides the administrative data.

What that might be --

Dr. Boyle: Okay. I can -- I can work with us to figure that out.

Dr. Insel: Yes.

Dr. Boyle: I'm -- the conversation

has been great, so I think that we can just work amongst us to -- to clarify this.

And I'm also including Lyn's idea of consistency in the number of sites and the specific sites over time.

Dr. Insel: Right. So, I think everybody appreciates that we've come some distance with surveillance, but it's still limited in the --

Dr. Boyle: Right.

Dr. Insel: -- kind of information we have in terms of -- of informing policy or recommending additional research questions.

So, unless there's anything else people have heartburn about, I'd like to move on so we don't just get hung up on the gaps.

Dr. Boyle: Okay.

Dr. Insel: Okay?

Dr. Boyle: All right. In terms of actual new research objectives --

Dr. Johnson: Sorry. This is Jennifer, another diplomatic thing I wanted to

mention in terms of gaps -- gaps, and that's related to the communication and information dissemination.

And I'm just wondering how communication and information dissemination is being conceptualized, and whether we consider this to include communication and information dissemination to people with autism spectrum disorders, family members and practitioners.

I think -- and the reason I ask is because oftentimes these are people who really want the information, but it's not always presented in a way that they can access it or they can find it.

So, I think there's a lot of gaps in terms of information dissemination to those types of audiences. So, are we including them in this?

Dr. Boyle: I guess I would open that up to others for considerations because I'm relatively new here.

Dr. Johnson: I guess, was that a

part of your discussions when you were reviewing this chapter?

Dr. Boyle: No, it hadn't been, but we can include that.

Dr. Johnson: And I think it's just -- what I'm trying to get at is the idea of how do we translate research and make it meaningful and understandable to people who are not traditionally researchers.

Dr. Boyle: Right.

Dr. Insel: So, Coleen, can you work that language into that particular paragraph?

Dr. Boyle: Sure. I'd be happy to.

Dr. Johnson: And if you need any information about gaps in this area I can try and help with that.

Dr. Boyle: Thanks, Jennifer. That's great.

Dr. Insel: Okay. Moving on. Are we ready to do the objectives?

Dr. Boyle: Sure. So what we did

was actually do a revision to two of the objectives, trying to work with those in terms of the gaps on information, just -- both of surveillance as well as the communication information disseminated piece.

So we revised Objectives B, which is -- was stated as "Conduct an annual State of the States assessment of existing state programs and supports for people and families living with ASD, and this is by 2009, which I don't think has been done, and make -- so we just added, "and make this available as well as state plans and other information developed regarding ASD, and make it available on a single ASD services and supports website location.

Ms. Blackwell: Coleen, this is Ellen. I was looking at this earlier and I had a couple thoughts. First, the correction "for the State of the States." It actually should say "2011."

Dr. Boyle: Oh, really? That fixes

that. Okay.

Ms. Blackwell: And then I have some thoughts about this web location. At one point we at CMS had discussed the establishment of a web portal.

Laura, in fact, brought it up, and it was part of a proposal that we kicked around here as something that we were going to fund, but what we ran into was the problem -- I'm sorry. We have an announcement going on here.

What we ran into was an issue with, you know, website maintenance. So, I don't know if you're aware of it, but the Department of Health and Human Services does have -- on the HHS website there is an autism page, www.hhs.gov/autism and so I think that that actually might be a page, for example, where the State of the States could reside.

Dr. Boyle: Oh, that's a great idea.

Ms. Blackwell: Yes. And the same

-- you might want to look at the same for your Objective M which talks about the web portal.

Dr. Boyle: Okay.

Ms. Blackwell: But I would urge caution regarding these state plans and state blue ribbon commissions and that sort of thing because I'm a little bit nervous or concerned about HHS would be -- you know, on our website we don't want to be endorsing what states are doing.

So -- but I'm totally okay with putting HHS-sponsored data, you know, on the -- including services data on the HHS website.

Dr. Boyle: Okay. I mean, now --

Ms. Blackwell: Does that make sense?

Dr. Boyle: Yes, but the only -- I guess the only issue I would have there, Ellen, is just the challenge with clearance but, you know, maybe that's not an issue. I don't know --

Ms. Blackwell: Well, I think we're

okay with, for example, you know, papers that come out of HHS. That doesn't seem to be a problem. In fact, there's already links and things --

Dr. Boyle: Yes.

Ms. Blackwell: -- up there, but --

Dr. Boyle: With a revised Objective B, we wouldn't -- I mean, I guess we could put links to this -- to other states, the state-related activities.

Ms. Blackwell: And see, I don't know how far you're going to get that with HHS, but --

Dr. Boyle: Right, I see what you're saying. So, do we need this idea of one portal for this kind of information?

Ms. Blackwell: I think that services information and HHS information could certainly be added to the HHS autism web page. You might want to just sort of look at this through a different lens and, you know, indicate that -- I don't know. I would give

this a little bit more thought.

And we also -- I don't know who the owner is of that page. Della or Susan, do you -- do you know?

Dr. Daniels: Which web page are you referring to?

Ms. Blackwell: The one on the HHS website that actually -- it actually has a lot of information about the committee itself on it. It's www.hhs.gov/autism/.

Dr. Insel: Yes. It went up on April 1st from HHS and I think that comes actually out of Howard Coe's office, is where that originated, but it's probably not the place for this to live. It's not that carefully curated.

I had a different question because the -- actually, the original objective was to have the State of the States done by 2009, and --

Dr. Boyle: That's what's in the plan, right.

Dr. Insel: Right.

Ms. Blackwell: And we have certainly learned along the way that, you know, putting together this type of effort and getting clearance for the survey process, I -- you know, it's taking, you know, longer than we anticipated.

We've talked about that before but we're definitely on track to finish the collection of the information, publish the first one in 2011. So, I think --

Dr. Boyle: Ellen --

Ms. Blackwell: -- that, as we go forward and that once we've developed the information collection instruments that are -- that we'll be in a much better position to whip this out on a yearly basis because it's mostly associated with how do you do this and how do you do it, and then can you just replicate it going forward. But, that is the reality.

Dr. Boyle: And so, Ellen, maybe we

can clarify this, you know, offline or later, but I guess I'm still a little confused in terms of the revised Objective B.

Are you okay with the idea of including the outcomes from the State of the States' yearly annual assessment, as --

Ms. Blackwell: Sure. Sure.

Dr. Boyle: Okay.

Ms. Blackwell: It's just that where does it -- where does it go? I mean, are we talking about here establishing a separate website, because that --

Dr. Boyle: Well, that is going to --

Ms. Blackwell: I mean, we learned that that would cost a lot of money, and we decided that CMS probably wasn't the place to do it.

So, establishing a web location, to me, is almost a separate objective.

Dr. Boyle: Okay. And we could separate it out, then.

Ms. Blackwell: And last we, as I said, you know, Tom, you didn't think it was practical maybe to use this one, the HHS website, but maybe there could be some exploration done there. I don't know.

Dr. Boyle: I think it would be -- I mean, I think it will be challenging to do it at the Assistant Secretary level. That's just -- just in terms of the clearance process.

Dr. Insel: Wouldn't it be sufficient to have a State of the States report that was electronic and posted? Because, if it's going to be updated every year, anyway, what more do you want beyond that?

Dr. Boyle: I think we were trying to capture other information, and that's -- the other ongoing state-related activities that could be helpful.

Dr. Insel: But it sounds like we're having so much difficulty just getting

the original objective done. This is one of those cases in which -- I don't know that -- how adding on more information is going to help make us -- is going to help us to deliver what we said we would do in 2009.

Ms. Blackwell: I actually think that a lot of the information is going to be in the State of the States report, other than the stuff that's coming out of the states, like the blue ribbon panels and the task forces, we didn't go to look at that. We looked more at state systems, social security, developmental disabilities, home- and community-based services waiting list.

So, you know, as I said, I mean, who would put together the information about whether a state has, you know, for example, a state plan or for education or for autism or a task force or a commission.

I -- who would be collecting that and then putting it up on this website, Coleen?

Dr. Boyle: Well, I'm not quite sure, Ellen. I mean --

Ms. Blackwell: yes.

Dr. Boyle: -- we could do that with every objective here.

Ms. Blackwell: Yes.

Dr. Boyle: I mean, I know HRSA is doing some of it. It's the idea of putting it -- doing it in a systematic way and, you know, giving good thought to this.

Dr. Dawson: This is Geri. And, Ellen, you may know about this: Doesn't Easter Seals do something like this?

I was at a presentation last summer where I heard the folks from Easter Seals speak about their ongoing comprehensive assessment of services state-by-state.

Ms. Blackwell: They do, Geri, and it's not going to be quite as extensive. It's not going to be as extensive as what we're doing with the State of the States project but, yes, Easter Seals does have something

that summarizes part of this. It's sort of a beginning effort.

Dr. Dawson: All right. Well, I just thought of it because I remember, in looking at it, that they did have information about, do they have, you know, a strategic plan, or do they have a task force, et cetera.

So they -- I think they might have drilled down a little deeper into some of those, so I just want to make sure we don't duplicate effort.

Dr. Insel: Are we ready to move on?

Dr. Boyle: Yes.

Dr. Insel: Okay.

Dr. Boyle: So, we did some revisions on Objective D. And, Geri, I think these are mostly yours except for we did add newborn blood spots as part of the repository -- potential repository information.

Dr. Dawson: So, I added the -- to the establishment of the International Network

of Biobanks the need to provide support for the postprocessing of tissue such as genotyping, RNA expression profiling and NMRI.

And then, in addition, I added the proposal to develop a web-based digital brain atlas to provide high-resolution 3-D images and quantitative anatomical data from tissue of patients with ASD in order to provide more accessibility of the data to a wider number of researchers.

Dr. Boyle: Okay. And then we revised Objective M to also include this idea of capturing information, again, for communication and dissemination purposes on some type of common web portal.

And then the remaining objectives are -- is that Geri did add, in response to gaps identified in the biomonitoring and data-sharing area.

So, Geri, do you want to talk us through those?

Dr. Dawson: Sure. So the first

one is to establish a robust network of clinical research sites in real world settings that can collect standardized and comprehensive diagnostic and biological and medical and treatment data to provide a platform for comparative effectiveness research in clinical trials.

The second has to do with, you know, the research workforce, particularly in the area of interdisciplinary training and early career scientists. That may be somewhere else in the plan. I'm not sure.

The third is a recommendation coming out of the Autism Informatics Consortium to create an information resource for ASD researchers similar to PHEN-X, which provides shared information about data-sharing and standardization of methods across projects, which would include common protocols instruments, designs and other procedural documents and updates new technologies about data-sharing.

And then the next one is resources and facilities to develop promising vertebrate and invertebrate model systems and to make these model systems more easily available to allow high throughput screening technologies in autism.

Dr. Insel: Okay. Questions or comments?

Geri, is the first one really describe the ATN? It just sounds a lot like what you mentioned in the part on what is new in this research area under biobanking.

Dr. Dawson: Yes. I think the issue there is that currently there's -- there's only a limited number of sites that are collecting the biological data, and also there's no network that's in -- of this kind that is collecting fibroblasts, and I think this still is a question about whether, you know, fibroblast still might be a better tissue.

So, anyway, I think --

Dr. Insel: You know, is that practical to do, to do the surgical excision for fibroblast in the community setting or real-world setting? Is that something you think is likely to fly?

Dr. Dawson: I don't think it's out of the question but, you know, and so -- and we could remove that. I don't -- but I don't think it's out of the question at all.

But I do think that, you know, the extension of collecting biological data on a more comprehensive network is pretty critical. I mean, that is a gap.

Dr. Koroshetz: This is Walter. Just a small point going up to revised Objective D. I thought that NDAR does take NMRI s and have fields for quantitative anatomical data in the MR. The 3-D image, I think they can do it.

I'm not convinced that there's a huge advantage to doing that, but I think NDAR is doing -- can do all those things, is that

not correct, in terms of the imaging?

Dr. Dawson: Well, I think that support would be needed. They're not doing that. But this -- and this recommendation actually comes from the scientific community.

So, we've been having a series of meetings with people that are in this area of research and this is something that comes up repeatedly as a resource that would be desirable. So, I put it in there really to represent that.

Dr. Insel: You know, Geri, I think this is bumping up against a really important issue, and it goes down to new Objective C.

And I -- you know, I think you say it, but I'm not sure that we've said it here clearly enough. The call for standardizing not only phenotyping in a clinical sense, but also imaging protocols so that they can be easily leveraged, usually integrated across studies.

It reminds me again that some piece

of this has been done as part of the Simons Simplex effort, those first 2,000, which will soon be 3,000 samples.

And maybe what we should think about is, in the coming year, putting a big focus on how to standardize the whole series of measures, both in terms of clinical assessment and in terms of imaging, and in terms of the collection of the kind of data that you're talking about for the biobank, because it really does matter how you collect the blood, how you collect the fibroblast, all of those things make a big difference in the extent to which you can integrate across different studies.

Dr. Dawson: Yes, and that's -- I couldn't agree more, and that really is what the Autism Informatics Consortium is trying to do. And it's great that, you know, we have pretty much all the, you know, major players at the table and, in fact, you know, the Simons Foundation, I think, is going to be,

you know, very, very helpful in this regard.

Dr. Insel: Should we have -- use as one of the objectives that -- to hold a meeting to establish a set of standards, especially I'm thinking for imaging where you won't be able to actually combine the data from all of these many trials, all of these many studies that all of us support unless you have some agreement ahead of time about how the data are collected.

And we've done this very well for genotyping. We haven't done it so well for other areas. I wonder -- I think this is so important, this Objective C.

Dr. Dawson: And one comment, Tom, it says in the August meeting, you know, there were 22 academic groups that participated as well as representatives from Simons Foundation and Autism Speaks and NDAR, and they established, I think, four different work groups or task forces that are -- some of which are focusing on the issues that you

brought up, others of which that are looking more at, you know, the IT infrastructure and data federation and data harmonization.

I can send you what came out of that, but I think we've really developed a very nice plan that we could build on.

Dr. Insel: Okay. Great.

Dr. Dawson: I think the issue is that there's not the resource there to necessarily implement, but there certainly is the organization and the will.

Dr. Insel: And did they talk about expectations for data-sharing?

Dr. Dawson: Absolutely. That's -- in fact, that's the core mission or centerpiece of the effort.

Dr. Insel: Is there a white paper or something that could be used? The reason I'm thinking about it is that, again, this is one of these cross-cutting themes, but it would be great if there was agreement across the field about what the expectations were for

both, have data or collect data and how they're shared.

And we all put those kinds -- that kind of language into grants that we fund, so that everything adds up and --

Dr. Dawson: Yes, that is --

Dr. Insel: -- we haven't done that.

Dr. Dawson: That's the -- that's exactly what the goal is.

Dr. Insel: Okay.

Dr. Dawson: And so, you know, and if we can, you know, publish these as standards and that when a grant comes in, one then evaluates it, you know, in relationship to these standards, then I think, you know, that will quickly move the field to be able to share data.

And so, that really is the goal here.

Dr. Insel: Okay. Good.

Dr. Koroshetz: NINDS has been

doing this. It's called the Common Data Elements Project. We've been going disease-by-disease and publicizing them on the website.

So, if you look at the NINDS Common Data Elements page, you can see how these were done from many different neurological disorders. But this is, as you said, to kind of use that language, encourage people to use it to get their grants.

Dr. Solomon: This is Marjorie. This also has been done, I believe, through the BIRN initiative.

Dr. Insel: Right. So, Marjorie, for the BIRN Initiative --

Dr. Solomon: I think it's called BIRN.

Dr. Insel: Yes. Yes. And BIRN has become -- is now in NDAR, so it's all migrated into one major data set.

Are we ready to go on? Any other comments about Chapter Seven?

Dr. Solomon: Just one about encouraging programs and funding mechanisms related to workforce. I think there is actually an excellent network of ARTPs, Autism Research Training Programs, funded by the NIH, and I don't see them coming up anywhere here.

They also are very good with respect to objectives of achieving a diverse workforce, so they might be mentioned somewhere, and I don't see them really classified in the --

Dr. Boyle: Marjorie, I'm having a hard time hearing because you're breaking up, or maybe somebody else heard it well.

Dr. Solomon: I was talking about the ARTP Network, Autism Research Training Program. It's a T-32, under B, Workforce Development as an excellent resource.

Dr. Insel: Okay. That's a great idea. So, Coleen, did you catch that?

Dr. Boyle: Not really, so go --

Dr. Insel: Okay. We can send you

the follow up. It's a T-32 for Autism Research Training.

Dr. Boyle: Okay. That may help.

Ms. Blackwell: And, Tom, very quickly -- and Coleen, on Objective M, I would just ask that you revisit the distribution of the information regarding the web portal. It sort of relates to our earlier discussion.

Dr. Boyle: Okay.

Dr. Koroshetz: And this is Walter. I just have one comment. I've just been reading Seven. I thought that it lacked kind of a patient/family focus in the sense that we talk about all the things that are happening, but it's all patients who have contributed.

So I thought that some language, you know, giving credit to the patient contribution would be important just to how the thing reads. And maybe also, you know, including in here ways in which patients and families can participate.

Dr. Dawson: That's a great

suggestion. Thank you, Walter.

Dr. Koroshetz: Okay.

Ms. Blackwell: And, Coleen, the only thing -- Walter -- that we talk about it as person-centered, so you might want to use person-centered instead of patient-centered, Coleen.

Dr. Insel: All right. Moving on to the introductions. Lyn, I think you took the lead on this one.

Ms. Redwood: Okay. I'm sorry. I had it on mute. It took me a minute to get it off.

Yes, and, Tom, I saw your comments and now I'm not wanting to make too many changes, but being production, it's a little bit different in that we're not really saying what we've learned or what's new, so there were just a few what I considered to be minor changes.

The first had to do with what the current numbers are with regard to autism, and

that was in the first sentence there where I included that it was more common than childhood cancer, juvenile diabetes, and pediatric AIDS, combined, just to sort of put it into perspective. And I thought that was important to add.

There were also just a few minor edits that you can see there in track change mode.

Dr. Insel: Before we go on, Coleen, can we defend the 1.5 million as our surveillance expert? Is that number well-supported in the literature?

Dr. Rice: Hi. This is Cathy Rice. Coleen had to step out for just one minute. She'll be right back.

Dr. Insel: Okay.

Dr. Rice: We don't know the number of adults, so we've typically just said the number of children estimated. So, the 1.5 million isn't a CDC number.

Dr. Insel: So what -- do we have a

good reference for that?

Dr. Rice: Yes. It would need a reference. We don't have a reference for that.

Ms. Blackwell: This is Ellen. I would be more comfortable to just talking about the CDC numbers that are coming out on the kids because we -- we just don't have the adult data.

Mr. Ne'eman: This is Ari. I would agree, although I do think we should make reference to the fact that, you know, there's a substantial number of undiagnosed adults and so I think we should acknowledge the fact that the numbers that we have for children are incomplete.

In addition, I really do object to the comparison with childhood cancer and pediatric AIDS. These are terminal conditions. Autism is a developmental disability and, you know, frankly, I don't know that the comparison is helpful.

You know, I think a more appropriate comparison in the context of autism is to Down's syndrome or intellectual disability. I know a good deal of people in the self-advocate community who would be somewhat offended by the comparison between cancer and AIDS.

Ms. Redwood: Ari, the point I was trying to make is that there is just so much more awareness of these other disorders like childhood cancer and also, I guess, to point even beyond that, is the level of funding from, you know, both the public and private sector doing toward these other disorders that are less prevalent than autism.

And that was really the point I was trying to get across --

Mr. Ne'eman: I respect the intention, but I do believe it's an apples-to-oranges comparison here, you know, and I really do request its removal, simply in the sense that I think it's -- communicates

something inaccurate as to what autism is.

And, you know, in that sense, really sends the wrong message, both to the self-advocate community which I think would find the comparison offensive and, you know, perhaps of more interest for the strategic plan concept, it sends the wrong message for the research community.

We're talking about very different types of researchers that are going to be exploring cancer and AIDS as compared to the kinds of researchers that are going to be looking into autism and other developmental disabilities.

Ms. Redwood: I guess, Ari, I understand what you're saying, but I'm not making the comparison between autism and AIDS or cancer. I'm looking at just the numbers of children affected with the disorder, and adults. That's what I'm making the comparison to. It's not the disease itself.

Dr. Insel: Ari, I think the -- you

know, the point of the sentence is that this is a national health emergency. Would you contest that as well or is that something that -- which was in the original language. That's not new.

Mr. Ne'eman: Well, I mean, I would argue that meeting the needs of autistic adults in terms of access -- and children, in terms of access to health care, services, supports, intervention and treatment, is a national health emergency in the sense that, you know, it's something that has not been done and there's a tremendous amount of unmet human need that cries out for action.

In the sense that autism, itself, is a national health emergency or is analogous to cancer or AIDS, you know, I don't know that I would agree with that.

I think we really should be focusing on the very practical level on improving the lives of autistic people, not conceptualizing autism as a tragedy or as an

epidemic, the latter of which I think would certainly be a scientific judgment that I think many people on this committee would not be prepared to make.

Dr. Insel: Well, I think it does beg, you know, a broader discussion because we have heard public comment about this introduction that it was too anemic or not -- it wasn't forceful enough in describing autism as a national health emergency.

And I suspect that Lyn's language here -- I don't want to speak for you, Lyn, but I think in some ways you're reflecting comments that the committee's heard over the last two years since the original document, that we need to step it up a notch in clarifying the national urgency of this problem.

(Simultaneous speaking.)

Mr. Ne'eman: -- clarify the urgency around improving people's lives. I don't know that the average person, you know,

wakes up in the morning and says, you know, "Well, have they found the cause or a cure yet?"

I think the average person wakes up in the morning and asks, "Well, where can I find better services? Where can I find better health care? Where can I find better employment support?"

So, I agree on the need for urgency, but let's make sure that we're prioritizing urgency in the right areas.

Ms. Blackwell: Tom, I have a suggestion. Maybe we could -- you know, Lyn, I understand what you're saying about these conditions, and I think -- but I'm thinking that, you know, maybe we could hearken back to the President's language when he visited NIH and maybe talk about autism as a focus, you know, that was singled out by the President, you know, in addition to cancer and heart disease. I mean, wouldn't that be appropriate?

Ms. Redwood: Well, I took this paragraph of this, what was inserted in red actually from the Autism Speaks website, and in terms of it being a tragedy, I just wanted to refer back to what Ari said, that it's not a tragedy.

We heard devastating testimony from families at our last meeting about the tragic loss of lives, and for many families who have children on the spectrum, they would classify it as a tragedy.

And so, I understand your perspective is not that, Ari, but I think we also need to have this plan incorporate a full range of perspectives, and when we get into this later on, we do include the urgent need for services and support.

So, I think this first introductory paragraph is just sort of framing -- framing the problem in terms of what -- what is facing us with regard to the numbers.

Ms. Singer: I think -- this is

Alison. I think --

(Simultaneous speaking.)

Mr. Ne'eman: I think it would be unfair to say that I do not believe or that anyone does not believe that the loss of life we heard at the last meeting is not a tragedy. It clearly is.

I think it would be inappropriate for us to say that loss of life is an inherent and, you know, unavoidable consequence of being autistic, and I think that's what we want to avoid here.

I would suggest we communicate the nature of urgency here by referring to the unmet needs of autistic people as national civil rights issue that calls out for actions.

Dr. Dawson: This is Geri. I just would suggest that we leave the language in that Lyn has suggested and, you know, put this before the broader committee because it's one that there's a diversity of viewpoints on.

I do feel, Ari, that the way in

which you're interpreting this sentence is not the way in which, I think, the sentence is intended or necessarily written because, what this is trying to say is, you know, there are other conditions that require research, which require services, which require interventions and support in our country that are in some sense getting more resources, more research and dollars, and yet autism is so much more prevalent.

And so, it really -- I think for the average person it puts in bold relief the idea that, you know, conditions that we're all familiar with and that are supported, you know, are ones that autism is not getting the level of support anywhere near those.

So, I think it does make a very important point and it is not saying that autism is AIDS or autism is like, you know, juvenile diabetes, necessarily, but rather has to do with the prevalence and the need.

Ms. Blackwell: This is Ellen. I'm

also okay with it. I would just ask that perhaps, Lyn, that you strike the estimate about how many people are affected, and we just, you know, stick with the -- with the child numbers that we feel confident about.

Dr. Johnson: This is Jennifer --

Ms. Singer: I also think -- this is Alison and I think that Ellen made a good point before, and it was one that really spoke to something that happened this year, and this really makes sense for an update, which is that this year, President Obama singles out autism as one of the three top health care crises in need of action.

I think that's a good way to frame it. I think -- the other two were heart disease and cancer, am I right?

Ms. Blackwell: Yes. That is correct.

Ms. Singer: So -- okay. So that's a way to get in the comparison of scope which, as Geri said, is the intent of this sentence

where autism is being compared to cancer, diabetes and pediatric AIDS.

It's not to say that autism is AIDS, but it's merely to make a comparison of scope, and I think we can do that while simultaneously including something that makes sense to include in an update, which is something that the President said this year.

Mr. Ne'eman: So, I'm not adverse to us taking this to the broader committee. You know, all I would ask here is, then, that we provide the opportunity for the committee to consider both this language and alternate language.

I'd be glad to provide some alternate language that's both consistent with the respect for autistic adults and the self-advocate community and also communicates the strong sense of urgency to which this clearly provides.

Then we can put it before the committee and we can accurately reflect the

diversity opinions that clearly exist.

Dr. Insel: Lyn, is that okay with you?

Dr. Johnson: I agree that it would be a good idea to send it back to the committee and I think the point that Ari is bringing up is that this is not only a health issue, but it's also a societal issue.

And when we think about this in terms of needs being met and the effects autism has on people's lives, I think that point needs to be brought out and it is not when we are focusing on it as a health issue.

And so I think that's a point that really needs to be addressed in this introduction, because it is an introduction to the strategic plan and if we're conceptualizing this solely as a health issue, then I think it raises questions about why we have certain questions in the plan.

Ms. Blackwell: That's in paragraph four, if you look down -- the cost in family

and society is enormous, I think it's reflected in that, unmet need for employment, housing, services and supports. That's all in paragraph four --

Dr. Insel: Well, I'm going to interrupt again. This is Tom. As the chair, let me just suggest that we have a motion that we get two versions of this first paragraph, we'll take them to the full committee and we'll have the same discussion with the full committee rather than trying to hash it out here.

It won't make it any shorter or easier, but at least then we'll have some finality, because whatever we take from this meeting will still have to be discussed with them, anyway.

Is that okay with the group?

And, Ari, can we depend on you to come up with the alternate language?

Mr. Ne'eman: Sure.

Dr. Insel: Okay.

Ms. Redwood: And, Tom, I'll also take out the estimated 1.5 million and put in the statement "by President Obama," from the recent speech.

Dr. Insel: Sounds good. Okay. Moving on.

Ms. Redwood: Okay. I'm trying to figure out -- I changed one word from "continuing research support" to "increased research support."

I added in a caveat in terms of the need to also include identification of mechanisms of injury because I think that's very important in terms of targeting treatment.

Dr. Insel: Can I ask you a little more about that? What did you have in mind under "mechanisms of injuries"?

Ms. Redwood: If we can figure out, Tom, exactly what is causing -- for example, the delayed neuronal migration and maturation in the brain, those types of things in terms

of what's causing this overgrowth of white matter in the brain. I think that's hugely important, and that's what I was trying to get at is, if we can identify what's causing that, it can also help us back us into what the etiology might be and what effective treatments might be available for that.

Dr. Koroshetz: I think that's great, but I think "injury" is probably the wrong word. I'm not sure, I have to rethink it, but "injury" usually is, you know, something that comes in and damages brains.

This is more -- so you're talking more about a defect in development or dysfunction, a network dysfunction and --

Ms. Redwood: If you want to come up with a better word or something, I'm open to that.

Dr. Insel: So would you say identification of mechanisms?

Dr. Solomon: Biological mechanisms?

Mr. Ne'eman: I think identification of mechanism is far more value-neutral.

Dr. Insel: I'm sorry, I missed that, Ari. Could you say that again?

Mr. Ne'eman: I said I like the phrase "identification of mechanism." I think it's far more value-neutral.

Ms. Blackwell: Lyn, this is Ellen. Can we go back to paragraph two. Can we put "people" back, only because the Department urges us to use person first.

Okay. We want to -- we want to talk about people. You know what I mean? It just makes it a little more personal. Okay?

Dr. Insel: First of all, that's a decision we made and that's all the way through.

Ms. Blackwell: Okay.

Dr. Insel: So, can we go back and start with this identification of mechanisms of injury? Would the committee be comfortable

with just taking out "of injury" and leaving "identification of mechanisms"?

Dr. Solomon: That sounds good to me.

Ms. Redwood: Okay. Consider it done.

Dr. Insel: Okay. Moving on.

Ms. Redwood: The next page, there weren't any changes. The only thing I added on page three was to try to capture the fact that this year we're including the bookends that monitor progress.

Dr. Insel: Great.

Ms. Redwood: So I added a progress toward accomplishing research objectives, and everything else stays the same.

And -- let's see. On page four there was a comment from the RFI regarding the use of "nonverbal" as a proxy for "level of functioning and impairment." And I thought that was an appropriate -- a nice comment, so I included that and took out "nonverbal," and

substituted instead "requires 24-hour care and supervision," because I thought that was the concept we were trying to get across.

So, any questions on that, or is that okay?

Dr. Insel: Okay.

Ms. Redwood: Okay. I'll move on. The other thing that I added, and this is probably the biggest change in terms of the cross-cutting themes and, you know, because this came up so many different times in the updates to the different chapters of the plan, I included something on medical comorbidities.

Now, if we want to call it something else, either "conditions secondary to autism," or "comorbid" or something that is a little bit more palatable, that's fine, but I just think this is such a large area where we can really make improvement on the quality of life for individuals with ASD.

And what you see here was actually taken out of the presentation that Geri did

back at the beginning of the year regarding, you know, what they're seeing in ATN with regard to these medical comorbidities.

So, everything there came out of the presentation from Geri, and I thought that was an important update to the plan to include as a cross-cutting theme when we're doing research.

And then the last thing that I added was I changed "considered" -- it has "ASD is a developmental brain disorder," and I just wanted -- there's some controversy whether or not it's actually the brain or it's the body, and this is from some of the lectures I've heard of Dr. Martha Herbert from Harvard.

And so that's why I just put "considered," because I think at times we know so little about what autism really is. So, that was just one of my own personal caveats. I'm not wedded to it. If people don't like that, I'm fine with removing it.

Ms. Blackwell: Lyn, this is Ellen. Under the changes that you've got in heterogeneity, I know that some of this language was in the plan initially, but I think that this sentence that says "the spectrum includes people with ASD who cannot live independently," I would propose that we change that to say, "who need assistance to live more independently," and then I would --

Ms. Redwood: Hey, Ellen, where is that exactly? That's in the --

Ms. Blackwell: On page four, under cost-cutting themes, heterogeneity. And then where it talks about "require 24-hour care and supervision," I would --

Ms. Redwood: We can take that out, yes.

Ms. Blackwell: Yes. I would strike that completely, because we don't talk about care, we talk about services and we certainly don't like to think about supervising people with autism.

So, I would just strike that, and then modify the language about people who can't live independently that was in the plan previously.

I think that we just need to say that these people need -- that that group perhaps needs assistance to live, you know, more independently.

Dr. Insel: Ellen, I'm not sure I follow you. I mean, I think if the point is to provide the full spectrum, what would you accept as a description of someone who would be at the most severe end of the spectrum?

It wouldn't be somebody who's living independently with assistance, would it?

Ms. Blackwell: Yes. Oh, well, I mean, I guess you're right. That's kind of an oxymoron but, I mean, people are independent even when they have assistance.

Ari, wouldn't you agree with that?

Dr. Insel: No, but I think --

Mr. Ne'eman: I think what you're identifying here, and then just to sort of translate it from the background that you and I have come from, that perhaps the terms that might be made more easily understandable here is I think you -- we want to avoid sending the message that we are endorsing the institutionalization of autistic people with more significant impairment.

And I think it's long been the Federal Government's priority in respect to the integration mandate to the Americans with Disabilities Act, that even people with very significant support needs can be supported effectively in the community.

And I think Ellen's point here is we would not wish to inadvertently communicate an inaccurate message around that. There's a lot of best practice to support people, even with very significant impairments and support needs in integrated community settings.

Dr. Koroshetz: I don't know, I

think we're getting hung up on the verbiage, but the point of the sentence is to just describe the spectrum from one end to the other --

Mr. Ne'eman: Why don't we say "Who have very significant impairments in communication and independent living"?

Dr. Koroshetz: Because it doesn't -- I don't think that gets the message in terms of what the most severe cases are. I mean, I think you've got to state -- you know, I mean, I think what you're saying, Ari, is there's a lot of stuff in the middle.

Mr. Ne'eman: I guess that is, in fact, accurate. There is a lot of stuff in the middle.

Dr. Koroshetz: Right.

Mr. Ne'eman: But if you look over the course of the scope of community services, for example, the State of Georgia, you know, just last month, in an agreement with the Department of Justice, announced that they're

going to stop admitting people into their developmental centers.

Ten states no longer have developmental disability institutions. There's a broad recognition that even for people with the most significant impairments--

Dr. Koroshetz: Right.

Mr. Ne'eman: Institutionalization is not an appropriate option. I --

(Simultaneous speaking.)

Dr. Boyle: Well, why don't we just take the word "care" out of what Lyn wrote? You know, I think -- I happen to think that what Lyn wrote here does capture it.

But if we take out the word "care" and it just says "The spectrum includes people who cannot live independently and require 24-hour supervision."

Mr. Ne'eman: Even then, I mean, I --

Ms. Blackwell: I don't think we're talking about -- can I make a suggestion for

language? Why don't we just say "The spectrum includes people with ASD who need a wide array of assistance to lead independent lives, and others who find gainful employment and live independently --"

(Simultaneous speaking.)

Ms. Redwood: The reality is that there are individuals with autism, in my opinion, who do not have independent lives. I know a child who's bedridden with a feeding tube, and requires 24-hour care, and I think --

Ms. Singer: But their life is not a failure because of that.

Ms. Blackwell: We have to accept reality. We are -- I mean, honestly, we don't use the word "care." We talk about services and supports. And to imply that a person with autism needs "supervision," is just not appropriate.

Ms. Singer: It's true. I mean, my daughter and my brother need 24-hour

supervision to prevent them from getting hit by a car.

Ms. Blackwell: They need support and services often that could include, you know --

Ms. Singer: Supervision?

Ms. Blackwell: -- assistance, but I wouldn't --

Ms. Singer: They don't need assistance. They need supervision. You know, I know where you're --

(Simultaneous speaking.)

Ms. Singer: I think you're ignoring.

Mr. Ne'eman: I think the question here is why we are -- why we're, you know, trying to come to recommendations on service provision options when we're -- obviously, that's something that has to be individualized.

And what we're talking about here is what we need is some very broad language

that can work for an introduction. You know, I'm comfortable with talking about some people having very intense and expensive support needs.

I'm comfortable with acknowledging the significant variability of the autism spectrum. What I'm concerned about here and what I think Ellen is concerned about here is, if you are endorsing particular, more restrictive, service provision modalities, that's a policy statement, at the same time that the Federal Government is working to promote less restrictive service provision settings that also take into account safety in different ways.

Ms. Redwood: I'm not endorsing that, Ari. I'm just trying to describe what the reality of the situation is, and Ellen is a nurse. I provide care to people. I don't provide support and services.

So, you know, I look at this from children that I mentioned before that have

feeding tubes and are bedridden, and they need care and it needs to be 24 hours.

Mr. Ne'eman: All right. I would presume at some point --

Ms. Redwood: That's the far end of the spectrum, not the, you know --

Mr. Ne'eman: I think if somebody is using a feeding tube they most likely have some co-occurring condition in addition to autism.

Dr. Johnson: Yes. Maybe if it is 24-hour health care, I mean -- again, I think we do need to be careful about how this being characterized.

I think Ari is raising some very good points about the approach and strategies the Government is encouraging the states to follow, and that is not institutional care, so, you know, I don't know if we're going to resolve it here on the phone today, but I think we need to work on this language to really reflect what is being promoted by the

Federal Government.

Dr. Insel: No, I think this is a different issue.

(Simultaneous speaking.)

Dr. Insel: Let me break in here. Again, as Chair, let me -- because, we're going to have to move on, and we won't probably resolve this.

But I think it's fair to say, from this conversation, that we've hit a very raw nerve in the way that people conceptualize autism, and it may be part of the reason why we struggle with so much of the language in the rest of the plan.

What I'm going to recommend is that, as with that first sentence, we just take this to the full committee.

And, Lyn, I mean, if you can take the comments that you've heard here and think about whether there's any additional adjustment you want to make. If someone wants to provide alternate language, I think Susan

here has come up with a rewrite of this sentence that might reflect more of both points of view.

This is really meant to actually describe the polarity, and not necessarily to accentuate it, but if we're not going to be able to find the perfect words here, let's take this one to the full committee, and we'll have a chance to rehash it.

And I'd like to do that by giving them a couple of options. So --

Mr. Ne'eman: Let's have Ellen come up with one.

Dr. Insel: Maybe Susan and Ellen, could you do that together?

Ms. Blackwell: Sure.

Dr. Insel: And, Lyn, if you think there's any adjustment you want to make, that's fine, too, although it sounds like several people on this phone call are very comfortable with the language you have.

And let's move on, then, to the

rest of this session, medical comorbidity.

Ms. Redwood: There were two more, Tom, at the end with regard to additions to public/private partnerships, that I added. One was at the very end of that sentence, that was also important to have these partnerships to prevent unnecessary duplication of research efforts.

And the next one was community engagement and how it's important to include stakeholders.

And, Ari, I think this gets to the point you were trying to make earlier in the discussion about community participatory research, and so I tried to capture that there as well. And that it's important that they be included so we can, you know, make sure that our scientific considerations and investment strategy -- and actually, I left out an "is" there, and research focus is critical, and that we needed to do something to increase community engagement.

And that was all. So these were all the recommendations I had for the introduction.

Mr. Ne'eman: I like it, actually, in regards to the community engagement. I think we may largely be in agreement on that point, Lyn.

The only thing I would suggest is we can include a line recognizing that historically, autistic adults and youths have been underrepresented in autism research discussions.

I think it would be good to acknowledge that historic inequity with the idea that there needs to be special emphasis to address it.

Ms. Blackwell: I kind of think "people with ASD" covers it. I'm comfortable with that, Ari.

Mr. Ne'eman: I kind of feel -- I mean, I think my concern is very often when we talk about, you know, autistic people and

families, it ends up being mostly or entirely families.

So I'd like to see a line specifically calling out the need to include autistic people in all aspects of research about us. I mean, that's the principle behind community-based participatory research/ participatory action research. And I think the special emphasis would be helpful.

Dr. Insel: Is the sentence about, as it stands now, about "the inclusion of stakeholders is also essential to ensure that the human dimension is reflected" -- does that imply that without the inclusion of stakeholders that the human dimension would be lacking?

Ms. Redwood: I guess it does, Tom. And I sort of think that's true. I think that by having stakeholders in this disease, you're able to understand more what the struggles are.

I think we learned a lot at our

last meeting from the presentations from NAA, and they brought something to our attention that wasn't on our radar screen.

Ms. Blackwell: Lyn, what if you just said "additional dimensions of the disorder," or, you know -- because I think Tom's right.

Dr. Insel: Maybe there's a way to word it in a more positive fashion, to say "Stakeholders ensure that the human dimension or the personal experience of the disorder is reflected."

Ms. Redwood: Okay. Do you want to change that to "personal dimension"?

Dr. Insel: Well, the main thing is to turn it into a more positive statement that says what stakeholders bring, rather than what's lacking if they're not there.

Ms. Redwood: Okay. I can try to make it positive.

Dr. Insel: Lyn, I worked on that medical comorbidities paragraph, but I never

sent you the text. It's mostly just syntax, but I think there's -- I think we can make it even a little bit stronger in a few places.

So, rather than going through it word-by-word now, maybe I'll just send you this and see if it's helpful or not.

Ms. Redwood: Sure. And again, I captured that out of the presentation from Geri at the beginning of the year.

Dr. Insel: Yes. I -- you know, I was the one who didn't want you to change anything, but I think this is really a great addition and after all, it shows up in so many of the chapters, we've already talked about that.

So why not have it as a cross-cutting theme, and it's also a topic that we've heard about enough at the meetings that I think to not have it here was a real neglect.

So, it's great. It's a good addition, and I just wanted to -- most of my

comments are stylistic, so they're not worth a long discussion here.

Ms. Redwood: Okay. Great. Send those over and I'll incorporate them, along with the other changes that I've heard today.

Dr. Insel: Anything else from these comments on the intro?

Dr. Koroshetz: I just want to say I like the medical comorbidity section as well. It's a great addition.

Dr. Insel: All right. So we have Chapters One, Two and Three that we have to finish in seven minutes. Let me know what you want to do in these last five minutes or so with the remaining chapters.

We'll have to -- obviously, we'll have to come back to these at an additional meeting on December 3rd. But, for those who have taken a lot of time to draft these, are there any major comments that you want to make sure that they see?

Or, one thing you can do, of

course, is send them comments before December 3rd.

Dr. Solomon: This is Marjorie. With respect to Chapter Two, I think we have the issue of the uncoded research projects and I think we've made some progress, but we did want to get some consultation from the committee on what we ultimately decided.

Remember, we had about 50 percent of projects that didn't really fit neatly into any objectives. Several of us undertook efforts to kind of look through them and try to figure out, really, where they belonged.

And two ideas were sort of surfaced. One would be to include sort of three different categories that other research could be plotted into and those were -- are really a great creation of Della and Susan, in consultation with us.

And the second was the idea to try to reclassify them under their rubric of the three questions that are in the preamble to

Question Two.

And both have their pros and cons, those ideas, but I think maybe one of the pros of the idea are classifying them under the few questions that are in the preamble, that really reflect better the process of the IACC.

And then I would be interested in hearing other people's opinions on the subject.

Dr. Daniels: Marjorie, this is Susan. I just wanted to add something with the idea of trying to reclassify under those three overarching questions at the beginning.

Those three overarching questions actually overlap a lot with the objectives, and so it would be really hard to determine what was already classified into an objective, whether it should stay there or move to another place, if need be.

Dr. Koroshetz: No. We would keep -- anything with an objective, we keep. The question is how do you deal with --

Dr. Hann: No, I think what Susan's referring to -- and correct me if I'm wrong, Susan -- is how we move forward in the future. We'll need to send this out to the people who do classifications for us because, if they're confused about where to put things, it will not produce what you're looking for.

Dr. Daniels: So we were looking for categories that were not reflected in the current objective, and so I -- you may disagree with the ones that we came up with, but we were looking for something that really more exclusive and not overlapping with other things.

Dr. Koroshetz: I think it's a generic issue. This question, all the questions have the same issue. So, I think that's something we could wait --

Dr. Daniels: We could also -- we could do a draft version of what some particular categories could be for all of the questions and have the committee look at them

and maybe revise them for next year.

Dr. Hann: Right. So, we would like to put a -- you know, finish essentially this year's portfolio analysis, so it would be good for just clarify what you all want to have happen with this year's analysis in Chapter Two, because we've taken care of the questions the committee has with regard to Chapter Three.

We're working with DoD with regards to their classification. They are very much wanting to take ownership of their classification for their research project.

So, I think, from OR's perspective, and we're trying to be mindful of that and sort of go along with their wishes, because they are very -- they're very involved.

Dr. Dawson: Yes. So we're making quite good progress with that and we've heard back from DoD, and actually came to quite a lot of consensus on that, between our office

and them, and what we feel the committee seemed like their direction was.

So, the DoD projects are in good shape, but we could, if you'd like, do a draft of how those unclassified items would look with a couple of different themes utilized.

Dr. Hann: But that's for the future.

(Simultaneous speaking.)

Dr. Dawson: Yes. I think that's for the future. I say table it at this time.

Dr. Hann: Yes, I think that would be for the future. I think what I'm hearing for Chapter Two is there were a few that you all felt comfortable putting under existing objectives.

Dr. Dawson: And those have been provided.

Dr. Hann: And then we can just sort of stop with this year's, and then we'll move forward next year when we begin the discussion about the portfolio analysis about what to --

how to better capture things for all of the chapters.

Dr. Dawson: Exactly.

(Simultaneous speaking.)

Dr. Hann: -- falling into unclassified for discussion.

Dr. Solomon: Right. That's the plan. We just thought that we weren't really in a position to track and institute a plan with 50 percent of our funded studies not classified.

Dr. Insel: Yes. Fair enough. I think that's really a problem.

Okay. Della, can you take us through the plans to close out the meeting? What are we going to do next, and when do we meet?

Dr. Hann: Okay. So, the next meeting for the subcommittee is scheduled for December the 3rd. It is basically a full-day meeting. It's scheduled to run, beginning at 10:00 a.m. and going till four o'clock in the

afternoon.

The primary things for the group will be looking at Chapters Five and Six, since those have yet to be vetted at all by the subcommittee.

And then, if there are additional changes, which I think there will be, given today's discussion, additional changes to the other chapters, that those also be put forward to the subcommittee, with the goal at the end of the December 3rd meeting, having a draft that can be taken to the full committee meeting on the 14th of December. At least, to begin that process with the full committee.

So, that will entail that anyone who's currently working on a draft, regardless of what stage you're in in terms of working on a draft update, we -- OARC will need to have those materials by November 30th, in order to prepare them.

Dr. Insel: So, for Chapters One, Two and Three, which we've heard about once,

and we have drafts of those. People may have comments on those drafts. Can -- should they send them to the authors of One, Two and Three, or what's the best way --

Dr. Hann: Yes. They should send those to the authors of One, Two and Three so the author -- the primary author for Chapter One is Coleen. The primary author for Chapter Two is Marjorie. And the primary author for Chapter Three is Geri.

Please include Susan and myself on that correspondence in order to -- that we stay completely in sync with FACA rules.

Ms. Blackwell: And Della, this is Ellen. I know that you're missing Five and Six. Could we address for a second how we're going to handle Five and Six?

I mean, I hope to get a draft to this group next week. Do people just want to send in electronic comments?

Dr. Hann: Yes. The way we've been doing it with the others, Ellen, is that the

lead drafter puts out a draft for -- you can do it just for your small subcommittee, or you can do it for the full subcommittee, whichever way you'd prefer.

People comment on that and again, then, the lead is responsible for taking all of those comments and incorporating it into a draft that can be then brought forward for discussion.

Ms. Blackwell: Okay. Well, thanks, everyone for --

Dr. Dawson: Della, may I ask a quick question? This is Geri. I just want to make sure I know my charge.

Dr. Hann: Okay.

Dr. Dawson: So, I've already done what I think you're asking for. Question Three, we've already sent it around and incorporated and reduced the number of objectives.

Dr. Hann: Correct.

Dr. Dawson: And then, for Chapter

Four, we got specific feedback about how to reduce and combine some of the bullets and reword some of the bullets, which I've written down.

And then, I'll assist Coleen on Chapter Seven.

Dr. Hann: Yes.

Dr. Dawson: Okay. Thank you.

Dr. Hann: You got it.

Dr. Insel: And for Five and Six, remember, the rule is that we don't need to do revisions unless we really need to do revisions.

So, this is -- you know, we want to set a pretty high bar for doing an update. Okay?

Ms. Blackwell: Yes. The bar is high, Tom, on Chapter Six.

Dr. Insel: Good. All right.

Any last comments from the subcommittee? Anyone else?

Ms. Redwood: Tom, this is Lyn. I

have a question. And it's just, you know, December is a really busy time of year for everyone, whether or not we could do some of these calls, or some of these meetings by phone, like we did today, versus in-person meetings?

Dr. Hann: Lyn, that's always an option for all committee members, for all of the meetings that we convene. So, we always have our conference call-in line for those who, for whatever reasons, are unable to be here in person.

Ms. Redwood: Right. I understand that, Della. But, again, it just seems -- I know it's better to be there in person and it gives different dynamics when half of the people are there in person and then other people are on the phone, in terms of not being able to get eye contact and feedback and things like that.

So that's why I was asking if it could possibly be by phone versus in-person.

And I know that it's always an option, but it would be nice if we could do as much work as we can by teleconference and even webinar, just to save on travel costs and also, you know, time away from our families.

Dr. Hann: I agree that's --

Ms. Redwood: I'm just --

Dr. Hann: I think, Lyn, though, given it's very difficult to track these changes when people aren't all in the room. It's very difficult for us to be able to then get these documents ready to go to full committee.

So, I would really strongly encourage that at the December -- for people who can come here for December 3rd, to do that, and obviously, then, the meeting on the 14th is a full committee meeting and generally people do come, but not everybody.

We've had several members who've only participated by phone.

Ms. Redwood: Right. No, I

understand for the full committee meeting that it, you know, is necessary to be there. I was just hoping for some of this work that we're doing in the subcommittees, that we could do by webinar or teleconference.

And if we had webinar capabilities, we could actually see the track change and go through them, and everybody could be looking at them at the same time.

Dr. Insel: Well, Della?

Dr. Hann: I just -- we have tried that in the past with this group and it has been very, very difficult, Lyn, to track all of it.

So, while I appreciate and understand and certainly you have the option of calling in, I really think we need to keep with the current format.

Ms. Redwood: Okay.

Dr. Insel: All right. I want to bring this to a close. Thanks, everybody, for joining. Marjorie, I think you get the prize

for getting up at five in the morning to be part of this meeting.

And while we didn't finish, we got at least halfway through what we needed to do. We've got more to do in front of us. You've all got assignments. Let's keep those timely so we can get comments back to those people who are the primary authors.

And we look forward to either hearing or seeing you on December 3rd. Thanks, everybody. Have a good Thanksgiving.

(Whereupon, at 11:06 a.m., the Subcommittee adjourned)